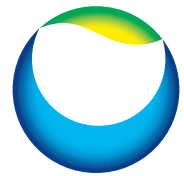


Passion for Innovation.  
Compassion for Patients.™



Daiichi-Sankyo

## Daiichi Sankyo Group Value Report 2014



# To Readers

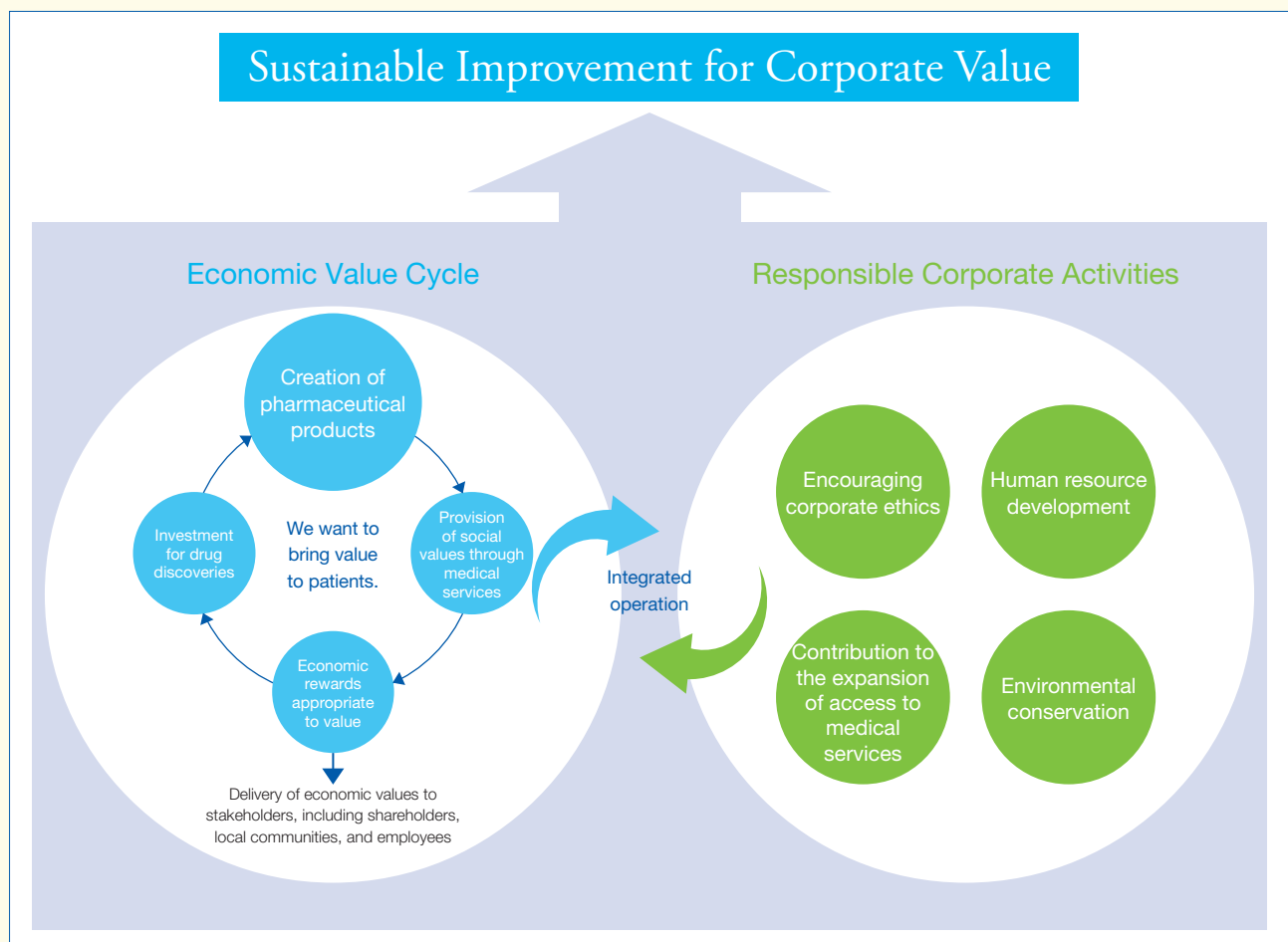
We thank you very much for your interest in our Value Report 2014, which is designed to describe our idea of sustainable improvement for the corporate value.

We sincerely hope that providing a full picture of our corporate activities geared toward sustainable improvement for the corporate value will help you understand what the true value is.

The raison d'être of a pharmaceutical company lies in addressing diverse medical needs around the world and helping patients through the creation of pharmaceuticals, which is the mainstay of our business cycles. For a pharmaceutical company, an improvement for the corporate value is based on a sustainable development of an economic value cycle, i.e., providing useful pharmaceuticals to society and receiving economic rewards in return, appropriately delivering the gained economic values to shareholders and other stakeholders, and making investments for future drug discoveries. We also believe that the sustainable

improvement for the corporate value can be realized by integrating responsible corporate activities, such as an encouraging corporate ethics, human resource development, environmental conservation, and contribution to the expansion of access to medical services, into the economic value cycle (see the figure below).

We hope that you will grasp the whole picture of the Daiichi Sankyo Group by reading this Value Report that summarizes our diverse corporate activities aimed at sustainable improvement for our corporate value.



## Research and development of new medicines is a long-term business cycle

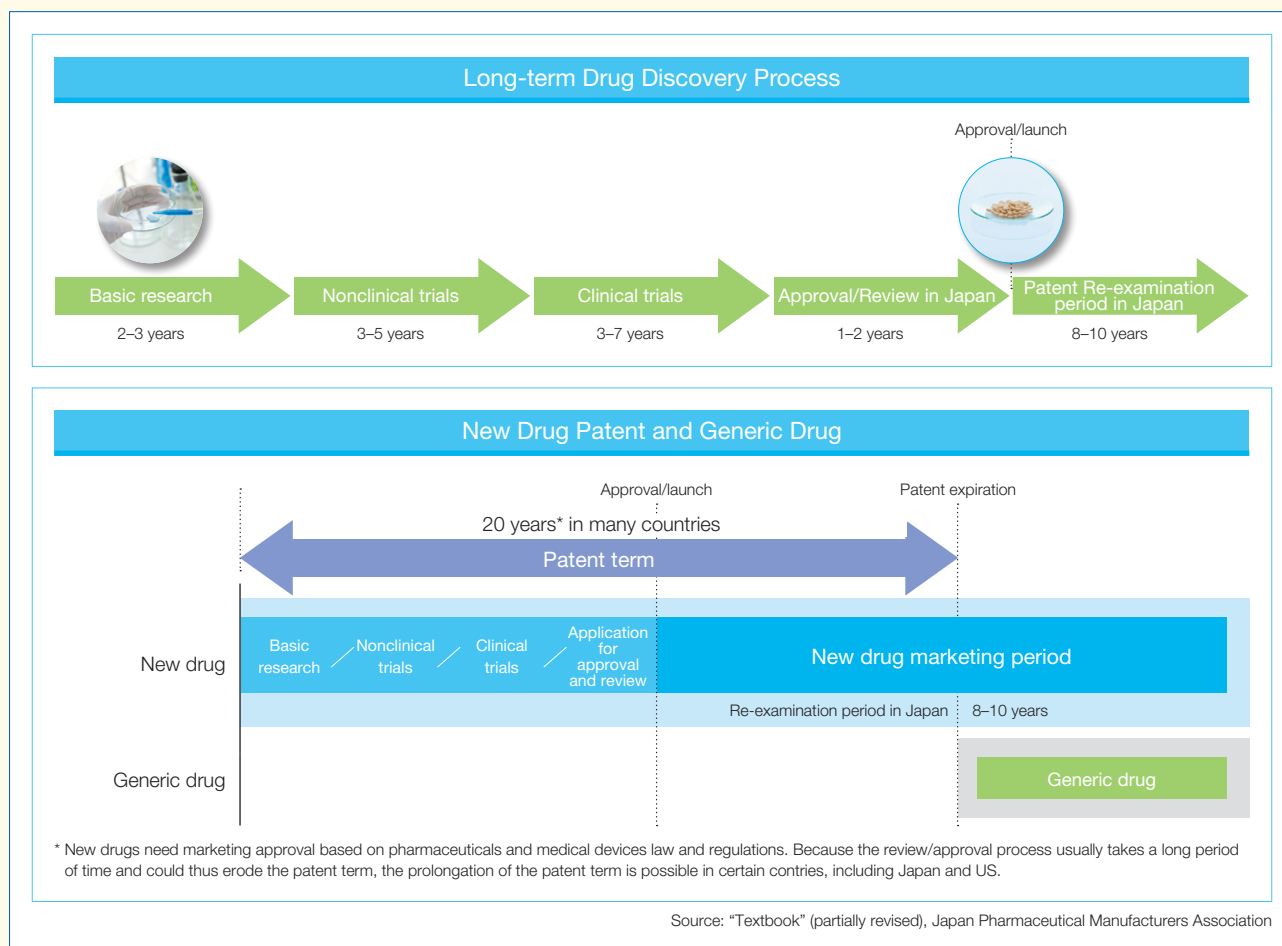
Drug discovery for the economic value cycle is a long-term process.

To establish safety and efficacy, new drugs must undergo an extremely strict process ranging from basic research and non-clinical and clinical trials to application for marketing approval and regulatory review. This process usually spans 9–17 years and requires enormous R&D investment. Even after the launch of approved drugs, in Japan they are required to go through the monitoring of their efficacy and safety during an 8–or 10-year re-examination period. Other regions also have extensive post-approval safety requirements. During this period, additional information on the drugs is collected so that, if necessary, action can be taken.

A pharmaceutical company obtains intellectual property rights, chiefly, patents, to exclusively manufacture and

distribute new drugs. A patent is a legal right to protect the invention and in many major markets patented drugs are protected for 20 years from the day of the patent application in Japan. Once the patent term is expired, other drug companies are able to manufacture and distribute drugs that contain the same active ingredients so long as they demonstrate bioequivalence to be the innovator's drug product. These drugs are called generic drugs.

Because the business cycle of drug discovery spans long periods of time, keeping a pipeline of potential new drug candidates in various stages of R&D while keeping an eye on the future entry of generic drugs in the market is vital to sustaining the company's investment in new drug development.





To contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals, and through the provision of pharmaceuticals addressing diverse medical needs.

We have established Our Values and Commitments as the criteria for our business activity and decision making. Our global brand is a pledge to our stakeholder of what our company is capable of delivering, now and in the future, based on the corporate culture created by Our Values and Commitments. Our corporate slogan succinctly states how we make efforts for what and for whom, based on Daiichi Sankyo's unique quality represented in Our Values and Commitments.

In addition, we have established the DAIICHI SANKYO Group Corporate Conduct Charter to act with the highest ethical standards and a good social conscience appropriate for a company engaged in a business that affects human lives.

#### The Criteria of the Value Judgment to Fulfill Our Mission

### Our Values and Commitments

#### Innovation

"Our Imperative"

1. To create first-in-class and best-in-class drugs
2. To take a global perspective, and respect local values
3. To foster intellectual curiosity and strategic insight

#### Integrity

"Our Strength"

4. To provide the highest quality medical information
5. To provide a stable supply of top-quality pharmaceutical products
6. To be an ethical, trusted, and respectful partner

#### Accountability

"Our Culture"

7. To be accountable for achieving our goals
8. To demonstrate professionalism, respect for others and teamwork

#### Corporate Slogan

Passion for Innovation.  
Compassion for Patients.™





## The Principles of Our Corporate Activities to Fulfill Our Mission

### DAIICHI SANKYO Group Corporate Conduct Charter

The DAIICHI SANKYO Group fulfills its mission to “To contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals, and through the provision of pharmaceuticals addressing diverse medical needs.” We comply with laws, regulations and rules regarding global corporate activities, and act with the highest ethical standards and a good social conscience appropriate for a company engaged in a business that affects human lives based on the following principles. We fulfill our corporate social responsibility (CSR) by actively responding to an ever-changing society and enacting improvements for corporate value.

- |            |   |
|------------|---|
| Article 1  | We diligently address medical needs by providing beneficial, safe, and reliable pharmaceuticals and services.   |
| Article 2  | We conduct business in an ethical, fair and competitive manner, and maintain a healthy and professional relationship with our stakeholders, which include medical professionals and governments.  |
| Article 3  | We actively communicate with our stakeholders by disclosing corporate information in a timely and appropriate manner in accordance with the principles of corporate accountability. We take appropriate measures to manage and protect personal and customer information and the confidential information of our and other companies.   |
| Article 4  | The globalization of business activities requires that we operate by being compliant with the laws of each country and region, and by being respectful to all international norms including human rights, various cultures and customs. As a result, we contribute to the development of the local economy and society.   |
| Article 5  | We respect diversity in the personal values, qualities and individuality of our employees, and ensure a safe and working environment that does not tolerate inappropriate treatment such as discrimination or harassment. We provide employees the opportunity to develop their skills and abilities for the mutual development of the employee and the corporation.  |
| Article 6  | We responsibly manage the environmental impact of our operations as environmental issues are common challenges for mankind and such concerns are integral to our corporate activities and our very survival.  |
| Article 7  | We actively engage in community activities and philanthropic programs focused on social causes.   |
| Article 8  | We do not support or conduct our business with antisocial forces, prohibited entities or groups that may threaten the order or safety of civil society.   |
| Article 9  | Executives of the DAIICHI SANKYO Group actively build and maintain effective systems to implement this Charter, ensure it is understood by all Group companies and make this Charter known to our business partners.  |
| Article 10 | If the Charter is violated, executives of DAIICHI SANKYO Group Companies ensure that there is a commitment to determine the cause of infringement, take corrective action as necessary and make efforts to prevent similar violations in the future. Executives are accountable for promptly making required disclosures and upon discerning responsibility regarding the infringement, impose appropriate disciplinary action, including upon Executives themselves. |

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## Description of Icons



References (related pages within this report)



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## Relevant Information

For investor relations (IR) and the latest information on our responsible corporate activities, please refer to our company website, which includes a variety of information, such as account settlement, audio distribution of briefing sessions for investors, and market data. The PDF and online version of this Value Report are also available on the website.

 <http://www.daiichisankyo.com>

• About us • Research & Development • Media & Investors



• Please read the CEO's determination toward the sustainable improvement for our corporate value.

• These chapters describe corporate governance and risk management.

• This chapter introduces the trail of Daiichi Sankyo Group as a drug innovator.

• This chapter explains why we think that our business operations and responsible corporate activities are inseparable.

• This chapter outlines creation of value through Business.

• This chapter outlines our responsible corporate activities that support our main business.





Based on a long-term view,  
the Daiichi Sankyo Group aims to  
sustainable improvement for our  
corporate value through contribution  
to the enrichment of quality of life  
around the world.



Joji Nakayama  
Representative Director,  
President and CEO



Daiichi Sankyo Group is committed, as a corporate mission, “To contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals and through the provision of pharmaceuticals addressing diverse medical needs.”

There are still many diseases for which the level of satisfaction with treatment is insufficient or for which there is no established treatment. Pharmaceutical companies have a significant mission of addressing these unmet medical needs and providing solutions to these problems.

In addition to that, based on current global demographics, if we consider how the world will change over the next 50 years or so, it is clear that developed nations will have to bear the burden of an aging population with slowing growth, whereas India, African nations, and other emerging countries will lead the growth of the global economy, and economic disparity will spread. Under such circumstances, health and access to medical care issues will involve more conflicts than ever, posing a variety of social challenges. In fact, this trend is already being observed in many parts of the world. We have to confront such problems.

With these environmental changes, we think that the Daiichi Sankyo Group with two pillars of new drugs and generics should aim to be able to provide global solutions as a Japan-based company in the future.

At present, the overall pharmaceutical industry is facing the serious problem of lost productivity in research and development. The larger issue is that we need to be able to serve patients with unmet medical needs. Therefore, we must look harder for ways to provide our society new innovative medicines and serve more patients. At the same time, we plan to put more of our efforts into social contribution, an area that cannot be accomplished only through ordinary business operations, so that such contribution can last much longer time in liaison with business.

For instance, we have initiated the promotion of open innovation in stronger alliance with academia in the drug discovery stage, partnership in vaccine businesses with foreign pharmaceutical companies, and public—private cooperation to fast-track new drug discovery processes for unmet medical needs, including muscular dystrophy.

For our pharmaceutical company, the enhancement of our corporate value is based on a cycle of economic values in which we generate innovative pharmaceuticals through R&D, deliver the gained economic values to stakeholders, including shareholders, local communities, and employees in a balanced manner and also make an investment for drug discovery activities, such as R&D toward the creation of pharmaceutical products. For the long-term, stable development of this value cycle, it is important to aggressively respond to the challenges created by ever-changing diverse social needs, perform our responsibilities and duties as social members, and grow with the society. More specifically, we have to operate an economic value cycle together with responsible corporate activities, such as encouraging corporate ethics, fostering excellent human resources, and our devotion to social agendas as a pharmaceutical company.

“We want to bring value to patients.” Realizing this earnest desire of ours by creating and providing innovative pharmaceuticals while earning the trust of stakeholders in the world is, I think, the goal that our company should strive for.

In fiscal 2013, Japanese economy modestly recovered, but the pharmaceutical industry remained in a very challenging business climate due to the tightening of safety and quality regulations and promotion of medical cost cutting measures. In this tough environment, the Daiichi Sankyo Group recorded increases in both revenues and profits in fiscal 2013, owing to domestic sales in Japan of pharmaceuticals.

The sales revenue increased by ¥123.6 billion, or 12.4% year on year, to ¥1,118.2 billion. [▶ Chart 1](#)

The operating income increased by ¥12.8 billion, or 13.0% year on year, to ¥111.6 billion.

The profit attributable to owners of the Company declined by ¥3.1 billion, or 4.8% year on year, to ¥60.9 billion. Higher income taxes partly reflected a reversal of deferred tax assets related to a change in the tax rate following the expiration of the special corporation tax for reconstruction.

Looking back on the fiscal year of 2013, Daiichi Sankyo Group had two big events.

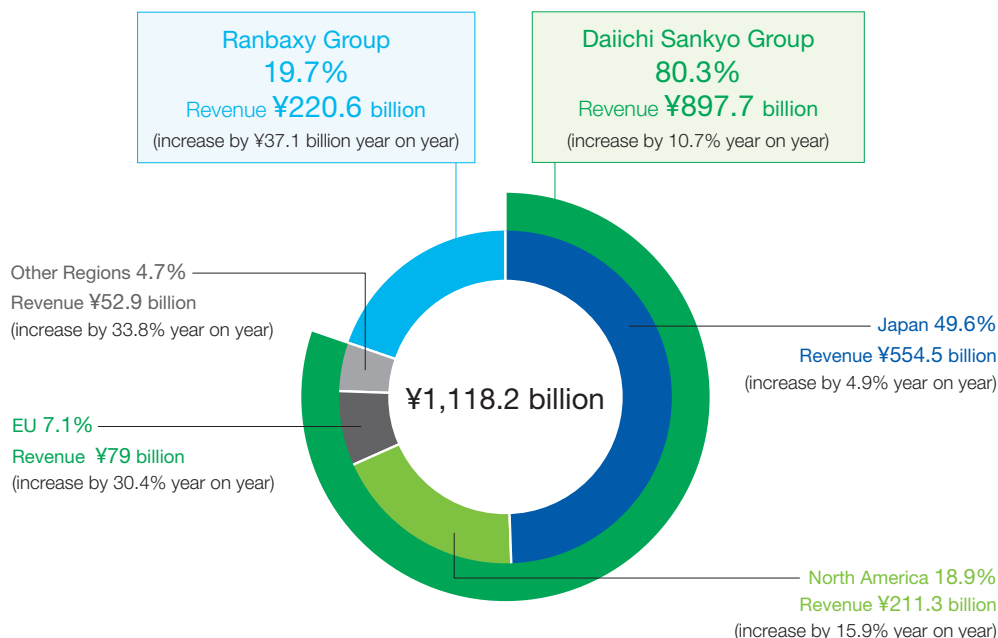
First, we completed New Drug Applications for the marketing of edoxaban, an anticoagulant expected to

become one of our next flagship products, in Japan, the US, and EU, supported by the favorable results of Hokusai-VTE and ENGAGE-AF trials. We anticipate approval and launch by the end of fiscal 2014.

In contrast, Ranbaxy Laboratories Ltd. ("Ranbaxy"), our generic drug subsidiary based in India, has strived to reinforce quality assurance and enhance data reliability, in response to the US Food and Drug Administration's ban on the import of products from four factories in India. In addition to our greater support for Ranbaxy, we considered different strategies to improve their business performance and corporate value and finally decided that the best strategy would be a merger of Ranbaxy into Sun Pharmaceutical Industries Ltd. ("Sun Pharma"), with Daiichi Sankyo Group receiving a stake of about 9% in the expanded Sun Pharma. As a result, the three companies concluded a contract on April 6, 2014. After the completion of the merger which is scheduled to occur at the end of December 2014 subject to final regulatory approvals, we will enter negotiations with Sun Pharma about partnership in our group operations in emerging countries.

▶ Chart 1

Composition Ratio of Fiscal 2013 Sales Revenue by Segment



Among our important business challenges in fiscal 2014, we will describe our ongoing corporate efforts from the viewpoints of fostering of global products, growth of individual regional operations, and achievement of revenue and profit growths.

## Fostering of Global Products

### 1. Maintenance and Expansion of Olmesartan

Antihypertensive Olmesartan, our anchor product, is distributed in more than 100 countries, including Japan, the US, and EU as major markets. Its sales in fiscal 2013 exceeded ¥300 billion in terms of yen. ▶ Chart 2

For the US and EU markets, where competition with branded and generic medicines in the same class or treating the same conditions, is extremely intense, we will further enhance the efficiency of our promotional activities and seek to expand the potential of the product.

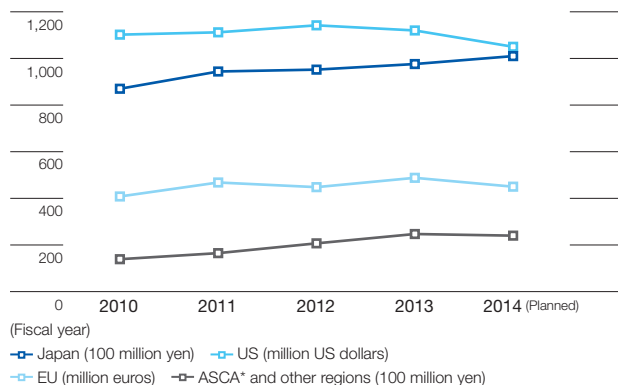
In other regions, we will strive to maintain the position of Olmesartan by focusing our efforts on new combination therapies.

The patent term of Olmesartan in major markets will expire in sequence from 2016 onward, which will inevitably exert a large impact on our sales performance. The strategy to foster global products that will serve as the mainstay of our company represents our principal business challenge.

▶ Chart 3

▶ Chart 2

#### Sales of Olmesartan (local currency basis)

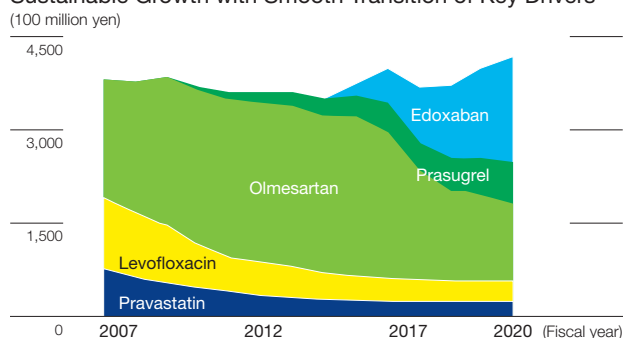


	FY2010	FY2011	FY2012	FY2013	FY2014 (Planned)
Japan (100 million yen)	870	944	952	976	1,010
US (million US dollars)	1,102	1,112	1,142	1,120	1,050
EU (million euros)	408	468	448	488	450
ASCA* and other regions (100 million yen)	139	165	207	247	240

\* Asia, South and Central America

▶ Chart 3

#### Sustainable Growth with Smooth Transition of Key Drivers



## 2. Fostering of Prasugrel into a Major Product

Prasugrel, an antiplatelet drug already well-established on the market in more than 70 countries, including the US and EU, was recently launched in Japan on May 27, 2014 (Product name: Efient).

Prasugrel is indicated in Japan to prevent vascular stenosis and occlusion by inhibiting platelet aggregation and is expected to reduce the recurrences of myocardial infarction and angina pectoris.

The dose tailored to Japanese subjects was lower than that used in the US and EU. In Phase III trials in Japan, prasugrel more effectively reduced cardiovascular events, including myocardial infarction from the early stage of treatment onward compared with the competitor clopidogrel. The stable effect of prasugrel and the same level of safety as with existing drugs have also been confirmed in these studies.

In Japan, a Phase III trial for an additional indication of ischemic stroke is currently ongoing.

The Japanese market for competitive drugs exceeds 180 billion yen on a drug price basis and has expanded by more than 30% over the past five years. We will emphasize the excellent profile of prasugrel to make it a major product and a standard treatment in Japan. ▶ Chart 4


▶ Chart 4

### Antiplatelet Prasugrel

**Toward Standard Treatment in Japan**

- Reduction of the recurrences of myocardial infarction and angina pectoris
- Dose tailored to Japanese subjects  
The reduction of cardiovascular events at the early stage of treatment, stable effect, and safety

**Launched  
on May 27,  
2014**







### 3. Edoxaban, a potential future growth driver

Edoxaban is a novel oral anticoagulant (NOAC) developed by Daiichi Sankyo that specifically inhibits factor Xa, which is a factor in the coagulation system that leads to blood clotting.

Under the name of LIXIANA, edoxaban was approved in Japan in April 2011, for the prevention of VTE after major orthopedic surgery and was launched in July 2011.

We submitted an application for additional indications in Japan for the prevention of ischemic stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAf) and for the treatment and recurrence prevention of venous thromboembolism (VTE) [deep vein thrombosis (DVT) and pulmonary thromboembolism]. Daiichi Sankyo has also filed for approval of once-daily edoxaban in both the U.S. and EU for the prevention of stroke in NVAf and for symptomatic VTE in patients with DVT and/or pulmonary embolism (PE). Regulatory review is currently under way.

In preparation for full-scale commercialization across the globe, we have analyzed the characteristics of the anticoagulant market and determined a desirable approach to commercializing this product. ▶ Chart 5

While the novel oral anticoagulant (NOAC) market is rapidly growing, warfarin still represents the standard of care. Currently the NOACs seem to have the potential to replace warfarin and are expected to gain new prescriptions for further growth and edoxaban will be one of the agents.

In the NOAC market, Bayer's rivaroxaban is a market leader at present. The reasons for its success may include the convenient once-daily dosing and their consistent brand strategy tailored to each market.

Geographically, this market mainly comprises developed nations including Japan, the US, and the EU.

Based on these market characteristics, we have concluded that "quality" is more important than "quantity [number of medical representatives (MRs)]" of our marketing efforts.

▶ Chart 5

#### Market Characteristics and Desirable Commercialization Mode

##### Marketing Characteristics

- The NOAC market is growing rapidly.
- Warfarin still accounts for a large part of prescriptions.
- Rivaroxaban is a market leader.
- The market mainly comprises developed countries, including Japan, the US, and the EU.

##### Desirable Marketing System

- "Quality" is more important than the "quantity" of marketing efforts.
- Ability to serve a variety of stakeholders
- Consistent brand strategy and speedy decision making

We believe that the determinant of success in this market is the qualitatively excellent business skills with which we can effectively approach a variety of stakeholders, rather than the quantitative approach focused on MR activities to physicians that is adopted in the antihypertensive market.

In the anticoagulant market, once a specific agent is prescribed, a patient tends to stay on that medication. As a result, there is very little switching from one anticoagulant medication to another. For this reason it is especially important that specialists who first treat patients understand edoxaban. Generating and conveying a wide variety of information that helps to provide helpful information about edoxaban to these specialists is key. A consistent brand strategy and speedy decision making are essential for such quality marketing activities.

The strengths of edoxaban are, as seen in Phase III trials, convenience of once-daily dosing and a high level of safety.

In addition, backed by data from clinical trials with multiple dose levels, the dose can be adjusted depending on patient conditions.

We conducted two global Phase III trials in a world largest scale: ENGAGE-AF TIMI 48 trial in 21,105 patients with a 2.8-year follow-up and Hokusai-VTE trial in 8,292 patients with a 12-month follow-up. In both high-quality trials, edoxaban was found to be non-inferior in efficacy and superior in safety to warfarin (the comparator medication) that was prescribed in an extremely well-controlled condition.

In Japan, edoxaban has already been prescribed to more than 150,000 patients since its initial sales in 2011 as an inhibitor of venous thromboembolism following orthopedic surgery, and a substantial body of safety data has been accumulated. ▶ Chart 6

▶ Chart 6

#### Strengths of Edoxaban

- Convenient once-daily dosing
- Less major bleeding than warfarin
- The dose can be adjusted depending on patient conditions.
- The results achieved in large, worldwide high-quality Phase III trials in a world largest scale.
- Accumulation of safety data from over 150,000 patients in Japan



Please refer to "Special Topic Edoxaban from Japan to the World" on page 26 for details.

One of the strengths of the Daiichi Sankyo Group's business operation is our experience in the cardiovascular and thrombosis fields through the active marketing of olmesartan launched in 2002 and prasugrel launched in 2009.

In the US and EU markets, olmesartan has been very successful in the market for antihypertensive drugs, supported by our own sales force network. We have established relationships with thrombosis specialists through the development of prasugrel and learned a great deal in the course of operating activities in this field.

We have high-quality marketing abilities in Japan, the US, and the EU.

As described above, we have concluded that we will be able to successfully commercialize edoxaban to maximize its value in the future, pending approval by health authorities where it is currently under review, if we capitalize on the strengths of the product as well as our business operations.

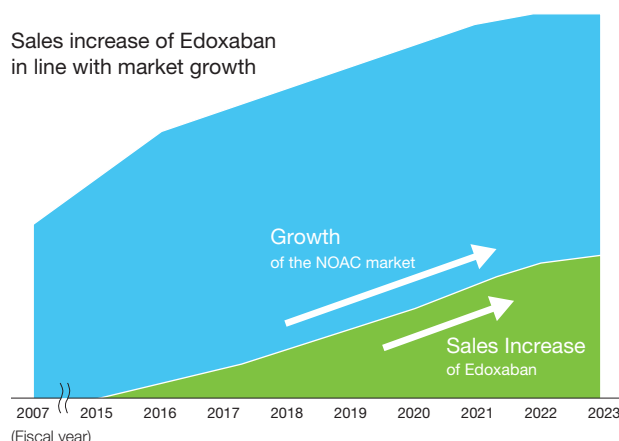
Daiichi Sankyo will act as the sole supplier of edoxaban in Japan, the US, and the EU. In other countries/regions, we will select the most suitable partners for individual countries/regions to commercialize edoxaban as a joint project, considering marketing conditions and our operating base in each country/region.

Sales of edoxaban have the potential to surpass the rate of growth of the overall NOAC market and become a key growth driver for our company. [▶ Chart 7](#)

▶ Chart 7

#### Expected Growth of Edoxaban

Sales increase of Edoxaban in line with market growth



## Maximization of Sales and Profits in Individual Regional Businesses

### 1. Further Market Penetration through Continued Growth of New Products

In Japan, our products launched from 2010 onward, namely, Rezaltas, Inavir, Mema, Nexium, Ranmark, and Pralia, have contributed to our sales increase and a rapid increase of our market share. [▶ Chart 8](#)

Our estimated share of the Japanese market was 5.26% in fiscal 2011, 5.53% in fiscal 2012, and 5.58% in fiscal 2013.

The launches of Efient in May 2014 and Canaglu, a treatment of type 2 diabetes mellitus, in August the same year has helped further reinforce our product portfolio. We are making every effort to increase our sales and market share with an aim to gain a top share in the Japanese market.

▶ Chart 8

#### Sales Plan for Main Products in Japan

			(Billions of yen)		
			FY2012	FY2013	FY2014 (planned)
Olmetec	Antihypertensive drug		78.3	79.1	79.0
Rezaltas	Antihypertensive drug		16.9	18.5	22.0
Loxonin	Anti-inflammatory analgesic		59.6	59.3	52.0
Nexium	Ulcer treatment		21.6	54.2	67.0
Memary	Alzheimer's disease treatment		23.8	33.3	50.0
Inavir	Anti-influenza agent		11.1	13.4	10.0
Ranmark	Treatment for bone complications		4.4	8.1	10.0
Pralia	Treatment for osteoporosis		—	3.2	12.0

## 2. Growth Path of Luitpold by Boosting Injectafer

Luitpold Pharmaceuticals in the US is pursuing growth opportunities by leveraging Injectafer for iron-deficiency anemia.

Injectafer, first launched in 2013, is indicated in a wide range of patients, not limited to patients with chronic kidney disease. It can be administered to patients who have a broad range of etiologies who either are intolerant to or respond poorly to the oral treatment of anemia. In this class of drugs, Injectafer can be used at the highest dose with confirmed safety and efficacy. The shortest infusion takes only 15 minutes, offering excellent convenience to patients and providers.

In the US, the non-dialysis market for treatments of iron-deficiency anemia, more specifically, gastrointestinal, oncological and gynecological market, currently suffers low treatment satisfaction due to the limitations of available options. Injectafer is able to address these limitations.

Because this market is expected to show a double-digit yearly growth, we are planning to target the non-dialysis market with the medium-term objective of making Injectafer into Luitpold's flagship product. ▶ Chart 9

▶ Chart 9

### Product profile of Injectafer

- Wide range of indications
- Significantly better treatment of anemia compared with oral drugs
- The highest dose is available among the same type of drugs
- The shortest workable infusion takes only 15 minutes



## Achievement of Revenue and Profit Increases

Through unified efforts in addressing the above-mentioned challenges, we are determined to increase our revenue and profit in fiscal 2014 to accomplish the estimated sales revenue of ¥920 billion (a 2.3% increase year on year) and the estimated operating income of ¥120 billion (a 6.3% increase year on year). ▶ Chart 10

\* The operation of Ranbaxy group will be discontinued after a merger with Sun Pharma that is expected to occur at the end of 2014. The figures shown here are, therefore, for the Daiichi Sankyo Group (continuing operations) excluding Ranbaxy group.

▶ Chart 10

### Consolidated Forecasts for Fiscal 2014

	FY2013	FY2014 Forecast	(Billions of yen)	
			Increase/decrease	
Revenue	899.1	920.0	+ 20.9	(+ 2.3%)
Operating income	112.9	120.0	+ 7.1	(+ 6.3%)
Profit attribute to owners of the Company	68.8	78.0	+ 9.2	(+ 13.3%)
Dividends per share	60 (yen)	60 (yen)		

## Responsible Corporate Activities Based on Corporate Conduct Charter

As a life-science oriented company, we comply with laws, regulations and rules regarding global corporate activities, and act with the highest ethical standards and a good social conscience appropriate for a company engaged in a business that affects human lives based on the following principles. We fulfill our corporate social responsibility (CSR) by actively responding to an ever-changing society and enacting improvements for corporate value. Daiichi Sankyo Group is performing responsible corporate activities based on the Daiichi Sankyo Group Corporate Conduct Charter as the corporate conduct principles (refer to page 03).

### 1. Encouraging Corporate Ethics

The conduct of our activities in accordance with national/regional laws and regulations, social norms, ethics, and convention must be ensured for sustained business operations. In particular, because of our industry's connection to patients' health, pharmaceutical companies are required to ensure legal compliance in all of their business activities from R&D and drug production to supply chain, quality assurance marketing, and sales. The Daiichi Sankyo Group has the Corporate Conduct Charter to ensure the highest ethical standards and good social conscience appropriate for a company. Based on the spirit of the Charter, Daiichi Sankyo and each Group company has developed a code of conduct suited to each region and its legal, regulatory, industrial and social requirements and holds all executive officers and employees accountable to it. Against the backdrop of increasing cross-border laws and regulations as well as growing social demands, we have developed a Group-wide policy concerning behavioral principles for corporate officers and employees on an individual level and base our sustained growth on their full compliance.

