Business Units (Japan)

Sales & Marketing Unit

(Innovative Pharmaceuticals Business)

As an ethical, trusted, and respected partner that is worthy of the position as the No. 1 pharmaceutical company in Japan, the Sales & Marketing Unit contributes to the progress of medicine in Japan by continually providing high-quality innovative pharmaceuticals and accurate information to ensure patients can feel safe undergoing treatments.

Sales & Marketing Unit 5-Year Business Plan

- Enhance our reputation as an ethical, trusted, and respected partner
- Advance field and product strategies based on information provision activities (BRIDGE*)
- Construct systems and functions compatible with operating environment changes
- Promote multichannel approach

* Bright Days Together (BRIDGE): By providing accurate information and products with an emphasis on the importance of interpersonal connections, we aim to form a bridge to bright days for patients, their families, and healthcare professionals. In addition, we hope that our ongoing efforts in this area will enhance Daiichi Sankyo's reputation as an ethical, trusted, and respected partner.

Major Achievements in Fiscal 2016

• Achieved revenue of ¥447.8 billion (up 1.9% year on year)

Revenue was impacted by national health insurance (NHI) drug price revisions and increased prescriptions of generic drugs. Nonetheless, overall revenue was up due to increased revenues from mainstay products, including *LIXIANA*, an anticoagulant; *NEXIUM*, an ulcer treatment; *Memary*, an Alzheimer's disease treatment; *PRALIA*, an osteoporosis treatment; *RANMARK*, a treatment for bone metastasis associated with cancer; *Efient*, an antiplatelet agent; and *TENELIA*, a type 2 diabetes mellitus treatment.

• MRs ranked No. 1 for fifth consecutive year

In fiscal 2016, Daiichi Sankyo was ranked No. 1 in Japan in an overall assessment of MR activities in both the entire market and the hospital and private practice market categories*. In the entire market category, we have maintained the top ranking for five consecutive years beginning with fiscal 2012. In addition, we have also been ranked No. 1 in media surveys by Nikkei Medical and other publications.

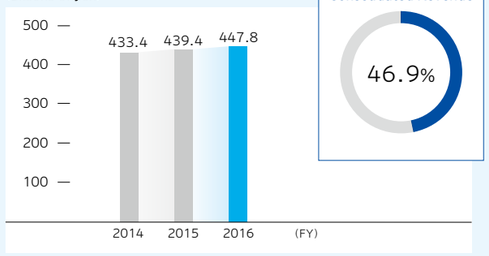
* Survey conducted by ANTERIO Inc.

• All MRs pass certificate test for seventh consecutive year

All MRs have passed the certificate test held in December for the seventh consecutive year since fiscal 2010.

Innovative Pharmaceutical Revenue

(Billions of yen)



Percentage of Total Consolidated Revenue

Initiatives for Fiscal 2017

• Achieve rapid growth in sales of mainstay innovative pharmaceuticals

We will continue to expand our business by achieving rapid growth in sales of mainstay innovative pharmaceuticals, including *LIXIANA* as well as *NEXIUM*; *Efient*; type 2 diabetes mellitus treatment *TENELIA*, *CANAGLU*, and *CANALIA*; *PRALIA*; *RANMARK*; and epilepsy treatment *VIMPAT*.

• Build upon MR activities based on BRIDGE

By providing accurate information and products with an emphasis on the importance of interpersonal connections, we aim to form a bridge to bright days for patients, their families, and healthcare professionals. In addition, we hope that our ongoing efforts in this area will enhance Daiichi Sankyo's reputation as an ethical, trusted, and respected partner.

• Promote and enhance area marketing

We will commence full-fledged operation based on the area marketing system we have been building throughout fiscal 2016 and prior, which entailed reorganizing sales offices and teams within medical community areas and appointing staff responsible for supporting community medical collaboration. With this new system in place, we will deploy and accelerate marketing activities based on regional characteristics as we pursue sustainable growth as an ethical, trusted, and respected partner.

• Enhance information provision capabilities through multichannel approach

By incorporating a multichannel approach utilizing lectures, e-promotions, and other venues in information provision activities by MRs, we will endeavor to provide information that is even more valuable in greater quantities.

• Promote compliance

We exercise thorough compliance with a strong focus on acting with the highest level of ethics and social consciousness, which is essential for a life science-oriented company, in order to further increase society's trust in Daiichi Sankyo.

Examples of CSR Activities

• Initiatives to become a trusted medical partner to healthcare professionals and patients Page 80

Business Units (Japan)

Sales & Marketing Unit: Daiichi Sankyo Espha Co., Ltd.

(Generic Business)

Daiichi Sankyo Espha takes advantage of the reputation for reliability and peace of mind we have fostered as an innovative pharmaceutical manufacturer to act as an innovator in the domestic generic pharmaceutical industry. With an emphasis on quality control, stable supply, information provision, and affordability, we will contribute to national healthcare in a rapidly aging Japan.

Daiichi Sankyo Espha Co., Ltd., 5-Year Business Plan

- Strengthen authorized generic (AG)*1 lineup
- Steadily launch AGs and other day-one generics*2 and secure market shares
- Step up coordination with partners in Japan and overseas

*1 Authorized generic (AG): Generic drug manufactured after receiving consent from the manufacturer of the original drug through the receipt of patent rights

*2 Day-one generics: Generic drugs launched on the first day that sale of a generic is possible

What are Authorized Generics?

Authorized generics are generic drugs manufactured after receiving consent from the manufacturer of the original drug through the receipt of patent rights. The same ingredients, additives, and manufacturing processes as the original drug are used to create a generic drug of the same quality as the original and authorized companies are granted priority permission to market these drugs ahead of other companies by using the patent rights.

Major Achievements in Fiscal 2016

• Achieved revenue of ¥20.2 billion (up 9.2% year on year)

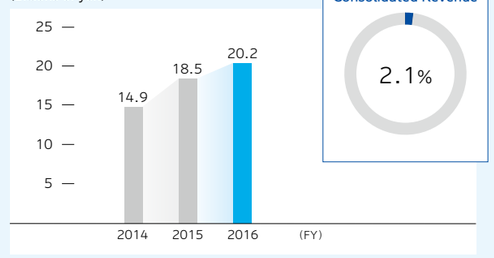
Although revenue was impacted by the NHI drug price revisions instituted in April 2016, we were able to achieve revenue growth that exceeded the market average thanks to government measures for promoting generic usage and the benefits of new products. *Levofloxacin tablet*, which was launched in December 2014 as the Group's first AG in Japan, continued to earn strong praise, maintaining a share of approximately 50% of the generic market.