In Japan, the regulatory authorities have requested pharmaceutical companies about the way of supporting clinical studies. We realigned our organizational functions by the end of fiscal 2013 in our continued efforts to address this issue.


 Please refer to "Promote Ethical Business Management in Compliance with Law" on page 56 for details.

### 2. Fostering Excellent Human Resources

The pharmaceutical industry is an innovation business, and innovation cannot be achieved without creative thinking and science. Therefore, it can be said that placing human resources as the most significant assets, securing excellent staff, and maintaining their motivation is one of our paramount management objectives.

Our researchers are ambitious to create excellent drugs for patients, and this ambition is one of the main drivers to realize innovation. Securing people with unique ideas and a venture spirit who can strive for innovation without the fear of failure is the foundation of our sustained growth.

It is also important for us to accomplish diversification and globalization at a faster pace than before to conduct our operational strategies. Sharing a clear attitude toward work with all of the Group employees is necessary in order for us, a group of people with different cultural backgrounds and ways of thinking and diverse talents, to make concerted efforts toward the same goal. We believe that our long-term success, in other words, the fulfillment of our corporate philosophy, will become a reality when our employees who share the values of our company grow together with Daiichi Sankyo through active open-minded communication and work with passion.

 Please refer to "Mutual Growth of Employees and the Company" on page 62 for details.





### 3. Our Devotion to Social Agendas as a Pharmaceutical Company

As health and medical issues are expected to become a critical and social concern, the Daiichi Sankyo Group regards expanding access to medicine as a social responsibility and is committed to contributing to society by globally providing solutions in various ways.

For instance, many people in developing countries are suffering a lack of access to medical services for economic reasons or owing to inadequate social infrastructure. As a member of the healthcare industry, we will contribute to the resolution of such global health issues in cooperation with NGOs, public administrators, and communities. In addition,

there are patients with rare diseases that require an adequate treatment, but have seen a poor progress in the research and development of pharmaceuticals or medical devices.

We will make Group-wide efforts in expanding access to medical services, including the resolution of global health issues and R&D activities for rare diseases, to meet unmet medical needs in the world. We firmly believe that such a strategic approach to the expansion of access to medical services will bring opportunities for our innovation and unique partnerships and these efforts will support our sustained growth.



Please refer to "Broaden the Opportunities of Access to Medical Services" on page 72 for details.

# Corporate Governance

## Policy and Structure

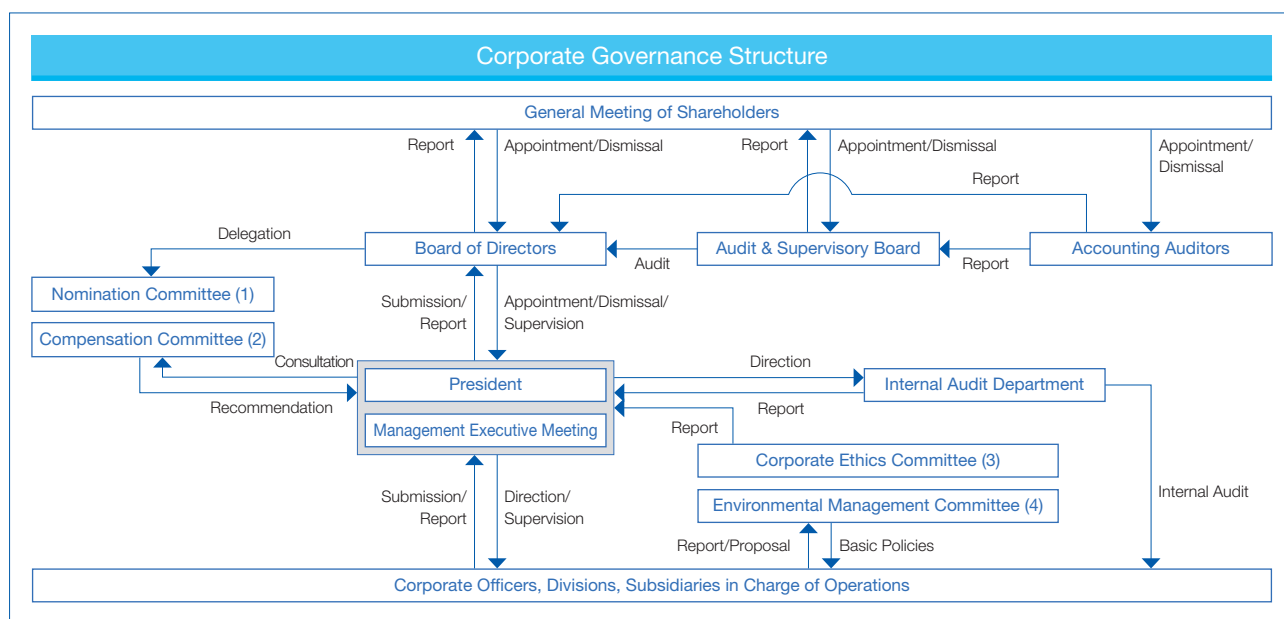
In addition to creating a management structure that can speedily and flexibly to changes in the business environment, the Daiichi Sankyo Group is working to secure legal compliance and management transparency and to strengthen oversight of management and the conduct of operations.

- To clarify Members' of the Board management responsibility and reinforce their oversight of management and the conduct of operations, their terms of office are set at one year, and four of our ten Members of the Board are brought in as Members of the Board (Outside).
- To ensure management transparency, the nomination of candidates for Member of the Board and Corporate Officer and compensation thereof are deliberated on by a Nomination Committee and a Compensation Committee, respectively, which are established as voluntary committees. These Committees consist of at least three Members of the Board, of whom Members of the Board (Outside) form a majority, and are chaired by a Member of the Board (Outside).
- For the audit of legal compliance and sound management, the Company has adopted an Audit & Supervisory Board system and established the Audit & Supervisory Board

comprising four members, including two Members of the Audit & Supervisory Board (Outside).

- Aiming at further clarification of these efforts, the Board of Directors Meeting and the Meeting of the Audit & Supervisory Board held on March 31, 2014 resolved specific criteria on the judgment of independence of Members of the Board (Outside) and Members of the Audit & Supervisory Board (Outside) and basic matters regarding execution of duties by Members of the Board for contributing to the reinforcement of future corporate governance.
- The Company employs a Corporate Officer System under the supervision of the Board of Directors, which contributes to appropriate and swift management decision making and the conduct of operations.

Please refer to "Criteria for Independence as Member of the Board (Outside)/ Member of the Audit & Supervisory Board (Outside)" on page 18 for details.



### (1) Nomination Committee

The Nomination Committee deliberates matters required for the nomination of Members of the Board and Corporate Officers at the request of the Board of Directors and contributes to the enhancement of management transparency.

### (2) Compensation Committee

The Compensation Committee deliberates matters required for a policy on compensation of Members of the Board and Corporate Officers at the request of the Board of Directors and contributes to the enhancement of management transparency.

### (3) Corporate Ethics Committee

The Corporate Ethics Committee promotes management that complies with domestic and international laws and regulations as well as corporate ethics and fulfills corporate social responsibility.

### (4) Environmental Management Committee

The Environment Management Committee promotes environment-friendly and balanced management which contributes to sustainable society through its overall corporate activities.

## ■ Directors and Auditors (As of June 23, 2014)




<p><b>1 Joji Nakayama</b> Representative Director, President and CEO</p>	<p><b>4 Takeshi Ogita, Ph.D.</b> Member of the Board, Senior Executive Officer</p>	<p><b>7 Hiroshi Hirabayashi</b> Member of the Board (Outside)</p>	<p><b>11 Kazuo Koike</b> Member of the Audit &amp; Supervisory Board</p>
<p><b>2 Yuki Sato</b> Representative Director, Member of the Board, Executive Vice President</p>	<p><b>5 Kazunori Hirokawa, M.D., Ph.D.</b> Member of the Board, Senior Executive Officer</p>	<p><b>8 Kunio Ishihara</b> Member of the Board (Outside)</p>	<p><b>12 Takashi Chiba</b> Member of the Audit &amp; Supervisory Board</p>
<p><b>3 Manabu Sakai</b> Representative Director, Member of the Board, Executive Vice President</p>	<p><b>6 Sunao Manabe</b> Member of the Board, Executive Officer</p>	<p><b>9 Noritaka Uji</b> Member of the Board (Outside)</p>	<p><b>13 Akiko Kimura</b> Member of the Audit &amp; Supervisory Board (Outside)</p>
		<p><b>10 Hiroshi Toda</b> Member of the Board (Outside)</p>	<p><b>14 Yutaka Katagiri</b> Member of the Audit &amp; Supervisory Board (Outside)</p>



## ■ Criteria for Independence as Member of the Board (Outside)/ Member of the Audit & Supervisory Board (Outside)

In nominating candidates for Members of the Board, Daiichi Sankyo shall include a person who satisfies the definition of Member of the Board (Outside), aiming at reinforcing decision-making functions from various perspectives and enhancing the supervising function for execution of operation. Outside Directors/Auditors (Member of the Board (Outside) and Member of the Audit & Supervisory Board (Outside)) are required to ensure their independence from the Company.

On March 31, 2014, the Board of Directors and the Audit & Supervisory Board resolved "Criteria for Independence" as follows:

1. A Member of the Board or a Member of the Audit & Supervisory Board shall be determined to be independent from the Company and may not have a conflict of interest with general shareholders of the Company unless he or she falls into any of the following categories:

(1) A candidate or his or her immediate family member\* who:

- i) is or has been an Executive Officer of the Company or brother company or subsidiary (referring to a director other than outside director, a corporate officer, an executive officer or other employee; provided, however, limited to those who are important persons in terms of relationship with immediate family members. The same shall apply hereinafter.); or
- ii) has received during any of the last three fiscal years more than 10 million yen in direct compensation for his or her services as a consultant, a specialist in law, accounting or tax, or a healthcare professional, etc. from the Company, other than director or member of audit & supervisory board compensation.

\* An "immediate family member" includes a person's spouse, parents, children, siblings, grandparents, grandchildren, mothers and fathers-in-law, sons and daughters-in-law, spouses of siblings, grandchildren-in-law, and brothers and sisters-in-law. The same shall apply hereafter.

(2) A candidate or his or her immediate family member who is or has been within the last ten years, an Executive Officer of a corporation or other association falling into:

i) Business relationship

- a) a company that has made payments to, or received payments from, the Group for products or services in an amount which, in any of the last three fiscal years, exceeds 2% of any of the companies' consolidated gross revenues;
- b) a consulting firm, law firm, auditing firm, tax accounting firm, or school corporation that receives remuneration from the Group exceeding 10% of its gross revenue in any of the last three fiscal years; or
- c) a lender from whom the Group obtained a loan of more than 10% of its consolidated total assets at the end of the fiscal year immediately before nomination.

ii) Major shareholder

A corporation or other legal entity that is a major shareholder of the Company or a corporation that the Company is a major shareholder at the time of determining the independence. A major shareholder means a shareholder holding at least 10% of total shares outstanding of the Company.

iii) Recipient of charitable contributions

An organization to which the Company's discretionary charitable contributions in any of the last three fiscal years are more than 10 million yen and 2% of annual gross revenues of that organization or other associations.

iv) Accounting auditor

An audit firm that is or has been for the last three years an accounting auditor of the Company group.

v) Cross-directorship arrangement

When an Executive Officer of the Company is a current Member of the Board (Outside) or Member of the Audit & Supervisory Board (Outside) in a cross-directorship arrangement with the listed company.

2. Even though a candidate for an outside director/auditor falls into any of the above, when the Board of Directors or the Audit & Supervisory Board judge him or her to be ensured of independence after a comprehensive review, he or she may be determined to have no problem with criteria for independence as an outside director/auditor.



## Independent Board Members

### Members of the Board (Outside)

#### Hiroshi Hirabayashi

##### Career Summary and Positions

Apr 1963 Entered Ministry of Foreign Affairs of Japan ("MOFA")  
 Aug 1993 Director General, Economic Cooperation Bureau, MOFA  
 Jan 1998 Ambassador Extraordinary and Plenipotentiary to India and to Bhutan  
 Sep 2002 Ambassador Extraordinary and Plenipotentiary to France and to Andorra  
 Jan 2003 Ambassador Extraordinary and Plenipotentiary to France and to Andorra and ambassador to Djibouti  
 Jun 2006 Ambassador in charge of inspection  
 Jun 2007 President, the Japan-India Association (Public Interest Incorporated Foundation) (to present)  
 Apr 2008 Visiting Professor, Waseda University, Graduate School of Asia-Pacific Studies  
 Jun 2009 Vice President, the Japan Forum on International Relations (Public Interest Incorporated Foundation) (to present)  
 Jun 2010 Member of the Board (Outside) of Daiichi Sankyo (to present)



##### Reason for Appointment

To reflect his knowledge and insight based on his global experience as a diplomat in the management of the Company.

#### Kunio Ishihara

##### Career Summary and Positions

Apr 1966 Entered Tokio Marine & Fire Insurance Co., Ltd. ("TMFI")  
 Jun 1995 Director and General Manager, Hokkaido Regional Headquarters, TMFI  
 Jun 1998 Managing Director and General Manager, Hokkaido Regional Headquarters, TMFI  
 Jun 2000 Senior Managing Director, TMFI  
 Jun 2001 President, TMFI  
 Apr 2002 President, Millea Holdings, Inc. (currently Tokio Marine Holdings, Inc.)  
 Oct 2004 President, Tokio Marine & Nichido Fire Insurance Co., Ltd. ("TMNFI")  
 Jun 2007 Chairperson of the Board, TMNFI  
 Jun 2007 Chairperson of the Board, Millea Holdings, Inc. (currently Tokio Marine Holdings, Inc.)  
 Jul 2008 Chairperson of the Board, Tokio Marine Holdings, Inc.  
 Jun 2010 Member of the Board (Outside) of Daiichi Sankyo (to present)  
 Jun 2013 Counselor, TMNFI (to present)



##### Reason for Appointment

To reflect his expertise in risk management and insight based on his corporate management experience in the management of the Company.

#### Noritaka Uji

##### Career Summary and Positions

Apr 1973 Entered Nippon Telegraph and Telephone Public Corporation  
 Jun 1999 Director, Senior Vice President, Advanced Information Network Services Sector, NTT DATA Corporation ("NTT DATA")  
 Sep 2000 Director, Senior Vice President, Corporate Strategy Planning Department, NTT DATA  
 Jun 2001 Director, Senior Vice President, Industrial System Sector, NTT DATA  
 Apr 2002 Director, Senior Vice President, Enterprise Business Sector, NTT DATA  
 Jun 2003 Managing Director, Executive Vice President, Enterprise Systems Sector and Enterprise Business Sector, NTT DATA  
 Jun 2005 Representative Director and Executive Officer, NTT DATA  
 Jun 2007 Representative Director and Senior Executive Vice President, Nippon Telegraph and Telephone Corporation ("NTT")  
 Jun 2012 Adviser, NTT (to present)  
 Jun 2014 Member of the Board (Outside) of Daiichi Sankyo (to present)



##### Reason for Appointment

To reflect his expertise on the information communication business and his insight on overall corporate management based on his corporate management experience in the management of the Company.

#### Hiroshi Toda

##### Career Summary and Positions

Apr 1975 Entered Nomura Securities Co., Ltd.  
 Jun 1991 President, Nomura Bank (Switzerland) Limited  
 Jun 1997 Director, Head of Financial Market, Nomura Securities Co., Ltd.  
 Jun 2000 Senior Managing Director, Head of Investment Banking, Nomura Securities Co., Ltd.  
 Oct 2001 Director of Nomura Holdings, Inc. and Senior Managing Director, Head of Global Wholesale, Nomura Securities Co., Ltd.  
 Jun 2003 Deputy President and Chief Operating Officer, Nomura Holdings, Inc., and Deputy President and Chief Operating Officer, Nomura Securities Co., Ltd.  
 Apr 2008 Vice Chairman, Nomura Securities Co., Ltd.  
 Jul 2010 Ambassador Extraordinary and Plenipotentiary to Greece  
 Jun 2014 Member of the Board (Outside) of Daiichi Sankyo (to present)



##### Reason for Appointment

To reflect his expertise on securities and finance and his insight based on his corporate management and diplomatic experience in the management of the Company.

### Members of the Audit & Supervisory Board (Outside)

#### Akiko Kimura

##### Career Summary and Positions

Apr 1973 Attorney-at-law, Nishimura, Komatsu & Tomotsune (currently Anderson Mori & Tomotsune)  
 Jan 1977 Partner, Nishimura, Komatsu & Tomotsune  
 Oct 1997 Member of the Council Committee on Foreign Exchange and Other Transactions, Ministry of Finance of Japan  
 Jan 2001 Member of the Council on Customs Duties, Foreign Exchange and Other Transactions, Ministry of Finance of Japan  
 Jan 2011 Of Counsel, Anderson Mori & Tomotsune (to present)  
 Jan 2014 Member of the Audit & Supervisory Board (Outside) of Daiichi Sankyo (to present)



##### Reason for Appointment

To reflect her knowledge and insight based on her abundant experience as a lawyer in the audit of the Company.

#### Yutaka Katagiri

##### Career Summary and Positions

Apr 1975 Entered National Police Agency  
 Feb 2001 Chief, Community Safety Bureau, Tokyo Metropolitan Police Department  
 Jan 2002 Director General, Kyoto Prefectural Police  
 Aug 2003 Chief Inspector General, National Police Agency  
 Aug 2004 Director General for Secretariat's Policy Matters, Commissioner General's Secretariat, National Police Agency  
 Jan 2007 Chief of Community Safety Bureau, National Police Agency  
 Aug 2008 Chief of Commissioner General's Secretariat of National Police Agency  
 Jun 2009 Deputy Commissioner General, National Police Agency  
 Oct 2011 Commissioner General, National Police Agency  
 Jun 2013 President, Council for Public Policy (to present)  
 Jun 2014 Member of the Audit & Supervisory Board (Outside) of Daiichi Sankyo (to present)



##### Reason for Appointment

To reflect his knowledge and insight based on his experience at administrative agencies, etc. in the audit of the Company.

## Basic Design of Remuneration to Members of the Board

- Remuneration to Members of the Board is set in place so as to help maximize the value of the Company. In specific terms, the Company grants a performance bonus as a short-term incentive and share remuneration-type stock option remuneration as a long-term incentive in addition to the fixed remuneration of basic remuneration.
- In order to ensure that Members of the Board (Outside) and Members of the Audit & Supervisory Board (Outside) have a sufficient supervisory function over the management, the Company pays only basic remuneration without a short- or long-term incentive.

## Procedures for Deciding Remuneration for Members of the Board

- The General Meeting of Shareholders has approved a basic remuneration for Members of the Board at a maximum annual limit of 450 million yen and a total amount of share remuneration-type stock options to be granted to Members of the Board at a maximum annual limit of 140 million yen. Profit-sharing bonuses are approved by the General Meeting of Shareholders for the relevant fiscal year.
- The General Meeting of Shareholders has approved a basic remuneration for Members of the Audit & Supervisory Board, which shall be the only remuneration they receive, at a maximum annual limit of 120 million yen.
- The remuneration for Members of the Board and Corporate Officers are deliberated by a Compensation Committee, a voluntarily established committee in which the majority of members are Members of the Board (Outside).
- The Compensation Committee shall deliberate on; the remuneration system and criteria for Members of the Board and Corporate Officers, the remuneration level for each position, the profit-sharing bonus results, and the granting of share remuneration-type stock options.

Classification	Members of the Board		Members of the Audit & Supervisory Board		Total	
	Number of Board Members who received remuneration	Amount of remuneration (million yen)	Number of Board Members who received remuneration	Amount of remuneration (million yen)	Number of Board Members who received remuneration	Amount of remuneration (million yen)
Fees (annual amount) [Outside Members]	11 [4]	440 [60]	4 [2]	105 [30]	15 [6]	545 [90]
Bonuses to Members of the Board [excluding Members of the Board (Outside) and Members of the Audit & Supervisory Board (Outside)]	6	105	—	—	6	105
Share remuneration-type stock option remuneration [excluding Members of the Board (Outside) and Members of the Audit & Supervisory Board (Outside)]	6	126	—	—	6	126
Total [Outside Members]	11 [4]	669 [60]	4 [2]	105 [30]	15 [6]	774 [90]

## Basic Policy on Establishing Internal Control Structure

On April 26, 2013, the Board of Directors of Daiichi Sankyo resolved the following basic policies on systems for ensuring compliance with laws and regulations and the Company's articles of incorporation in the execution of duties by Members of the Board and other systems for ensuring proper operations.

### Systems for Ensuring Compliance with Laws and Regulations and the Company's Articles of Incorporation in the Execution of Duties by Members of the Board

- The Company shall establish a compliance system by stipulating the Daiichi Sankyo Group Corporate Conduct Charter, Daiichi Sankyo Code of Conduct for Compliance, etc. as the code of conduct for Members of the Board and employees and setting up a meeting body, including outside experts.
- The Company shall appoint Members of the Board (Outside) for the strengthening and enhancement of the function to supervise management.
- Members of the Audit & Supervisory Board shall audit the execution of duties by Members of the Board, legality and appropriateness of decision making, and the status of the establishment of internal control systems.

### Systems Regarding the Retention and Management of Information Related to the Execution of Duties by Members of the Board

- The Company shall establish information security systems and properly store and manage information relating to the execution of duties by Members of the Board, including the minutes of the Board of Directors, in accordance with laws and internal regulations of the Company.

### Rules and Other Systems for Risk Management

- The Company shall stipulate various internal regulations to establish risk management systems.
- The Internal Audit Department shall audit the status of operation of the systems mentioned above.

### Systems for Ensuring the Efficient Execution of Duties by Members of the Board

- The Company shall form a Management Executive Meeting—consisting of Members of the Board, excluding Members of the Board (Outside), and executives appointed by the President who are responsible for main regions, corporate bodies and functions – which shall deliberate important matters for strategic decision-making by the President. The Company shall also set up an approval system as a means of decision-making.

- The Company shall introduce a corporate officer system in consideration of speedy decision making and execution of duties.

#### Systems for Ensuring Compliance with Laws and Regulations and the Company's Articles of Incorporation in the Execution of Duties by Employees

- The Company shall establish a compliance system by stipulating Daiichi Sankyo Group Corporate Conduct Charter, Daiichi Sankyo Code of Conduct for Compliance, etc. as the code of conduct for Members of the Board, Member of the Audit & Supervisory board and employees and setting up a meeting body, including outside experts.
- Vice Presidents and executives responsible for the main regions, corporate bodies, and functions who receive orders from the President shall manage duties in their charge and supervise, manage, and direct the members of their business units in accordance with the "Global Management Regulations," the "Organizational Management Regulations" and other Company rules.
- Each of the functions related to the improvement of systems concerning personnel management, risk management, etc. shall convey policies to manage and guide each department.
- The Internal Audit Department shall implement an internal audit of the status of compliance with laws and regulations, the Articles of Incorporation, and internal regulations.

#### Systems for Ensuring the Proper Operation of the Group, Consisting of the Company and its Subsidiaries

- The Company shall establish "Global Management Regulations" and "Group Company Management Regulations" to clarify the management control system of the Group, operate systems such as compliance, risk management, and personnel systems.
- The Company shall transmit management policies, etc. to Group companies and manage them.
- The Company shall establish "Internal Control System Establishment Regulations" and ensure the reliability of financial reporting by properly implementing those regulations.
- The Company shall establish "Internal Audit Regulations" and implement internal audit on Group companies.

#### Systems Regarding Employees Assisting Duties of Members of the Audit & Supervisory Board, when Members of the Audit & Supervisory Board Ask to Appoint Such Employees

- The Company shall appoint full-time staffers who assist duties of Members of the Audit & Supervisory Board.

#### Matters Regarding the Independence of the Employees Specified in the Preceding Paragraph from Members of the Board

- Full-time staffers assisting Members of the Audit & Supervisory Board shall be independent of Members of the Board and shall execute duties under the directions and orders from Members of the Audit & Supervisory Board.
- Personnel changes, performance appraisal, etc. of full-time staffers assisting Members of the Audit & Supervisory Board shall require prior consent of the Audit & Supervisory Board.

#### Systems of Reporting to Members of the Audit & Supervisory Board by Members of the Board and Employees and Other Systems Regarding Reporting to Members of the Audit & Supervisory Board

- Members of the Board shall establish a system under which when they find facts that could badly hurt the Company, they shall immediately report the facts to Members of the Audit & Supervisory Board.
- When an audit is carried out by Members of the Audit & Supervisory Board under the annual audit plan, Members of the Audit & Supervisory Board shall receive reports on the status of execution of duties from executives, such as Members of the Board, Vice Presidents, and head of subsidiaries.
- Members of the Audit & Supervisory Board shall attend the Management Executive Meeting and other important meetings.
- To verify the legality and appropriateness of the details of approvals, the Company shall send approval documents to Members of the Audit & Supervisory Board consistently.

#### Other Systems for Ensuring the Effective Audit by Members of the Audit & Supervisory Board

- Members of the Audit & Supervisory Board shall have meetings with Representative Directors on a regular basis to check management policies and exchange views concerning important issues related to auditing.
- Members of the Audit & Supervisory Board shall exchange information with Members of the Audit & Supervisory Board of the Group and closely cooperate with them.
- Members of the Audit & Supervisory Board shall coordinate and exchange views with Outside Members of the Audit & Supervisory Board and the Internal Audit Department.

#### Basic Policies and Systems for Eliminating Antisocial Forces

- The Company shall take a firm stance toward antisocial forces and organizations that threaten the order and safety of civil society. To prevent antisocial forces and organizations from being involved in the Company's management activities and to stop such forces and organizations from harming the Company, the Company shall stipulate, as its basic policy, in the Daiichi Sankyo Group Corporate Conduct Charter and the Daiichi Sankyo Code of Conduct for Compliance that it shall thoroughly forbid relations with antisocial forces and organizations. In addition, the Company shall establish an organizational structure to that end and strive to eliminate relations with antisocial forces and organizations through methods, such as collecting information in cooperation with the police and other bodies and conducting activities to train Members of the Board and other Officers and employees.

# Risk Management

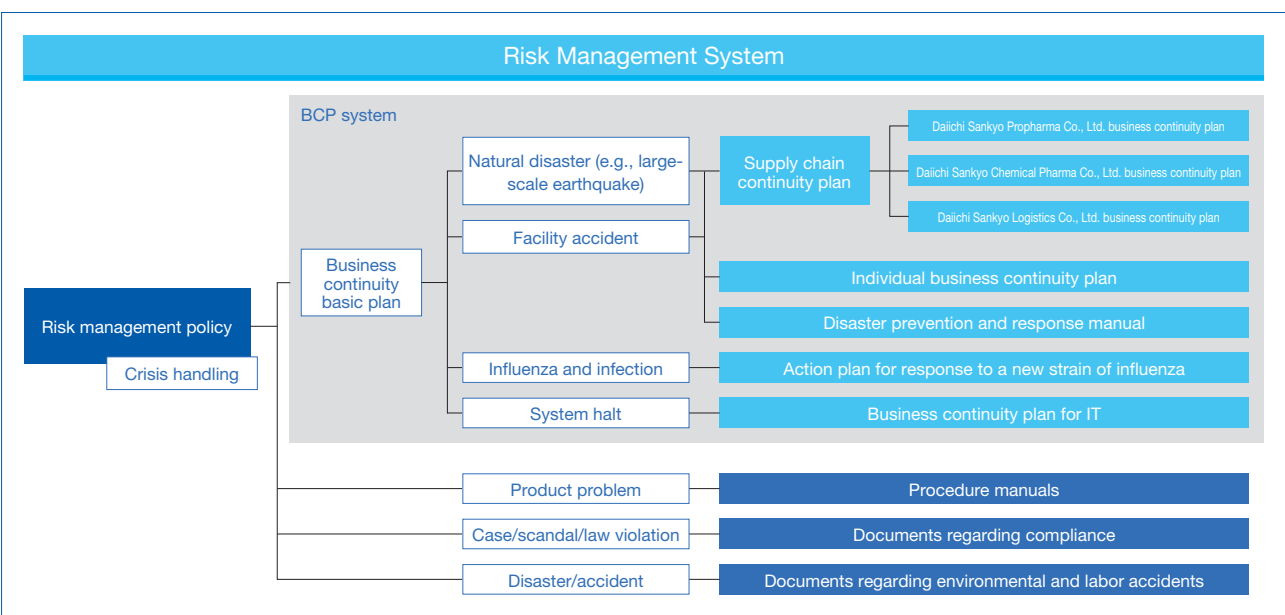
## Risk Management

The Daiichi Sankyo Group defines risks as factors that may prevent the Group from attaining its organizational goals, and most of these factors can be predicted beforehand. The corporate management should assume major responsibility for risk management by dealing with the underlying risks of its business activities (by retaining, reducing, avoiding or eliminating them), appropriately managing the impacts of those risks and minimizing all human, social, and corporate damage.

The Head of the Corporate Management Unit controls risk management across the Group as the Chief Risk Management Officer (CRMO), promotes risk management education, and operates the risk management system. In each division, the responsible person autonomously manages risks in their efforts in attaining the organizational goals, by analyzing/evaluating individual risks, making and

implementing a yearly risk management plan, and providing employees with information on underlying risks in the organization, education, and insight concerning risk management. As a measure to address significant risks, the Group has a system in which the responsible person in each division deals with such risks in cooperation with the CRMO. Moreover, in board meetings and management meetings, we regularly seek to identify and assess underlying risks that are likely to exert a critical impact on our business management and take appropriate measures to prevent surfacing.

As part of the risk management scheme, the Group has a Business Continuity Plan (BCP) that stipulates preparations for and measures in the event of disasters as well as procedures for managing crisis in emergencies (refer to the chart below).



## ■ Business Continuity Plan (BCP)

The Group has a Business Continuity Plan (BCP) to prepare against four major threats (natural disaster, facility accident, new influenza viruses/infection, and system failure). Based on its experiences with the Great East Japan Earthquake, the Group established a new BCP in 2012 to quickly restore operations in the event of an emergency and ensure a stable supply and a security of quality of medical products to support the medical system.

Considering the social needs, the new BCP has a regularly revised list of priority drugs to ensure a smooth supply of “drugs used by a large number of patients”, “emergency drugs”, and “drugs with no substitutes.”

The company is taking steps to strengthen its backup system by dispersing production and distribution hubs and maintaining multiple sources for purchases and has installed private electric generators to help minimize the impact of any interruption in the supply of electricity. For a stable supply, the company has also strengthened the IT infrastructures, such as by doubling the main systems.

We will continue to improve our business continuity planning in view of any change in the circumstances that impact our business and will continue to conduct in-house educational programs to ensure preparedness.

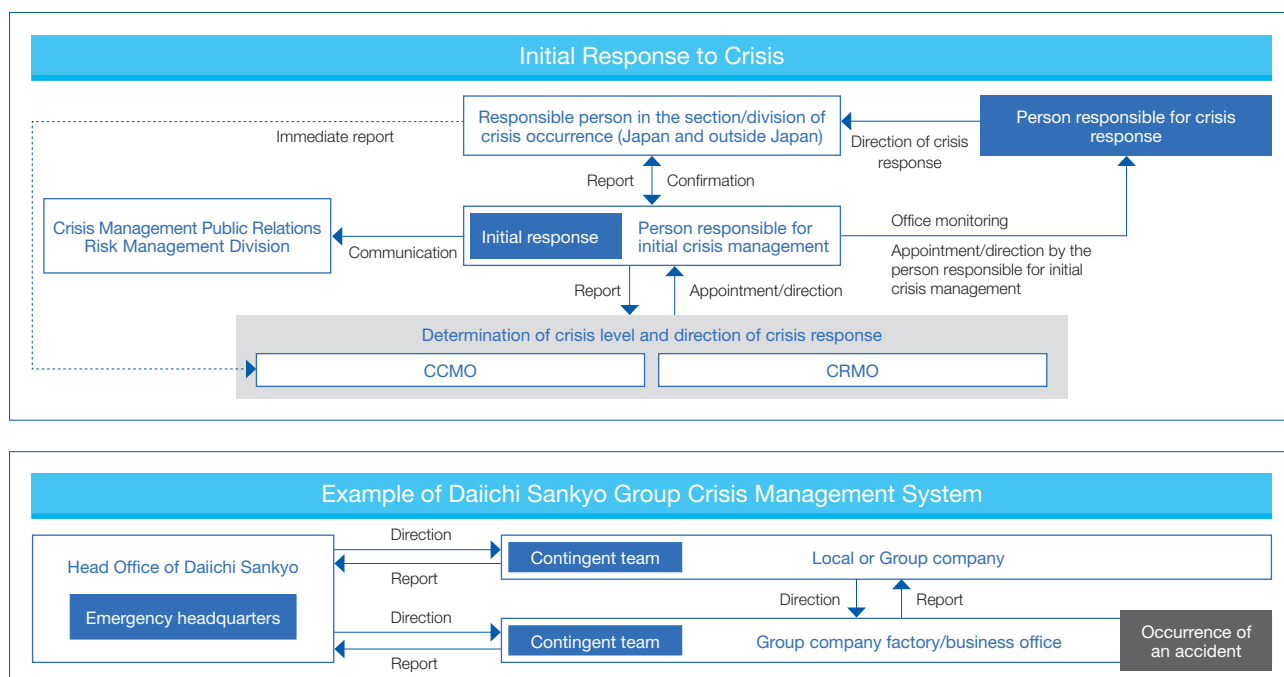
## ■ Crisis Management

The Daiichi Sankyo Group defines crises as factors that may cause an adverse event or secondary events arising from an initial occurrence could lead to serious negative effects on the Group and its stakeholders. Crisis management is defined by the Group as appropriate responses to such events while promptly and rationally managing and analyzing their potential impact.

In the event of a crisis, the responsible person in the section or division of the occurrence shall initially report to the person responsible for initial crisis management (Vice President of General Affairs and Procurement Department),

who shall then make a judgment whether company-wide measures are necessary or not and report to the president (or the officer appointed under the responsibility of the president) who would serve as the Chief Crisis Management Officer (CCMO) and also share the information with the CRMO to ensure prompt crisis response and emergency procedures.

In responding to any crisis, the Group places priority on the health, safety and ease of all of its stakeholders, including patients, healthcare professionals, residents in our local communities, and employees.





# Ceaseless Steps of Innovation: Prologue to innovation leading to Edoxaban

## History of Sankyo Co., Ltd., “Steps of Innovation”

First president of Sankyo Co., Ltd.



### Jokichi Takamine

He extracted an enzyme, one of the amylases known as diastase that degrades starch, and invented “Taka-Diastase”; he then succeeded in extracting the world's first hormone (adrenaline).



Adrenaline, adrenomedullary hormone

#### Launched in Japan in 1902

In 1900, Jokichi Takamine, the first president of Sankyo Co., Ltd., succeeded in extracting an adrenal hormone for the first time in the world. In 1902, an agreement for exclusive distributorship in Japan was entered into with Jokichi Takamine, who was a resident of the USA at the time, and the commercialization of the product commenced.



Chloromycetin®, an antibiotic agent

#### Launched in Japan in 1952

Chloramphenicol, a broad spectrum antibiotics, was developed by Parke-Davis & Company Co., Ltd. (currently Pfizer Inc.).

The agreements for exclusive distributorship in Japan and for technical assistance were entered into in July 1950 and 1951, respectively; domestic production started in 1952. In the same year, domestic production using p-nitroacetophenone bromide, a starting raw material produced in Japan, replaced the original manufacturing process. This enabled the product to be produced at a lower cost domestically then importing the product.



Loxonin®, an analgesic and anti-inflammatory agent

#### Launched in Japan in 1986

Loxonin® is a prodrug of a phenylpropionate analgesic and anti-inflammatory agent. It has been continuously used by many patients since it was first marketed as an analgesic and anti-inflammatory agent provided with “3S,” potent analgesic effect (strong), fast acting (speedy) and highly safe (safety). The current dosage forms include tablets, fine granules, tape, gel, and cataplasm; it has also been sold as an OTC drug since 2011.



Mevalotin®, a therapeutic for hyperlipidemia

#### Launched in Japan in 1989

While a variety of statins are currently used as therapeutics for hyperlipidemia all over the world, the first statin in the world was discovered at a research institute of Sankyo Co., Ltd. in 1973. Pravastatin, also developed by Sankyo, as a result of an invention that modified that first statin, is now commercially available in more than 70 countries in the world.

## History of Daiichi Sankyo Co., Ltd.



#### 2005

Daiichi Sankyo Co., Ltd. (joint holding company of Sankyo Co., Ltd. and Daiichi Pharmaceutical Co., Ltd.) was founded and started.

#### 2006

Daiichi Sankyo Healthcare started business.

#### 2007

New Daiichi Sankyo Group was started.

### Daiichi Sankyo Group's Goal Realization of Global Pharma Innovator

#### Expanding our business reach

##### Global

Establish operations in key areas and strengthen worldwide presence

#### Fulfilling unmet medical needs

##### Pharma

Concentrate resources to consistently produce and supply innovative pharmaceutical products that address diverse medical needs

#### Building new business model

##### Innovator

Extend innovation beyond science and technology to encompass our business model

#### 2008

Ranbaxy Laboratories Ltd., India, joined the group.

#### 2009

Prasugrel, antiplatelet agent, was launched with brand names of “Efient®” (Germany) and “Effient®” (USA).

#### 2010

Daiichi Sankyo Espha Co., Ltd. started operations.

#### 2011

Kitasato Daiichi Sankyo Vaccine Co., Ltd. started operations.

“Memory®” for treatment of Alzheimer-type dementia, “Lixiana®” as an oral FXa inhibitor and “Nexium®” as a proton pump inhibitor were launched (Japan).



Memory®, a treatment for Alzheimer-type dementia

## History of Daiichi Pharmaceutical Co., Ltd. “Steps of Innovation”

Founder of “Arsemin Shokai,” the predecessor of Daiichi Pharmaceutical Co., Ltd.



### Katsuzemon Keimatsu

As the importation of drugs from Germany was stopped due to the First World War, he nationalized the production of salvarsan, a therapy for syphilis, was nationalized. He founded Arsemin Shokai, the predecessor of Daiichi Pharmaceutical Co., Ltd. subsequently.



Transamin®, an anti-plasmin medicine

### Launched in Japan in 1965

“Ipsilon,” the world’s first antiplasmin agent (originally developed and launched in Japan in 1954), was modified and was successful as a hemostatic agent in and outside Japan.

This product was stored in a time capsule at Osaka Expo held in 1970 as an excellent drug to be passed down through the generations.



Ticlopidine, an antiplatelet agent

### Launched in Japan in 1981

Ticlopidine was introduced from Parcor (current Sanofi S.A.), France and its indications were expanded as a result of the progression of research and development as an oral antiplatelet agent for the prevention of thrombosis.

Subsequently, the drug was recommended in a leading guideline of antiplatelet therapies.

In October 2007, the commercialization right was succeeded by Sanofi-Aventis K.K. (current Sanofi S.A.)



Tarivid®, a broad-spectrum oral antibacterial agent

### Launched in Japan and Germany in 1985

The drug was discovered from among more than 1000 derivatives of which lead compound was Wintomylon, introduced from the USA and launched in 1964. It was developed solely as a synthetic new quinolone antibacterial agent and has been used in 120 countries in the world.



Cravit®, a broad-spectrum oral antibacterial agent

### Launched in Japan in 1993

It is the enantiomer of Tarivid which improved antimicrobial potency and safety. Cravit has played an important role for the treatment of infections in and outside Japan.

## 2012

“RANMARK®”, an anti-RANKL antibody was launched (Japan).



RANMARK®, an anti-RANKL antibody

Japan Vaccine Co., Ltd. started operations.

“TENELIA®” for treatment of type 2 diabetic mellitus was launched (Japan).

## 2013

In April, participation in the establishment as well as the contribution to Global Health Innovative Technology Fund was started.

In June, “PRALIA® Subcutaneous Injection Syringe 60 mg” for the treatment of osteoporosis was launched in Japan.

In July, “Injectafer,” a therapeutic agent for iron deficiency anemia, obtained a new drug approval (USA).



PRALIA Subcutaneous Injection Syringe 60 mg for the treatment of osteoporosis



“Injectafer,” a therapeutic agent for iron deficiency anemia

In September, an open innovation business (OIDE fund) utilizing a new investment fund was started.

From December, the results of a large-scale clinical trial of “edoxaban” were published and application for the approval was started.

## 2014

In May, an antiplatelet agent, prasugrel, was launched in Japan with the brand name of “Efient®.”

## Towards Edoxaban

# Edoxaban from Japan to the World

From the birth of edoxaban to global application for approval

## What is Edoxaban?

Edoxaban, an anticoagulant, is a therapeutic agent for thrombosis created that leverages the strength in the field of thrombosis that has been accumulated by Daiichi Sankyo over its long history. It has been developed as a drug that prevents the clogging of blood in the veins and atrium, where the blood flow is stagnant and that prevents serious diseases, such as pulmonary embolism and ischemic stroke from occurring.

The drug warfarin has been used as a standard anticoagulant for over 50 years. Warfarin is associated with considerable variability in its effect due to interactions with foods and drugs used concomitantly. As a result, it requires patients to undergo routine blood tests and frequent dose adjustments to maintain efficacy while trying to minimize the risk of bleeding events.

Our challenge in the research and development of edoxaban was to develop a drug with less inter-individual variations and a wider therapeutic safety range in order to overcome the main drawbacks of warfarin.

Edoxaban was approved in Japan in April 2011, for the prevention of VTE after major orthopedic leg surgery, and was launched in July 2011 under the brand name LIXIANA®. The name, edoxaban, derives from Edogawa-ku, where Kasai Research and Development Center of Daiichi Sankyo, the birth place of the drug, is located. The use of "Hokusai" in our trial name, "Hokusai-VTE," comes from Katsushika Hokusai, a famous Japanese artist during the Edo period. Hokusai was born in Katsushika-gun and present Edogawa-ku was also a part of Katsushika-gun in the era of Katsushika Hokusai.

Like Hokusai, edoxaban has emanated from Japan to the rest of the world.

## What is Thrombosis?

Thrombosis is a condition in which a blood clot (thrombus) is formed within a blood vessel and blocks blood flow. Thrombosis is classified into arterial thrombosis and venous thrombosis.

Arterial thrombosis is a blood clot that is initiated by platelet aggregation within an artery (where blood flow is rapid) and may cause various diseases such as acute myocardial infarction. Prasugrel inhibits the formation of this type of thrombosis.

Venous thrombosis is a blood clot formed within a vein (where blood flow is slow). Blood coagulation may lead to the formation of a fibrin clot and cause cardioembolic stroke and venous thrombosis including economy-class syndrome. Edoxaban inhibits the formation of this type of thrombosis.

In 2013, Marketing applications for edoxaban in Japan,

Europe, and the United States were submitted for the indications of the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation and for the treatment and secondary prevention of venous thromboembolism in patients with deep vein thrombosis or pulmonary embolism.

In developed countries, atrial fibrillation affects 1% to 2% of people, and venous thromboembolism causes the deaths of more than 500,000 patients in Europe and 300,000 patients in the United States every year.

With two different types of drugs for the treatment of various types of thrombosis, prasugrel and edoxaban, Daiichi Sankyo will continue to provide effective therapies for patients suffering from these conditions.

## The Long Road of Research to Discovery of Edoxaban

Research and Development began exploring the development of a drug that might overcome some of the disadvantages of previously mentioned warfarin and that 1) is orally administered, 2) shows less individual variations, 3) is effective, 4) causes less major bleeding, and 5) does not require routine blood monitoring.

### Initiation of a program for FXa inhibitors

An exploratory research project of FXa (activated coagulation factor X) inhibitors was started in 1979.

### Selection of three candidate compounds

After more than 10 years of research and development, three candidate compounds were identified.

1979

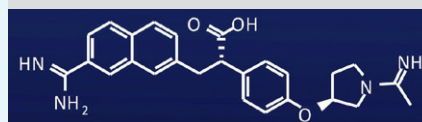
1991

2003

### World's first discovery of a direct FXa inhibitor, DX-9065a

The world's first direct FXa inhibitor, DX-9065a, was discovered after 10 years of exploratory research. It was developed as an injection due to low oral absorption, and its efficacy and safety were studied in a clinical trial.

DX-9065a

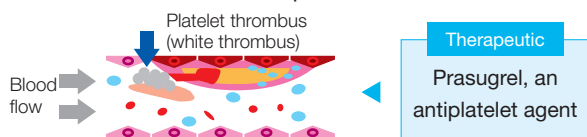


Edoxaban from Japan to the World



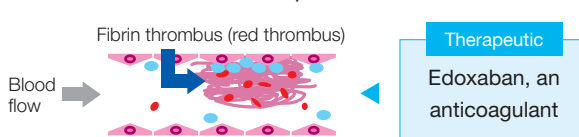
Efilant®

Arterial thrombus formed in places where blood flow is fast.



Lixiana®

Venous thrombus formed in places where blood flow is slow.





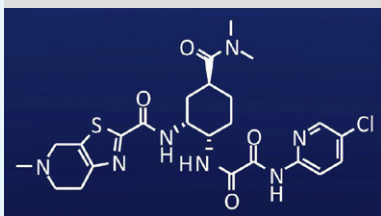
## Phase 1 Clinical Trial to Global Clinical Trial of Edoxaban

A clinical trial was started by narrowing down many compounds to three candidate compounds. It took 10 years from 2003, when a phase 1 clinical trial was started, to 2013, when two global clinical trials, the Hokusai-VTE and ENGAGE AF-TIMI 48 trials, were completed.

### Selecting edoxaban as the lead compound

Phase 1 clinical trials of edoxaban and other two candidate compounds were simultaneously conducted aiming at an acceleration of clinical development with higher probability of success, and edoxaban was selected as the compound with the best drug profile, such as oral absorbability.

Selecting edoxaban as the compound with the best drug profile



### Approval in Japan

In Japan, development progressed in the field of orthopedic leg surgery aiming at obtaining approval as the first-in-class drug among oral FXa inhibitors and achieved this goal in April 2011.

2011

2010

2008

2006

2003

Start of a late phase 2 clinical trial

Start of ENGAGE AF-TIMI 48 trial

Start of Hokusai-VTE trial

### Implementation of STARS between 2006 and 2010

STARS is a collective study name for late phase 2 and phase 3 clinical trials of edoxaban in patients undergoing orthopedic leg surgery. In the phase 3 clinical trial conducted in Japan, edoxaban exhibited efficacy not only non-inferior but also superior to that of enoxaparin, which was used as a comparator in patients with total knee replacement and total hip replacement.



## Voice

### With a lot of opportunities and challenges from edoxaban

My role (clinical pharmacology) is to select optimal doses in terms of risk-benefit balance. We evaluated the most suitable doses and incorporate them in the clinical study plans. After completing the studies, we analyzed the data and incorporated the results in the description of package insert. While I had worked on several projects and approval applications, this is the first time I was involved in a global study or a global simultaneous application prior to edoxaban. We experienced many difficulties in discussions with project team members from many functions within Daiichi Sankyo Group, and it was not always easy to reach the agreement in some of the meetings. I encountered a number of problems when I worked in the global team, including barriers of language, time and location. However, we achieved many things with the help of colleagues, and with science as our common language. Over a period of about ten years, as the project moved through Phase 1, Phase 2 and Phase 3, my roles expanded dramatically. Edoxaban provided me with both opportunities and challenges, through which I have learned a great deal.

This time, I am here as only to follow a path laid out for me by

colleagues. Next time, I should be ready and willing to start blazing a trail for others. It has inspired me to want to take on a new challenge and further to improve my abilities over the next ten years, so that I can contribute, in my own small way, to provide patients everywhere with drugs that address unmet medical needs to help patients with serious diseases.



Takako Shimizu Ph.D.

Clinical Pharmacology Group, Translational Medicine Department,  
Japan Development Supervising Department, Research and Development Head Office  
Daiichi Sankyo Co., Ltd.

## ENGAGE AF-TIMI 48 Trial

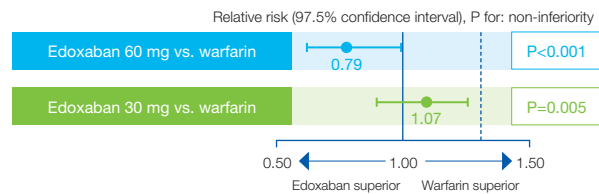
This global study was conducted in 46 countries and compared the efficacy and safety of edoxaban 60 mg and 30 mg to those of warfarin in 21,105 patients with non-valvular atrial fibrillation.

The annual incidence of stroke or systemic embolic events, the primary efficacy endpoint, was 1.18% in the edoxaban 60 mg group, 1.61% in the edoxaban 30 mg group, and 1.50% in the warfarin group, demonstrating the non-inferiority of edoxaban 60 mg and 30 mg to warfarin.

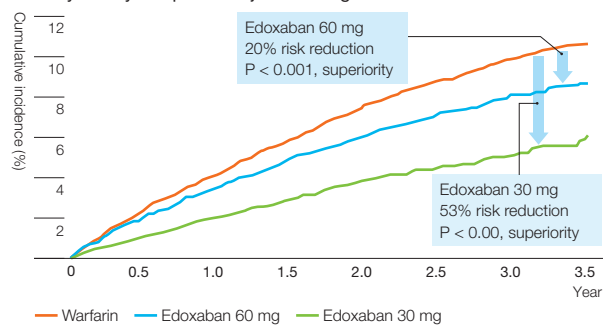
The annual incidence of major bleeding, the primary safety endpoint, was 2.75% in the edoxaban 60 mg group, 1.61% in the edoxaban 30 mg group, and 3.43% in the warfarin group. Edoxaban 60 mg and 30 mg reduced the risk of major bleeding by 20% and 53%, respectively, compared to warfarin, demonstrating its superiority at both doses.



### Primary Efficacy Endpoints: Stroke or, Systemic Embolism



### Primary Safety Endpoint: Major Bleeding



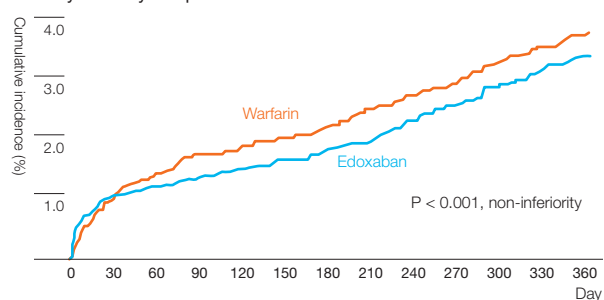
## Hokusai-VTE Trial

This global study was conducted in 37 countries and compared the efficacy and safety of edoxaban to those of warfarin in 8,292 patients with symptomatic deep vein thrombosis or/and pulmonary embolism.

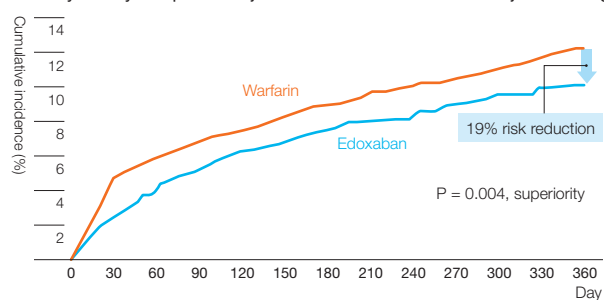
The incidence of venous thromboembolism (VTE), the primary efficacy endpoint, was 3.2% in the edoxaban group and 3.5% in the warfarin group, demonstrating the non-inferiority of edoxaban to warfarin. The incidence of major or clinically relevant non-major bleeding, the primary safety endpoint, was 8.5% in the edoxaban group and 10.3% in the warfarin group. Edoxaban reduced the risk of bleeding by 19%, compared to warfarin, demonstrating its superiority for the primary safety endpoint.



### Primary Efficacy Endpoint: Venous Thromboembolism



### Primary Safety Endpoint: Major or Clinically Relevant Non-Major Bleeding



## Edoxaban: Competitive Advantage

### 1. Unique combination of both once-daily convenience and less major bleeding than warfarin

Edoxaban currently approved for marketing only in Japan is administered once daily to patients with any of the indicated diseases, thus providing a high level of convenience.

### 2. Patient specific dosing based on patient's condition

Unlike warfarin, edoxaban does not require the patient to undergo periodic laboratory tests to monitor blood levels. Moreover, it has a flexible dosage regimen, allowing an optimal dose to be selected for patients at higher risk of bleeding.

### 3. Results from the large single comparative studies in SPAF and VTE with very high quality

The efficacy and safety profile of edoxaban has been confirmed based on data from two robust global phase 3 clinical trials.

### 4. Accumulated safety data from more than 150,000 patients in Japan

In Japan, edoxaban was launched in July 2011 as a drug for the prevention of venous thromboembolism after major orthopedic leg surgeries. For approximately three years since its market launch, edoxaban has been administered in more than 150,000 patients. Therefore, a substantial body of safety data had been accumulated by the time supplemental new drug application for AF and VTE indications was submitted.

In two large-scale global clinical trials, ENGAGE AF-TIMI 48 and Hokusai-VTE, the non-inferiority of the efficacy of edoxaban and superiority of its safety in the incidence of clinically significant bleeding were evidenced against warfarin in 2013. The drug was submitted for marketing approval in Japan, the United States, and Europe for the reduction in risk of stroke and systemic embolic events (SEE) in patients with non-valvular atrial fibrillation (NVAf) based on the results of the ENGAGE AF-TIMI 48 study and for the treatment and recurrence prevention of venous thromboembolism (VTE) based on the Hokusai-VTE study.

## Voice

### Thanks to my fate as a person responsible for the global clinical trials of edoxaban

Edoxaban is part of my life. It was exciting to join Daiichi Sankyo to work in thrombosis again since my days at the University of Perugia. Truthfully, I could not predict how intense my days were going to be. I couldn't predict what would have been necessary to do to get the job done. But this is, essentially, why I am so fortunate, having a fantastic job filled with science, medicine, methodology, innovation, and excellence. All are necessary to fulfill a single goal; offering new therapies to patients and their doctors. 2013 was the pinnacle of my scientific career. It was rewarding to work with many talented colleagues. It was humbling to work closely with the best academic minds and learn almost daily from Dr. Eugene Braunwald and Professor Harry Buller. It was electrifying to listen to the presentations of Hokusai VTE and ENGAGE AF-TIMI 48 at the European Society of Cardiology (Amsterdam) and at the American Heart Association (Dallas). I was left speechless to see the articles in the prestigious New England Journal of Medicine. Grazie edoxaban.



Michele Mercuri, MD, Ph.D.

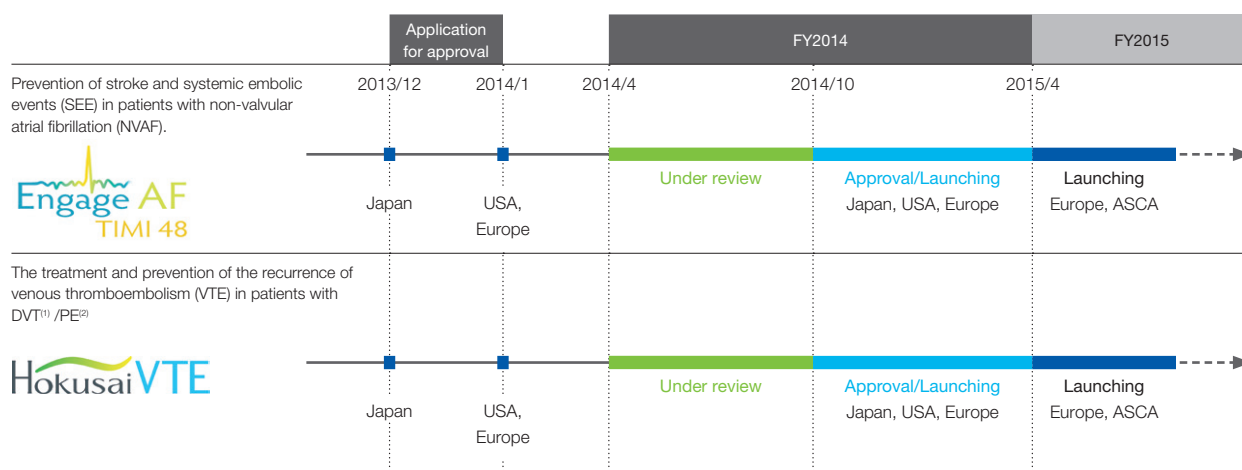
Senior Vice President  
Chief Medical Advisor and North America Head of Clinical Development  
Daiichi Sankyo Pharma Development

## Future of Edoxaban

Daiichi Sankyo Group has accumulated variety of experiences in the fields of cardiovascular and thrombosis through olmesartan (launched in Europe and in the United States in 2002) and with prasugrel (launched in 2009). In Europe and USA, Daiichi Sankyo has achieved great success by marketing this product almost on our own with olmesartan, and also has developed strong relationships with thrombosis specialists through the co-promotion business with prasugrel. In addition, we have the top-class commercial capabilities in Japan in terms of both “quality” and “quantity” as shown through the increase of sales recently.

We have considered various options to optimize the global launch and marketing strategies for edoxaban. During this exercise, we have concluded that the capabilities necessary in the anticoagulant market requires more of “quality” rather than “quantity”. For example, the required “quality” includes capabilities to adequately respond to the needs of specialists who make the initial treatment decisions, and also other key stakeholders such as other health care providers, payers and patient organizations. We have considered that these capability “quality” would become more important than having capability “quantity” that is represented by putting more weight on providing traditional share of voice through the sales reps.

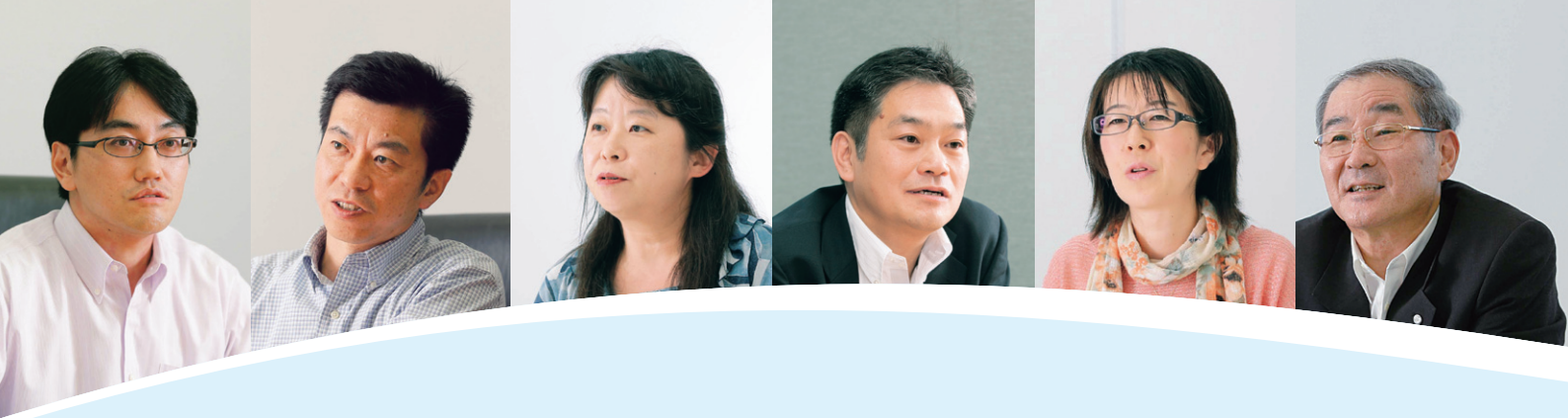
### Approval and Launch Plans for Edoxaban



(1) DVT: Deep vein thrombosis, (2) PE: Pulmonary embolism

ASCA: Asia, South and Central America





# Organized Efforts Aiming at Sustainable Improvement of Corporate Value

## ■ Creation of Value through Business

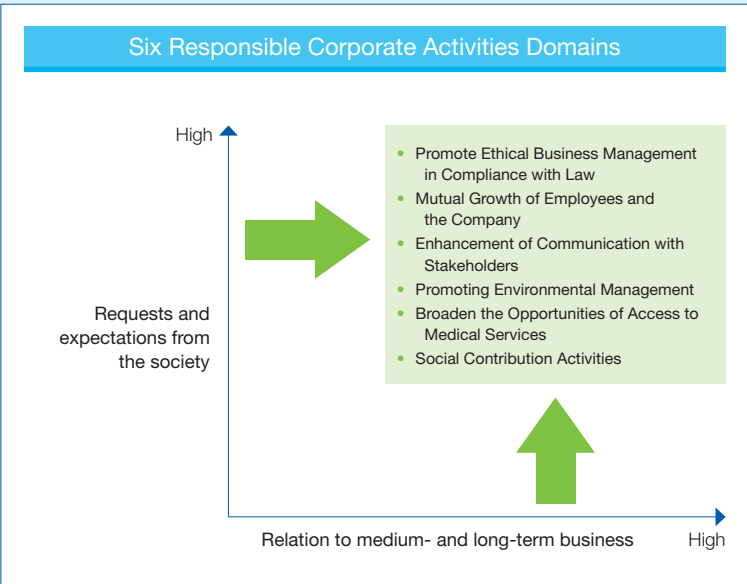
Each of our business activities originates from the mission of Daiichi Sankyo Group, “To contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals, and through the provision of pharmaceuticals addressing diverse medical needs.”

We believe that helping patients and sustainably growing economic circulation through business activities are the backbone for creating value as a pharmaceutical company. Four main units, R&D, pharmaceutical technology, supply chain, and quality and safety management, all work to develop a global value chain collaborating together with business units which are responsible for developing marketing and sales strategies in their respective regions.

## ■ Responsible Corporate Activities Supporting Business

For a business enterprise to be accepted as a critical part of society, it is important to fulfill our duties demanded from the society and to deal with various stakeholders in a responsible manner. We believe that a full understanding of the demands and expectations, including corporate ethics, environmental protection and respect for human rights, placed on the business enterprise at various stages of its growth and development is essential for the business enterprise to continue to grow with society.

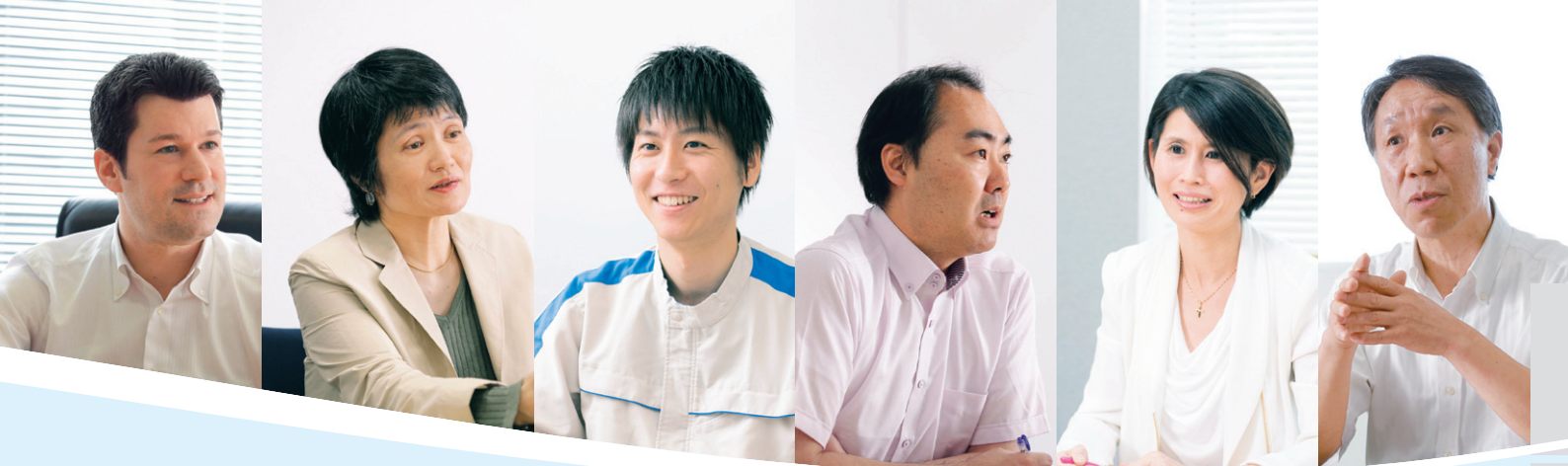
Daiichi Sankyo Group has defined six responsible corporate activities based on social demands and expectations (captured from global CSR initiatives, such as UN Global Compact and survey results on CSR) and medium- and long-term relation to our business (see the figure below).



**Participation in the UN Global Compact**

The UN Global Compact is a voluntary initiative in which businesses demonstrate responsible and creative leadership and act as upstanding members of society by participating in this global framework aimed at realizing sustainable growth.

Daiichi Sankyo Co., Ltd. declared participation in the Global Compact in April 2012 and clarified our corporate stance on the ten principles in four areas (human rights, labor standards, environment, and anti-corruption) linking to the individual activities of our employees.

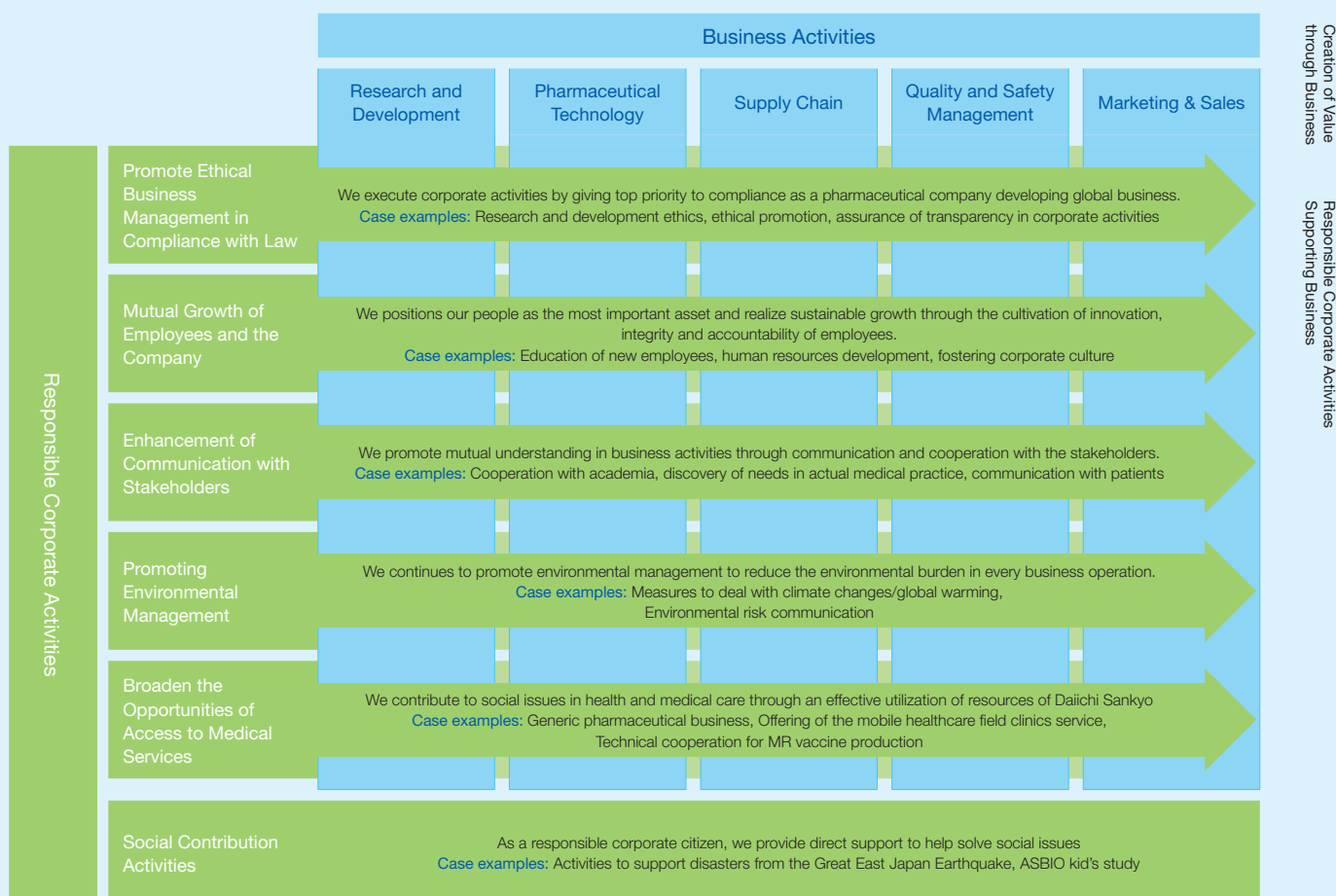


## ■ Indivisible “Business and Responsible Corporate Activities”

CSR concepts are integrated into all of our business activities, whether they are in research and development, pharmaceutical technology, supply chain, quality and safety management, marketing and sales. With regard to responsible corporate activities

straddling various business activities, the CSR Department introduces policies in each of the six domains to support the business.

We understand that business and responsible corporate activities are indivisible and practice unified operations aimed at sustainably improving our corporate value (see the figure below).



# Research and Development

Towards Realization of Global Pharma Innovator

We will continue to create innovative drugs with the inquisitive minds and a desire to contribute to human health.



## ■ For Continuous Creation of Innovative Drugs

Daiichi Sankyo Group aims to provide a continuous supply of innovative drugs to patients with emphasis on the research and development of first-in-class drugs as a Global Pharma Innovator. The inquiring minds of our researchers and their desire to contribute to human health issues are the forces driving us.

In the current pharmaceutical market, sustainable growth cannot be expected with the conventional business model due to environmental changes, such as decrease of novel compound approvals, increase in biologics, and increase in R&D costs. Under such circumstances, we need to tackle unknown life phenomena with flexible ideas created by a challenging organization pursuing innovation based on the accumulated knowledge and to further raise productivity from R&D. We also need to encourage cost reduction to control the R&D expenses that are increasing due to necessity for conducting large-scale clinical trials to demonstrate efficacy and safety. In order to solve these two tasks at the same time, the R&D Division has posted three principles, leadership, innovation and efficiency, with the intention for transforming the business model with these as the driving power. Furthermore, we have our values constituting common standards for value judgment in the Daiichi Sankyo Group as essential and universal basis for daily activities in the R&D Division.

## ■ Transformation of Mindset for Exercising Leadership

We capture leadership and empowerment as things important, and intend to create an organization with challenges and the value of innovation. All members engaged in R&D are required to be proactive and demonstrate leadership in their field of responsibility, and are expected to clearly recognize that it is their obligation to accomplish results. Everyone is empowered to play a leading role in their respective area of expertise in order to facilitate swift decision-making unhindered by a fear of possible failure.