• Expanded product portfolio

We launched generic drugs with two new active ingredients in June 2016 and two new ingredients in December, bringing our total portfolio to 163 products with 64 active ingredients. In order to strengthen our AG lineup, a central pillar of our 5-year business plan, we acquired manufacturing and marketing approval for AGs with 10 new active ingredients in February 2017, including AGs for such major drugs as *olmesartan*, the *telmisartan* family, and *rosuvastatin*. These products were not limited to AGs of Daiichi Sankyo products but also included AGs for which permission was acquired from other companies.

Daiichi Sankyo Espha Revenue

(Billions of yen)



Percentage of Total Consolidated Revenue

Initiatives for Fiscal 2017

• Reinforce operating foundations and prepare to launch major products

The multiple AGs for which manufacturing and marketing approval was acquired in February 2017 will no doubt make large contributions to earnings in fiscal 2017 and beyond. Accordingly, we will work to ensure smooth launches of these products.

• Improve recognition and understanding regarding AGs

The Japanese government has set the goal of raising the portion of the pharmaceutical market represented by generic drugs to more than 80% on a unit basis. Accomplishing this goal will require the development of an environment in which both healthcare professionals and patients are able to more proactively choose generics.
Daiichi Sankyo Espha is working to improve recognition and understanding regarding AGs to make patients with concerns regarding generics more willing to choose AGs among other generics.

Examples of CSR Activities

• Provision of information on premium generics featuring formulation, display, and packaging innovations via the website

Business Units (Japan)

Vaccine Business Unit

(Vaccine Business)

As vaccines become increasingly more important to Japanese society, the Vaccine Business Unit is working to contribute to public health in Japan by creating innovative vaccines that address social needs and reliably supplying high-quality vaccines.

Vaccine Business Unit 5-Year Business Plan

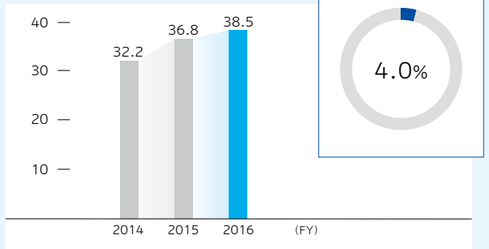
- Establish stable and low-cost supply systems
- Complete the establishment of a development and production system for new influenza vaccines* and maintain production systems in preparation for future pandemics
- Develop and encourage early adoption of new influenza vaccines boasting potential for high efficacy and new, exceptionally convenient combination vaccines

* Open application project spearheaded by the Ministry of Health, Labour and Welfare to establish development and production systems for new influenza vaccines and secure venues for swift supply in the case of influenza outbreaks or pandemics

Major Achievements in Fiscal 2016

- **Achieved revenue of ¥38.5 billion (up 4.7% year on year)**
  Squarekids, a 4-valent combination vaccine for the prevention of pertussis, diphtheria, tetanus, and poliomyelitis (polio), contributed to higher revenues.
- **Stably supplied HA vaccine for seasonal influenza**
  By basing vaccine supply activities on the seasons in which the vaccines are used, we realized a substantial decrease in the amount of vaccines returned.
- **Recommenced production of measles-rubella combined vaccine (MR vaccine)**
  Following the voluntary recall of the MR vaccine in fiscal 2015, we resolved the issues faced by this vaccine and recommenced production to resume shipments.

Vaccine Business Unit Revenue
(Billions of yen)



Percentage of Total Consolidated Revenue

Initiatives for Fiscal 2017

- **Maintain reliable supplies and reduce costs to secure profits**
  In fiscal 2017, new organizations specializing in planning, production, and other functions were established. Coordination will be pursued among these organizations to revise operating processes in order to reduce costs at production sites and lower expenses through refinements to the manufacturing processes for existing vaccines.
- **Reinforce foundations for quality and safety management**
  We aim to contribute to stable supplies of high-quality products by enhancing quality assurance systems. In addition, training, education, and other human resources development initiatives will be implemented in order to reinforce internal foundations for quality and safety management.
- **Advance project for establishment of a development and production system for new influenza vaccines**
  We will formulate manufacturing measures that guarantee to establish a vaccine supply system for 40 million people in six months, and work toward the accomplishment of the project's targets.
- **Conduct research and development**
  Daiichi Sankyo will move ahead with the research and development of highly convenient vaccines such as trivalent combination vaccine for the measles, mumps, and rubella and new vaccines such as nasal spray influenza live attenuated vaccines, DPT-IPV / Hib vaccines, for which social needs are high.

Examples of CSR Activities

- Provision of basic knowledge on vaccines to patients via the website

Business Units (Japan)

Daiichi Sankyo Healthcare Co., Ltd.

(OTC Business)

As a consumer healthcare company, Daiichi Sankyo Healthcare promotes self-medication and self-care. We seek to contribute to higher quality of life for all individuals hoping to be healthier and more attractive through the provision of OTC medicines as well as skincare and oral care products.

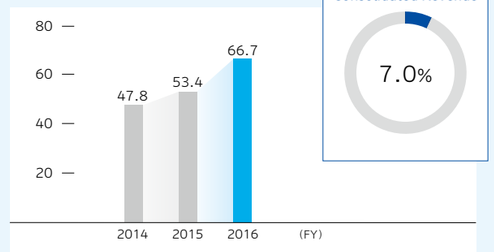
Daiichi Sankyo Healthcare Co., Ltd., 5-Year Business Plan

- Improve product brand value in the OTC business
- Accelerate growth of the direct marketing business through synergies with Im Co., Ltd., in the direct marketing business
- Achieve independence in overseas businesses
- Strengthen operating foundations to ensure responsiveness to market environment changes

Major Achievements in Fiscal 2016

- **Achieved revenue of ¥66.7 billion (up 25.0% year on year)**
  Substantial revenue growth was achieved due to the steady expansion of sales of mainstay OTC medicine brands, higher sales in the functional skincare field, and contributions from Im Co., Ltd., a direct marketing company for which all shares were acquired in 2015.
- **Grew sales through improved brand value and enhanced lineup**
  Smooth sales growth was once again seen for *Lulu* and *MINON* brand products. As for the *Loxonin S* brand, we enhanced our lineup of ingested medicines with the launch of *Loxonin S Premium* while also introducing external application *Loxonin S* products, including tapes, cataplasms, and gels.
- **Increased sales of direct marketing subsidiary Im**
  In addition to establishing direct marketing operating foundations, we achieved a large increase in sales of Im's mainstay *RICE FORCE* brand of skincare products.
- **Expanded overseas**
  A new operating base was established in China, and we succeeded in launching *MINON Amino Moist* in this market.