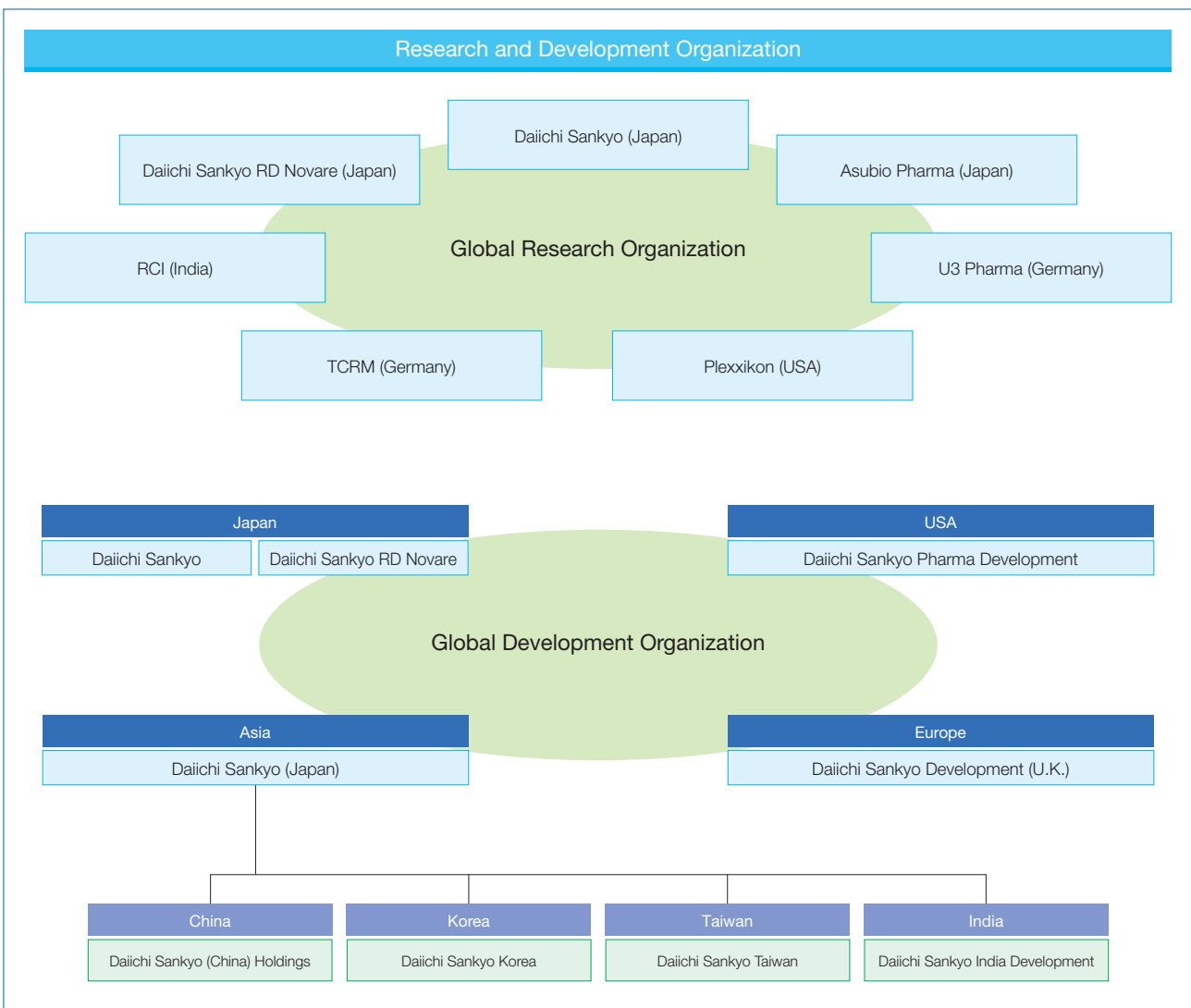
Furthermore, the promotion of world-class R&D requires bold ideas that break through existing boundaries. That is why we endeavor to strengthen communication in each other between research part and development part, in all regions such as Japan, the United States, Europe and Asia. We also make efforts to promote cross-cultural understanding of diverse views and backgrounds, and to provide a common ground for frank and constructive debate. We hope that collaboration will be born without restriction by functional or local boundaries, and will conceive many creative and groundbreaking ideas.

## ■ Initiative towards Realization of Innovation

### Innovation created from diversity

Our researches are working globally in close cooperation with laboratories in Japan, USA, Germany, and India. In Japan, Daiichi Sankyo (Shinagawa, Kasai, Tatebayashi) acting as a core, Daiichi Sankyo RD Novare acting as the pharmaceutical technology platform, and Asubio Pharma specializing in pharmaceutical core functions (basic research to early-phase clinical trials) are present. In other countries, there is U3 Pharma specializing in antibody drugs targeted for oncology, Plexxikon with scaffold-based drug design (SBDD), Daiichi Sankyo Life Science Research Centre in India (RCI) and Tissue and Cell Research Center Munich (TCRM) in Germany, and they are advancing new drug researches utilizing individual strengths.

For our development, we have strongholds in Japan, USA, and Europe. In addition, we also have those in Asia such as India, Korea, and China. They are in close cooperation to reach global development candidates to medical fronts in too many countries as early as possible. We successfully completed two large-scale phase 3 clinical trials of edoxaban with the cooperation of 29,200 or more patients in total in Japan, USA, Europe, and Asia. We submitted approval applications with two indications, venous thromboembolism and non-valvular atrial fibrillation, in Japan in December 2013 and then, in USA and Europe in January 2014.





## Initiative towards Realization of Innovation

### Consolidation of biologics research functions

Biologics are the drugs produced from Biological materials (such as cells, viruses, bacteria) and containing proteins (such as growth hormones, insulin, antibodies) as active ingredients. Because of their large molecular weight and highly complex chemical structure, the properties of the end product are affected by various factors that are related to the manufacturing process. Therefore, a key issue in the production of biopharmaceuticals is to produce follow-on versions that are completely identical to the original product, and this can pose significant business risks. Furthermore, due to the complex production process, the Good Manufacturing Practice (GMP) requirements and specifications must be strictly adhered for maintaining the safety and efficacy of the end product. Due to these specific characteristics, it is desirable that a consistent R&D system be created that encompasses research and production (upstream to downstream) functions to reinforce research into biopharmaceuticals by integrating the biopharmaceutical R&D functions, dispersed throughout the research centers, into the Biologics Oversight Function.

### Challenge of Venture Science Laboratories

In April 2013, we established Venture Science Laboratories (VSL), consisting of small groups of scientists, to reinforce our drug discovery research capabilities. This is a small entrepreneurial entity inside the company, and squeezes innovative solutions based on a venture-inspired spirit. The management of these labs enjoys a high degree of independence to facilitate swift decision-making. Here, drug discovery research in therapeutic areas with highly unmet medical needs is being pursued (see Voice below). In April 2014, we entered into a joint research partnership with the University of California in San Francisco to accelerate drug discovery directed at the development of diagnostic agents and new treatments for neurodegenerative diseases.

## Voice

### Challenge of Venture Science Laboratories

Venture Science Laboratories (VSL) is an in-house start-up organization which was established in April 2013. Unlike typical start-ups, VSL was not built on a platform of special technologies or projects/products. Its only assets were human resources. That was why VSL people spent a lot of time in discussion in pursuit of a



**Takashi Fukuoka, D.V.M., Ph. D.**

Vice President, Venture Science Laboratories  
R&D Division  
Daiichi Sankyo Co., Ltd.

strategic approach that enables initial success to enhance the probability of success of subsequent projects. To address the global issue of aging societies, VSL has selected aging-associated diseases, such as neurodegenerative diseases, as targets and has contracted with the Institute for Neurodegenerative Diseases at the University of California San Francisco (UCSF-IND) as the first step in its inaugural project.

There is still plenty of room for further development in terms of maximizing its assets, human resources. We strive to create a project where human resource development leads to innovative drug development, VSL members learn from activities of innovative drug development and thus develop more innovative drugs. We aim to strengthen VSL, whose only asset was human resources, to continuously create innovative and novel drugs to patients worldwide from Daiichi Sankyo and Japan. The more diversified the team the greater the variety of ideas that will be generated. In collaboration with internal and external partners, VSL will continue to take bold steps toward development of novel drugs.

## Open innovation

For the realization of “competitive pipelines, quick and consistent creation of innovative drugs,” we need to bring wisdom in and out of the company. Daiichi Sankyo Group is promoting open innovation willingly, and the collaborative drug discovery project (TaNeDS\*<sup>1</sup>) started from 2011 is one of such projects. The selected research themes progressed cooperatively, and the results are already accumulating. We are implementing TaNeDS global programme in Germany, Switzerland, and Austria from 2013 (see Voice on the right).

We also set up the OiDE\*<sup>2</sup> fund in September 2013 by a joint investment of Daiichi Sankyo, Mitsubishi UFJ Capital and Organization for Small & Medium Enterprises and Regional Innovation, Japan and are upbringing seeds by investment business. The company supports the cultivation of new basic research themes by exploring promising ideas that may become fundamental pharmaceutical technology based on the research results of Japanese universities and by founding venture enterprises.

Further, we concluded research partnership for exploring novel pharmaceutical targets with Virtici, LLC, and Celdara Medical, LLC in USA in November 2013, and a joint research by three companies is ongoing through close networks with academia in USA.

In May 2014, we concluded an alliance with Sanford—Burnham Medical Research Institute, USA, to study novel drug targets in cardiovascular-Metabolic Diseases.

As another new initiative, we formed a compound library sharing partnership for approximately 400,000 selected compounds with Astellas Pharma Inc.

We hope that all of these initiatives lead to the creation of new innovative drugs by the most effective utilization of resources and company talent.

\*1 Take a New Challenge for Drug diScovey

\*2 Open innovation for the Development of Emerging technologies

## Voice

### Hope brought up by partnership

Today, drug creation calls for the bringing together of the latest technologies. It is becoming increasingly difficult for a single company to complete this mission on its own. We have been seeking to identify effective forms of collaboration for R&D. One such is the TaNeDS Programme. When the programme was launched in 2011, we encountered several problems typical of any new endeavor. Few of us had any idea as to the extent that academia and industry would be able to cooperate with each other. The only way to find the answer was through trial and error. However, in the course of that process, it gradually became clearer to us what issues academia and industry would need to address. As the requirements for the programme became more sharply defined, those involved in the programme became more motivated.

But, not all ideas that are applied can be accepted. Even in relation to unaccepted cases, we can still enhance our relationships with academic specialists if we carefully review such ideas and make meaningful suggestions.

We will continue to utilize this programme to develop and supply drugs that meet the needs of patients. This is and will continue to be both our sole mission and a driving force behind sustainable growth for Daiichi Sankyo.



Yoshito Kanazawa

External Science Group, R&D Planning Department  
R&D Division  
Daiichi Sankyo Co., Ltd.

### About the TaNeDS Logo Mark



A symbol of “hope to grow by partnership.” Two people facing each other, holding hands expresses the intention of collaboration, to foster the seeds of hope together.

## ■ Improvement of R&D Efficiency/Productivity

### Global decision-making and effective investment of resources

To ensure the effective global investment of our human and material resources, from both the earliest stage of research we engage in robust discussions on the productivity of our research projects from the scientific and business perspectives. Moreover, while actively promoting empowerment, we are constantly improving the meeting process so that swifter decision-making can be achieved. In particular, the Global Executive Meeting of R&D (GEMRAD), at which issues related to the later stage of development are discussed, and the Translational Research-GEMRAD (TR-GEMRAD), at which issues related to the early stage of development are addressed, act as the highest decision-making bodies in the R&D process. Participants are not confined to members of the R&D Division but also include representatives from a wide range of specialized functions such as regulatory affairs, product portfolio management, and licensing. This ensures that appropriate decisions are made from a broad perspective. Moreover, GEMRAD also prioritizes development projects so that research resources are invested effectively based on portfolio strategies.

### Management of global R&D

Every year we set three numerical targets in our R&D Division for the third mid-term business management plan. These targets are (i) to launch two new products for major indications, (ii) to advance four projects into late phase clinical developments after POC<sup>\*1</sup>, and (iii) to advance nine projects into clinical phase I studies. The results that we achieved in 2013 surpassed these targets. In 2014, our goal is not only to meet these numerical targets and to build a competitive product pipeline, but also to create innovative drugs that can meet a range of unmet medical needs.

### Prioritization of fields in R&D

In our approach to R&D, we concentrate on identifying unmet medical needs, and then focusing our R&D accordingly. In this way are able to contribute to greater satisfaction with medical care in the future. Our resources for R&D are mainly assigned to the areas of oncology, and cardiovascular & metabolic, which have been established as the primary focus of our present R&D activities. Moreover, as a frontier area beyond these categories, we are also actively engaged in researching new drugs and treatments based on biological mechanisms.

<sup>\*1</sup> Abbreviation of the proof of concept, meaning identification of predicted features relating to the efficacy and safety of a new drug through clinical trials.

## ■ R&D Ethics

It is important for the company to sustainability earn the trust of society in relation to its business activities and managerial strategies. In order to avoid managerial risks, it is vital to remain constantly aware of the importance of research compliance. In life science-oriented industries, in particular, higher ethical standards are required. We are aware that our research is strongly related to human health and safety, and therefore we emphasize values based on bioethics.

### Ethical considerations in research using human samples

Before conducting a clinical trial that involves the administration of human-derived materials (such as tissue, blood, or genes), it is necessary to estimate and predict both its pharmacological effects and its side effects. Moreover, in recent years, there have been rapid advances in research on human-derived cells, such as embryonic stem (ES) cells and induced pluripotent stem (iPS) cells. In accordance with Japanese guidelines including the Ethical Guidelines for Clinical Research, and Ethical Guidelines for Human Genome and Genetic Sequencing Research, we have established the Ethical Evaluation Committee on Human Tissue and Other Human Material Research. The purpose of the committee is to objectively ascertain the necessity and usefulness of such research, and to prioritize the human rights and dignity of the donors of the samples used relative to the scientific and social benefits of such research. We also give full consideration to obtaining voluntary prior consent from research subjects and to protecting their personal information including their genetic information.

### Considerations in animal experiments

In recent years, transparency of animal studies is required with regard to the health, well-being and welfare of laboratory animals. Along with the acceleration of the humane management on animals used for scientific purposes. We are in the process of seeking accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). We have been applied for AAALAC accreditation, and also have established Detailed Rules on Animal Experimentation that comply with Japan's Act on Welfare and Management of Animals, and strive to promote the principles of replacement (applying alternative testing methods), reduction (reduction of the number of laboratory animals), and refinement (minimizing pain and distress in laboratory animals). All animal experiments that are conducted at our facilities have been undergone rigorous examination beforehand by our Institutional Animal Care and Use Committee. In addition, we believe that thorough self-inspection is one of the significant prerequisites of excellent results.

### Measures to deal with biohazards

In order to appropriately handle pathogens and pathogen-containing materials, we have established Rules for Biosafety. The Biosafety Committee is working on to observe the laws under the Infectious Disease Prophylaxis and the Act of Domestic Animal Infectious Disease Control. Regarding genetically modified organisms, we have formulated Rules for Recombinant DNA Experiments so that containment is appropriately implemented in compliance with Cartagena Protocol on Biosafety. Moreover, we are recognizing potential risks of experimental accidents caused by researchers engaging in recombinant DNA experiments, and are preventing by enhancement of appropriate handling techniques through outside training sessions.

### Fair utilization of genetic resources

Concerning the conservation of biodiversity, sustainable use, and fair and equitable sharing of the benefits arising out of the utilization of genetic resources, we abide by the Convention on Biological Diversity, and the Bonn Guidelines. Moreover, we are giving full consideration to recent developments related to the Nagoya Protocol, which was adopted on the 10th Meeting of the Conference of the Parties to the Convention on Biological Diversity (COP 10).

### Ethics in clinical trials

The development of new drugs requires clinical studies designed to evaluate their safety and efficacy. Clinical studies need to be conducted in accordance with the Declaration of Helsinki that defines the standards for ethical human experimentation. This includes obtaining voluntary informed consent from participating subjects, ensuring their human rights, protecting personal information, safeguarding the lives and health of subjects and giving full consideration to their well-being. We comply with regulations such as the Japan Pharmaceuticals and Medical devices Affairs Act, and Good Clinical Practice (GCP) (Ordinance of the Ministry of Health, Labour and Welfare), and only include subjects in our clinical studies after having obtained their informed consent. Moreover, we have set up Daiichi-Sankyo ethical and scientific Review Board that monitors the compliance with ethical standards and scientific validity of all clinical studies that we conduct, and ensures that appropriate medical tests are being conducted. Outside Japan we conduct our clinical studies in accordance with ICH\*2-GCP and the regulations of the respective country. To ensure transparency we disclose information relating to our clinical studies in accordance with the regulations of the respective country, the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), and voluntary standards of the industry.

## Voice

### Always from the patient's perspective

We are administrative office for the Daiichi-Sankyo Ethical and Scientific Review Board (DS-ESRB), which reviews "protocol" and "informed consent forms and written explanations" prior to the conduct of a clinical trial. We confirm "whether the contents of these are scientifically justified, that they are not imposing any burden or disadvantage to patients, and that safety considerations are provided."

The DS-ESRB members selected from each field identify questions mainly in their specialty fields and discuss the matters imagining that they or their family members are the patients; whether the contents of these documents are easy to understand, accurately convey information, and encourage participation in clinical trials. The comments provided from the DS-ESRB members are fed back to the persons in charge of development, thereby improving the quality of clinical trials.

DS-ESRB has held more than 100 meetings since incorporation in 2007. We handle our daily activities with high motivation and care, and our vision is that one day drugs reviewed by DS-ESRB will debut in the market as a product that we or our family members will

use. We will manage and support the committee so as to win the confidence of doctors and patients, assured that "participation in clinical trials by Daiichi Sankyo is safe."



Seiko Shimizu

Naoko Kawagoe

Support Group, R&D Administration and Support Department  
R&D Division  
Daiichi Sankyo Co., Ltd.

\*2 Abbreviation of International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use



## ■ Protection of Intellectual Property

A variety of intellectual properties, such as ideas overcoming scientific and technical issues (patents, utility models), easy to use design (design), and branding for identification of drugs (trademarks) are required from emerge from the research and development of a drug to its commercialization and eventual use by many patients.

Daiichi Sankyo Group is able to contribute to the creation of excellent drugs and contribute to the improvement of global health\*<sup>1</sup> by seeking an appropriate protection of these intellectual properties. We have created a patent portfolio covering substance patent protecting the active ingredient itself, and patents relating to manufacturing process, pharmaceutical technology, and new efficacy and effect for protection of product. We also pursue to not only inventions involved directly with the product but also various tools and biomarkers necessary for research and development and basic techniques necessary for manufacturing, which are recognized as important intellectual properties.

We are seeking to secure business opportunities while protecting our intellectual properties and respecting intellectual property rights of other companies in the fields of biological drugs, generic products, biosimilars, vaccines, and OTC drugs in order to support the business development. In alignment with the global business development, we are expanding countries where we own intellectual properties. We have assigned persons responsible for intellectual properties in Japan, USA, and Europe to take proper and timely actions, which consider regional characteristics. We are also building cooperative relationship with external partners who have the most up to date scientific and technical knowledge through open innovation and open development in order to achieve the continuous creation of innovative drugs.

## ■ Lineups Responding to Medical Needs

The product portfolio of Daiichi Sankyo includes drugs for the treatment of hypertension, infections, and hyperlipidemia. It is our goal to establish a product lineup in disease areas where there is a high demand for unmet medical needs, and in the future we will focus our R&D on oncology, cardiovascular & metabolics, and frontier areas.

### Prasugrel (CS-747)

In Japan, prasugrel was launched in May 2014 with the indication to ischemic heart diseases accompanying percutaneous transluminal coronary angioplasty (brand name: Effient). We are conducting a phase 3 trial in patients with ischemic cerebrovascular diseases.

### Denosumab (AMG162)

Denosumab is an antibody agent involved in bone metabolism, and the company has obtained development/marketing rights in Japan from Amgen Inc., USA. The drug was launched in Japan in April 2012 with the brand name of RANMARK indicated to bone lesions due to multiple myeloma and bone lesions due to metastasis of solid cancer to bone. In June 2013, it was launched with the brand name of PRALIA for the treatment of osteoporosis. In May 2014, the drug obtained an approval for partial changes of approved matters concerning bone giant cell tumor. In addition, we are conducting a global phase 3 trial in patients on postoperative adjuvant therapy for breast cancer and a domestic phase 3 trial in patients with rheumatoid arthritis.

### Tivantinib (ARQ197)

Tivantinib is a molecularly targeted drug inhibiting Met, which is a receptor of the hepatocyte growth factor (HGF) involved in a variety of cellular signal transductions, such as cell proliferation, induction of apoptosis, neoangiogenesis, and infiltration and we have concluded licensing agreement with ArQule, USA, for joint development and commercialization all over the world except for Japan, China (including Hong Kong), Korea, and Taiwan. At present, we are conducting a phase 3 trial in patients with Met-high hepatocellular carcinoma.

### Nimotuzumab (DE-766)

Nimotuzumab is an antibody agent that specifically binds to the epidermal growth factor receptor (EGFR), which is one of the receptors for cell growth factors and has been created by CIMAB (Cuba). Daiichi Sankyo has obtained development and sales rights in Japan from CIMAB and CIMYM BioSciences (Canada) and is currently conducting a domestic phase 3 trial in patients with gastric cancer.

\*1 Issues concerning health and healthcare beyond borders

### Hydromorphone (DS-7113)

Hydromorphone is a narcotic analgesic marketed for more than 80 years outside Japan and has been positioned as a standard drug for pain control in the WHO (World Health Organization) guidelines for the treatment of cancer pain although it has not been approved in Japan. Therefore, this

drug has been designated as an unapproved drug at the “evaluation committee on unapproved and off-label drugs with high medical needs”<sup>\*2</sup> and Daiichi Sankyo is conducting its development in Japan in view of social responsibilities of the company.

### Major R&D Pipelines (As of July 2014)

Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular- Metabolics	<ul style="list-style-type: none"> <li>DS-7309 (Diabetes / Glucokinase activator)</li> <li>DS-1040 (Acute ischemic stroke/TAFIa inhibitor)</li> </ul>	<ul style="list-style-type: none"> <li>CS-3150 (JP) (Hypertensive, DM nephropathy/MR antagonist)</li> <li>DS-8500 (JP) (Diabetes / GPR119 agonist)</li> </ul>	<ul style="list-style-type: none"> <li>Prasugrel (JP) (CS-747/ ischemic stroke/anti-platelet agent)</li> <li>Prasugrel (US) (CS-747/ Sickle Cell Disease/ anti-platelet agent)</li> </ul>	<ul style="list-style-type: none"> <li>Edoxaban (US/EU/JP) (DU-176b/AF/oral factor Xa inhibitor)</li> <li>Edoxaban (US/EU/JP) (DU-176b/VTE/oral factor Xa inhibitor)</li> </ul>
Oncology	<ul style="list-style-type: none"> <li>U3-1565 (US/JP) (Anti-HB-EGF antibody)</li> <li>DS-7423 (US/JP) (PI3K/mTOR inhibitor)</li> <li>DS-3078 (US/JP) (mTOR inhibitor)</li> <li>DS-3032 (US) (MDM2 inhibitor)</li> <li>PLX7486 (US) (Fms/Trk inhibitor)</li> <li>DS-8895 (JP) (Anti-EPHA2 antibody)</li> <li>DS-8273 (US) (Anti DR5 antibody)</li> <li>PLX8394 (US) (BRAF inhibitor)</li> </ul>	<ul style="list-style-type: none"> <li>Patritumab (US/EU) (U3-1287/anti-HER3 antibody)</li> <li>Vemurafenib (US/EU) (PLX4032/BRAF inhibitor)</li> <li>PLX3397 (US) (Fms/Kit/Flt3-ITD inhibitor)</li> </ul>	<ul style="list-style-type: none"> <li>Tivantinib (US/EU) (ARQ 197/ HCC /Met inhibitor)</li> <li>Denosumab (JP) (AMG 162/breast cancer adjuvant/anti-RANKL antibody)</li> <li>Nimotuzumab (JP) (DE-766/Gastric cancer/ Anti-EGFR antibody)</li> </ul>	
Others	<ul style="list-style-type: none"> <li>PLX5622 (Rheumatoid arthritis/ FMS kinase inhibitor)</li> <li>DS-1093 (Anemia of chronic kidney disease/ HIF-PH inhibitor)</li> <li>DS-3801 (Chronic constipation/ GPR 38 agonist)</li> <li>DS-1971 (Chronic pain)</li> </ul>	<ul style="list-style-type: none"> <li>Mirogabalin (Global) (DS-5565/Chronic pain/ <math>\alpha 2\delta</math> ligand)</li> <li>SUN13837 (US/EU) (Spinal cord injury/ Modulator of bFGF signal system)</li> <li>Laninamivir (US/EU) (CS-8958/anti-influenza/ Outlicensing with Biota)</li> <li>Ioforninol (JP) (GE-145/ X-ray contrast media/ Angiography)</li> </ul>	<ul style="list-style-type: none"> <li>Levofloxacin (JP) (DR-3355/anti-infection/ New quinolone)</li> <li>Denosumab (JP) (AMG 162/rheumatoid arthritis/ anti-RANKL antibody)</li> <li>Hydromorphone (JP) (DS-7113/Narcotic analgesic/opioid mu-receptor regulator)</li> </ul>	

<sup>\*2</sup> Conference established by the Ministry of Health, Labour and Welfare aiming at the promotion of the development of unapproved drugs and off-label drugs, which have been approved in Europe and USA but not in Japan, by pharmaceutical companies

# Pharmaceutical Technology

Towards Realization of Global Pharma Innovator

We will develop candidate compounds into commercially available pharmaceutical products.



## ■ What is Pharmaceutical Technology?

Pharmaceutical technology is a collective term of technologies to bring up candidate compounds discovered or created to “pharmaceutical products”, which are produced from chemical compounds with useful effects on human bodies, to high-quality dosage forms that can exhibit effects appropriately against diseases.

Pharmaceutical technology is largely divided into “Process technology”, “Formulation technology” and “Analytical and quality evaluation technology”. “Process technology” investigates a synthetic method to manufacture candidate compounds efficiently and consistently in large amounts and with high-quality. “Formulation technology” investigates the dosage form, formulation and package based on absorption into bodies, stability, and usability in consideration with the characteristics of candidate compounds. “Analytical and quality evaluation technology” establishes a variety of analytical and quality evaluation systems to assure the quality of the pharmaceutical products properly and appropriately.

Daiichi Sankyo Group has an important role to offer pharmaceutical products highly satisfying with customer by developing these pharmaceutical technologies.

## ■ Creation of High-Value Added Products by Pharmaceutical Technology

There is no doubt that efficacy and safety are the primary requirements for any pharmaceutical products. Moreover, it has become significantly important to provide pharmaceutical products that can be more easily used by patients, healthcare workers and caregivers in order to correspond to rapidly aging of societies and/or advanced medical cares. Examples of user-friendly pharmaceutical products to meet the needs of patients include extended-release tablets which reduced the frequency of administration, and orally disintegrating (OD) tablets which can be taken without water. On the other hand, as examples of innovation for healthcare workers, there are prefilled syringes already loaded with the drug solution to reduce the dispensing burden or the risk of needlestick injuries, and IC tags on pharmaceutical products or packages which are helpful in preventing medical errors. Additionally, we provide user-friendly pharmaceutical products added new value using various formulation technologies such as package designs to prevent inadequate administration, and product name printing on tablets, etc.



See “Modification of Pharmaceutical Products Meeting Medical Needs” on page 44 for details.

We are also focusing on the development of new synthetic processes for candidate compounds based on the practical concept of “green chemistry”, which aims to achieve global environmental sustainability by preventing pollution and reducing consumption of materials and energy.

Daiichi Sankyo provides Olmetec, Rezaltas Combination Tablets, Memary, Inavir, Omnipaque, Pralia, Efient and Lixiana by adopting these new pharmaceutical technologies adequately in each product.

## ■ Major Initiatives

### Creation of high quality products by advanced technology

We are actively working on product quality designs based on the concept of Quality by Design (QbD), a new framework used for quality assurance. As an example of our Lixiana tablets, real time release testing (RTRT) was approved by applying advanced QbD approaches. RTRT is a system for assuring high quality of product by the use of advanced quality control technology, through simultaneous quality control during pharmaceutical products manufacturing. We commit to address earnestly the quality assurance for our products by applying advanced technologies actively now and in the future.

### Initiatives for creation of high-value-added pharmaceutical product: Discovery of needs at actual medical practices

We are always striving to provide high value-added products that meet the needs of patients, healthcare worker, and caregivers in terms of both formulations and package. In the past, research was conducted based on information obtained in-house or from the pharmaceutical industry. Consequently, our researchers tended to investigate within the conceivable idea based on such information. However, now we are trying to put new ideas into breaking through the stereotype of pharmaceutical products. Therefore we are proactively conducting the activities to collect the user needs in formulation or package by visiting at actual medical practice to create the high value-added products (refer to Voice, right side). One example of the successful outcome of these activities in other company is a “micro needle” composed of numerous fine needles to insert under the skin surface. This makes it possible to perform injections painlessly for everyone from children to the elderly in contrast to the conventional injection, which was considered painful for granted. Through such new ideas and their realization, we develop high value-added pharmaceutical products aiming to enhance medication adherence in patients.

### Medication support for patients

It is difficult for patients with dementia to manage their medication by themselves. It is also common for such patients to refuse to take their medicines, and therefore it is often the case that caregivers have to manage the medication plan and to help administration. Under these circumstances, OD tablets are considered suitable for patients with difficulty in swallowing food or fluids, also help to reduce the burden on caregivers.

Our Memary OD tablets, launched in 2014 and developed using Daiichi Sankyo's OD tablets platform technology, are dispersed with saliva or small amounts of water. This means the patients with not only dysphagia but also limitation of fluid amounts can take the tablets easily by individuals. In addition, by suppressing the bitter tastes, Memary OD tablets support and enhance medication adherence in patients who spit out their tablets, or require some time to swallow the tablets.

## Voice

### My highest priority is to develop user-friendly drug formulations for both patients and healthcare workers

It has been four years since I joined this company. I had an opportunity to visit and observe the work of the pharmacists at hospital pharmacies. I have seen and heard what I would not know or overlook in my working place. For example, the hardness of a tablet has an influence on its grind ability, and the action that is easy to corrupt one or two tablets becomes very hard when there are tens or hundreds of tablets. I have also been very impressed hospital pharmacists handle with a great variety of products within quite a limited time, in addition, they are required highly accuracy and consistency. Based on this experience, I strongly commit to promote research and development activities aimed at creating user-friendly pharmaceutical products that patients find easy to swallow or easy to use, and that healthcare workers find easy to handle, and easy to dispense so that “Daiichi Sankyo's pharmaceutical products are considered “user-friendly”.”



**Shinji Yoshinaga**

Solid Formulation Research Group 1,  
Formulation Technology Research Laboratories  
Pharmaceutical Technology Division  
Daiichi Sankyo Co., Ltd.



# Modification of Pharmaceutical Products Meeting Medical Needs

## Development of pharmaceutical products easier to use and easier to take

### Labeling and Packaging Technologies for Preventing Misuses

In designing Efient tablets launched in Japan in May 2014, Daiichi Sankyo asked for the opinions of pharmacists about “desirable tablets.” The below photograph shows the designed form based on the results. Based on these opinions, the brand name and dose were printed on the tablet so that patients and pharmacists would know that the drug was “Efient tablet” and that it contained either of the two doses (3.75 mg tablet or 5 mg tablet) at a glance. In addition, details were printed on “both sides” of Efient tablets to reduce the burden on pharmacists, who inspect the multiple pharmaceutical products packaged in one package at the pharmacy, as they have to turn the package and inspect the back if they are printed on only one side.

Moreover, we have also devised the blister design of Efient tablet. For 5 mg tablets, four tablets of which are administered at the same time, a packaging design with excellent visibility to remind the number of tablets has been adopted to prevent incorrect administration.



Direct printing of the brand name and dose on both sides of tablet

Labeling of the brand name of Efient tablet 5 mg



Design making aware of the number of tablets taken

Efient tablet 5 mg “PTP 8-tablet sheet”

### Packaging with Improved Distinguishability of Healthcare Workers

We launched OMNIPAQUE Syringe in 1993 as a hygienic and highly convenient prefilled syringe\*1 and have set out a large number of product line-ups and continuously modified the products corresponding to medical needs. In 2006, we launched a product attached with an IC tag for preventing mixed-up accidents by an automatic recognition of information on contrast media using an automatic injector and contributed to the safety aspect of medical care.

However, automatic injectors mounted with IC reading device have not necessarily been popularized among all medical institutions although many types of contrast media are available on the contrast medium market. Thus, we have adopted a design based on scientific data utilizing design psychology considering that the improvement of visibility by creating distinguishability in the labeling design is important in medical safety.

At present, the packaging of the designed OMNIPAQUE Syringe aimed at the improvement of distinguishability of healthcare workers was highly valued as the packaging design to prevent medical accidents and won a prize in “Drug/Medical Device Packaging Division of 2014 Japan Packaging Contest.”

Packaging with improved distinguishability



OMNIPAQUE Syringe

\*1 Product prefilled with a drug solution in a syringe (injector)

## ■ Modification of Formulations in Orphan Drugs

While Biopten Granules 2.5% were administered to children with BH4-reactive hyperphenylalaninemia at 1 packet/kg body weight /day in Japan, the number of packets to be taken daily due to an increase in the body weight accompanying growth considerably increased, and the modification of the formulation was strongly awaited (see “Voice from outside the company” below). With such backgrounds, we tackled the development of Biopten 10% Granules containing 100 mg of sapropterin hydrochloride per package (1 g) as a high-concentration formulation to contribute to the improvement of medication adherence\*2

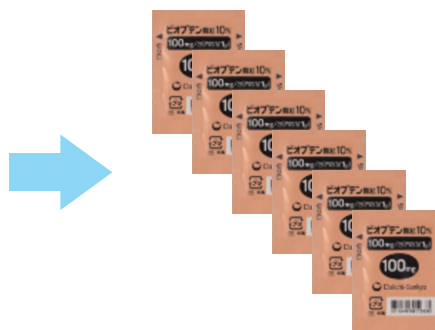


Biopten Granules 2.5%, existing drug formulation  
(10 mg as the active ingredient)  
60 packets to be taken per day (in 1–3 divided doses/day)

and reduction of physical burden of the product, and launched this formulation in November 2013.

### BH4-reactive hyperphenylalaninemia

Hyperphenylalaninemia is a rare disease, affecting a small number of patients; its incidence in Japan is 1:80,000 and the number of patients diagnosed since 1977 when the Jmass screening of newborns was started in Japan is approximately 600. Regarding hyperphenylalaninemia, the pathology in which there is no abnormality in the synthetic pathway of tetrahydrobiopterin (BH4) and phenylalanine level drops by the administration of BH4 is defined as BH4-reactive hyperphenylalaninemia. Approximately 30% of the patients with hyperphenylalaninemia are classified into this type.



Biopten Granules 10%  
(100 mg as the active ingredient)  
6 packets to be taken per day

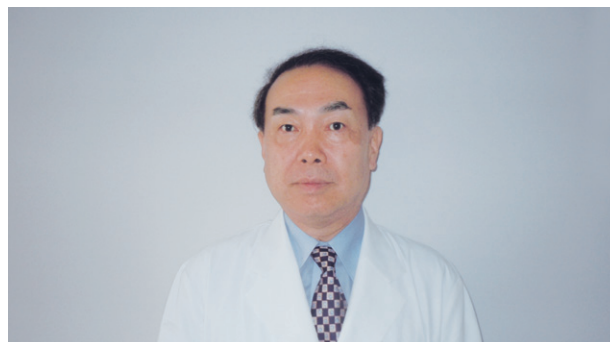
## External Voice

### Dramatic improvement of medication convenience by Biopten Granules 10% (brand name and dose of a high-concentration drug formulation)

The existing Biopten Granules 2.5% that contains 10 mg of sapropterin hydrochloride per packet was administered in patients with BH4-reactive hyperphenylalaninemia from 1 packet/kg/day. Therefore, its dose increased to 60 packets per day when the body weight of a child increased to 60 kg, imposing great effort to bring back the drug from a hospital or pharmacy and when the drug was actually taken by opening the packages. Therefore, the development of a high-concentration formulation was demanded. It was an ardent appeal of patients and their families.