Daiichi Sankyo Healthcare Revenue
(Billions of yen)



Percentage of Total Consolidated Revenue

Major Brands of Daiichi Sankyo Healthcare

- *Loxonin S*
- *MINON*
- *Transino*

Initiatives for Fiscal 2017

- **Expand new product pipelines based on consumer perspective**
  In April 2017, two new organizations were established, one equipped with marketing research, product planning, and licensing functions and the other designed to quickly reflect customer input in business activities. Through these new organizations, we will formulate product strategies and conduct product planning based on a consumer perspective to cultivate strong brands and products that win customer favor.
- **Maximize revenue of the *Loxonin S* and *Lulu* brands and further expand skincare and oral care brand revenue in OTC business**
- **Expand sales of Im's mainstay *RICE FORCE* brand and launch new *BRIGHTAGE* skincare brand in direct marketing operations**
  Leveraging Im's infrastructure and know-how, we will seek to quickly cultivate the new *BRIGHTAGE* brand to further grow skincare product sales.
- **Expand overseas operations in China**
  MINON Amino Moist will be positioned as a strategic brand in China, which we entered into with the establishment of a Group operating site in 2016, and other countries as we endeavor to expand into new areas.

Examples of CSR Activities

- Provision of product information in various languages via the websites

Business Units (United States)

Daiichi Sankyo, Inc.

(DSAC*)

Daiichi Sankyo, Inc., is branching out from the cardiovascular field, which centers on physicians in private practices, to transform into a company with product portfolios for the pain, oncology, and other specialty fields. This company is committed to contributing to the advancement of medicine in the United States by supplying new drugs that help people live longer and healthier lives and providing reliable evidence based on high-quality clinical and outcomes data.

* Daiichi Sankyo, Inc., Administrative & Commercial Operations

Daiichi Sankyo, Inc., 5-Year Business Plan

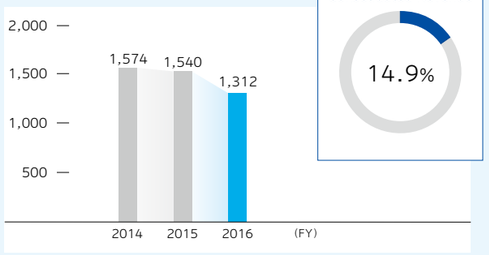
- Become a leader in pain care
- Build and grow oncology capabilities
- Maximize profit for mature products through LOE* timeframe

* LOE: Loss of exclusivity

Major Achievements in Fiscal 2016

- **Achieved revenue of US$1,312 million (down 14.8% year on year)**
  Effient grew, but total sales revenue decreased due to the impact of LOE of *olmesartan*.
- **Grew *MOVANTIK*, a treatment for opioid-induced constipation (OIC)**
  Co-promoting with AstraZeneca, the co-promotion revenue was US$38 million increased by US$22 million year on year.
- **Integrated LPI sales force into DSAC**
  Launched *Injectafer* into new key markets for the treatment of iron deficiency anemia, with a priority on gastrointestinal conditions (GI). Follow up with women's health, cardiovascular and other key markets where unmet medical needs exist.
- **Bolstered our pain franchise**
  Signed licensing agreement with Inspirion Delivery Sciences, LLC for two ADF opioids: *MorphaBond ER* (morphine sulfate) and *RoxyBond* (oxycodone hydrochloride).
  Launched www.CommitmentsinPainCare.com, which hosts an overview of our company's approach to responsible pain management and our dedication to being part of the solution to controlled substance abuse as we prepare to enter the opioid marketplace.
- **Divested packaging plant in Bethlehem**

Daiichi Sankyo, Inc., Revenue
(Millions of US$)



Percentage of Total Consolidated Revenue

Initiatives for Fiscal 2017

- Accelerate *MOVANTIK* growth
- Accelerate *Injectafer* revenue
  Expand into new markets with unmet medical needs
- Demonstrate launch success for *MorphaBond ER* and *RoxyBond*
- Maximize remaining opportunities for *Effient*, *Welchol* and hypertension products
- Enhance operational excellence

Examples of CSR Activities

- Participation in U.S. Initiative for Ending Hunger around the World Page 87

Business Units (United States)

Luitpold Pharmaceuticals, Inc.

Luitpold Pharmaceuticals, Inc., is contributing to healthcare in the United Sates as an injectable medication specialty pharmaceutical company. This company is driving the growth of the IV iron market with its high-value branded injectable medications while also increasing the flexibility of its growing generic injectable medication franchise in response to market needs.

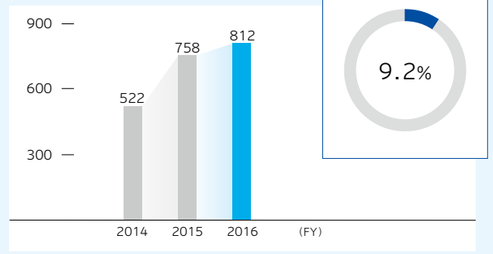
Luitpold Pharmaceuticals 5-Year Business Plan

- Build *Injectafer* into flagship product and market leader
- Expand generic injectable portfolio with a variety of products to support customer needs

Major Achievements in Fiscal 2016

- **Achieved revenue of US$812 million (up 7.2% year on year)**
- **Initiated business collaboration on *Injectafer* with DSAC**
  Expanded market reach by leveraging the established market presence in Hem/Onc and marketing excellence.
- **Initiated phase 3 trial to investigate *Injectafer* for heart failure patients with iron deficiency**
- **Expanded generic injectable portfolio**
  Submitted 4 ANDAs* and gained 1 ANDA approval.
  * Abbreviated New Drug Applications
- **Enhanced manufacturing capabilities**
  Started capital investment to become a one of top players in the U.S. generic injectable market.

Luitpold Pharmaceuticals Revenue
(Millions of US$)



Percentage of Total Consolidated Revenue

Initiatives for Fiscal 2017

- Accelerate *Injectafer* growth
  Strengthen leading position in the IV iron market segment with *Venofer* and *Injectafer*.
- Expand generic injectable franchise
  Grow business via optimization of in-market assets and new pipeline development.
  Submit 3 NDAs and 3 ANDAs.
- Execute R&D and clinical programs to support business growth
- Continue to increase manufacturing capacity and execute the capital project plan

Examples of CSR Activities

- Heart Walk Event for Raising Heart Disease Prevention Awareness in the United States Page 87

Business Units (Europe)

Daiichi Sankyo Europe GmbH

Daiichi Sankyo Europe GmbH is evolving into a specialty care-focused company to complement the manufacturing and sales foundations it has established in the cardiovascular field. As the most prominent Japanese pharmaceutical company with operating foundations in Europe, Daiichi Sankyo Europe develops its business in 12 European countries will partnering with companies in other parts of Europe to contribute to the advancement of medicine in this region.

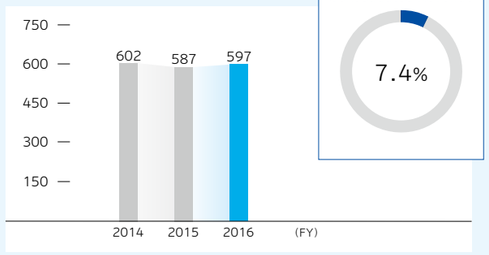
Daiichi Sankyo Europe 5-Year Business Plan

- Maximize profit from established brands through focused investment
- Maximize *LIXIANA*'s potential
  Rapid penetration in countries where Daiichi Sankyo Europe has a presence, in other countries collaboration with sales partners
- Diversify portfolio
- Establish oncology business
- Develop organization to further evolve into specialty care provider

Major Achievements in Fiscal 2016

- Achieved revenue of €597 million (up 1.8% year on year)
- Further launches of *LIXIANA*
  After *LIXIANA* launched in five European countries (Germany, the United Kingdom, the Netherlands, Switzerland and Ireland) in Fiscal 2015, launched in Belgium, Spain, Italy, Austria and Portugal in Fiscal 2016.
- Partnership for *LIXIANA*
  Agreement for a sales partnership with MSD* for the distribution rights for *LIXIANA* in 14 Northern and Central Eastern European countries as well as agreed with Servier Russia in 15 Russia and CIS countries. *LIXIANA* launched in Sweden, Norway and Denmark via the partnership with MSD.
  * Merck Sharp & Dohme Corp.: a European subsidiary of Merck & Co., Inc.
- Very good performance of *LIXIANA* in Germany
  Since its launch, *LIXIANA* has grown steadily and the market share reached 7.2% in March 2017.
- Licensing agreement with Nektar Therapeutics for *ONZEALD*
- Adaptation of organizational structures for further evolution into a specialty care provider

Daiichi Sankyo Europe Revenue
(Millions of euro)



Percentage of Total Consolidated Revenue

Initiatives for Fiscal 2017

- Grow market share of *LIXIANA* in countries where DSE has a presence
- Launch *LIXIANA* in more European countries via partnerships
- Strengthen life-cycle management (LCM) activities
  Our longest and largest pivotal studies as well as our ongoing clinical research program help to reassure healthcare professionals of the dosing, safety and efficacy when prescribing *LIXIANA* to their patients.
- Establish oncology business
  Build-out of oncology business unit for flawless execution of our oncology strategy.
- Further evolution into a specialty care provider
  Continue to work within the market access model and maintain alignment of European organizational structure with go-to market strategy.

Examples of CSR Activities

- Receipt of Award for Patient-Accommodating Package Design ····· Page 80

Business Units (ASCA*)

ASCA Company

The network of the ASCA Company stretches throughout the ASCA region with manufacturing and sales bases in China and Brazil and sales bases in South Korea, Taiwan, Hong Kong, and Thailand. By developing operations that respond to the market and customer needs and regional value* of each country, the ASCA Company contributes to the development of medicine in these countries.

* Country- and region-specific business strategies

* Asia, South & Central America

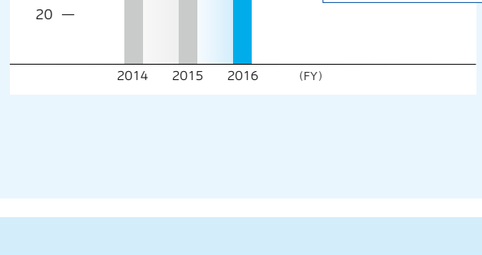
ASCA Company 5-Year Business Plan

- Maintain and expand sales of existing products
- Quickly develop, launch, and expand sales of new products
- Enhance portfolio of products matched to the specific needs of respective regions and countries
- Accelerate product development in China
- Strengthen business capabilities and implement measures targeting growth markets with an eye to fiscal 2021 and beyond

Major Achievements in Fiscal 2016

- Achieved revenue of ¥72.1 billion (down 4.2% year on year)
  Revenue was down year on year due to the impacts of foreign exchange rate movements. Nonetheless, we witnessed steady growth in revenue in each country of operation when calculated on a local currency basis. Factors contributing to this growth included efforts to maximize sales of *Cravit*, *Olmetec*, and other mainstay products as well as the proactive utilization of external resources through alliances (joint sales and promotions) and product in-licensing. In China, specifically, we strengthened coordination with local alliance partners and thereby achieved increases in sales of products including *Cravit*; *Asmeton*, a cough suppressant and expectorant; *Olmetec*; and *Mevalotin*.
- Launched and expanded sales of *LIXIANA*
  In South Korea, where *LIXIANA* saw its first ASCA region launch in February 2016, the share of sales accounted for by this product grew steadily, coming to 15.6% on March 31, 2017. In addition, we were able to release *LIXIANA* in Taiwan, Hong Kong, and Thailand in fiscal 2016.

ASCA Company Revenue
(Billions of yen)



Percentage of Total Consolidated Revenue

Initiatives for Fiscal 2017

- Maximize sales of *Olmetec*, *Cravit*, *Mevalotin*, and other existing mainstay products
- Rapidly grow sales of *LIXIANA*
  Daiichi Sankyo plans to directly introduce *LIXIANA* into the Brazilian market. In countries where we do not possess our own sales bases, this product will be commercialized via alliances with other companies.
- Augment production capacity in China
  In China, following the commencement of a new injectable production line at the Beijing Plant, we have been constructing a new formulation manufacturing building at the Shanghai Plant. In this manner, we plan to augment production capacity in line with the growth of our operations in China.
- Launch other pipelines on schedule
  In addition to *LIXIANA* and other global products, we will focus on launching pipelines that address the needs and regional value of specific countries on schedule.
- Create business opportunities and enhance product portfolio by acquiring and utilizing external resources
  The ASCA Company is working to enhance its product portfolio by acquiring external resources through means such as in-licensing from companies in other countries. In addition, we are forming alliances with local companies in each country of operation and with regard to specific product lines and otherwise utilizing external resources. Through these efforts, we aim to efficiently establish sales networks and increase sales productivity in order to further increase revenue and operating profit.