The Japanese Society for Inherited Metabolic Diseases has also submitted a petition for the development of a high-concentration formulation to Daiichi Sankyo Co., Ltd. Considerable improvement in the convenience of administering Biopten by the development of a high-concentration formulation by Daiichi Sankyo Co., Ltd. has greatly satisfied the patients and their families as well as healthcare professionals supporting the patients. It was greatly welcomed by patients, who say “reduction of dose to one-tenth made taking, opening, and transporting the drug much easier” or “I could even take the drug at my school lunch because taking the medication was so much easier.”

Listening to the patients' voices is the origin of medical care. It is the joy of healthcare workers to see more patients smiling. I am anticipating the continued contributions of Daiichi Sankyo Co. Ltd. to medicine.



Haruo Shintaku, M.D., Ph.D.

Professor  
Department of Pediatrics Osaka City University Graduate School of Medicine

\*2 Voluntary participation of a patient in deciding the treatment policy and receiving the decided treatment.

# Supply Chain

Towards Realization of Global Pharma Innovator

We will efficiently produce consistently high-quality drugs.



## ■ Transformation of Supply Chains in Response to Age

The pharmaceutical industry is currently operating in an environment that is changing at a dizzying pace. Companies must have the ability to deal with variegating supply chains, from the procurement of raw materials to the production and distribution, while facing the complications of operating a supply chain that can provide quality assurance and a stable supply of drugs in the face of expanded distribution areas, caused by globalization of markets and diversifying needs for drugs. The attainment of an alert and flexible supply chain is a must, particularly in an age of such drastic changes.

## ■ Sharpening “Supply Chain Technology”

With globalization of the business as a whole, we are establishing and optimizing the global supply chain structure, suited to each life cycle of global products by the maximal utilization of strength at each manufacturing hub.

Our “supply chain technology” is the indispensable foundation to enable a variety of prescription by the physicians of each country (see Voice below). Outstanding technologies covering the entire supply chains are indispensable, including not only production technologies, such as quick industrialization in collaboration with our research laboratories, establishment of optimal production conditions, and modification of manufacturing processes,

## Voice

### Our “technology” supporting global supply chains

“Consistently produce better products at lower cost and deliver them.” As its name suggests, the Supply Chain Unit is a comprehensive organization that organically combines the activities of material procurement, production, and delivery, and the technologies that support these activities. “The product quality is not up to specifications.” “Only one material have not been delivered.” “Inventory control was not correctly estimated.” “Validation has failed.” The smallest of mistakes could result in stock-out and inconvenience to patients. Accordingly, members of the Supply Chain Unit always exercise extreme care in their work.

Today, Daiichi Sankyo’s supply chain is undergoing worldwide expansion. We have established a supply system for edoxaban that will see the drug supplied to all parts of the world from seven plants in Japan, Germany, the US and Brazil. Thanks to the efforts made by all personnel concerned, these plants have successfully met the inspection criteria of the regulatory authorities in the respective countries and are now ready to start operation. Hiratsuka Plant in Japan and Pfaffenhofen Plant in Germany have adopted Real Time Release Testing, which allows final products to be released based on in-process data. We are challenging a technology innovation.

Through our pursuit of what we call Supply Chain Technology;

namely, manufacturing technology and other technologies, including supply and demand control and material procurement processes, we support the sustainable growth of Daiichi Sankyo all over the world, and we are committed to contributing to improvement of healthcare services for patients around the world who are waiting for Daiichi Sankyo products.



**Tatsuro Morino**

Senior Director, Formulation Technology Group, Supply Chains Technology Department  
Supply Chains Division  
Daiichi Sankyo Co., Ltd.

but also management technologies, such as cost planning and drafting flexible production plan. We are continuously pursuing quality, cost, and stable supply simultaneously, including transformation to a manufacturing process backed by sophisticated technology and the implementation of cost reduction measures using inexpensive raw materials by cooperating with business partners.

We are practicing business operations with “seamless” as a common goal, referring to the conditions without barriers in information supply and communication among organizations, countries, and regions. In order to achieve high-quality results in the age of drastic changes, importance is attached to an invisible resource to share direction of thinking in the whole group. We will continue to aim for the highest quality by sharpening and gathering individual “supply chain technology” supported by the knowledge and the experience.

## Major Initiatives

### Towards obtaining approval for Edoxaban

To obtain health authority approval for a new product, it is critical that a manufacturer demonstrate that its manufacturing process and quality meet the GMP\*<sup>1</sup> standards of distributing countries through inspection of the manufacturing sites by regulatory authorities. Regarding edoxaban, through preparation for inspection and subsequent speedy and rigorous follow-up are one of the most important tasks in and outside Japan for helping to obtain health authority approval. We were well-prepared for the pre-approval inspections of the three hubs in Japan, conducted by the FDA\*<sup>2</sup> in 2014. We will continue to leverage all our strengths among domestic and overseas group companies to meet the latest inspection standards of regulatory authorities to countries and contribute to obtaining worldwide approval.

### Continuous cost reduction and streamlining of business operations towards maximization of corporate value

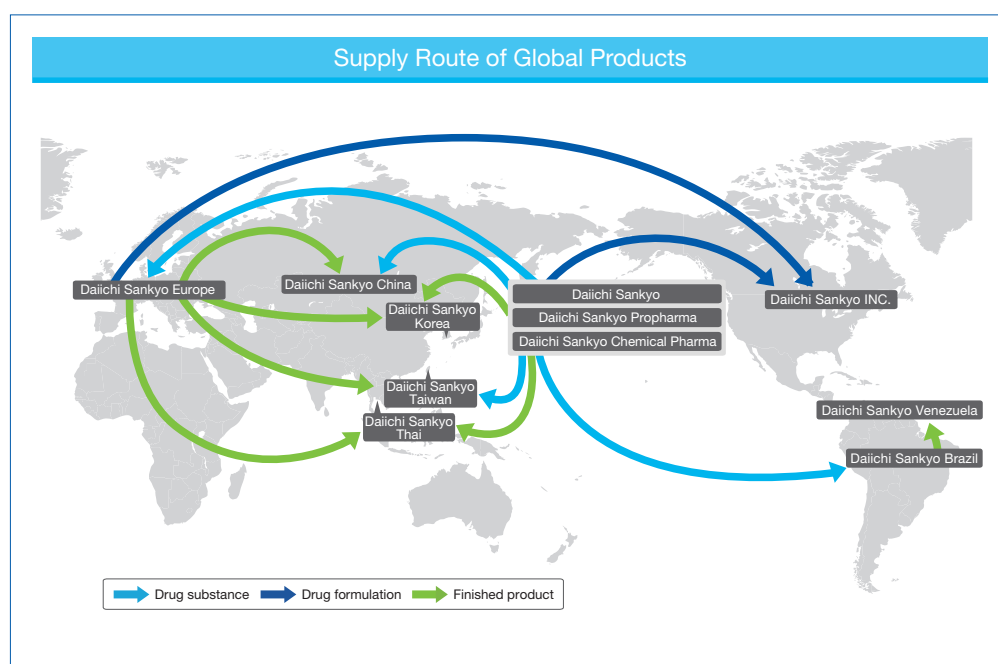
The most important responsibility of the supply chain unit is to strengthen the corporate growth platform by achieving continuous cost reduction while assuring quality level demanded by markets, including a stable supply. In addition to the

realization of the target cost based on the cost planning for edoxaban, we will continue to promote actions aiming at securing competitive strengths at a global level, including global procurement and optimization of transportation means in pursuit of outcomes.

Altogether, we will continuously optimize the global supply chain structure to surely and efficiently meet the pharmaceutical affairs regulations and commercial practices around the world, including the restructuring of domestic supply chain function company to be implemented in 2015, and deal with an early launch of new products, such as edoxaban and quickly respond to changes in demand in the future. We are the unceasing challenger to efficient business management as the Supply Chain Unit playing a part of continuous corporate growth platform.

### Promotion of CSR procurement

At the supply chain unit, we are conducting periodical assessment of abilities of domestic business partners to deal with quality, stable supply, and so on in the procurement of raw materials aiming at further promotion of CSR procurement. We have analyzed the results of questionnaires answered by 185 domestic business partners (recovery rate of 95% on the transaction amount basis) and fed back the results to the respective partners. Moreover, we are deepening our activities with a concept of “CSR procurement activities walking together with partners (suppliers),” such as starting bidirectional discussion with the partners towards improvement. In addition to quality, cost, and stable supply, we will promote CSR procurement as one of the corporate activities, considering sustainability.



\*1 Abbreviation of Good Manufacturing Practice

\*2 Abbreviation of Food and Drug Administration



# Quality and Safety Management

Towards Realization of Global Pharma Innovator

We will secure quality and safety to deliver reliable drugs.



## ■ For Reliable Drugs of Daiichi Sankyo Brand

“Drugs” includes investigational products consisting of “products” and “information,” and they cannot accomplish their mission as a drug if either of these is insufficient. We, Quality and Safety Management Unit, are focusing the following three points in order to deliver reliable drugs to the patients (including those undergoing clinical trials) and healthcare workers all over the world and contribute to the world’s health and culture.

- ✓ Quality assurance of the drugs (products) being supplied stably to the world from clinical trials to post-marketing
- ✓ Safety assurance in patients who use drugs based on information on adverse drug reactions from clinical trials to post-marketing
- ✓ Quality assurance of data (efficacy and safety information) from research and development to post-marketing, warranting the effects scientifically

These points support the value chains of research and development, pharmaceutical technology, supply chains, and marketing & Sales, which are the major activities of a pharmaceutical company and contribute to the maintenance and improvement of the Daiichi Sankyo brand and continued growth of the corporation.

## ■ Towards New Quality and Safety Management

### Innovative quality assurance and adoption to PIC/S

We have introduced “real-time release tests (hereinafter, referred to as RTRT) that monitors the quality in the manufacturing process in real time. This helps ensure that final edoxaban product meets high-standards of manufacturing. In performing RTRT, innovative technology called process analytical technology is required, which goes one step further than the conventional quality system of judging the quality simply by seeing whether the finished product passes the quality test. Using this new innovation, we have assured the quality at a level higher than the existing quality test for the finished product using this new innovation (see Voice in page 49).

In fiscal year 2014, Japan officially joined the “Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).” This accession to PIC/S will accelerate the globalization of Japan’s GMP. From now on, we will make an effort to deliver secure and safe drugs more quickly to patients all over the world by collaboration with the supply chain unit and overseas group companies and by a complete utilization of the manufacturing and quality controls based on the GMP\*<sup>1</sup> of the global level.

### Promotion of pharmacovigilance\*<sup>2</sup> (PV) by the introduction of IPOS

Daiichi Sankyo Group started the new global safety database, “IPOS (Integrated Pharmacovigilance Operations System)” in March 2014 aimed at the global integration of

\*<sup>1</sup> Abbreviation of Good Manufacturing Practice

\*<sup>2</sup> Pharmacovigilance. To detect, interpret, evaluate and analyze adverse effects of drugs (including investigational products) or other drug-related matters and implement activities for their prophylaxis.



safety data and standardization and upgrading of pharmacovigilance activities. We are intending to promote global safety measures stepping ahead of risks by a positive utilization of the IPOS. We will also deal with the enhancement of pharmaceutical regulations and the diversifying business strategies around the world by further strengthening each region.

 See "Collection of Information and Feedback" on page 67.

## Major Initiatives

### Towards obtaining approval for edoxaban

We applied for the additional indications of edoxaban in Japan in December 2013 and for a new drug approval in USA and Europe in January 2014. (Further information, please see "Edoxaban from Japan to the world" from page 26.)

Prior to the application in each country, we evaluated patients with adverse reactions among a vast number of cases from patients by the global clinical trial, including Japan and prepared for post-marketing safety measures. In addition, quality assurance of research and development was conducted through audits (inspections) both its research and development system and its resulting documents, leading to the high-quality application dossiers which more than fulfill the regulatory requirements of relevant countries. Furthermore, we as the entire group have fully prepared for the investigation and inspection by the regulatory authorities of relevant countries during each approval review so that GCP<sup>\*3</sup>/GMP compliant outcomes would be obtained without significant findings. We have tackled the matter with the wish "to deliver secure and safe edoxaban at the earliest possible timing to patients." in our hearts.

### Strengthening of safety measures for new product

In Japan, the establishment of a "risk management plan (RMP)" was required for all applications for marketing approval of new drugs and biological generic drugs filed after April 2013.

Daiichi Sankyo proactively put an RMP in place after obtaining approval for denosumab (indicated for osteoporosis). We promoting the proper use of the drug, considering its known risks of adverse drug reactions aiming at risk minimization.

Prasugrel was launched in May 2014 in Japan based on the RMP discussed with the regulatory authorities during the approval review.

### Penetration of awareness of "delivering security and safety"

While a variety of changes are progressing in the business environment, such as globalization, multilateralization, and tightening of regulations, our Quality and Safety Management Unit continues to always act with the consideration, "what is most important for the security and safety of patients and healthcare professionals". We are devising measures based on the latest facts, knowledge, and technology as well as scientific grounds and will make the effort to supply vital information to you regarding quality assurance, further improvements, and proper use.

Through the accumulation of these data, our group wishes to achieve the creation of innovative drugs and supply them to meet the variegated medical needs, and remain a trusted medical partner for patients and healthcare professionals around the world.

## Voice

### High quality assurance with inter-division cooperation

Data reliability is becoming a critical issue in our industry. An automatic data collection system is used for Real Time Release Testing (RTRT), and the collected data are managed by a robust system that does not allow intentional data manipulation. With no need to perform quality testing of end products, RTRT can shorten the lead-time from the start of manufacturing to product release. If RTRT is used for drug products for which frequent production runs are required, it can also contribute to "quality cost" improvement.

Through efficient operation of the RTRT-based quality assurance system, which Daiichi Sankyo put into practical application ahead of other companies thanks to the efforts made by units such as the R&D unit and the pharmaceutical technology unit, we aim to assist the company in providing high-quality drugs to patients.



**Hisashi Takeuchi**

Quality Assurance Group, Quality Assurance Department  
Quality and Safety Management Division  
Daiichi Sankyo Co., Ltd.

<sup>\*3</sup> Abbreviation of Good Clinical Practice

# Marketing & Sales

Towards Realization of Global Pharma Innovator

We continue providing appropriate medical information and remain as a bridge between patients and their families and healthcare professionals



## ■ Japan

Daiichi Sankyo has launched a number of new products since fiscal 2010. These drugs include Rezaltas, an antihypertensive agent; Memary, a treatment of Alzheimer's disease; Nexium, a treatment for reflux esophagitis; Ranmark, a treatment for bone complications; and Pralia, a treatment for osteoporosis, and these products will become even more important as the population of Japan continues to age.

In fiscal 2014, EfiEnt, an antiplatelet agent, was launched in May. EfiEnt and Lixiana, an oral factor Xa inhibitor, have the potential to become the standard treatments for thrombosis and embolism.

For diabetes drugs, in addition to Tenelia, which is manufactured by Mitsubishi Tanabe Pharma Corporation and was launched in fiscal 2012, we also became partners for the marketing of Canaglu, for which Daiichi Sankyo obtained the marketing authorization from Mitsubishi Tanabe Pharma in July 2014.

We will promptly nurture these new products as part of our core products and achieve sustainable growth by utilizing our extensive product portfolio. We will build strong trusting relationships with patients, their families, and healthcare professionals to be recognized as a trusted partner by continuing Daiichi Sankyo's original MR\*<sup>1</sup> Crosswise Structure\*<sup>2</sup>

and via various channels, such as collaborating with Group companies. Sales of ethical drugs in Japan in fiscal 2013 showed a significant growth for Nexium and Memary based on a healthy movement of Olmetec as a result of active promotion. A revenue of 481.4 billion yen (a year-on-year increase of 4.7%) was recorded owing to the expansion of Ranmark, a treatment for bone complications, launched in April 2012 and Pralia, a treatment for osteoporosis, launched in June 2013.

Medical representatives (MRs) in Japan provide an important foundation to sustainable growth by supporting patients' health through the provision of medical information on products. We emphasize the education and training of MRs and from junior to experienced MRs. They continuously learn and build trusting relationships with healthcare professionals. In particular, the education and training for newly employed MRs has a reputation for its quality, and all MRs passed the MR certificate test held in December every year for 4 consecutive years from fiscal 2010. This is a remarkable accomplishment for the first time in the industry in Japan (see Voice on P51).

To be recognized as a trusted partner by all healthcare professionals, we must strive to provide information that considers more patients and their families, as medical needs change and diversity.

\*1 Abbreviation of medical representative (person in charge of medical information)

\*2 A structure that links MRs who call on certain medical facilities and regional areas with MRs supplying specialized data in specific medical and therapeutic fields, ensuring the provision of high-quality information.

With information provided by Daiichi Sankyo MRs as a base, we will accurately, promptly, and carefully provide information to healthcare professionals, patients, and their families using a multi-channel approach, such as collaborating with marketing specialists (MSs), hosting lectures, and utilizing websites.

We will deliver information on not only one medicine but also information considering the total care of patients to healthcare professionals who are engaged in the treatment of patients with various symptoms and diseases.

Furthermore, we will provide information necessary to meet the rapidly changing healthcare environment to healthcare professionals striving for the delivery of reliable and safe healthcare.

In our efforts to provide useful information on a wide range of therapeutic areas, we will emphasize provision of information, particularly in the areas of dementia, osteoporosis, and cardiovascular/metabolism, including thrombosis.

We will strengthen trusting relationships with all healthcare professionals through these information provision activities and contribute to the improvement of quality of life for as many patients as possible. We hope to remain a bridge between patients and their families and healthcare professionals by ensuring the delivery of top-quality pharmaceutical products and appropriate medical information so that patients can receive treatment safely.

## Voice

### All newly employed MRs passed the MR certificate test for 4 consecutive years

In order to be equipped to effectively handle any assigned MR activity, each MR needs to enhance his/her knowledge, skills, and thinking. In other words, MRs are required to be informed and knowledgeable not only with Daiichi Sankyo products but also in respect of such fields as anatomy, physiology, pharmacology, pathology, treatment methods, ethics, law, PMS, and healthcare systems. Ability to pass the accreditation test is only the minimum requirement for MRs. We provide instruction for newly employed MRs and work which them extensively to support their success on the accreditation.

The target is to achieve 80% score of the accreditation test in August, following completion of the introductory training. However, because a significant proportion of new MRs have liberal arts backgrounds, every new MR cannot always achieve this target. In the course of coaching, we encourage them to identify their success



factors as well as their areas for improvement to apply the PDCA method to their own cases. Instead of pushing them to achieve, we guide them and encourage them to take an active role in their own success. I think it is

important for MRs to be active, not passive, and to keep moving forward.

We also place high value on group game activities in which members of each group cooperate with one another in order to compete with other groups. By the time all of the members of a group have passed the test, they will have shared their knowledge and skills with each other and strengthened the bonds between them. Our record of "all passing the test" through consecutive intakes may be attributable to this Daiichi Sankyo environment.



Yuichi Kimura

Training Group X, Training Information Department  
Sales & Marketing Division, Japan Company  
Daiichi Sankyo Co., Ltd.

## ■ North America

In fiscal 2013, Daiichi Sankyo, Inc. maintained its share of Olmesartan sales and enjoyed growth from Effient and Welchol, a treatment for both hypercholesterolemia and type 2 diabetes mellitus.

Goals for fiscal 2014 are a continued pursuit of maintenance and increases in sales of Olmesartan and Effient, thorough preparation for the potential launch of generic drugs in early 2015 after the expiration of the Welchol patent, and approval, launch and a successful market entry of edoxaban. In-licensing of new products from external parties is helping Daiichi Sankyo, Inc. efficiently use its sales capabilities. For example, we signed the agreement for the development and marketing of CL-108, combination opioid analgesic containing an antiemetic, with Charleston Laboratories, Inc. (Florida, USA) in August 2014. Daiichi Sankyo, Inc. will continuously engage in in-licensing activities.

Luitpold Pharmaceuticals, Inc. launched Injectafer, a new treatment for anemia, in August 2013 and has made a successful market entry. Quality assurance issues related to the 2011 and 2012 inspections by the FDA\*<sup>1</sup> have resulted in a number of new systems and processes. We made significant capital investments toward resolution of these issues in fiscal 2013 to be prepared for re-inspection by the FDA. Luitpold is also concurrently moving toward future production capacity expansion.

Luitpold is focused on rapid expansion of Injectafer in fiscal 2014. For Venofer (anemia treatment for patients with chronic kidney disease), a mainstay product, Luitpold will work to maintain sales and share under challenging circumstances, including price competition. We aim to normalize operations in the Shirley plant in New York with the new quality systems and commence manufacturing activities in the new Ohio plant as soon as approval is granted by the FDA.

In fiscal 2013, revenue of 211.3 billion yen (a year-on-year increase of 15.9%) was recorded for the two companies combined.

## ■ Europe

Daiichi Sankyo Europe GmbH enjoyed sales growth mainly from combination therapy with Olmesartan in fiscal 2013. However, the sales growth of Effient slowed down due to severe circumstances surrounding it. Considering the future trend of Olmesartan and preparation for the launch of edoxaban, pending approval by health authorities the sales force was reduced to 800 HC from 1,200 HC for the optimization of the sales representatives in the entire European region.

Revenue recorded 79 billion yen (a year-on-year increase of 30.4%).

In fiscal 2014, Daiichi Sankyo Europe strives to maintain sales of Olmesartan and Effient. The current sales structure of Olmesartan and other mainstay products uses the Share of Voice model, which focuses on the promotion of the appropriate use of Daiichi Sankyo products through direct visits to physicians by sales professionals and emphasizes the number of sales professionals and interactions with physicians. Furthermore, Daiichi Sankyo Europe will establish a sales structure of the Access model, which allows a strategy to flexibly deploy in accordance with the needs of several stakeholders based on recognition that there will be multiple stakeholders to be accessed in the future.

## ■ ASCA

In fiscal 2013, the ASCA (Asia, South and Central America) regions implemented initiatives, including the maximization of Olmesartan, Cravit, and other existing products, launch of new products (Effient, Urief, a treatment of dysuria due to prostatic hyperplasia in China, etc.), and utilization of external resources through alliances and in-licensing. In fiscal 2013, a revenue of 52.9 billion yen (a year-on-year increase of 33.8%) was recorded. Sales of the Olmesartan family are growing, particularly in China, Korea, and Brazil.

In fiscal 2014, the ASCA regions aim for sustainable growth of sales income and operating profit through key initiatives, the maximization of the existing products, promotion of hybrid business expansion of branded generic drugs, early development and launch of new products, promotion of use of external resources (alliance, in-licensing) and efficient use of expenses. In China, Korea, and Brazil, we aim to further strengthen and utilize alliances with global and local companies for maximization of the results.

\*1 Abbreviation of Food and Drug Administration

## ■ Generic Business

In Japan, the government has reinforced the promotion of the use of generic drugs by introducing incentives, such as the premiums for generics dispensing systems and premiums for generics prescribing in order to inhibit the increase of the medical costs with Japan's rapidly aging society. The Ministry of Health, Labour and Welfare announced the road map for the enhancement of further use of generic products to aim for the volume-based penetration rate of 60% or over by the end of March 2018. The use of generic drugs is expected to expand even more.

Based on the trust and safety of the Daiichi Sankyo brand, Daiichi Sankyo Espha has been advocating a concept of "premium generic drugs," high value-added generic drugs, with an aim of becoming the first choice of patients who require generic drugs. For Donepezil 10 mg OD tablets\*<sup>2</sup>, a treatment for Alzheimer's disease, also launched in fiscal 2013, Daiichi Sankyo Espha applied laser printing of the name of the drug/company/strength/specifications on both sides of the OD tablets in addition to the standard tablets, developed formulations with improved treatment compliance by reducing bitter taste, and launched medications of the pharmacies' and patients' choice. As a result, all three of the generic drugs launched in fiscal 2013 ranked top three in share of sales.

In fiscal 2014, Daiichi Sankyo Espha aims to launch new major ARB\*<sup>3</sup> products and continuously expand the generic business. In contrast, the generic drug market is going to face a major turning point due to increasing competition resulting from the amendment of the generic drug pricing system in April 2014 and emergence of a series of authorized generic drugs\*<sup>4</sup>.

Daiichi Sankyo Espha aims to further expand the market share by introducing high value-added generic drugs to the market with the concept of "premium generic drugs," and adheres to the growth path through cost reduction and an efficient management of expenses as company in Daiichi Sankyo Group which is responsible for the Japanese generic business.

\*<sup>2</sup> Orally Disintegrating Tablets, are dispersed with saliva or small amounts of water.

\*<sup>3</sup> Angiotensin II Receptor Blocker

\*<sup>4</sup> Generic drugs, which are marketed with the authorization from the marketing authorization holder of the original drug and the manufacturer

\*<sup>5</sup> Abbreviation of Chemical, Manufacturing and Controls

\*<sup>6</sup> Abbreviation of Good Manufacturing Practice

## ■ Vaccine

Japan is promoting further enhancements of vaccination policy by announcing the intention to eradicate rubella in Japan by 2020, the Tokyo Olympic Game Year, as a result of the rubella epidemic in 2013. Furthermore, two vaccines pneumococcus for adult and varicella were added on the routine immunization list starting in 2014, and longstanding "vaccine gaps" as compared to the US and Europe are being resolved.

In such circumstances, Daiichi Sankyo pursues R&D of new and improved vaccines to address globally unmet medical needs, including the development of vaccine with new administration routes i.e. using an intradermal device etc., and the conclusion of joint research agreement for norovirus vaccine with UMN Pharma Inc.

We will strengthen our integrated system of research, development, production, marketing and sales through organic collaborations with Japan Vaccine Co., Ltd., a joint venture with GlaxoSmithKline K.K. (GSK) established in 2012 for late phase clinical development and sales, and Kitasato Daiichi Sankyo Vaccine Co., Ltd. (KDSV) specialized in production and CMC\*<sup>5</sup>, in order to promote the discovery and stable supply of vaccines necessary in Japan.

In fiscal 2014, Daiichi Sankyo will focus on the following 3 vaccine initiatives.

### ☑ Promote R&D of vaccines desired in Japan

The Daiichi Sankyo Group actively engages in the R&D of "high priority vaccines" incorporated in "the basic immunization plan" issued by the Japanese Ministry of Health, Labour and Welfare (MHLW) in March 2014.

### ☑ Enhance the manufacturing/CMC structures and improve manufacturing efficiency

KDSV proceeds to improve existing buildings and new buildings to ensure the global standard of PIC/S GMP\*<sup>6</sup> for the stable supply of high quality vaccines.

### ☑ Contribution national project for pandemic influenza vaccine

Through "the Initiative to Build Development and Production Capacity" by MHLW, we have promoted the development and establishment of production system for pandemic influenza. In March 2014, KDSV obtained approval for the manufacturing and marketing of a cell-cultured H5N1 influenza vaccine. Although we could not fulfill the requirement of creating a vaccine supply schemes as originally planned by the end of March 2014, we have improved the yield in the manufacturing process and are continuously working at the improvement of the manufacturing method to complete the required amount of supply.



## ■ OTC Business

### ☑ Initiatives and results in fiscal 2013

Due to less pollen dispersion, the sales of eye drops, therapeutic agents for rhinitis, and allergy agents were sluggish in fiscal 2013. Sales remained the same as the previous year for other indications. Also due to the last-minute demand before the rise in the consumption tax, there was a significant increase in the Japanese market in March, particularly in the segments of revitalizers, nutrients, and nutritional supplements compared with the previous year, and the annual sales were higher than those in the previous year.

Under such circumstances, Daiichi Sankyo Healthcare focused on the customer-oriented development of new products and marketing activities and worked to revitalize the market through proactive approaches to growing areas and further enhancement of information provision and in-store promotion activities. As a result, the OTC business sold 48.1 billion yen (a year-on-year increase of 2.1%).

In addition to increases in sales of Transino, a drug to improve spots and Trafal, an anti-stomatitis agent, to which new products were added, continued sales expansion of Loxonin S, an analgesic and anti-inflammatory drug, on the market for 4 years contributed. For the direct marketing business, skin troubles were reported in some customers who used the major skincare series of "Derma-energy," and all products of this series were withdrawn from the market placing priority on the customers' safety.

### ☑ Goals and key initiatives in fiscal 2014

The market for OTC drugs, consumer products, is undergoing a significant change due to the advancement of the super-aging society and increased health consciousness. Daiichi Sankyo Healthcare promptly responds to these changes and focuses on the development of products that meet the customers' needs. In particular, we will strengthen the development of switch-OTC drugs utilizing our know-how, and activities of provision of information on Loxonin S and other category 1 OTC drugs, and expand sales and improve our income structure through product prioritization and focused approach.

### ☑ Initiatives to growing markets

We will expand sales in the growing functional skin care market and oral market through active investment. In the direct marketing business, we will continuously make efforts to restore the customers' trust and build a business foundation. We also explore new global business opportunities.

## ■ Execution of Ethical Promotion by MRs

In Japan, a medical representative (MR) is primarily responsible for visiting physicians, pharmacists, and other healthcare professionals to compile and provide information on the quality, efficacy, and safety of pharmaceutical

products in order to ensure that the products are used appropriately.

Daiichi Sankyo complies with the "Daiichi Sankyo Promotion Code for Prescription Drugs" (DS-P code), the company's ethical code of conduct, in addition to the Japan's Pharmaceutical Affairs Act, other related laws, and Fair Competition Regulations, as set forth in the Code of Practices for Pharmaceutical Industry, and performs medication information activities placing the highest priority on compliance. We plan to review the DS-P code in response to changes in the medical environment, social situation, etc. In the Sales & Marketing Division, each sales office manager announces important items of the DS-P code to MRs in their monthly internal meetings to improve the awareness of compliance in each MR and prevent violations of the DS-P code. Further, a person in charge of Fair Competition Regulations provides a direct training to MRs in each sales office twice a year (see Voice below).

## Voice

### Hold training in an atmosphere where MRs can easily consult

I have been responsible for the application of the DS-P code on fair competition for the past nine years. My mission is to ensure that each sales office in Yokohama Branch is fully familiarized with fair competition rules, relevant laws, and the significance of ethical compliance, and to create an environment in which no misconduct will occur. The Yokohama Branch has 11 business offices, and workshops on DS-P code are held at 14 offices/departments including the branch office. I carefully organize these workshops so as to ensure that they are not merely one-way lectures. By presenting case studies of DS-P code violations and encouraging trainees to participate in workshop activities, I work to deepen their understanding of the DS-P code so that they will always be conscious of it while working for Daiichi Sankyo.

For whose benefit do we need to comply with the DS-P code? The answer is "for the benefit of patients." The DS-P code was established for patients and should be used as a fundamental benchmark for any patient-related activity. If each of us, in undertaking a task, follows the ethical rules, the value of that task will be enhanced. It is important to create an open atmosphere that allows everyone to feel free to consult the DS-P code before starting anything. I believe that this will help to prevent misconduct while establishing a platform for sustainable growth.



Kazuhiko Yamada

Yokohama Branch, Sales & Marketing Division, Japan Company  
Daiichi Sankyo Co., Ltd.

## Major Products

## Innovative Pharmaceuticals

## Olmesartan

Anti-hypertensive agent



## Prasugrel (Effient®)

Antiplatelet agent



## Edoxaban

Anticoagulant



## Memory®

Treatment for Alzheimer's disease



## Nexium®

Treatment for reflux esophagitis



## Pralia®

Treatment for osteoporosis



## Generic Pharmaceutical

## Vaccine

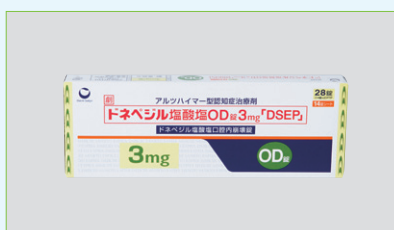
## Tenelia®

Treatment for type 2 diabetes mellitus



## Donepezil

Treatment for Alzheimer's disease



## ActHIB®

Haemophilus b conjugate vaccine



## OTC

## Loxonin® S

Category 1 OTC drug, analgesic, and anti-inflammatory drug



## Transino® II

Category 1 OTC drug, drug to improve spots (chloasma only)



## Trafal® Ointment

Category 3 OTC drug, stomatitis treatment



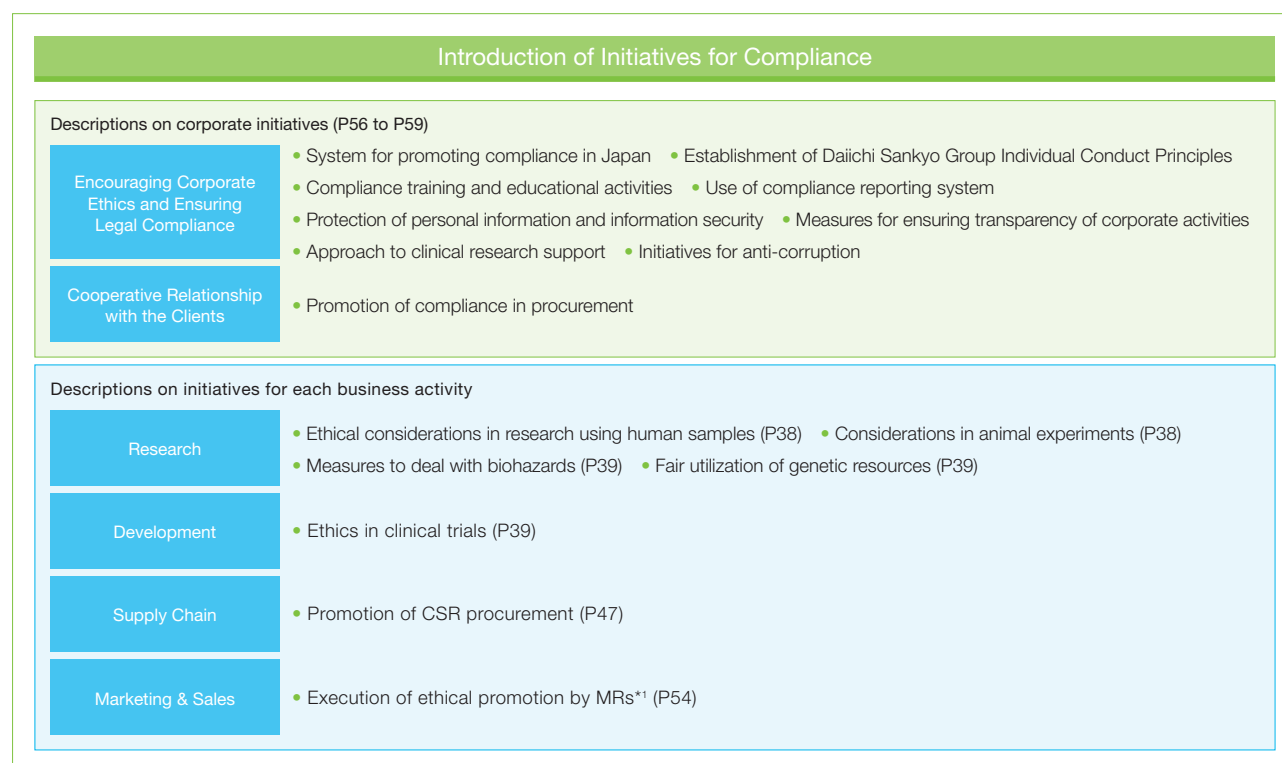


# Promote Ethical Business Management in Compliance with Law

Along with excellent business performance and results, it is critical to ensure compliance. The Daiichi Sankyo Group, as a global pharmaceutical company, executes its business operations by giving top priority to compliance.

## ■ Initiatives for Compliance

Our corporate initiatives and initiatives for each business activity are described in the figures below.



\*1 Abbreviation of medical representative (person in charge of medical information)



## ■ Encouraging Corporate Ethics and Ensuring Legal Compliance

It is the policy of Daiichi Sankyo Group to comply with all applicable laws and regulations in its business operations worldwide to ensure that compliance is treated with the highest priority in its corporate management and conducts compliance management with a strong focus on ethics and practical solutions that are relevant to a life-science oriented company.

“The Daiichi Sankyo Group Corporate Conduct Charter” fulfills the Group’s corporate social responsibility (CSR). Based on the spirit of the Charter, each group company has developed a code of conduct suitable for each region and its legal, regulatory, industry and social requirements as detailed internal rules and holds all executive officers and employees accountable to it.

### System for promoting compliance in Japan

The Global Head of CSR (Head of CSR Department) oversees the Group’s overall compliance.

At Daiichi Sankyo, the head of the Legal Affairs & CSR Division was appointed to the position of Compliance Officer to oversee all compliance matters, including the Standard of Conduct for Compliance for Japan and related rules and implementation plans. The Compliance Officer also serves as the chairperson of the Corporate Ethics Committee in Japan. The Corporate Ethics Committee, a decision-making body on compliance, is made up of 11 internal members, including the chairperson, and an external attorney to ensure that the committee is administered in a transparent and reliable manner. The committee meets twice a year. A compliance officer is appointed in each group company in Japan to promote and oversee compliance matters.

### Establishment of Daiichi Sankyo Group Individual Conduct Principles

Global companies are required to establish a global policy regarding individual behaviors in the organization and external declaration of it in order to conduct business activities with integrity.

Based on the above background, in fiscal 2013 the Daiichi Sankyo Group started developing “the Daiichi Sankyo Group Individual Conduct Principles,” a global policy regarding individual behaviors to supplement the Daiichi Sankyo Group Corporate Conduct Charter. The Daiichi Sankyo Group Individual Conduct Principles is planned to be rolled out in the group companies in Japan and overseas in fiscal 2014.

### Compliance training and educational activities

In fiscal 2012, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) implemented the IFPMA Code of Practice. In line with this, the Japan Pharmaceutical Manufacturers Association (JPMA) made its Code of Practice effective in April 2013.

In response, Daiichi Sankyo and its group companies in Japan revised each company’s code of conduct for compliance, held training sessions with e-learning to promote a better understanding of the code of conduct for compliance and were proactive in providing compliance training and education tailored to the unique characteristics of each workplace.

We also encouraged awareness of individual employees in the group companies in Japan by asking for slogans to raise awareness and putting up a slogan poster at all workplaces in Japan.

In fiscal 2014, we will perform a compliance awareness survey across the group companies in Japan to understand and analyze the awareness of employees. The feedback on the results of the survey will be provided to each group company to utilize them for the next year’s compliance program plan and promotion of compliance within the Daiichi Sankyo Group.

### Use of compliance reporting system

In Japan, the DS-hotline has been set up in Daiichi Sankyo and its group companies as a hotline system. The DS-hotline comprises reporting channels that include an internal contact and external attorneys. It receives reports, such as violations of laws, sexual harassment, and power harassment and takes actions for the prompt resolution of problems and appropriate measures.

Furthermore, each group company in Japan provides reporting channels for whistleblowers at each company, such as a hotline or e-mail system.

Daiichi Sankyo and its group companies in Japan have devised rules to govern the handling of internal whistleblowing cases in Japan, which specify that the whistleblower’s confidentiality will be protected and that they will be protected from any unfavorable treatment as a consequence of reporting.

In overseas companies, the compliance reporting systems have been set up according to the circumstances in each country and region.

For example, in the United States, Daiichi Sankyo, Inc. runs a 24-hour hotline to receive report anonymous information regarding potential compliance concerns.

### Protection of personal information and information security

We protect information attentively and handle personal information appropriately in accordance with applicable laws and our internal regulations. In Japan, we have thorough precautionary measures in place to protect information contained on company computers and laptops. In Japan, employees also carry emergency contact card so that they can immediately contact the right official if anything happens. We have also implemented enhanced security measures to prevent and manage information leaks or disclosures.

## ■ Encouraging Corporate Ethics and Ensuring Legal Compliance

### Measures for ensuring transparency of corporate activities

Based on the Japan Pharmaceutical Manufacturers Association (JPMA) “Guidelines for Transparency in Relationships between Corporate Activities and Healthcare Institutions”, we issued “Basic Policy on Transparency in Relationships between Daiichi Sankyo and Healthcare Institutions” in Japan in November 2011 to ensure the transparency of relationship between corporate activities and healthcare institutions. We collected information on payments to Japanese healthcare institutions in fiscal 2013 and disclosed it on the corporate website in August 2014. The “Sunshine Act” went into effect in the United States in 2013 and requires collecting and reporting data reflecting payments or transfer of values made to physicians and teaching hospitals to the government. We collected information for fiscal 2013 within the Daiichi Sankyo Group and reported it to the government in the United States in June 2014.

In Japan, based on “The Action Guideline for Cooperation with Patient Groups” and “The Guideline for Transparency of Relationships between Corporate Activities and Patient Groups” developed by the JPMA, we established “The Basic Policy on Transparency in Relationships between Daiichi Sankyo and Patient Groups” in February 2013 to ensure the transparency of relationship between corporate activities and patient groups. We collected information on payments to patient groups in fiscal 2013 and disclosed it on the corporate website in August 2014.

### Approach to clinical research support

Since the establishment of “The Review Committee for Clinical Research Plan of Antihypertensive Drugs” under the Minister of Health, Labour and Welfare in August 2013, various issues regarding the overall modality of clinical research in Japan have been discussed.

In a nod to the significance of clinical research support, Daiichi Sankyo has set up an intelligence sharing organization under the leadership of the department responsible for communication with government and industry (Public Relations Division) in August and started sharing information on the government policies among relative departments, understanding the current status of Daiichi Sankyo, and identifying issues/challenges. In October 2013, the intelligence sharing organization was reformed to “the taskforce for clinical research” consisting of officials from a wider range of departments appointing the Head of Business Intelligence Division as the leader, aiming at a prompt organizational response. We gave top priority to ensure further transparency for scholarship donations among the issues discussed in the taskforce and transferred scholarship donation activities in all companies to the CSR Department during fiscal 2013. We have started a new operation in fiscal 2014, which thoroughly confirms conflicts of interest before making donations.

In April 2014, the Japan Pharmaceutical Manufacturers Association issued a notification of “the basic principle of the modality of clinical research support in pharmaceutical companies” for the member companies. We will continuously comply with the basic principle of this notification in conducting activities for clinical research support.

#### Scholarship donations in Japan

Of donations for the promotion of academic research and research, donations for scholarship for education and research made to university and research institutions are defined as scholarship donations.

Scholarship donations are essential for research in these research institutions. Scholarship donations are accepted in accordance with the accounting rules at each research institution and used based on strict rules, including specifying the purpose of use to detailed academic research objectives. As a matter of course, these donations will not be offered in exchange of purchases or prescriptions of company's products, and they will not affect the procedures of research activities that research institutions and healthcare professionals perform (abstract from the Japan Pharmaceutical Manufacturers Association material).





## Initiatives for anti-corruption

Group companies implement local anti-corruption code of conduct, rules policies and procedures. For example the Daiichi Sankyo Code of Conduct for Compliance in Japan prohibits acts that can be construed as bribery or corruption, in particular forbidding the provision of entertainment or goods to public hospitals or other healthcare professionals with which there are opportunities to do business.

In light of an increasing risk for extraterritorial application of the laws of combating bribery of foreign public officials in international business transactions to companies that conduct global business activities, we held training sessions in Japan on the Unfair Competition Prevention Act in Japan and laws and regulations in overseas (US: FCPA<sup>\*1</sup>, UK: UKBA<sup>\*2</sup>, China: commercial bribery) for the management and employees of the Company and group companies in Japan and promoted a better understanding of knowledge, which needs attention in fiscal 2013.

In fiscal 2014, we will reinforce the individual norm for anti-corruption in the Daiichi Sankyo Group Individual Conduct Principles and promote global business activities with attention paid in particular to countries and regions associated with a potentially high risk of bribery.

<sup>\*1</sup> Foreign Corrupt Practices Act

<sup>\*2</sup> UK Bribery Act 2010



In-house training on "the laws of Combating Bribery of Foreign Public Officials in International Business Transactions"

Also see "Anti-Corruption Initiatives in Business Expansion in Emerging Countries" on page 60.

## Cooperative Relationship with the Clients

### Promotion of compliance in procurement

Daiichi Sankyo and its group companies in Japan have improved internal rules on procurement under "compliance" as one of the procurement missions and stipulated compliance with the laws concerning procurement (Antimonopoly Act, Act Against Delay in "Payment, etc." to Subcontractors, other laws). In 2011, we established the CSR Procurement Standard (see the figure below) to encourage all of our supplies to engage in socially responsible actions. The Company and group companies in Japan are working on the clarification of the procurement process and realization of optimal procurement, based on these standards concerning procurement. In 2014, the Daiichi Sankyo Group plans to establish the global procurement policy, which stipulates that procurement activities in accordance with laws and applicable regulations in each region are the basis and promote compliance-based procurement activities in both Japan and overseas in line with global practices.

#### CSR Procurement Outline

Daiichi Sankyo encourages all of its suppliers to engage in socially responsible actions to meet the following requirements and works together with them to provide support to achieve their goals.

##### 1. Comply with laws and enhance CSR activities

- (1) Protect human rights, labor rights
- (2) Ensure workplace safety and health
- (3) Comply with relevant laws and international conventions
- (4) Contribute to society and community

##### 2. Promote fair trade and ethics

- (1) Prohibit corruption and bribery
- (2) Promote fairness, transparency, free competition and sound trade

##### 3. Consider environment

- (1) Reinforce environmental management systems
- (2) Reduce waste and use of resources effectively
- (3) Control hazardous chemicals in products
- (4) Green Procurement

##### 4. Secure optimal quality & cost

- (1) Establish and implement quality management system
- (2) Secure good product quality
- (3) Offer competitive prices

##### 5. Ensure stable supply

- (1) Secure steady delivery times and stable supply

##### 6. Keep information security

- (1) Secure computer networks against threats
- (2) Prevent the leakage of personal and customer confidential information

## Anti-Corruption Initiatives in Business Expansion in Emerging Countries

While global companies are expanding their business in rapidly growing emerging countries, bribes of foreign public officials have drawing attention. We invited Attorney Daisuke Morimoto, who is familiar with handling the anti-bribery related laws and regulations, and asked for anti-corruption initiatives with respect to how Daiichi Sankyo should operate business, what we should consider, and what risk management we should implement.



### Shuji Handa

Executive Officer, President of ASCA Company Daiichi Sankyo Co., Ltd.

He works on the development of business strategy plans in Asia, South and Central America regions (the ASCA regions). As Executive Officer, he works on improving the presence of the Daiichi Sankyo Group in the ASCA regions.



### Daisuke Morimoto

Attorney-at-Law, Admitted in Japan & New York  
Partner of Nishimura & Asahi Law Firm

He is engaged in the overall corporate legal affairs, such as corporate cases, including M & A and corporate governance in Japan and overseas; crisis management, including handling the US FCPA and other anti-bribery laws and regulations and internal investigations; and Japanese and cross-border law suits and disputes.



**Yogosawa:** I am Yogosawa from Daiichi Sankyo Co., Ltd., the moderator of today's interview. I am engaged in promoting compliance management in the Daiichi Sankyo Group as Global Head of CSR.

Mr. Handa will explain Daiichi Sankyo Group's business expansion in the ASCA regions and initiatives for compliance. Mr. Morimoto, who is specialized in handling anti-bribery laws and regulations, will explain the trend of the anti-bribery laws and regulations.

### Acceleration of Business and Risk for Corruption in Emerging Countries

**Handa:** ASCA Company has local subsidiaries in 8 countries and regions (see the map below) and sell pharmaceutical products in the regions. China and Brazil have production

lines of pharmaceutical products. They also conduct licensing business for the surrounding countries. With an improved standard of living and increased health awareness, the overall market is estimated to show 10% growth a year on average in the next 5 years, and the ASCA regions are essential for the growth strategy of the Daiichi Sankyo Group.

**Morimoto:** The ASCA regions include regions with a high risk of corruption due to rampant bribes. In addition to measures to anti-bribery laws and regulations in each country that should be considered in communications with foreign public officials in the course of business activities in each country, measures for the extraterritorial application of laws in the United States such as the US FCPA (the Foreign Corrupt Practices Act) should be also considered. The interpretation of the US FCPA significantly varies, and there is a possibility to face several unexpected risks depending on how you approach it.

#### ASCA Regions

Abbreviation of Asia, South and Central America. This is internal terminology, indicating markets outside Japan, the United States, and Europe. These are rapidly growing emerging regions and we have operations in these regions as potentially important regions of Daiichi Sankyo.



ASCA: Asia, South and Central America



## Daiichi Sankyo's Initiatives for Overall Compliance

**Handa:** We have stipulated in the Daiichi Sankyo Group Corporate Conduct Charter to act with the highest ethical standards and good social conscience appropriate for a company engaged in a business that affects human lives. All employees working in the ASCA regions comply with its spirit in conducting daily activities. In addition, each group company has developed its code of conduct for compliance to respond to country-specific trends of laws and regulations in line with the Charter and improve its promotion of compliance management.

The pharmaceutical business requires government approval and license and is strictly managed in all countries. There is an increased risk of bribery of public officials and other issues due to a high frequency of communication with public officials, and each employee engaged in business needs to operate activities with an awareness of compliance.

**Morimoto:** I agree with you. It is very important to establish a compliance system and train all employees engaged in business activities. What I want to emphasize with respect to bribery is bribes made by agents and distributors. You may become involved in bribes without realizing. Recent bribery cases have shown that just paying attention to yourself is not sufficient.

## Recognition of Corruption Risk as Pharmaceutical Company

**Handa:** In addition to the approval and licensing activities of pharmaceutical products, pharmaceutical companies consider that contact/communication with physicians, pharmacists, and other healthcare workers for the adoption and prescription of pharmaceutical products are at high risk in relationships with public officials. We need to understand where risks specific to pharmaceutical companies exist and consider countermeasures at each stage.

**Morimoto:** It is an important initiative for risk mitigation to consider which aspects of business activities are at a higher risk of bribery. Cases related to the US FCPA and bribery cases in emerging countries have recently occurred, and it is essential for pharmaceutical companies to understand and address risks.

**Yogosawa:** Yes, Daiichi Sankyo is committed to compliance with the laws and regulations that prohibit bribery. Our company Charter requires that all Group companies comply with laws, regulations and rules regarding global corporate activities, and act with the highest ethical standards.

**Handa:** It is important to establish robust compliance programs for anti-corruption as well as establishing not only the compliance programs but also a system which appropriately functions and continuously works on PDCA cycle. We should not just leave it to operations. Compliance needs to be understood and checked at both sides.



Moderator

**Katsuyuki Yogosawa**

Global Head of CSR  
Vice President of CSR Department  
Daiichi Sankyo Co., Ltd.



# Mutual Growth of Employees and the Company

The biggest driving power to fulfill the corporate mission is that employees who embody the values of the Daiichi Sankyo Group find their work worthwhile. The Daiichi Sankyo Group places “People” as the most important “Asset.” Through Innovation, Integrity, and Accountability, we realize sustainable growth.

## ■ Promoting Human Resources Management Initiatives in Accordance with Daiichi Sankyo’s Mission

The Daiichi Sankyo Group treats our people as the most important asset in management. We believe that the daily efforts of individual employees to embody the “3 values”, which the Group values the most, and accomplish the “8 commitments” promised internally and externally will lead to the fulfillment of our corporate mission and vision.

The Daiichi Sankyo Human Resources Management Philosophy, a human resources policy, is a management commitment to treat and foster employees, who follow integrity, are passionate toward work, and are innovative, and support fulfillment of their potential in a fair manner regardless of his/her location in the world. The Philosophy requests employees to make efforts to fulfill the corporate mission and comply with ethics and norms.

Improvement in the speed and quality of global business activities of the Daiichi Sankyo Group requires a close collaboration and cooperation among regions. Through personnel exchanges, involving different countries and regions, employees learn to work in diverse and globalized environments, respect different cultures and values, and understand diversity, aiming to facilitate global business expansion.

## ■ Reinforcement of Human Resources Management

### Promoting diversity

In order to expand our business globally and innovatively, a diverse environment is crucial, with each employee living up to their maximum potential, regardless of personal characteristics such as their race, culture, gender or age. The Daiichi Sankyo Group Corporate Conduct Charter stipulates that diversity is one of the most important principles to create an environment in which various talents live up to their maximum potential. Our Human Resource Management Philosophy also states that diversity should be of the utmost concern in order to drive the company forward. We work at the mutual growth of employees and the Company by turning the diversity of individual employees into successful organizational achievement.

### Career development support and working style for diverse employees

We offer the assignments optimizing individual skills as well as opportunities to develop, irrespective of personal characteristics and have an evaluation system that contributes to the growth of employees’ career development. We continuously improve the environment to realize ideal working conditions for diverse employees. For example, the introduction of a new system in Japan which allows employees who raise children or have family members in need of nursing care to shorten their working hours in a day so that they can focus on working feeling their job is worthwhile, without giving up their career due to life events, such as marriage, childcare, and nursing.



### Career development support for women at Daiichi Sankyo Japan

We have introduced some new systems in Japan that allow more flexibility to women's working style, minimizing the influence of certain life events. We have set promotional requirements, so that the childcare leave period does not work as a disadvantage, and prepared the re-employment system (re-member system) for employees who leave the company for any reason. We also run the Women in Leadership (WiL) program to further raise the awareness of female employees in Japan.

### Reemployment of retirees at Daiichi Sankyo Japan

We have started a reemployment system for all employees who are reaching the retirement age and hope to continue working with us. We will continuously place reemployment of retirees as one of the important factors of diversity, and with respect to the active use of human resources, review the basic principles for employment, assignment, and treatment policy as well as any necessary adjustment to the working environment.

### Promotion of employment of physically or mentally challenged persons

Based on the mid-term policy on the employment of persons with disabilities, our group companies in Japan and Daiichi Sankyo Happiness Co., Ltd., a special subsidiary company

established in line with the "The Act for Promotion of Employment of Persons with Disabilities," promote the employment of physically or mentally challenged persons and improve the working environment through communicating with the employees and their line managers, to ensure they are able to continuously perform their fullest potential.

### "KURUMIN" certification

The Daiichi Sankyo Group proactively and continuously provides child support programs in Japan from the viewpoints of "creating friendly environment to utilize childcare systems" and "creating systems that respond to diversity." Since earning the first "KURUMIN"<sup>\*1</sup>, the accreditation of Support Raising Next-Generation's Children in fiscal 2009, Daiichi Sankyo has continuously obtained the certification. Our group companies also have advanced efforts at Asubio Pharma, Daiichi Sankyo Business Associe, Daiichi Sankyo Propharma, Daiichi Sankyo RD Novare, and Daiichi Sankyo Healthcare that they are accredited for "KURUMIN." We continue enhancing child support programs to obtain certification for all group companies in Japan.



## Systems and Measures to Support Diverse Ways of Working in Japan

Names of the Systems/Measures	Details
Flextime	While working hours are adjusted on a monthly basis, working hours of the day are allowed to be flexible.
Shorter working hours for childcare (fixed time system and flextime system)	Employees who raise children up to the end of the third grade in elementary school are able to shorten their working hours during the day. Under flextime system, the system can also be applied.
Shorter working hours for nursing care (fixed time system and flextime system)	Employees who have family members in need of nursing care are able to shorten their working hours during the day. Under flextime, the system can also be applied.
In-house nursery (KIDS GARDEN)	In-house nurseries are established as a support measure for children waiting for admission to a nursery. Childcare is provided either full-time or temporarily. <b>Full-time childcare</b> Children of the employees on the waiting list for authorized nurseries, between the ages of 57 days after birth to pre-school, are generally admitted. <b>Temporary childcare</b> Regardless of the waiting status, it can be used when local nurseries or kindergartens are on holiday and by the pre-registration along with the predetermined review.
Adjusted area and working time system (short time work system for MR <sup>*2</sup> )	MRs are allowed to adjust the working hours (days) depending on the circumstances of the family and to request a consideration for work location.

<sup>\*1</sup> A nickname of an employee child support program accredited by the Ministry of Health, Labour and Welfare. Companies and legal entities, which fulfill certain criteria, including childcare support are allowed to add the KURUMIN mark to their advertisements and products.

<sup>\*2</sup> Abbreviation of medical representative (person in charge of medical information)



## Human Resource Development in Japan

### Fostering leaders

Our basic policy is to foster professionals who have a broad perspective through on-the-job experience. We train and support talents who will take important roles at several workplaces by combining the cycle of job rotation, on-the-job-training, and evaluation with self-study and trainings at each level. In addition, we screen new or mid-level managerial employees as potential candidates for executive managers who will look over each and every operational and functional unit and manage them as a whole. We provide several development opportunities, such as in-house and external trainings, challenge for new areas, and human resource exchange at a global level. (see Voice below)

### Voice

#### Japan-specific Career Development Attracts Global Talents

I think Daiichi Sankyo is doing a great job in promoting different views and different opinions. Diversity and equality are visible every day and I am confident that we will see more hiring of international employees in the future. Of course we have to be patient: change comes in very small steps. Daiichi Sankyo has a unique career developing system and international employees can choose from a great variety of career options that allow them to find the right path for their dreams and ambitions.

During the last three years, I was very lucky to have been surrounded by colleagues with a modern vision who supported my career development (I passed the assessment test for new managerial employees last year) and helped me to grow into a role with more responsibility. Daiichi Sankyo is now a large global corporation and I believe that such initiatives will help to further promote diversity and Daiichi Sankyo's sustainable growth.



**Martin Hager Dr.**

Planning Group, Translational Medicine & Clinical Pharmacology Department, Japan Development Oversight Function, R&D Division  
Daiichi Sankyo Co., Ltd.

### Fostering junior and mid-career employees in Japan

In alignment with our Human Resource Management Philosophy, we focus on fostering our employees who can embody "Innovation," "Integrity," and "Accountability" through daily operations. For junior employees, we offer opportunities to learn from on-the-job experience and autonomous and professional attitude for the sake of their own improvement. For mid-career employees, we offer job rotation optimizing their skills as well as training programs and opportunities to study, which help them acquire practical knowledge and strong leadership skills necessary for corporate leaders.

### Enhancement of opportunities for line managers to study

We enhance opportunities for line managers to study in order to "create a workplace, which fosters talents who autonomously adjust to environmental changes and continuously generate results." In addition, we will place and appoint qualified employees to manage each line of business, which strengthens organizational management capability.

## Fostering Corporate Culture

### Basic principles of respecting human rights

It is recognized that corporate activities must respect human rights, and that this is critical for developing a global business. We respect the core labor standards of the International Labour Organization (ILO) as the rights of working employees, and we recognize that a material approach of respect for human rights involves the management of personal information in human genome/gene analysis research as well as informed consent and observing ICH-GCP\*1 set up under the spirit of Declaration of Helsinki (ethical principles for medical research involving human subjects), etc.

To heighten awareness of the importance of respecting human rights, a message was sent by the Global Head of CSR to all the employees of Daiichi Sankyo Group on Dec. 10, Human Rights Day. We are also working on the human rights issue in collaboration with business partners, concerning the procurement and outsourced manufacturing under the Corporate Conduct Charter.



Also see "R&D Ethics" on page 38.

### Initiative on respecting human rights

In Japan, we provide ongoing training on respect for human rights at all job grades, from new hires to managerial employees, in our efforts to create a comfortable workplace environment for our various employees. In addition to regular educational activities about harassment, we provide training to employees working at harassment counseling desks, which are set up at the head office, other offices, and the labor union. This training provides counselors case studies and improves their consultation skills. In dealing with violations, we emphasize on social fairness and consult with lawyers and other external parties rather than keeping the

\*1 Good Clinical Practice by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)



issue closed within the company. Each case is dealt with strictness and reported to the Corporate Ethics Committee; we take measures to prevent the repeat of misconduct.

### Communicating with the labor union

In Japan, we have concluded a labor agreement with the labor union that guarantees the right of employees to organize and bargain and act collectively. Under our Human Resources Management Philosophy that the utmost consideration must be paid to communications with the labor union, the rights of employees are assured by conducting positive discussions focusing on resolving problems and disclosing information with high transparency to address many labor-management issues. We have established the Labor Management Committee for Japan to address industrial safety & health and labor time management through the PDCA cycle.

### Promoting “Work-life Cycle” in Japan

The Daiichi Sankyo Group has established a “Work-life Cycle” not as a simple measure to reduce working hours or providing a better benefit package, but, more importantly, as a means to enhance and support the values of the company. We advocate and pervade our unique policy under the term of “Work-life Cycle” with meaning of having a significant positive influence on each other through virtuous cycle of work and life rather than a image of juggling or balancing both work and life.

## Fostering Industrial Safety and Health

We consider securing the safety of the working environment and the health of our employees to be an important responsibility of the Daiichi Sankyo Group, and it is a

cornerstone of all business activities. As a matter of course, priority is given to prevention of the occurrence and recurrence of industrial accidents and work-related sickness. Furthermore, we have strived to improve employee satisfaction through creating a work environment in which employees can safely work with vibrancy and enhance their productivity by implementing a sense of independence and sense of ownership among employees toward their own working environment.

### Initiatives regarding industrial safety and health

We are actively involved in preventing industrial accidents and ensuring the physical and mental health of our employees, particularly by promoting industrial safety and health, as well as carefully managing working hours. We have set up a Group Central Safety and Health Committee to promote these safety management activities in Japan. Based on principles and measures established in consultation with the labor union, Safety and Health Committee meetings have been held at all group companies in Japan twice a year and at each office once a month. The activity results are summarized in the minutes to be shared with all employees. Industrial physicians are also actively involved in the committee meetings.

Furthermore, a chief industrial physician has been placed by Human Resources Department at the group headquarter as a part of a system, which provides support using a unified approach throughout Japan. We have also set up a counseling system available for employees and their families in affiliation with an external employee assistance program (EAP)\*2. We also conduct our initiatives in cooperation with the Daiichi Sankyo Group Health Insurance Association.

### Systems and Initiatives in Japan for Industrial Safety and Health in Japan

Systems and initiatives	Details
Measures for employees working long hours	Physician consultation for employees working long hours. Those requiring follow-up care are provided individualized guidance by the industrial physician and line managers.
Medical checkup program	With the aim to encourage employees to take medical checkups, we cooperate with the Health Insurance Association.
Fostering mental health	The stress check results showed that stress levels of our employees were low compared with the nationwide average. Self-care and line-care training programs are provided as a measure to foster mental health.
Return-to-work assistance	The return-to-work assistance program is conducted under the mental health system led by a chief industrial physician at the group headquarter to improve the number of employees who return to work from administrative leave and reduce the number of work-loss days.
Health databank	The databank has included central data management function for the medical checkup results, where employees can have an access to their results and a self-care function (stress check and fatigue assessment test).
Group Long-Term Disability insurance system (GLTD)	The group long-term disability insurance system guarantees a fixed portion of incomes to employees rendered incapable of working due to sickness or injury, up to the retirement age.

\*2 Abbreviation of Employee Assistance Program. An employee support program



# Enhancement of Communication with Stakeholders

We will communicate and cooperate with stakeholders in every business activity and promote mutual understanding. We strive for enhancing communication with healthcare professionals, patients, and local communities.

## ■ Communication with Healthcare Professionals

### To become an trusted partner

The role of the MRs\*<sup>1</sup> in Japan is particularly vital in gathering, providing, and disseminating information for healthcare professionals, such as doctors and pharmacists. Daiichi Sankyo's goal is to be recognized as a trusted medical partner by the entire healthcare profession.

We hope to be a bridge between patients, their families, and healthcare professionals through a provision of high-quality drugs and appropriate relative information in a wide range of therapeutic areas. We strive to provide information considering patients and their families, support healthcare professionals, and contribute to improve the patients' quality of life.

As part of these efforts, the Sales & Marketing Division strives to improve and enhance MR activities on an ongoing basis by periodically surveying our customers to obtain meaningful and actionable feedback.

Daiichi Sankyo was ranked first among competitors by all responded physicians in an overall assessment on MR activities in fiscal 2013. Daiichi Sankyo was also ranked as No.1 by cardiologists.

### Assessment by Questionnaire

	FY2011	FY2012	FY2013
Overall assessment of MRs (all physicians responded)	No. 2 (n=2,440)	No. 1 (n=2,451)	No. 1 (n=4,337)
Overall assessment of MRs (cardiologists)	No. 1 (n=300)	No. 1 (n=308)	No. 1 (n=442)

Conducted by Daiichi Sankyo with the cooperation of an outside research company (FY2011–FY2012), conducted by ANTERIO Inc. (FY2013)

### Provision of high quality information

We have established the Medical Affairs Department in Japan, which is responsible for activities, such as post-marketing surveillance and implementation of life cycle management and support of investigator initiated studies (IIS) based on contract in fiscal 2013.

Pharmaceutical products build on the risk—benefit balance in their nature. Therefore, it is important to rely on high-quality information on efficacy and safety for the promotion of proper use. In particular, in the early phase after the launch of a new product, information available is not sufficient to meet various needs in the medical practice though the efficacy and safety have been confirmed in clinical studies. Based on this background, our different functions cooperates each other to identify lacking information from each professional viewpoint in order to provide information using the most appropriate method in a timely manner and enhance the value of our products through the contribution to medical cares.

\*1 Abbreviation of medical representative (person in charge of medical information)

High-quality information should be medically and scientifically valuable as well as compliance with applicable laws and guidelines paying. We have to pay attention to ethical matters, appropriately handle conflict of interest and ensure transparency.

For IISs based on a contract, relevant functions cooperatively review the study proposal submitted by the investigator in terms of ethical and scientific nature in details to decide whether to support the study. In our activities to provide high-quality information, we ensure transparency of studies and appropriately address conflict of interests contracting with external institutes for research activities in Japan.

### Collection of information and feedback

We collect approximately 17,000 safety reports a year from domestic healthcare professionals via our MRs in Japan, if we add this to the reports from clinical trials, medical literature and our domestic and foreign partners, we receive a total of approximately 75,000 safety reports a year. Pharmacovigilance Department enters and evaluates the safety information on the IPOS<sup>\*2</sup>, a new global safety database, and reports to the regulatory authorities without delay as per the criteria stipulated by the regulations (see Voice on the right). We also perform tabulated analyses and cause analyses to provide healthcare professionals with the latest proper-use information via our MRs.

## Voice

### To provide information that supports proper use of medications

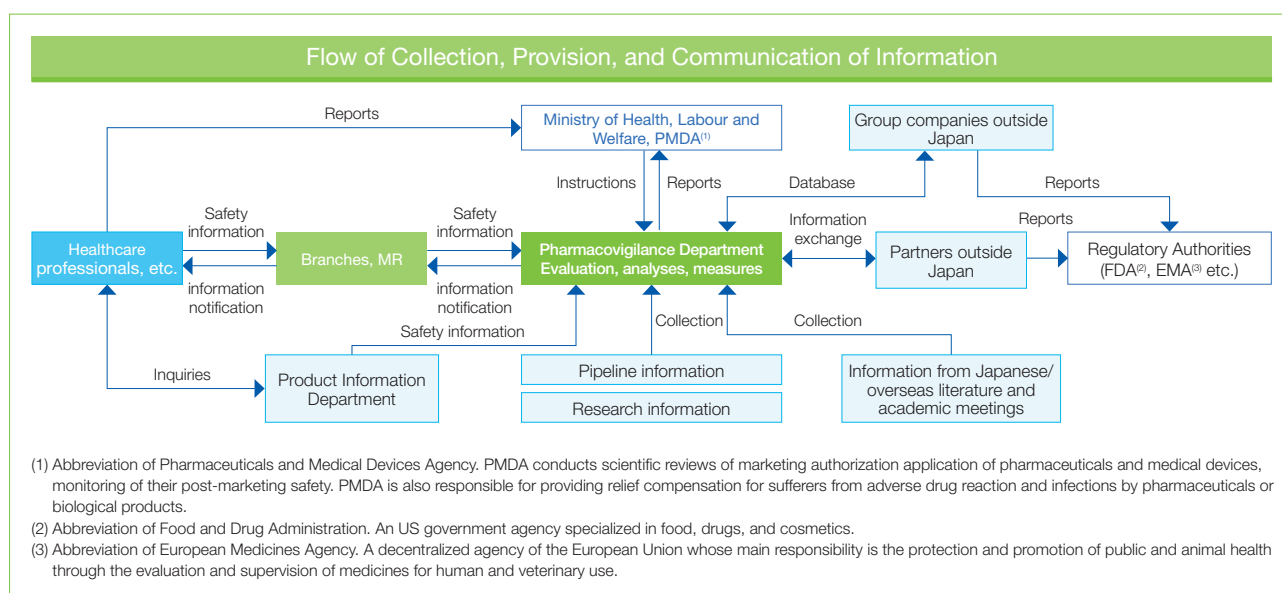
Use of the IPOS is expected to help bring about standardization of activities and information collation among group companies worldwide. Until recently, safety information had to be collected from each key office and then re-collated. Henceforth, collation and analysis of global safety information will be carried out on the IPOS, enabling all global group companies to forward the information needed for establishing safety measures and proper-use information.

Daiichi Sankyo follows applicable laws and regulations governing the collection of safety data according to each region's requirements. A global drug safety function coordinates the sharing of such data about Daiichi Sankyo products among our local affiliates.



Mamoru Tsunoda, Toshimi Kubota

Pharmacovigilance Management Group  
Pharmacovigilance Department  
Daiichi Sankyo Co., Ltd.



<sup>\*2</sup> Abbreviation of Integrated Pharmacovigilance Operations System

## ■ Communication with Patients

The Daiichi Sankyo Group values communication with patients. We communicate with patients through multiple channels, such as the Product Information Center, which directly receives inquiries regarding information on Daiichi Sankyo Group's products prescribed at medical institutions or prescription pharmacies, indirect communication via drug development and healthcare professionals, and supplementary communication to help understand drugs via "Kusuri-no-Shiori (Drug Information Sheet)."

### COMPASS on beginning

"Compassion for Patients" Strategy (COMPASS) has just started in R&D Division to operate as an important initiative to promote the awareness of corporate slogan "Passion for Innovation. Compassion for Patients.™". COMPASS aspires to the consciousness of colleagues in R&D for drug discovery based on "Compassion for Patients." through several programs, such as on-site learning at hospitals, communication with medical professionals, and so on. (see Voice below).

### Communication with patients through voluntary activities

Daiichi Sankyo holds "Daiichi Sankyo Presents Family Tie Theater" and invites cancer patients and their family members to enjoy musicals by the Shiki Theatre Company. This program is implemented in cooperation with the Shiki Theatre Company and a non-profit organization called "Cancer Support Community Japan," who understand and support the spirit of this activity that we want to inspire and energize patients through musicals. It is held every year and the 4th program was held in 2013. Daiichi Sankyo employees have participated as volunteers. We received positive feedback from patients and their family members such as "We look forward to innovative drugs from Daiichi Sankyo" through direct communication with patients. This program is a good opportunity for us to think back about drug discovery.

## ■ Communication with Local Communities

### Operation of "Daiichi Sankyo Kusuri Museum" as the center for comprehensive information on medicine

In 2012, Daiichi Sankyo Kusuri Museum was founded in Nihonbashi, which has been known as the town for medicine ever since for the promotion of public understanding of Company's activities and contribution to our communities. We have provided hands-on-experience aligned with the idea of medical education\*. During summer holiday, we hold science sessions for senior children at elementary school to raise the awareness of youth toward "science" and "medicine" through exposure to the fun and wonder of science.