Examples of CSR Activities

- Cultivation of healthcare workers in China ····· Page 85
- CPR training in South Korea ····· Page 87

Functional Units

R&D Unit

The R&D Unit is tasked with utilizing the R&D capabilities Daiichi Sankyo has fostered over years of operation as a drug discovery-oriented company in order to continuously create innovative pharmaceuticals. Our passion is to develop treatments and preventative methods that can improve patients' health and become global standards of care.

R&D Unit 5-Year Business Plan

- Continuously generate innovative pharmaceuticals changing the standard of care in the primary focus area of oncology as well as the new horizon areas of pain, central nervous system diseases, heart and kidney disease, and rare diseases
- Acquire approval of at least two major indications per year
- Proceed to phase 3 with at least four major indications per year
- Enter phase 1 with at least 9 new molecular entities per year

Major Achievements in Fiscal 2016

- Acquired approval for two drugs
  - *Narurapid Tablet* (immediate-release tablets) for cancer pain (JP)
  - *Narusus Tablet* (extended-release formulation) for cancer pain (JP)
- Submitted applications for two drugs
  - *Hydromorphone Injection* for cancer pain (JP)
  - *PRALIA Subcutaneous Injection Syringe* for rheumatoid arthritis (JP: Application for partial change related to additional indication)
- Began phase 3 clinical trials for two indications
  - *Quizartinib*: Acute myeloid leukemia (first-line treatment)
  - *Esaxerenone* (*CS-3150*): Essential hypertension
- Began phase 1 clinical trials for two new compounds
  - *DS-1001*: Malignant brain tumors (gliomas)
  - *U3-1402*: HER3 positive refractory and metastatic breast cancer
- Other accomplishments
  - Reorganized oncology R&D organizations
    In April 2016, Daiichi Sankyo integrated its oncology R&D organizations, inviting Antoine Yver, an individual with a breadth of experience and an accomplished background in the field of global cancer treatment development, as its leader. This organization, named the Cancer Enterprise, selected two franchises to focus allocation of management resources, antibody drug conjugate (ADC) and acute myeloid leukemia (AML) franchises.
  - Promoted open innovation
    Daiichi Sankyo commenced joint research with Asahikawa Medical University regarding capillary stem cells (CapSCs) in April 2016 and also began research on new immuno-oncology treatments with the National Institutes of Biomedical Innovation, Health and Nutrition in March 2017.
  - *DS-8100* (*Heartcel* cell therapy for ischemic heart failure)
    In May 2016, we concluded an in-licensing agreement with U.K.-based Cell Therapy Ltd. (Celixir at present) granting exclusive development and sales rights for *Heartcel* in Japan.
  - *DS-8201* (anti-HER2 ADC)
    In November 2016, *DS-8201* received Fast Track Designation for HER2 positive metastatic breast cancer from the U.S. FDA.
  - *KTE-C19* (anticancer cell therapy)
    In January 2017, Daiichi Sankyo entered into a strategic partnership with Kite Pharma, Inc., of the United States that grants the Company exclusive rights for development, manufacturing, and commercialization in Japan of *KTE-C19* as well as optional licensing rights for other product candidates, some of which will progress into the clinical development stage over the next three years.

Examples of CSR Activities
- Initiatives based on R&D ethics ····· Page 77
- Good clinical practice and other development-related training ····· Page 106

Initiatives for Fiscal 2017

- Pass major milestones identified for fiscal 2017
- Entrench operation of Cancer Enterprise and activate further
  The R&D Unit will accelerate development and maximize the value of *DS-8201* and other compounds belonging to either the ADC or AML franchise.
- Optimize R&D procedures for cardiovascular-metabolics and other therapeutic areas
- Improve productivity in research, translational research, biomarker and companion diagnostics*, and development
- Enhance portfolio of competitive pipelines
  In-licensing and open innovation activities will be stepped up.
- Efficiently and effectively manage financial and human resources

* Pre-examination to predict the effects and adverse drug reaction risks of specific pharmaceuticals in individual patients

Fiscal 2017 Major R&D Milestone Events

As of August 2017

Project	Indication/Study	Q1	Q2	Q3	Q4	FY18-Q1
Denosumab	Rheumatoid arthritis (JP)	Approved				
Mirogabalin	Fibromyalgia Phase 3 study (US / EU)	TLR*				
	PHN Phase 3 studies (JP / Asia)	TLR				
	DPNP Phase 3 studies (JP / Asia)		TLR			
Pexidartinib	Tenosynovial giant cell tumor Phase 3 study (US / EU)		TLR			Submission
Quizartinib	QuANTUM-R AML 2nd line treatment Phase 3 study (US / EU / Asia)	Interim analysis				TLR
Esaxerenone (*CS-3150*)	Hypertension Phase 3 study (JP)			TLR	Submission	
	Diabetic nephropathy Phase 3 study (JP)			Study initiation		
DS-8201	HER2-positive Breast Cancer (*T-DM1* failure) Phase 2 study (pivotal) (JP / US / EU)		Study initiation			
	HER2-positive Gastric Cancer (*Herceptin* failure) Phase 2 study (pivotal) (JP / Korea)			Study initiation		
U3-1402	EGFRm NSCLC Phase 1 study			Study initiation		
DS-5141	Duchenne Muscular Dystrophy Phase 1/2 study (JP)	SAKIGAKE			TLR	

* Topline results

Major R&D Pipelines (In-House Development Projects, as of August 2017)