## Voice

### Drug discovery with "Compassion for Patients"

To provide pharmaceutical products, which meet medical needs closely feeling the Daiichi Sankyo's slogan "Compassion for Patients." Against the background of strong desire to further reinforce this awareness, COMPASS initiated activities in Feb 2014.

Through on-site careful looking at outpatient physical examinations and operations at hospitals, lectures by healthcare professionals, internal discussions, and communication with patient organizations, COMPASS promotes R&D activities rooted in "Compassion for Patients." and contributes to patients in a way of as early as possible manufacturing of innovative pharmaceutical products to patients.

All seven COMPASS office members are assigned to each activity described above in addition to their primary activities, and responsible for its planning and operation. Increases in workload cannot be denied, but all of these members have a strong sense of fulfillment. Discussions get very intense during COMPASS meetings and the next thing we know, the discussions continue beyond scheduled time. Members take these discussions very seriously.

COMPASS will enhance the awareness of compassion for patients with as many colleagues as possible through its activities and strive to be considered, such as "Daiichi Sankyo's Products have Compassion for Patients" on some day.



Hayato Iwadare, Kiyomi Okamoto, Fumihiko Okada

COMPASS Office  
R&D Division  
Daiichi Sankyo Co., Ltd.

\* Understanding the effectiveness and side effects of medication and understanding how to correctly use medication.





## System to Utilize the Customer Feedback

Daiichi Sankyo's Product Information Center in Japan, under the auspices of the Product Information Management Department, strives to personally serve patients and healthcare professionals by delivering accurate information with innovation, integrity, and accountability, which are the Group's 3 shared values. We, particularly focus on two of our eight corporate commitments: to provide the highest quality medical information and to be an ethical, trusted, and respectful partner.

At Daiichi Sankyo, we are committed to convey accurate, error-free information that people can easily understand, and we do our utmost to bring peace of mind to healthcare professionals and worried patients, their families, and caregivers. We have established a new system in fiscal 2013, which assigns employees dedicated to patients, with an aim to deliver safety to worried patients.

We exercise care in the provision of high-quality, consistent information by consulting a wide range of pharmaceutical materials and information databases.

After the renewal of the internal systems for literature information, basic product information, and Q&A in fiscal 2014, Daiichi Sankyo now provides more prompt and rich information to inquiries.

We also use the VOC (Voices of Customers) Portal in Japan, which is shared and utilized in-house for the valuable information from patients and healthcare professionals received by Product Information Center to analyze as well as visualize problems (see Voice on the right). Step-by-step, we have reflected these voices from customers on the improvement of formulations and packages. We aim to utilize this information to continually improve our business and our products, thus contributing to a better world.

## Voice

### Company which values the customer feedback

We promote the use of the "VOC Portal," a system for sharing and utilizing in-house feedback from patients and healthcare professionals in Japan.

Product Information Center receives about 120,000 inquiries a year. This system launched in 2010 allows us to internally share actual customer feedback and therefore is expected to contribute to the improvement of products, planning of new products, and enhancement of risk management based on the customer feedback, and improvement of customer satisfaction as well as increased corporate value.

In the early phase of system introduction, we were not familiar with the use of the system though we recognized the importance of the customer feedback. There were various hurdles, such as first-time users could not get information they were looking for, it took time to analyze a large amount of information, for the system to be used in other departments.

In order to overcome these hurdles, we conducted interviews at each department and customized the screens according to user activities. We also propose analytical methods in monitoring activities and issue VOC News Letter to increase the utilization. These activities have led to changes in the labeling and formulations of each product.

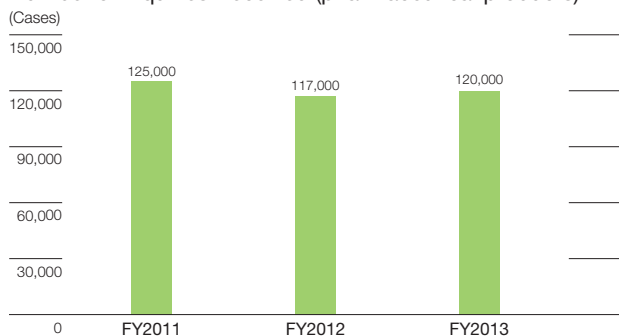
We continue to contribute to people's health by responding more promptly to as many voices as possible by playing a role in Daiichi Sankyo's Mission "To contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals and through the provision of pharmaceuticals addressing diverse medical needs."



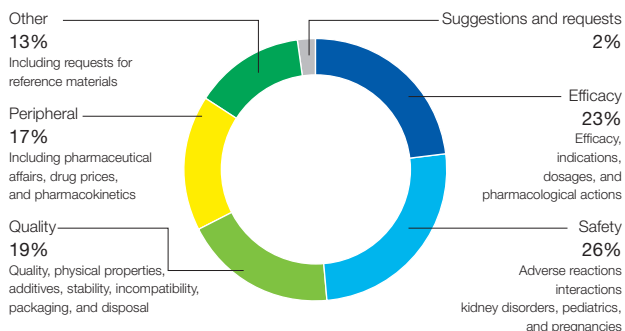
Kaina Isobe

Information Management Group, Product Information Department  
Business Intelligence Division, Japan Company  
Daiichi Sankyo Co., Ltd.

Number of Inquiries Received (pharmaceutical products)



Breakdown of Inquiries by Content (fiscal 2013)





# Promoting Environmental Management

Sustainable corporate activities, which care for the environment are required. Initiatives for environmental issues are one of key social challenges. Daiichi Sankyo Group recognizes the environmental burden in every business operation and promotes environmental management.

## ■ Environment Management System

Recognizing that caring for the environment is one of its key social responsibilities, the Daiichi Sankyo Group not only complies with the law, but has also stipulated in the Daiichi Sankyo Group Corporate Charter: “We responsibly manage the environment impact of our operations as environmental issues are common challenges for mankind and such concerns are integral to our corporate activities and our very survival.”

The Group has also formulated rules for conducting environmental management and established its Basic Environment Management Policy based on these rules.

### Basic Environmental Management Policy

Safeguarding the environment is the bedrock of all Group operational management. We pursue environmental management that contributes to a sustainable society and enhances our good corporate citizenship.

Based on the results of the analysis and assessment on the environmental impact of corporate operations of Daiichi Sankyo Group, we focus on major environmental issues, such as countermeasures for climate change, effective usage of natural resources, proper management of chemical substance, and biodiversity consideration. We establish, operate, and improve an environmental management system for the above issues and communicate with stakeholders.

Also, the Third Mid-term Business Management Plan's CSR activity starting in fiscal 2013 is defined as “Responsible Business Actions for a Sustainable Society.”

## Environmental management promotion system

Daiichi Sankyo's Global Head of CSR oversees the Group's environmental management. In this system, environmental management is implemented in a system of environmental management units established for each business unit, such as the corporations and companies that control regions and businesses, with the Global Head of CSR managing all of these environmental management units. In addition, the officials of the environmental management units oversee the bases, for instance the offices that make up the environmental management units.

For example, an environmental management unit comprising Daiichi Sankyo and the Group companies in Japan was set up, with the head of the Legal Affairs & CSR Division (current Member of the Board and Senior Executive Officer) of Daiichi Sankyo Co., Ltd., taking responsibility for this unit (serving as chief executive officer of environmental management). This head officer advances environmental management by overseeing the environmental management classification (organization and size) established on a per-office basis. In addition, office managers take responsibility for these environmental management classifications and operate environmental management systems through ISO 14001 and other programs. Further, the Environmental Management Committee has been set up to discuss important issues related to the environment, chaired by the chief executive office of environmental management.

Daiichi Sankyo also pursues environmental management in North America, Europe, Asia, Central and South America and India with programs similar to those in Japan.

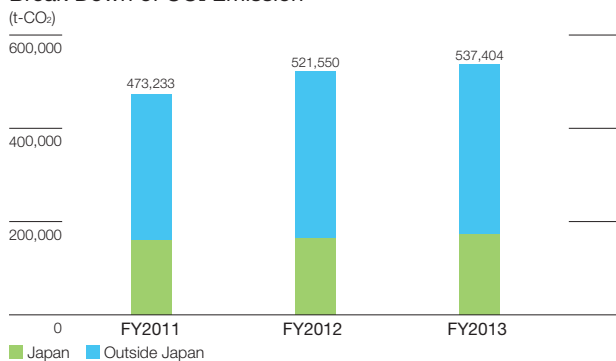
## ■ Initiatives for Climate Change and Global Warming

As part of mitigation measures for climate change and global warming, the Daiichi Sankyo Group is striving to use resources/energy efficiently and reduce CO<sub>2</sub> in all of its business activities to help curb global warming as stated in the Third-term Environmental Management Policy; “Use energy efficiently and reduce carbon dioxide emissions in all operations to help prevent global warming”

Moreover, we believe it is necessary for the Daiichi Sankyo Group to pay attention to the climate change-related risks on our business strategy and profit, such as the emission regulations based on the international agreement on greenhouse gases, physical impacts induced by natural environment change. We also recognize it is important to appropriately manage the apparent risks.

Furthermore, assuming the frequent occurrence of abnormal weather as a result of climate change and the influence on the health of people due to the change of disease structure, the review of these is necessary for life science-oriented companies

### Break Down of CO<sub>2</sub> Emission



### CO<sub>2</sub> Emission by Scopes in 2013 (t-CO<sub>2</sub>)

	Scope 1	Scope 2	Scope 1 and 2 total
Japan	100,166	71,388	171,554
Outside Japan	110,158	255,691	365,850
Overall	210,324	327,079	537,404

## ■ Evaluation of the Environmental Impact of Pharmaceutical Product

The Daiichi Sankyo Group considers the possible negative impact of medical products and their byproducts on environments as one of the risks associated with business activities.

In the US and EU, authorities mandate the provision of data on environmental impact assessments (environmental risk evaluation) based on guidelines when applying for the approval of new pharmaceutical products. The Daiichi Sankyo Group conducts environmental impact assessments of its

drugs based on guidelines in the relevant country and addresses any issues appropriately.

With the growing concerns over the detection of medical products and their byproducts in rivers and other natural environments and their environmental impacts, pharmaceutical companies are requested to communicate with the government, businesses, and research organizations to discuss and develop a better method for risk evaluation and risk management.

Further, during fiscal 2013, we invited Professor Ryota Shinohara, a water environmental science specialist, for an internal lecture (see External Voice) on the theme of findings on environmental risk of medical product, risk assessment, and risk management.

### External Voice

#### Risk communication is important and information collection for it is necessary

Medical products and their byproducts are being detected in rivers in Japan. Their impacts on the ecosystem and humans have not been fully understood due to significantly low detection levels. This is not an easily-resolved issue. Therefore, risk communication between the government, specialists, business enterprises, and citizens is important, and information on the environmental impact assessments of medical products is necessary for it.

The pharmaceutical industry should immediately collect information on the environmental impact assessments released by the government (in particular the Ministry of the Environment) and investigate degradability in water environments. A bioassay method called the WET (Whole Effluent Toxicity) method is effective in the risk assessments of industrial waste.

As the primary discharge route of medical products in the water environment is effluents from sewage treatment facilities, it is one of the options to introduce of ozonation and UV + titanium oxide treatment to supplement the limitations of treatment with chlorine and active sludge process.

We need to consider some legal regulations, such as the implementation of a detailed field survey and more effective treatment methods before the environment risk becomes evident.



Ryota Shinohara, Ph.D.

Professor Emeritus  
Prefectural University of Kumamoto



# Broaden the Opportunities of Access to Medical Services

Broadening the opportunities of access to medical services is an important mission as a pharmaceutical company.

We contribute to health and medical issues by utilizing Daiichi Sankyo's resources.

## ■ Our Devotion to Social Agenda as a Pharmaceutical Company

As a pharmaceutical company expanding its business on a global scale, we seek out not only to offer various medical services that satisfy a range of patients' needs but also to contribute, more generally, toward addressing the world's medical issues. In emerging countries and developing countries in Africa and Asia, there are many medical issues that need to be resolved.

Under the "Millennium Development Goals (MDGs)" advocated by the United Nations, there are 8 goals, which were set with a target achievement date of 2015. These include eradication of extreme poverty and hunger, 3 of which are healthcare-related goals, such as Goal 4 (reduce child mortality), Goal 5 (improve maternal health), and Goal 6 (combat HIV/AIDS, malaria, and other diseases). However, the current situation in South Asia, South America, and sub-Saharan Africa is that it is required effort to attain Goal 4 and 5. In addition, for Goal 8: Develop a global partnership for development, they seek to obtain necessary pharmaceutical products at a low price for people in developing countries by cooperating with pharmaceutical companies.

In developing countries, there are still a number of regions that do not have adequate access to medical services, including medicine; thus, under MDGs, the improvement of healthcare in such regions has been the first priority as the challenge of global health beyond borders. The provision of affordable and essential medical products and vaccines to patients suffering from three major infections (HIV/AIDS, malaria, tuberculosis) and neglected tropical diseases epidemic in developing countries is required. The Daiichi Sankyo Group has participated in the Global Health Innovative Technology Fund "GHIT Fund," which was a public-private partnership in Japan supported by the Government of Japan, 5 Japanese pharmaceutical

### United Nations Millennium Development Goals (MDGs)

- Goal 1: Eradicate Extreme Poverty & Hunger
- Goal 2: Achieve Universal Primary Education
- Goal 3: Promote Gender Equality and Empower Women
- Goal 4: Reduce Child Mortality
- Goal 5: Improve Maternal Health
- Goal 6: Combat HIV/AIDS, Malaria, and Other Diseases
- Goal 7: Ensure Environmental Sustainability
- Goal 8: Develop a Global Partnership for Development

companies, and the Bill & Melinda Gates Foundation in April 2013 under the concept that the public-private partnership was necessary for the promotion of manufacturing of drugs to combat these infectious diseases. Daiichi Sankyo explores candidate compounds for the treatment of drug-resistant tuberculosis and malaria through a screening platform process by the GHIT fund to combat infectious diseases in developing countries.

There exist issues related to preventive medicine and the treatment of rare diseases in developed countries. In the field of orphan drugs,<sup>\*1</sup> Daiichi Sankyo offers products such as Biopten and ITB therapy,<sup>\*2</sup> capitalizing on its knowledge and technology.



See "Modification of Formulations in Orphan Drugs" on page 45 for Biopten.

<sup>\*1</sup> Medical products targeting rare diseases with a small number of patients.

<sup>\*2</sup> Therapeutic method to ease spasms by directly injecting baclofen (brand name: Gabalon Intrathecal Injection) to areas surrounding the spinal cord, the site of action.

## Contribution to Capacity Building in Relation to the Access to Medical Services

In developing countries, there are many factors, such as insufficient public healthcare system and medical infrastructure, insufficient numbers of people working on medical product manufacturing and quality control and poverty, preventing people from accessing healthcare services.

### Offering a mobile healthcare field clinics service

In India, Cameroon, and Tanzania, we have been operating mobile healthcare field clinics cooperating with international NGOs, the local governments, and local communities in order to contribute to the regions where medical infrastructure, doctors, and transportation to hospitals are all in insufficient supply.

Activities, such as vaccination and antenatal physical examination started in fiscal 2011 to contribute “Goal 4: Reduce Child Mortality” and “Goal 5: Improve Maternal Health” of the MDGs. The status of activities in fiscal 2013 is as follows. In Cameroon, a significantly large number of children received vaccinations or physical examination in collaboration with the Maternal Health Week operated by the Regional Delegation of Public Health of the Ministry of Environment.

Fiscal 2013 Achievements			
	India	Cameroon	Tanzania
Number of mobile healthcare field clinics (times)	501	996	202
Number of infants receiving preventative vaccinations (people)	4,546	220,742	2,239
Number of pre-natal checkups (people)	494	9,157	325

To support these activities, Daiichi Sankyo strengthens local alliances between governments, private, and NGOs and focuses on the fostering of community healthcare workers who can support healthcare activities. The community healthcare workers play important roles in watching over maternity and infant health. They manage health of people during periods where mobile health clinic does not visit villages, or notify the schedule of the mobile health clinic service in villages. In November 2013, we visited villages for mobile healthcare field clinic service, local governments, the local Japanese Embassy, and international NGO in Cameroon and Tanzania to support local activities. We collected information on issues and challenges they had and discussed supportive measures. We also held an award ceremony recognizing 28 community healthcare workers who are excellent role models to in order to share their best practices.



Please click the link below to watch a video on our activities in Africa.

[http://www.daiichisankyo.com/about\\_us/responsibility/philanthropy/medicalaccess/b3d2.html](http://www.daiichisankyo.com/about_us/responsibility/philanthropy/medicalaccess/b3d2.html)

\*3 Center for Research and Production of Vaccines and Biologicals in Vietnam

## Technical cooperation for MR vaccine production

In Vietnam, there is an urgent need to establish a domestic production for measles—rubella combined vaccine (MR vaccine) to stabilize the supply of vaccines because the infection rate of rubella is significantly high. The Kitasato Institute (Now, Kitasato Daiichi Sankyo Vaccine, Co., Ltd.) had provided the technical cooperation for “the Strengthening Capacity for Measles Vaccine Production” to POLYVAC\*3 in Hanoi, Vietnam from March 2006 to March 2010 as international cooperation between Japanese and Vietnamese government. Following this, Kitasato Daiichi Sankyo Vaccine, Co., Ltd. has also been providing technical cooperation utilizing the production technology for MR vaccine under a 5-year contract starting in May 2013 (see Voice below). We will contribute to the establishment of MR vaccine production in Vietnam and support a decrease in the infection rate of measles and rubella.

### Voice

#### Great happiness working for a pharmaceutical company

Our technical cooperation for measles—rubella combined vaccine (MR vaccine) production started in May 2013 at POLYVAC, the site of the technological transfer, with technological instruction and training for bulk production of rubella vaccine. Besides this, a wide range of technologies are needed for MR vaccine production, including cell culture, pathological examination, adventitious virus testing, and attenuation marker testing. Some of the tools and equipment required, although easily available in Japan, were difficult to obtain in Vietnam. The transfer of technology was much more difficult than expected. However, we were impressed by the strong enthusiasm and intellectual curiosity of the Vietnamese trainees and by their diligent and thoughtful approach.

Earlier this year, there was an epidemic of measles in Vietnam. As a member of the project team for technological transfer, I was pleased to learn that a large quantity of high-quality measles vaccine was urgently supplied to the affected area. We still have a number of issues to resolve. Through the project activity, we hope to deepen our relationship with POLYVAC and, by contributing to control of measles and/or rubella infection, to support Vietnam's ongoing development.



Tomio Lee Ph.D.

Production Division  
Deputy General Manager, Technology Transfer Project of MR Vaccine in Vietnam  
Kitasato Daiichi Sankyo Vaccine Co., Ltd.





# Social Contribution Activities

We will not only contribute to the society through business but also directly support the resolution of social issues as a good corporate citizen.

## ■ Becoming a Better Corporate Citizen

Daiichi Sankyo social contribution activities provide people with hope through contributions to life and science. Our policies encourage employee voluntarism and engagement in collaborative programs and foster the shift from mere funding to participating in worthwhile programs. The Group formulated Basic Policies on Group Social Contribution Activities, which guide initiatives worldwide that contribute to the development of science and research (medical and pharmaceutical), and initiatives related to conservation of the environment.

### Basic Group Social Contributions Policy

- We will help create a sustainable society, engaging in activities to contribute to society.
- We will particularly prioritize progress in medicine and pharmacology, social welfare, and environmental conservation. We will assist with disaster restoration, youth education, and promote culture and arts.
- We will foster healthy social development by participating in and supporting voluntary activities.
- We will engage with and prosper with communities.

We consider the activities to promote social contribution as a kind of investments in society, and we will continue to identify social issues and challenges on which we should focus. As for approach, we emphasize on collaborating with a wide range of stakeholders, such as NPO/NGO, volunteer groups of the local community, government, and public sectors. In addition, we are putting our efforts into improving the environment and creating opportunities to support our employees' participation in voluntary activities.

### Reconstruction Support Effort following the Great East Japan Earthquake

We are supporting the Coastal Forest Restoration Project (Natori city, Miyagi) as a part of reconstruction support effects following the Great East Japan Earthquake.

Due to the tsunami, the coastal forest along the coast of Tohoku area was flattened. The coastal forest had played an important role in preserving the environment as a disaster prevention forest with functions, such as sand prevention, storm protection, protection against the tide, and reduction of the force of Tsunami.

Coastal Forest Restoration Project started up in 2011 aiming at the restoration of the local coastal forest (ca. 100 hectares) lost by Tsunami through a program in which the affected people are assigned to take care of more than about 50 thousand nursery trees by 2020. In fiscal 2013, in addition to economical support, employees volunteered for

transplanting the nursery trees, and mowing grass in the nursery. As reforestation will start in fiscal 2014, we are planning to implement long-term support to the project in line with growth of Japanese black pines by weeding, improvement cutting, etc. in response to the request for long-term physical support.



Volunteer activities by employees

### Supporting children for a healthy and socially stable life

Daiichi Sankyo Europe helps children without a family in Eastern Europe so they can lead a healthy and socially stable life in their home countries. All affiliates in Europe participated in the “Make your heart feel good” campaign, which supports the charity “Little Hearts.”. Our employees measured blood pressure and learned why it is important to know it to prevent stroke, myocardial infarction and atrial fibrillation. They could also make donations plus a matching donation from the company have been used to renovate parts of an orphanage so the children can now live in a family-like environment. Our employees are protecting their own “big hearts” and do something for the “Little Hearts” at the same time. Daiichi Sankyo Europe will further develop this initiative in the future.



Jan Van Ruymbeke, CEO of Daiichi Sankyo Europe explaining our initiative

### Expanding the interest of youth in science

Through communication, exchange with researchers, and helping to conduct experiments, we are seeking to expose the younger generation to the fun and wonder of science. We are carrying out these types of activities to raise awareness of youth towards “science” and “medicine” in the area where our office is located in Japan.

Asubio Pharma held the 2nd “ASUBIO Kids Study” to provide an opportunity for parents and children to get familiar with science; 60 families participated in the program. They mixed an aqueous solution of purple yam with something familiar, such as detergents and beverages and confirmed the aqueous solution changing its color from purple to red or green. They studied the properties of CO<sub>2</sub> using dry ice. We received feedback from the participating children, such as “I have learned a lot of things, which I did not know. It was a valuable experience and I enjoyed it,” “I felt that I want to be a scientist in the future,” “I want to develop drugs, which are beneficial to people in the future.”



ASUBIO Kids Study

# Environment, Social, and Governance Data (ESG Data)

## Environment

Aspect	Page	Classification	Items	Scope	Unit	FY2011	FY2012	FY2013
CO <sub>2</sub>	71	Breakdown of CO <sub>2</sub> emissions	Sales vehicles <sup>(1)</sup>	In Japan	t-CO <sub>2</sub>	8,579	7,845	7,433
				Global	t-CO <sub>2</sub>	37,369	37,908	35,058
			Offices	In Japan	t-CO <sub>2</sub>	4,904	5,017	5,099
				Global	t-CO <sub>2</sub>	12,972	19,690	15,274
			Plants and R&D centers	In Japan	t-CO <sub>2</sub>	146,080	152,052	159,022
				Global	t-CO <sub>2</sub>	422,892	463,951	487,071
	71	CO <sub>2</sub> emissions by Greenhouse Gas Protocol	In Japan	Total	t-CO <sub>2</sub>	159,563	164,914	171,554
				Global	t-CO <sub>2</sub>	473,233	521,550	537,404
			Scope 1	In Japan	t-CO <sub>2</sub>	85,159	94,192	100,166
				Global	t-CO <sub>2</sub>	182,519	217,257	210,324
			Scope 2	In Japan	t-CO <sub>2</sub>	74,404	70,722	71,388
				Global	t-CO <sub>2</sub>	290,715	304,293	327,079
Energy	—	Breakdown of energy use (in Japan)	Electricity	In Japan	1,000 GJ	1,800	1,836	1,850
			City gas	In Japan	1,000 GJ	1,339	1,443	1,642
			Others (LPG, LNG heavy oil, kerosene, diesel, gasoline)	In Japan	1,000 GJ	329	351	282
			Steam	In Japan	1,000 GJ	31	28	31
			In Japan	Total	1,000 GJ	3,499	3,659	3,806
	—	Breakdown of energy use (Group overall)	Electricity	Global	1,000 GJ	4,400	4,678	4,937
			City gas	Global	1,000 GJ	1,468	1,571	1,827
			Others (LPG, LNG heavy oil, kerosene, diesel, gasoline)	Global	1,000 GJ	2,067	2,338	2,053
			Global	Total	1,000 GJ	7,935	8,616	8,847
Water resources	—	Water used		In Japan	1,000 m <sup>3</sup>	13,327	13,535	13,460
				Global	1,000 m <sup>3</sup>	15,651	16,199	15,617
		Wastewater		In Japan	1,000 m <sup>3</sup>	13,708	13,284	12,363
				Global	1,000 m <sup>3</sup>	14,072	14,386	13,521
Water pollution	—	BOD		In Japan	t	40	42	31
		COD		In Japan	t	22	23	22
Waste	—	Waste generated		In Japan	t	39,437	39,421	35,925
		Outsourced waste treatment		In Japan	t	18,833	26,824	23,412
		Recycled waste		In Japan	t	11,347	12,894	12,324
		Recycling rates		In Japan	%	60.3	48.1	52.6
		Final disposal volume		In Japan	t	365	158	165
		Final disposal rate		In Japan	%	0.93	0.40	0.46
		Amount of office paper consumed		In Japan	Million sheets	70.78	69.70	67.59
Air	—	SO <sub>x</sub>		In Japan	t	0.9	0.6	1.1
				Global	t	598	198	388
		NO <sub>x</sub>		In Japan	t	46	35	43
				Global	t	53	354	232
PRTR	—	Amount handled		In Japan	t	5,704.0	6,087.1	6,248.8
		Amount discharged (air)		In Japan	t	121.7	112.8	108.5
		Amount discharged (water)		In Japan	t	3.6	3.3	4.4
		Amount discharged (sewer)		In Japan	t	43.9	47.7	47.7
		Amount discharged (waste)		In Japan	t	3,237.7	2,495.2	1,958.0
Containers	—	Containers and packaging		In Japan	t	2,321	2,380	2,222
Management	—	ISO14001-certified sites		In Japan	Sites	7	8	7
				Global	Sites	13	14	15

(1) Carbon offset-type sales vehicles in Japan were leased so that CO<sub>2</sub> emissions from sales vehicle were entirely offset from FY2008 to FY2012.

### Referenced Guidelines

- UN Global Compact
- Global Reporting Initiative (GRI) "Sustainability Reporting Guidelines Version 3.1"
- Japanese Ministry of the Environment's "Environmental Reporting Guidelines, 2012 edition"
- ISO26000
- IIRC (International Integrated Reporting Council) "International Integrated Reporting Framework"

**Social**

Aspect	Page	Classification	Items	Scope	Unit	FY2011	FY2012	FY2013
Compliance	57	Training by job category	Training new hires	In Japan	Persons	101	104	97
			Training newly appointed managerial employees	In Japan	Persons	217	191	185
			Training newly appointed executive candidates	In Japan	Persons	104	81	37
			Training mid-career hires	In Japan	Persons	23	33	28
			Total	In Japan	Persons	445	409	347
Research and development	—	Number of reports to DS-hotline		In Japan	Cases	13	7	3
Research and development	—	R&D expenses <sup>(1)</sup>	R&D expenses	Consolidated	¥ Billion	185.1	183.0	191.2
			R&D expenses to net sales	Consolidated	%	19.7	18.3	17.1
Patients and medical professionals	66	Evaluation of corporate stance and MR activities	MRs rated <sup>(2)</sup>	In Japan	Rank	December: Second	December: Second	December: Second
			Evaluation in cardiovascular medicine field <sup>(2)</sup>	In Japan	Rank	December: First	December: First	December: First
Patients and medical professionals	69	Number of inquiries received (pharmaceutical products)		In Japan	Cases	125,000	117,000	120,000
Business partners	47	Questionnaires about CSR procurement	Number of companies requested to take surveys	In Japan	Companies	—	185	—
Employees	—	Number of employees by region <sup>(3)</sup>	In Japan <sup>(4)</sup>	In Japan	Persons	9,338	9,251	9,145
			Outside Japan <sup>(4)</sup>	Outside Japan	Persons	8,642	8,277	8,111
			Ranbaxy Group	Outside Japan	Persons	14,479	14,701	15,535
			Total	Consolidated	Persons	32,459	32,229	32,791
	62	Employee data <sup>(5)</sup>	Number of men employees	In Japan	Persons	7,400	7,305	7,170
			Number of women employees	In Japan	Persons	2,176	2,183	2,157
			Average years of service	Non-consolidated	Years	17.2	17.9	18.6
			Average annual salary	Non-consolidated	Yen	10,067,599	9,981,713	10,362,700
			Percentage of women employees	Non-consolidated	%	19.3	19.0	22.0
			Percentage of women in managerial positions	Non-consolidated	%	3.3	3.6	4.5
	64	Human resource development	Number of company-wide award winners <sup>(6)</sup>	In Japan	Persons	54	49	51
	63	Challenged workers <sup>(7)</sup>	Employment rate of people with physical or mental challenges	In Japan	%	2.20	2.15	2.21
	63	Persons taking child care leave	Women taking child care leave	In Japan	Persons	158	147	155
			Men taking child care leave	In Japan	Persons	12	5	2
	65	Occupational health and safety management	Paid vacation usage rate	In Japan	%	60.0	55.5	56.1
			Total annual hours worked	In Japan	Hours	1,890	1,901	1,868
			Frequency <sup>(8)</sup>	In Japan	—	0.44	0.39	0.65
			Accident severity rate <sup>(8)</sup>	In Japan	—	0.01	0.01	0.002
			Percentage/rate of participation in a labor union	In Japan	%	100.0	100.0	100.0
Shareholders	—	Dividends per share	Interim	Non-consolidated	Yen	30	30	30
			Year-end	Non-consolidated	Yen	30	30	30
			Total	Non-consolidated	Yen	60	60	60
Social	74~75	Amount of contributions		Non-consolidated	¥ Million	3,242	2,926	2,780
			Number of visitors to Kusuri museum <sup>(9)</sup>	Non-consolidated	Persons	3,761	13,951	11,811
			Number of visitors to our factories	In Japan	Persons	Approximately 1,300	Approximately 1,500	Approximately 1,600

(1) Under IFRS (International Financial Reporting Standards) in FY2013

(2) Conducted by Daiichi Sankyo with the cooperation of an outside research company (FY2011—FY2012), conducted by ANTERIO Inc. (FY2013)

(3) Figures are as of the end of the settlement period at each Group company.

(4) Excluding Ranbaxy Group

(5) The data shows the figures as of April 1 in the following fiscal year of each fiscal year. Scope of data: same as the financial statements. As for the data on average years of service, Daiichi Sankyo Logistics is not included.

(6) The total number of employees who received a prize from the culture—building awards and the achievement awards.

(7) Employment rate of people with physical or mental challenges as of June 1 of each year following the fiscal year. The percentage of women employees and percentage of managerial positions filled by women as of April 1 of each year following the fiscal year.

(8) Scope of data: Daiichi Sankyo, Daiichi Sankyo Espha, Daiichi Sankyo Healthcare, Daiichi Sankyo Propharma, Daiichi Sankyo Chemical Pharma, Daiichi Sankyo Logistics, Asubio Pharma, Daiichi Sankyo RD Novare, Daiichi Sankyo Business Associe

(9) Number of visitors in fiscal 2011 is the visitors during 2 months after opening.

**Governance**

Aspect	Page	Classification	Items	Scope	Unit	FY2011	FY2012	FY2013
Governance	16~21	Structure of Board of Directors	Number of directors	Non-consolidated	Persons	10	10	10
			Number of outside directors	Non-consolidated	Persons	4	4	4
			Number of woman directors	Non-consolidated	Persons	0	0	0
		Structure of Board of Kansayaku (statutory auditors)	Number of Kansayaku	Non-consolidated	Persons	4	4	4
			Number of outside statutory auditors	Non-consolidated	Persons	2	2	2
		Compensation of directors	Total	Non-consolidated	¥ Million	652	669	669
		Compensation of statutory auditors	Total	Non-consolidated	¥ Million	105	105	105

# Operations and Financial Position

## ■ Adoption of International Financial Reporting Standards (IFRS)

Daiichi Sankyo and its consolidated subsidiaries (“the Group”) have adopted IFRS starting in the fiscal year ended March 31, 2014. Having considered what accounting and financial reporting standards would be best to contribute to the growth in corporate value through a concerted global business development program, Daiichi Sankyo has made this move to help diversify the Group’s methods of fund procurement in global capital markets.

### Main differences between Japanese GAAP and IFRS (presentation of account)

- “Revenue” under IFRS corresponds to “net sales” under Japanese GAAP.
- Profits generated in relation to operating activities are presented as “operating profit.” The composition of this item under IFRS differs from “operating income” under Japanese GAAP. Under IFRS, operating profit includes non-financial items that would be presented under Japanese GAAP as “non-operating income,” “non-operating expenses,” “extraordinary income,” or “extraordinary losses.”
- IFRS does not apply the concept of “ordinary income.”
- “Profit attributable to owners of the Company” under IFRS corresponds to “net income” under Japanese GAAP.

Japanese GAAP		IFRS	
	Fiscal 2013 (Billions of yen)		Fiscal 2013 (Billions of yen)
Net sales	1,118.8	Revenue	1,118.2
Cost of sales		Cost of sales	
Selling, general, and administrative expenses		Selling, general, and administrative expenses Research and development expenses	
		Other income	
		Other expenses	
Operating income	115.9	Operating profit	111.6
Non—operating income			
Finance income			
Other income			
Non—operating expenses			
Finance expenses			
Other expenses			
Ordinary income	105.0	(No description)	
Extraordinary income			
Extraordinary losses			
Income taxes		Income taxes	
Net income	65.7	Profit attributable to owners of the Company	60.9



## ■ Consolidated Financial Results for Fiscal 2013

### Revenue

Group revenue in the fiscal year ended March 31, 2014 increased by ¥123.6 billion, or 12.4% year on year, to ¥1,118.2 billion.

At the Daiichi Sankyo Group, major products generating growth in revenue in the year under review included the antihypertensive agent olmesartan, the antiplatelet agent prasugrel, the ulcer treatment NEXIUM®, and the Alzheimer's disease treatment Memary®. Depreciation of the yen against the U.S. dollar and the euro also made a positive contribution to higher consolidated revenue (of approximately ¥53.7 billion) at the Group as a whole.

### Operating Profit

Operating profit increased by ¥12.8 billion, or 13.0% year on year, to ¥111.6 billion.

Operating profit at the Daiichi Sankyo Group increased, although operating profit at the Ranbaxy Group decreased, resulting in an increase for the Group as a whole.

### Profit before Tax

Profit before tax increased by ¥3.9 billion, or 4.1% year on year, to ¥99.8 billion.

Higher profits by the Daiichi Sankyo Group more than offset a decline in profits by the Ranbaxy Group associated with the depreciation of the Indian rupee against the US dollar, which led to higher financing expenses.

### Profit Attributable to Owners of the Company

Profit attributable to owners of the Company declined by ¥3.1 billion, or 4.8% year on year, to ¥60.9 billion. Higher income taxes partly reflected a reversal of deferred tax assets related to a change in the tax rate following the expiration of the special corporation tax for reconstruction.

### IFRS basis

(Millions of yen; all amounts have been rounded down to the nearest million yen.)

	Fiscal 2012	Fiscal 2013	YoY change
Revenue	994,659	1,118,241	+ 123,582 [+ 12.4%]
Operating profit	98,743	111,552	+ 12,809 [+ 13.0%]
Profit before tax	95,861	99,775	+ 3,913 [+ 4.1%]
Profit attributable to owners of the Company	64,027	60,943	(3,084) [- 4.8%]

Note) Following a change of fiscal year-end, the accounting period for fiscal 2013 of Ranbaxy Laboratories Ltd. and its subsidiaries and associates ("the Ranbaxy Group") is the 15-month period from January 1, 2013 to March 31, 2014.

### (Reference) J-GAAP basis

(Millions of yen; all amounts have been rounded down to the nearest million yen.)

	Fiscal 2012	Fiscal 2013	YoY change
Net sales	997,852	1,118,764	+ 120,912 [+ 12.1%]
Operating income	100,516	115,904	+ 15,388 [+ 15.3%]
Ordinary income	99,147	105,016	+ 5,868 [+ 5.9%]
Net income	66,621	65,650	(970) [- 1.5%]

### Revenue of global mainstay products

(Millions of yen; all amounts have been rounded down to the nearest million yen.)

Item name		Fiscal 2012	Fiscal 2013	YoY change
Olmesartan	Antihypertensive agent	258,842	300,173	+ 41,331
Prasugrel	Antiplatelet agent	16,235	22,267	+ 6,032

### Research and development expenses

(Millions of yen; all amounts have been rounded down to the nearest million yen.)

	Fiscal 2012	Fiscal 2013
Research and development expenses	184,393	191,212
Ratio of research and development expenses to revenue	18.5%	17.1%

### Yen exchange rates for major currencies

(Average rate for year)

	Fiscal 2012	Fiscal 2013
Yen/USD	83.11	100.24
Yen/EUR	107.15	134.38
Yen/INR	1.50	1.68

## ■ Reports by Segment

### Daiichi Sankyo Group

**Revenue: ¥897.7 billion (increased by 10.7% year on year), composition ratio: 80.3%**

The Daiichi Sankyo Group reported revenue of ¥897.7 billion, a year-on-year increase of 10.7%.

Operating profit increased by 38.0% year on year to ¥112.9 billion (prior to consolidated adjustments).

### Japan

**Revenue: ¥ 554.5 billion (increased by 4.9% year on year), composition ratio: 49.6%**

Revenue in Japan increased 4.9% year on year to ¥554.5 billion.

Revenue in Japan from prescription drugs increased 4.7% year on year to ¥481.4 billion. This reflected a solid sales performance by Olmetec® as well as substantial growth in sales of NEXIUM® and Mema®. Additional contributions came from RANMARK®, a treatment for bone complications stemming from multiple myeloma or bone metastases from solid tumors launched in April 2012, and from PRALIA®, a treatment for osteoporosis launched in June 2013.

Revenue from royalty and exports increased 17.4% year on year to ¥21.8 billion.

Growth in sales of the analgesic antipyretic Loxonin S® helped boost revenue from healthcare (OTC) products by 1.5% year on year to ¥48.1 billion. Group subsidiary Daiichi Sankyo Healthcare Co., Ltd. manages this business. In December 2013, the company discontinued sales of the skincare series Derma Energy, a dedicated mail-order product as it was confirmed that some customers had been experiencing skin trouble.

#### Revenue composition in Japan

(Billions of yen; all amounts have been rounded off to the nearest single decimal place.)

Category	Fiscal 2012	Fiscal 2013	YoY change
Prescription drugs	459.9	481.4	+ 21.5 + 4.7%
Royalty and exports	18.6	21.8	+ 3.2 + 17.4%
Healthcare (OTC) products	47.4	48.1	+ 0.7 + 1.5%

#### Revenue of Japan company mainstay pharmaceuticals (Billions of yen)

Product		Fiscal 2012	Fiscal 2013	YoY change
Olmetec®	Antihypertensive agent	78.3	79.1	+ 0.8
Rezaltas®	Antihypertensive agent	16.9	18.5	+ 1.5
Loxonin®	Anti-inflammatory analgesic	59.6	59.3	(0.3)
Cravit®	Synthetic antibacterial agent	35.9	33.5	(2.4)
NEXIUM®	Ulcer treatment (Proton pump inhibitor)	21.6	54.2	+ 32.7
Mema®	Alzheimer's disease treatment	23.8	33.3	+ 9.5
Mevalotin®	Antihyperlipidemic agent	25.8	21.5	(4.3)
Artist®	Antihypertensive agent	22.4	22.4	+ 0.0
Omnipaque®	Contrast medium	20.2	19.7	(0.5)
URIEF®	Treatment for dysuria	11.1	11.4	+ 0.3
INAVIR®	Anti-influenza agent	11.1	13.4	+ 2.3
RANMARK®	Treatment for bone complications	4.4	8.1	+ 3.6
PRALIA®	Treatment for osteoporosis	—	3.2	+ 3.2

### North America

**Revenue: ¥211.3 billion (increased by 15.9% year on year), composition ratio: 18.9%**

Revenue in North America increased 15.9% year on year to ¥211.3 billion. Revenue in local currency terms fell 3.9% to approximately US\$2,100 million.

At Daiichi Sankyo, Inc. in the United States, although sales of TRIBENZOR®, Welchol®, Effient® and others increased, sales of other products including Benicar®/ Benicar HCT® and AZOR® declined. As a consequence, this company's revenue was roughly level with the same period of the previous fiscal year at US\$1,700 million.

With regard to Luitpold Pharmaceuticals Inc., decrease of the sales of Venofer®, despite the sales contribution of Injectafer®, a novel treatment for iron deficiency anemia launched in August 2013, resulted in revenue of US\$400 million, a decline of 14.9% year on year.

#### Revenue of Daiichi Sankyo, Inc. mainstay products

(Millions of US\$; all amounts have been rounded off to the nearest million US\$.)

Product		Fiscal 2012	Fiscal 2013	YoY change
Benicar®/ Benicar HCT®	Antihypertensive agent	881	857	(25)
AZOR®	Antihypertensive agent	179	174	(5)
TRIBENZOR®	Antihypertensive agent	82	90	+ 8
Welchol®	Hypercholesterolemia treatment/type 2 diabetes mellitus inhibitor	399	422	+ 23
Effient® (Co-promotion revenue)	Antiplatelet agent	127	154	+ 27

#### Revenue of Luitpold Pharmaceuticals, Inc. mainstay products

(Millions of US\$; all amounts have been rounded off to the nearest million US\$.)

Product name		Fiscal 2012	Fiscal 2013	YoY change
Venofer®	Anemia treatment	284	248	(36)

## Europe

**Revenue: ¥79.0 billion (increased by 30.4% year on year), composition ratio: 7.1%**

Revenue in Europe increased 30.4% year on year to ¥79.0 billion. Revenue in local currency terms increased 4.0% to approximately EUR590 million. Olmetec®/Olmetec Plus® and Sevikar HCT® contributed to the revenue growth.

### Revenue of Daiichi Sankyo Europe GmbH mainstay products

(Millions of euro; all amounts have been rounded off to the nearest million euro.)

Product		Fiscal 2012	Fiscal 2013	YoY change
Olmetec®/Olmetec Plus®	Antihypertensive agent	304	331	+ 27
Sevikar®	Antihypertensive agent	100	100	(0)
Sevikar HCT®	Antihypertensive agent	44	57	+ 13

## Other regions

**Revenue: ¥52.9 billion (increased by 33.8% year on year), composition ratio: 4.7%**

In other regions, revenue rose 33.8% year on year to ¥52.9 billion.

The Group generated higher sales in countries including China, South Korea, and Brazil.

In China, key products contributing to sales growth included Olmetec®, Mevalotin®, and Asmeton®, a cough suppressant and expectorant. In April 2013, the Group also launched Urief®, a treatment for dysuria.

Sales of Olmesartan and other mainstay products showed growth in South Korea and Brazil.

## Ranbaxy Group Segment

(15-month period from January 1, 2013 to March 31, 2014)

**Revenue: ¥220.6 billion (increased by ¥37.1 billion year on year), composition ratio: 19.7%**

The accounting period was the 15-month period from January 1, 2013 to March 31, 2014 as the Ranbaxy Group changed its accounting period as the period from April 1 to March 31 of the following year.

Segment revenue was ¥220.6 billion (an increase of ¥37.1 billion from the previous fiscal period). The Ranbaxy Group recorded an operating loss of ¥1.0 billion for fiscal 2013 (a decrease of ¥20.9 billion compared with the previous fiscal period before consolidated adjustments).

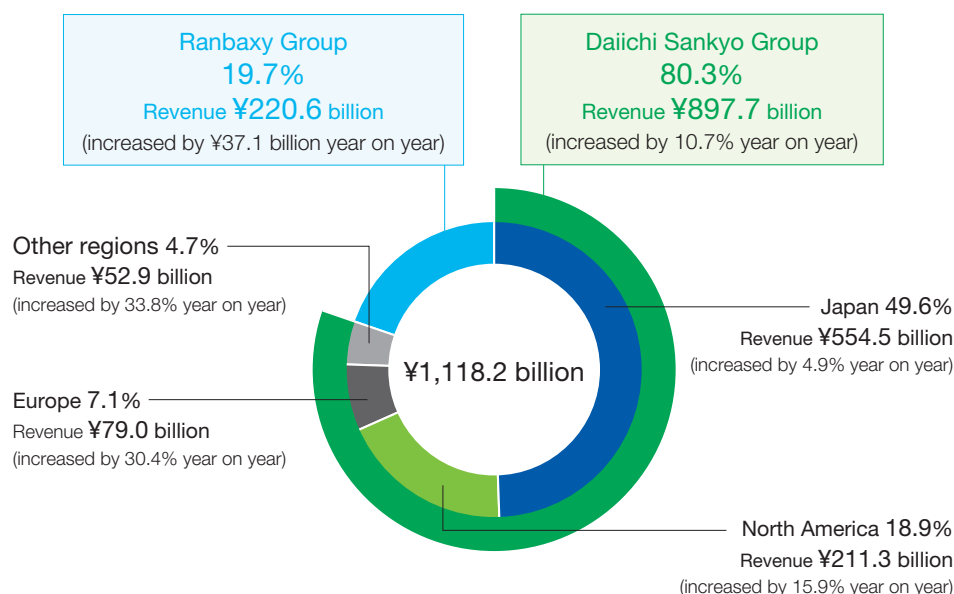
Revenue in North America declined substantially because the previous fiscal year had included a sales contribution from the introduction of generic atorvastatin in the United States. Ranbaxy Group revenue increased year on year because of the offsetting effects of the 15-month accounting period together with higher sales in emerging markets.

### Revenue of Ranbaxy Group by major country and region

(Millions of Indian rupee)

	Fiscal 2012 (12 months)	Fiscal 2013 (15 months)	YoY change
North America	53,336	42,003	(11,333)
India	21,346	27,930	+ 6,584
Eastern Europe and CIS	13,160	19,980	+ 6,820
Western Europe	9,720	10,798	+ 1,078
Africa and Middle East	10,188	12,966	+ 2,778

### Composition Ratio of Revenue by Segment for Fiscal 2013



# Consolidated Financial Statements

## ■ Consolidated Statement of Financial Position

	(Millions of yen)	
	Fiscal 2012 (As of March 31, 2013)	Fiscal 2013 (As of March 31, 2014)
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	191,145	183,070
Trade and other receivables	262,851	269,194
Other financial assets	182,367	324,160
Inventories	173,828	189,408
Other current assets	19,593	24,769
Total current assets	829,786	990,603
Non-current assets		
Property, plant and equipment	290,648	316,304
Goodwill	84,738	85,518
Intangible assets	171,137	171,417
Investments accounted for using the equity method	4,775	2,624
Other financial assets	145,127	141,553
Deferred tax assets	141,950	122,550
Other non-current assets	16,785	23,464
Total non-current assets	855,162	863,433
Total assets	1,684,949	1,854,037

(Millions of yen)

LIABILITIES AND EQUITY	Fiscal 2012 (As of March 31, 2013)	Fiscal 2013 (As of March 31, 2014)
Current liabilities		
Trade and other payables	225,873	245,422
Bonds and borrowings	66,073	160,326
Other financial liabilities	9,531	15,115
Income taxes payable	22,998	5,636
Provisions	59,872	22,702
Other current liabilities	40,207	11,985
Total current liabilities	424,556	461,188
Non-current liabilities		
Bonds and borrowings	200,742	263,289
Other financial liabilities	23,625	14,177
Post-employment benefit liabilities	31,258	8,947
Provisions	1,385	3,747
Deferred tax liabilities	38,732	39,838
Other on-current liabilities	26,169	55,320
Total non-current liabilities	321,912	385,321
Total liabilities	746,468	846,509
Equity		
Equity attributable to owners of the Company		
Share capital	50,000	50,000
Capital surplus	105,194	105,267
Treasury shares	(14,460)	(14,408)
Other components of equity	85,067	121,753
Retained earnings	680,844	717,320
Total equity attributable to owners of the Company	906,645	979,933
Non-controlling interests		
Non-controlling interests	31,835	27,594
Total equity	938,480	1,007,527
Total liabilities and equity	1,684,949	1,854,037



## ■ Consolidated Statement of Profit or Loss and Consolidated Statement of Comprehensive Income (Consolidated Statement of Profit or Loss)

	(Millions of yen)	
	Fiscal 2012 (For the year ended March 31, 2013)	Fiscal 2013 (For the year ended March 31, 2014)
Revenue	994,659	1,118,241
Cost of sales	338,485	402,289
Gross profit	656,173	715,952
Selling, general, and administrative expenses	373,037	413,187
Research and development expenses	184,393	191,212
Operating profit	98,743	111,552
Financial income	14,726	16,577
Financial expenses	17,220	26,928
Share of loss of investments accounted for using the equity method	387	1,426
Profit before tax	95,861	99,775
Income taxes	29,955	46,417
Profit for the year	65,906	53,357
Profit attributable to:		
Owners of the Company	64,027	60,943
Non-controlling interests	1,878	(7,585)
Profit for the year	65,906	53,357
Earnings per share		
Basic earnings per share (Yen)	90.96	86.57
Diluted earnings per share (Yen)	90.81	86.41

## ■ Consolidated Statement of Comprehensive Income

(Millions of yen)

	Fiscal 2012 (For the year ended March 31, 2013)	Fiscal 2013 (For the year ended March 31, 2014)
Profit for the year	65,906	53,357
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	18,837	7,968
Remeasurements of defined benefit plans	(547)	7,688
Items that may be reclassified subsequently to profit or loss		
Exchange differences on the translation of foreign operations	42,895	43,053
Cash flow hedges	1,198	(1,510)
Share of other comprehensive income of investments accounted for using the equity method	104	75
Other comprehensive income (loss), net of taxes	62,488	57,275
Total comprehensive income	128,395	110,632
Total comprehensive income attributable to:		
Owners of the Company	123,891	115,255
Non-controlling interests	4,503	(4,623)
Total comprehensive income	128,395	110,632

## Consolidated Statement of Changes in Equity

(Millions of yen)

	Equity attributable to owners of the Company						
	Other components of equity						Financial assets measured at fair value through other comprehensive income
	Share capital	Capital surplus	Treasury shares	Subscription rights to shares	Exchange differences on the translation of foreign operations	Cash flow hedges	
Balance as of April 1, 2012	50,000	105,194	(14,558)	1,297	—	198	26,952
Profit for the year	—	—	—	—	—	—	—
Other comprehensive income	—	—	—	—	40,530	762	18,840
Total comprehensive income	—	—	—	—	40,530	762	18,840
Acquisition of treasury shares	—	—	(12)	—	—	—	—
Disposal of treasury shares	—	—	109	(54)	—	—	—
Share-based payments	—	—	—	261	—	—	—
Dividends	—	—	—	—	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	—	—	—	(3,735)
Other	—	—	—	—	14	(1)	(0)
Total transactions with the owners	—	—	97	206	14	(1)	(3,735)
Balance as of March 31, 2013	50,000	105,194	(14,460)	1,504	40,545	959	42,057
Profit for the year	—	—	—	—	—	—	—
Other comprehensive income	—	—	—	—	39,708	(957)	7,969
Total comprehensive income	—	—	—	—	39,708	(957)	7,969
Acquisition of treasury shares	—	—	(31)	—	—	—	—
Disposal of treasury shares	—	—	83	(55)	—	—	—
Share-based payments	—	—	—	231	—	—	—
Dividends	—	—	—	—	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	—	—	—	(10,205)
Other	—	73	—	—	(1)	(2)	(0)
Total transactions with the owners	—	73	52	175	(1)	(2)	(10,205)
Balance as of March 31, 2014	50,000	105,267	(14,408)	1,680	80,252	—	39,821

(Millions of yen)

	Equity attributable to owners of the Company					
	Other components of equity					Total equity
	Remeasurements of defined benefit plans	Total other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	
Balance as of April 1, 2012	—	28,449	655,644	824,730	26,578	851,308
Profit for the year	—	—	64,027	64,027	1,878	65,906
Other comprehensive income	(270)	59,863	—	59,863	2,624	62,488
Total comprehensive income	(270)	59,863	64,027	123,891	4,503	128,395
Acquisition of treasury shares	—	—	—	(12)	—	(12)
Disposal of treasury shares	—	(54)	(54)	0	—	0
Share-based payments	—	261	—	261	634	895
Dividends	—	—	(42,235)	(42,235)	—	(42,235)
Transfer from other components of equity to retained earnings	270	(3,465)	3,465	—	—	—
Other	—	12	(3)	9	118	128
Total transactions with the owners	270	(3,246)	(38,827)	(41,976)	752	(41,223)
Balance as of March 31, 2013	—	85,067	680,844	906,645	31,835	938,480
Profit for the year	—	—	60,943	60,943	(7,585)	53,357
Other comprehensive income	7,592	54,312	—	54,312	2,962	57,275
Total comprehensive income	7,592	54,312	60,943	115,255	(4,623)	110,632
Acquisition of treasury shares	—	—	—	(31)	—	(31)
Disposal of treasury shares	—	(55)	(27)	0	—	0
Share-based payments	—	231	—	231	594	825
Dividends	—	—	(42,237)	(42,237)	—	(42,237)
Transfer from other components of equity to retained earnings	(7,592)	(17,798)	17,798	—	—	—
Other	—	(3)	—	70	(212)	(142)
Total transactions with the owners	(7,592)	(17,625)	(24,466)	(41,966)	381	(41,584)
Balance as of March 31, 2014	—	121,753	717,320	979,933	27,594	1,007,527

## Consolidated Statement of Cash Flows

(Millions of yen)

	Fiscal 2012 (For the year ended March 31, 2013)	Fiscal 2013 (For the year ended March 31, 2014)
Cash flows from operating activities		
Profit before tax	95,861	99,775
Depreciation and amortization	45,260	51,486
Impairment loss	10,336	5,457
Financial income	(14,726)	(16,577)
Financial expenses	17,220	26,928
Share of (profit) loss of investments accounted for using the equity method	387	1,426
(Gain) loss on sale and disposal of fixed assets	(2,116)	(12,939)
(Increase) decrease in trade and other receivable	1,642	3,200
(Increase) decrease in inventories	4,342	(6,258)
Increase (decrease) in trade and other payables	(12,672)	2,885
Other, net	4,466	(8,688)
Subtotal	150,002	146,696
Interest and dividends received	6,900	6,368
Interest paid	(4,130)	(11,184)
Settlement expenses paid	—	(49,764)
Income taxes paid	(23,487)	(54,810)
Net cash flows from operating activities	129,284	37,304
Cash flows from investing activities		
Purchase of time deposits	(121,286)	(154,006)
Proceeds from maturities in time deposits	111,566	118,942
Acquisition of securities	(282,381)	(388,411)
Proceeds from sale of securities	234,881	303,377
Acquisitions of property, plant, and equipment	(72,226)	(47,497)
Proceeds from sale of property, plant, and equipment	2,394	11,947
Acquisition of intangible assets	(7,124)	(7,017)
Payments for loans receivable	(736)	(1,863)
Proceeds from collection of loans receivable	131	644
Other, net	25,944	2,515
Net cash flows from investing activities	(108,837)	(161,368)
Cash flow from financing activities		
Proceeds from bonds and borrowings	27,112	194,121
Repayments of bonds and borrowings	(42,198)	(50,500)
Purchase of treasury shares	(12)	(31)
Proceeds from sales of treasury shares	0	0
Dividends paid	(42,240)	(42,238)
Other, net	(889)	(1,030)
Net cash flows from financing activities	(58,227)	100,322
Net increase (decrease) in cash and cash equivalents	(37,780)	(23,742)
Cash and cash equivalents at the beginning of the year	212,948	191,145
Effect of exchange rate change on cash and cash equivalents	15,976	15,667
Cash and cash equivalents at the end of the year	191,145	183,070

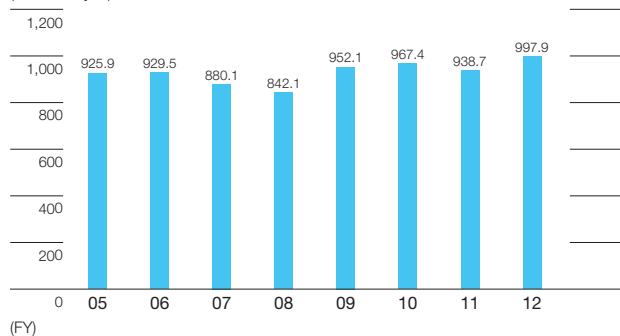
# Historical data (Japanese GAAP)

## Financial Highlights

	FY2005	FY2006
Net sales	¥ 925,918	¥ 929,506
Operating income	154,728	136,313
Net income (loss)	87,692	78,549
Sales outside Japan	307,265	356,701
Sales outside Japan to net sale	33.2%	38.4%
R&D expenses	158,716	170,662
R&D expenses to net sales	17.1%	18.4%
Depreciation and amortization expenses	41,128	39,986
Total assets	1,596,126	1,636,835
Total net assets	1,237,529	1,272,148
Return on shareholders' equity	7.3%	6.3%
Net cash flows from operating activities	132,759	106,429
Net cash flows from investing activities	(39,258)	45,305
Free cash flow	93,501	151,734
Net income (loss) per share of common stock	¥119.49	¥107.75
Cash dividends per share	25	60
Dividends on equity	2.9%	3.5%

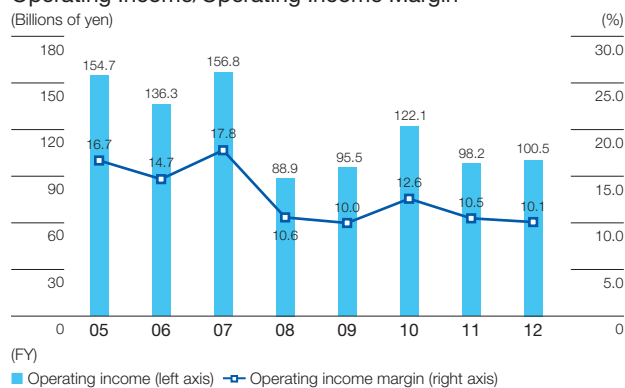
### Net Sales

(Billions of yen)



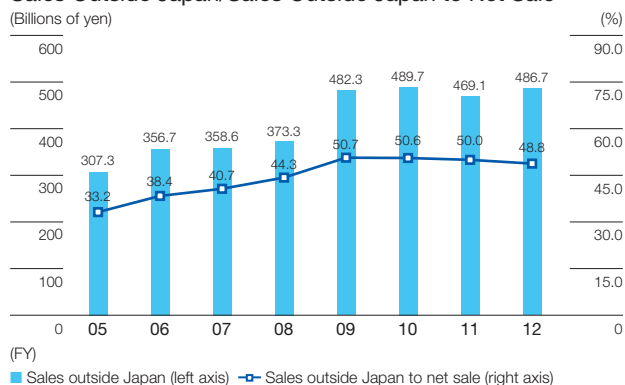
### Operating Income/Operating Income Margin

(Billions of yen)



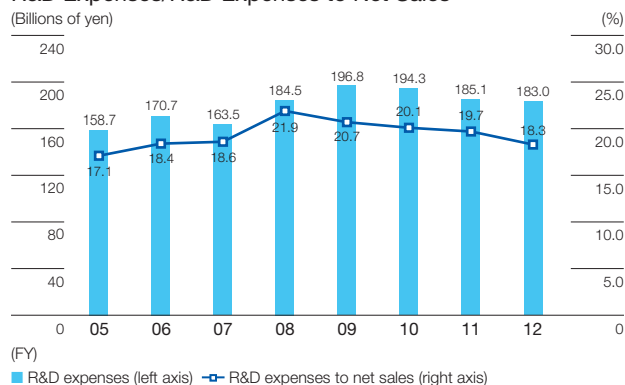
### Sales Outside Japan/Sales Outside Japan to Net Sale

(Billions of yen)



### R&D Expenses/R&D Expenses to Net Sales

(Billions of yen)



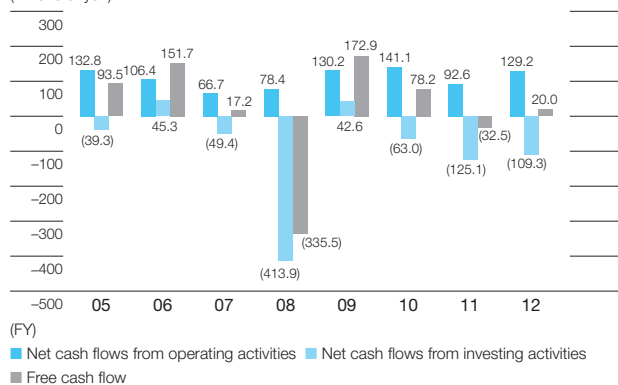


(Millions of yen)

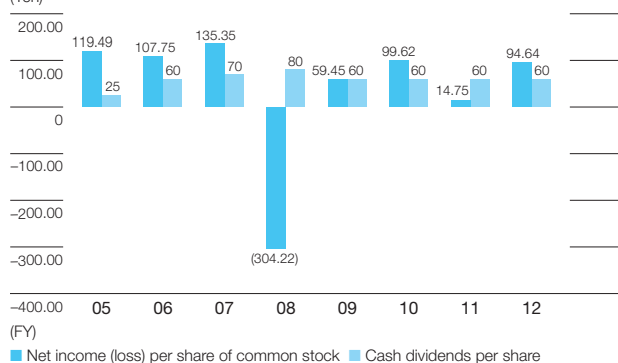
FY2007	FY2008	FY2009	FY2010	FY2011	FY2012
¥ 880,120	¥ 842,147	¥ 952,105	¥ 967,365	¥ 938,677	¥ 997,852
156,827	88,870	95,509	122,143	98,202	100,516
97,660	(215,499)	41,852	70,121	10,383	66,621
358,639	373,254	482,337	489,735	469,085	486,658
40.7%	44.3%	50.7%	50.6%	50.0%	48.8%
163,472	184,539	196,802	194,330	185,052	183,047
18.6%	21.9%	20.7%	20.1%	19.7%	18.3%
38,733	40,582	45,942	43,945	46,305	41,423
1,487,888	1,494,599	1,489,510	1,480,240	1,518,479	1,644,071
1,244,512	888,617	889,508	887,702	832,749	915,745
7.8%	(20.5)%	4.9%	8.2%	1.3%	7.9%
66,667	78,383	130,235	141,139	92,569	129,247
(49,437)	(413,851)	42,627	(62,965)	(125,095)	(109,281)
17,230	(335,468)	172,862	78,174	(32,526)	19,966
(Yen)					
¥135.35	¥(304.22)	¥59.45	¥99.62	¥14.75	¥94.64
70	80	60	60	60	60
4.0%	5.4%	4.9%	5.0%	5.1%	5.0%

## Cash Flow

(Billions of yen)

Net Income (Loss) per Share of Common Stock/  
Cash Dividends per Share

(Yen)



# Corporate Information

(As of March 31, 2014)

## ■ Corporate Profile

**Company name:** DAIICHI SANKYO COMPANY, LIMITED

**Established:** September 28, 2005

**Business:** Research and development, manufacturing, import, sales, and marketing of pharmaceutical products

**Paid-in capital:** ¥50,000 million

**Headquarters:** 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, 103-8426, Japan

**Branches:** Sapporo, Tohoku, Tokyo, Chiba, Saitama, Yokohama, Kita-Kanto, Koshinetsu, Tokai, Kyoto, Hokuriku, Osaka, Kobe, Chugoku, Shikoku, Kyushu



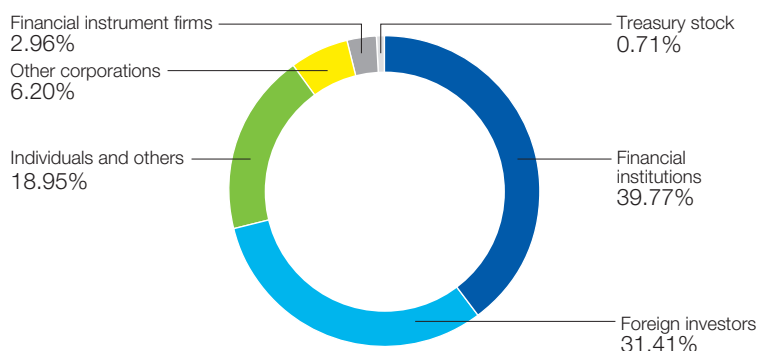
## ■ Common Stock

**Number of shares authorized:** 2,800,000,000

**Number of shares issued:** 709,011,343

**Number of shareholders:** 118,816

## ■ Distribution of Shareholders



## ■ Major Shareholders

Name	Number of shares held (Thousands of shares)	Ratio (%)
The Master Trust Bank of Japan, Ltd. (trust account)	45,201	6.38
Japan Trustee Services Bank, Ltd. (trust account)	39,667	5.59
Nippon Life Insurance Company	36,717	5.18
JP Morgan Chase Bank 385147	17,335	2.44
Trust & Custody Services Bank, Ltd., as trustee for Mizuho Bank, Ltd., Retirement Benefit Trust Account re-entrusted by Mizuho Trust and Banking Co., Ltd.	14,402	2.03
Sumitomo Mitsui Banking Corporation	11,413	1.61
Employee stock ownership of Daiichi Sankyo Group	11,180	1.58
State Street Bank and Trust Company 505225	9,156	1.29
The Bank of New York 133522	8,890	1.25
Mizuho Bank, Ltd.	8,591	1.21

## ■ Main Group Companies

Region	Company name	Main business activities
Japan	Daiichi Sankyo Espha Co., Ltd.	Manufacturing and sales of pharmaceuticals
	Daiichi Sankyo Healthcare Co., Ltd.	Manufacturing and purchase/sale of pharmaceuticals, over-the-counter products, cosmetics, medical equipment, food products and drinking water
	Daiichi Sankyo Propharma Co., Ltd.	Manufacturing of pharmaceuticals
	Daiichi Sankyo Chemical Pharma Co., Ltd.	Manufacturing and contract manufacturing of active pharmaceutical ingredients and intermediates
	Daiichi Sankyo Logistics Co., Ltd.	Distribution and distribution-related services
	Asubio Pharma Co., Ltd.	Research and development of pharmaceuticals
	Daiichi Sankyo RD Novare Co., Ltd.	Research and development of pharmaceuticals
	Daiichi Sankyo Business Associe Co., Ltd.	Group business support
	Daiichi Sankyo Happiness Co., Ltd.	Group business support
	Kitasato Daiichi Sankyo Vaccine Co., Ltd.	Research and development, manufacturing, and sales of vaccine
U.S.A.	Daiichi Sankyo, Inc.	Research, development and marketing of pharmaceuticals
	Luitpold Pharmaceuticals, Inc.	Manufacturing and marketing of pharmaceuticals and drugs for animals
	Plexxikon Inc.	Research of prescription drugs
Europe	Daiichi Sankyo Europe GmbH	Control of Group development in Europe and pharmaceutical manufacturing
	Daiichi Sankyo France SAS	Sale and marketing of pharmaceuticals
	Daiichi Sankyo Deutschland GmbH	Marketing of pharmaceuticals
	Daiichi Sankyo Italia S.p.A.	Marketing of pharmaceuticals
	Daiichi Sankyo España, S.A.	Marketing of pharmaceuticals
	Daiichi Sankyo UK Ltd.	Marketing of pharmaceuticals
	Daiichi Sankyo (Schweiz) AG	Marketing of pharmaceuticals
	Daiichi Sankyo Portugal, Lda.	Marketing of pharmaceuticals
	Daiichi Sankyo Austria GmbH	Marketing of pharmaceuticals
	Daiichi Sankyo Belgium N.V.-S.A.	Marketing of pharmaceuticals
	Daiichi Sankyo Nederland B.V.	Marketing of pharmaceuticals
	Daiichi Sankyo Ilac Ticaret Ltd. Sti.	Marketing of pharmaceuticals
	Daiichi Sankyo Ireland Ltd.	Marketing of pharmaceuticals
	Daiichi Sankyo Altkirch S.a.r.l.	Manufacturing of raw materials for pharmaceuticals
	U3 Pharma GmbH	Research of prescription drugs
	Daiichi Sankyo Development Ltd.	Development of prescription drugs
ASCA <sup>*1</sup>	Ranbaxy Laboratories Ltd.	Research, development, manufacturing, and marketing of pharmaceuticals
	Daiichi Sankyo (China) Holdings Co., Ltd.	Management of Chinese subsidiary business and investment
	Daiichi Sankyo Pharmaceutical (Beijing) Co., Ltd.	Development, manufacturing, and marketing of pharmaceuticals
	Daiichi Sankyo Pharmaceutical (Shanghai) Co., Ltd.	Research, development, manufacturing, and marketing of pharmaceuticals
	Daiichi Sankyo Taiwan Ltd.	Marketing of pharmaceuticals
	Daiichi Sankyo Korea Co., Ltd.	Sales and marketing of pharmaceuticals
	Daiichi Sankyo (Thailand) Ltd.	Marketing of pharmaceuticals
	Daiichi Sankyo Hong Kong Ltd.	Sales and marketing of pharmaceuticals
	Daiichi Sankyo Mexico S.A. de C.V.	Marketing of pharmaceuticals
	Daiichi Sankyo Brasil Farmaceutica LTDA.	Manufacturing and marketing of pharmaceuticals
	Daiichi Sankyo Venezuela, S.A.	Marketing of pharmaceuticals
	Daiichi Sankyo India Pharma Private Ltd.	Research, development, and marketing of pharmaceuticals

<sup>\*1</sup> Abbreviation of Asia and South and Central America. This is internal terminology, indicating markets outside Japan, the United States, and Europe.



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## Precautions for future prospects

This report contains future prospects, such as the Company's plan, strategy, and business performance. These prospects are based on our conclusions from information that is currently available. Therefore, please be advised that the actual business performance will be influenced by various risks and uncertainties and could achieve different results from these prospects. Examples of factors that could influence future prospects are including, but are not limited to, the economic environment, competition, related laws, change in product development circumstances, or fluctuation of exchange rates that surround the Company's business domain.

## Period covered

April 1, 2013—March 31, 2014 (fiscal 2013)

## Main external recognition related CSR in FY2013

MEMBER OF

**Dow Jones  
Sustainability Indices**

In Collaboration with RobecoSAM

Daiichi Sankyo was included in the Asia Pacific Index of the Dow Jones Sustainability Indexes (DJSI Asia Pacific) in September 2013.



Daiichi Sankyo was included in the FTSE4Good Global Index and index of firms that meet globally recognized corporate responsibility standards, in fiscal 2013.



Daiichi Sankyo was included in the Climate Performance Leadership Index (CPLI) as a company for high performance quality of strategies for climate change and emission reduction.

## Value Report 2014 was printed using environmental-friendly paper, inks, and manufacturing method.

Paper



This report uses FSC certified paper, which indicates that the paper used to print this report was produced from properly managed forests.

Inks



This report was printed using 100% biodegradable printing inks from vegetable oil.

Printing



The waterless printing method used for this report minimized the use and release of harmful liquid wastes.