Therapeutic area	Phase 1 Conduct trials on healthy volunteers*1 to assess safety of drug, including side effects	Phase 2 Conduct trials on a small group of patient volunteers to assess safety, efficacy, dosage and administration regimen	Phase 3 Conduct trials on a large number of patient volunteers to assess safety and efficacy in comparison with existing drugs	Application
Oncology	■ *DS-3032* (US / JP) (MDM2 inhibitor) ■ *PLX7486* (US) (FMS / TRK inhibitor) ■ *PLX8394* (US) (BRAF inhibitor) ■ *DS-6051* (US / JP) (NTRK/ROS1 inhibitor) ■ *PLX9486* (US) (KIT inhibitor) ■ *DS-3201* (JP / US) (EZH1/2 inhibitor) ■ *PLX73086* (US) (CSF-1R inhibitor) ■ *PLX51107* (US) (BRD4 inhibitor) ■ *DS-8273* (US) (Anti-DR5 antibody) ■ *DS-8201* (JP / Asia) (anti-HER2 ADC) ■ *DS-1123* (JP) (Anti-FGFR2 antibody) ■ *U3-1402* (JP) (Anti-HER3 ADC) ■ *DS-1001* (JP) (IDH1m inhibitor)	■ *Patritumab* (EU) (U3-1287 / Anti-HER3 antibody) ■ *Pexidartinib* (US) (PLX3397 / Glioblastoma / CSF-1R / KIT / FLT3-ITD inhibitor) ■ *DS-1647* (JP) (Glioblastoma / G47Δ virus) ■ *Quizartinib* (JP) (AC220 / AML-2nd / FLT3-ITD inhibitor) ■ *DS-8201* (JP / US / EU) (HER 2 positive breast cancer (T-DM 1 failure)/ Anti-HER 2 ADC)	■ *Denosumab* (JP) (AMG 162 / Breast cancer adjuvant / Anti-RANKL antibody) ■ *Nimotuzumab* (JP) (DE-766 / Gastric cancer / Anti-EGFR antibody) ■ *Vemurafenib* (US / EU) (PLX4032 / Melanoma adjuvant / BRAF inhibitor) ■ *Quizartinib* (US / EU / Asia) (AC220 / AML-2nd / FLT3-ITD inhibitor) ■ *Quizartinib* (US / EU / Asia) (AC220 / AML-1st / FLT3-ITD inhibitor) ■ *Pexidartinib* (US / EU) (PLX3397 / TGCT / CSF-1R/KIT / FLT3-ITD inhibitor)	
Cardiovascular Metabolics	■ *DS-1040* (US / EU / JP) (Acute ischemic stroke / TAFIa inhibitor) ■ *DS-2330* (Hyperphosphatemia) ■ *DS-9231 / TS23* (Thrombosis / α2-PI inactivating antibody)	■ *Esaxerenone* (JP) (CS-3150 / DM nephropathy / MR antagonist)	■ *Edoxaban* (JP) (DU-176b / AF / FXa inhibitor) ■ *Prasugrel* (JP) (CS-747 / Ischemic stroke / Anti-platelet agent) ■ *Esaxerenone* (JP) (CS-3150 / Hypertension / MR antagonist)	■ *Edoxaban* (ASCA*2, etc.) (DU-176b / AF / FXa inhibitor) ■ *Edoxaban* (ASCA, etc.) (DU-176b / VTE / FXa inhibitor)
Others	■ *DS-1971* (Chronic pain) ■ *DS-1501* (US) (Osteoporosis / Anti-Siglec-15 antibody) ■ *DS-7080* (US) (AMD / Angiogenesis inhibitor) ■ *DS-2969* (US) (Clostridium difficile infection / GyrB inhibitor) ■ *DS-5141* (JP) (DMD / ENA oligonucleotide) ■ *VN-0102 / JVC-001* (JP) (MMR vaccine)	■ *Laninamivir* (US / EU) (CS-8958 / Anti-influenza / out-licensing with Biota)	■ *Mirogabalin* (US / EU) (DS-5565 / Fibromyalgia / α2δ ligand) ■ *Mirogabalin* (JP / Asia) (DS-5565 / DPNP / α2δ ligand) ■ *Mirogabalin* (JP / Asia) (DS-5565 / PHN / α2δ ligand) ■ *VN-0105* (JP) (DPT-IPV / Hib vaccine) ■ *Laninamivir* (JP) (CS-8958 / Anti-influenza / nebulizer)	■ *Hydromorphone* (JP) (DS-7113 / Cancer pain / Opioid μ-receptor agonist) <Injection> ■ *Intradermal Seasonal Influenza Vaccine* (JP) (VN-100 / prefilled i.d. vaccine for seasonal flu) ■ *VN-0107 / MEDI3250* (JP) (Nasal spray flu vaccine)

*1 Patient volunteers may be included depending on the tests
*2 Asia, South & Central America

Functional Units

Biologics Unit

Established in April 2017

The Biologics Unit is responsible for all processes spanning for the discovery to the marketing of high-quality and reliable biologics* that are also safe and effective. To fulfill this duty, the Biologics Unit pursues seamless collaboration with R&D and pharmaceutical technology functions in order to determine the optimal forms of modality for drug discovery targets and construct systems for swift and efficient production process development and investigational drug provision.

* Biologics differ from small molecule drugs in that they are derived from genes, proteins, cells, viruses, and other biological mater or utilize biological functions. Daiichi Sankyo is developing such biologics as well as others that include chemically synthesized pharmaceuticals, known as medium-sized molecule compounds, such as nucleic acids, peptides, and other synthesized materials.

Biologics Unit 5-Year Business Plan

- Contribute to accelerating launch of *DS-8201* and other ADC franchise drugs
- Develop manufacturing technologies and accelerate clinical development for biologics
- Discover innovative and cutting-edge forms of modality
- Construct and reinforce technology and human resource platforms for commercializing cell therapies and other biologics

Initiatives for Fiscal 2017

- Prepare for accelerating commercialization of *DS-8201*
- Swiftly launch products under development and enhance technology platforms through promotion of development projects
  The on-schedule supply of antibody drug substances will be pursued to maximize the value of *DS-8201* and other biologics through swift launches and expansion of indications. The Biologics Unit will accumulate experience through these efforts to further enhance technology platforms.
- Deploy advanced multi-modality strategies
  The Biologics Unit will establish competitive and innovative modality technologies for next-generation ADCs, peptides, nucleic acids, and other substances and make contributions to new drug discovery projects through coordination with the R&D Unit. (See table below)
- Construct technology platforms in relation to cell therapies
  The Biologics Unit will undertake the formulation and promotion of concrete plans related to investigation drugs and commercial production processes for *KTE-C19* and other development projects. Also, cell therapy-related platforms will be established by introducing technologies from partners and by drafting development and regulatory affairs strategies.
- Cultivate human resources capable of contributing to diverse biologics drug discovery projects
- Achieve efficient operation of new organization and formulate clear vision for future
  Functions related to biologics will be effectively consolidated within the new organization in order to quickly stabilize its operations, increase the speed and accuracy of decision-making, and flexibly and appropriately allocate resources. At the same time, research productivity will be improved, human resources will be secured and cultivated, and facilities and equipment will be optimized in order to ensure compatibility with cell therapies and the diverse range of other biologics.

Deployment of Multi-Modality Strategies

Modality (Molecule Type)	Strategy
Antibodies	Create foundations for quick launches of *DS-8201* and other biologics and establish innovative and competitive modality technologies for drugs such as next-generation ADCs
Antibody drug conjugates (ADCs)	
Bispecific antibodies Antibodies with two antigen-binding sites enabling them to bind to different types of antigens	Utilize Daiichi Sankyo's globally competitive, original T-cell-activated agonist antibody to cultivate important platforms for conducting drug discovery in the immuno-oncology field
Proteins and peptides Newly designed and prepared proteins and peptides that do not exist naturally in the human body	Expand range of target molecules for drug discovery that possess high specificity and compatibility
	Target development of platform for oral administration modalities for peptides
Nucleic acids (ENA® oligonucleotides, etc.) Natural nucleic acids, which contain DNA, RNA and other genetic information, and modified nucleic acids	Continue trend of *DS-5141*, which utilizes Daiichi Sankyo's proprietary ENA® oligonucleotide technology, to develop pipelines targeting rare diseases
Vaccine and adjuvants	Pursue preventative medicine and treatment benefits through development of adjuvants that are administered together with vaccines to augment their effectiveness
Viruses	Provide innovative treatment methods for previously difficult to treat diseases, such as modifying viruses for therapeutic purposes, administering normally functioning cells to support the functioning of abnormal cells, and utilizing cells from a patient or another individual to treat diseases
Genes	
Cells	

Utilize diverse and innovative modalities to broaden the possibilities for drug discovery

Functional Units

Pharmaceutical Technology Unit

The Pharmaceutical Technology Unit is committed to contributing to product value in terms of ease of use, customer satisfaction, and peace of mind. It thus works to realize a timely supply of the new drug candidates discovered through R&D in the form of investigational drugs. The unit also designs manufacturing processes for realizing consistent manufacturing of high-quality pharmaceuticals.

Pharmaceutical Technology Unit 5-Year Business Plan

- Accelerate and improve efficiency of oncology development
- Enhance key technologies of biologics manufacturing platforms (for ADCs)
- Develop high-value-added formulations, reduce costs, and establish new production methods

- Process technology
- Formulation technology
- Analytical and quality evaluation technology

▶ Develop compounds into pharmaceutical products

Major Achievements in Fiscal 2016

- Provided flexible support for accelerating the development of *DS-8201*
  Close coordination was pursued with the Cancer Enterprise to realize the quick and efficient supply of investigational drugs to support the acceleration of clinical development.
- Developed formulations that accurately address patient needs and improve quality of life
  Applications for manufacturing and marketing approval were submitted for *LIXIANA OD Tablet* (a highly stable orally disintegrating tablet*1 that does not require a drying agent) and *Memary Dry Syrup**2. At the same time, manufacturing and marketing approval was received for *Narurapid Tablets* (immediate-release tablets*3) and *Narusus Tablets* (extended-release tablets*4), two narcotic analgesics that alleviate pain over different periods of times.

  *1 Tablets that dissolve in the mouth without water
  *2 Formulations in the form of granules or powders that become syrups when mixed with water and are thus easy to preserve and transport
  *3 Tablets that immediately release their active ingredient
  *4 Tablet designed to release their active ingredient gradually over time
- Quickly launched *LIXIANA OD Tablet* through strategic application
  A quick launch of *LIXIANA OD Tablet* was achieved by strategic consulting with the authorities and carrying out efficient clinical trials to submit approval applications six months ahead of schedule (in August 2016).

Initiatives for Fiscal 2017

- Advance CMC strategies* and reinforce fundamental technologies for ADC development
  In addition to promoting the transfer of technologies to prepare for commercial production of *DS-8201*, the Pharmaceutical Technology Unit will acquire fundamental ADC technologies and apply these technologies to pipelines. In addition, CMC strategies will be formulated and implemented to facilitate applications and approvals for ADC franchise drugs.

  * Chemistry manufacturing and controls strategies: R&D strategies pertaining to drug substances, formulations, and quality that aim to maximize the value of pharmaceuticals
- Accelerate and improve efficiency of development projects to expand product pipelines
  Accelerate development of anticancer drugs while also enhancing technology management to maximize product value.
- Develop and utilize advanced technologies
  New technologies will be developed and utilized in regard to the manufacture and quality assessment of drug substances and formulations.
- Quickly and effectively launch under-development products to increase earnings
  Supply investigational drugs and transfer manufacturing technologies as required by development strategies in a timely and waste-free manner while steadily submitting applications and receiving approval.

Formulation Technologies Catering to Diverse Needs

LIXIANA anticoagulant
OD tablets (orally disintegrating tablets)
Memary Alzheimer's disease treatment
Dry syrup
▶ Easy-to-use medicine
Tablets that dissolve in the mouth without water
Tablets that are easy to preserve and transport

Narcotic analgesics
Narurapid Tablets (immediate-release tablets)
Narusus Tablets (extended-release tablets)
Oxycodone
▶ Pain control as part of total cancer care
Tablets with different release behavior of API

Examples of CSR Activities

- Incorporation of input from overseas healthcare professionals into formulation development Page 80

Functional Units

Supply Chain Unit

The Supply Chain Unit consistently supplies high-quality drugs to patients around the world by utilizing its advanced technological capabilities to carry out efficient production. In response to changes in product variety, the unit promotes and supports the early launch of new products and the expansion of businesses with existing products.

Supply Chain Unit 5-Year Business Plan

- Transform and rebuild supply chain structures adopted to change the product volume and the product mix in the medium-to-long term
- Advance cost reduction measures globally
- Establish new manufacturing systems and absorb new technologies based on pipeline and life-cycle management strategies
- Optimize inventory and capital expenditure globally
- Contribute to expansion of the opioid analgesics business in Japan

Major Achievements in Fiscal 2016

- **Commenced construction of manufacturing systems for anticancer drugs and biologics**
  Established capital investment and staffing plans for manufacturing Active Pharmaceutical Ingredients (API) and Drug Product (DP) to support biologics, such as *DS-8201* and also for wide-variety, low-volume product of anticancer drugs. These plans were implemented to work toward quick launches of products in these areas.
- **Developed manufacturing and supply systems optimized to specific regions**
  The Hiratsuka Plant of Daiichi Sankyo Chemical Pharma Co., Ltd., completed its final product activities (and is scheduled for closure on September 30, 2017) and the Bethlehem Plant of a U.S. subsidiary was sold. Meanwhile, production facilities were augmented at the Beijing Plant and the Shanghai Plant in preparation for the expansion of operations in China. These moves will enable us to optimize our global manufacturing and supply systems over the medium-to-long term.
- **Achieved stable supply corresponding to *edoxaban* demand forecast**

Initiatives for Fiscal 2017

- **Construct manufacturing systems for anticancer drugs and biologics**
  Based on API and DP equipment investment plans, we will design and commence construction of equipment for product, including wide-variety, low-volume product, of ADCs. At the same time, we will secure human resources for the biologics field and enhance their skills to furnish the foundations for manufacturing systems.
- **Support introduction of *edoxaban* into other countries and maintain stable supply**
  In addition to Japan, the United States, and Europe, manufacturing and supply systems will also be introduced into the ASCA region in order to support the introduction of *edoxaban* into other countries and maintain a stable supply.
- **Contribute to expansion of opioid analgesics business in Japan**
  The Supply Chain Unit will help ease the pain of patients suffering from cancer pain and improve their quality of life by stably supplying opioid analgesics, developing new formulations, and preparing for launches.

Transition to Supply Chain Compatible with Shift to Oncology and Biologics

Changes in Conditions

- Loss of exclusivity for *olmesartan*
- Focus on oncology and other specialty fields

→ **Drastic changes in product mix**
Introduction of new technologies and equipment

Previous → Current → Future

Small molecule drug centered production technologies

- Stable, full-year operation
  Dedicated drug substance plant
  Mass production line for formulations
- No need for containment

Addition of antibodies and ADCs
- Compatibility with biologics
- Shift to wide-variety, low-volume product items (anticancer drugs)

Addition of high-activity substances
- Containment structure design

Support application of advanced technologies to treatments

Examples of CSR Activities
- Sustainable Procurement Promotion ····· Page 77

Functional Units

Quality & Safety Management Unit

The Quality & Safety Management Unit strives to deliver reliable medicines to patients and healthcare professionals around the world. To this end, it strives to ensure product quality and safety for patients, guarantee the accuracy of data and application materials, create information that matches the needs of the medical field, and practice good regulatory affairs compliance.

Quality & Safety Management Unit 5-Year Business Plan

- Continue post-marketing study on *edoxaban* and *prasugrel* to create additional evidence
- Introduce quality risk analysis and evaluation systems for new fields and new technologies
- Strengthen safety monitoring measures and verify effectiveness of safety measures

Major Achievements in Fiscal 2016

- **Steady advancement of safety measures and post-marketing study for innovative pharmaceuticals**
  - Safety measures were advanced by the provision of information to healthcare professionals on the importance of monitoring seasonal blood pressure fluctuations.
  - Safety information was globally collected and identified risks were distributed to Japanese healthcare professionals
  - We sought to reinforce platforms for the practical application of medical database research utilizing big data.
  - Post-marketing study coordinators were introduced, and large-scale studies on *edoxaban* and *prasugrel* were carried out as planned.
- **Improvement of product quality (GMP) and application materials reliability**
  - Quality management systems in factories were reinforced to assure product quality.
  - Audit systems were established to ensure that clinical trials in China were advanced appropriately.
- **Implementation of regulatory affairs measures that contribute to product life-cycle management**
  - Proper regulatory affairs measures were implemented to facilitate new product launches, expand existing products, and maintain stable supplies.
  - Inspections for consistency between marketing approval documents and actual manufacturing process were conducted to confirm that there were no issues that could impact product quality or safety.

Initiatives for Fiscal 2017

- **Steadily advance safety measures and post-marketing surveillance for innovative pharmaceuticals**
  - Appropriate measures will be taken to ensure patient safety.
  - Systems will be constructed to grow oncology field operations into a core business.
  - Medical database research will be accelerated in light of revisions to ordinances pertaining to good post-marketing study practices.
  - Large-scale post-marketing studies on *edoxaban* and *prasugrel* will be advanced steadily.
- **Continue to improve reliability with regard to products manufactured by the Daiichi Sankyo Group (adhere to GMP) and application materials**
  - Quality management systems will be established in preparation for the launch of *DS-8201*.
  - Reinforce quality management systems with a view to the growth of mainstay products and launches of new products.
- **Realize regulatory affairs measures that contribute to product life-cycle management**
  - Appropriate regulatory affairs measures will be implemented to expand usage and ensure stable supplies of existing products on a global scale.
  - Scientific data inspections will be enhanced and compliance measures will be reinforced in response to regulatory affairs-related laws and systems.
- **Support efforts to receive approval for regenerative medicines and establish related systems**

Examples of CSR Activities
- Good vigilance practice training related to pharmaceutical safety ····· Page 106

Functional Units

Medical Affairs Division

The Medical Affairs Division implements a value linkage scheme that connects functions related to the collection, analysis, evaluation, creation, and distribution of information related to pharmaceuticals. Through this scheme, the division strives to maximize product value evaluated as contribution to treatment in the medical field and thereby contribute to the development of medicine.

Medical Affairs Division 5-Year Business Plan

- Conduct large-scale observational studies for *prasugrel* and *edoxaban* and collect clinical evidence
- Create and distribute information on priority drugs and new products based on the Medical Strategies*
- Develop more sophisticated medical affairs systems corresponding to environment changes
- Strive to improve customer loyalty
- Enhance medical information (information related to pharmaceuticals)
- Entrench practice of utilizing Voice of Customer (VOC)

* Strategies for improving product value and establishing and increasing Daiichi Sankyo's market presence that entail identifying clinical questions and creating and distributing information in response to these questions

Major Achievements in Fiscal 2016

- Quickly achieved target enrollment of large-scale observational studies for *prasugrel* and *edoxaban*
- Started new clinical research for collecting clinical evidence in relation to priority drugs
- Established Daiichi Sankyo Medical Library* as a new information distribution tool

  * New tool for distributing medical information to healthcare professionals through the Internet
- Established guidance for Medical Affairs Division staff when interacting with individuals from outside of the Company and conducted education programs to improve compliance
- Formulated grand design for new global systems and decided to appoint medical science liaisons* inside Japan organizations

  * Position responsible for collecting clinical evidence and identifying and answering clinical questions by engaging in medical and scientific discussions with healthcare professionals and researchers and by promoting clinical research and academic activities
- Ranked No. 1 in inquiry responses by pharmacists working in pharmacies utilizing health insurance plans

  * Based on a survey we conducted through an outside private research company

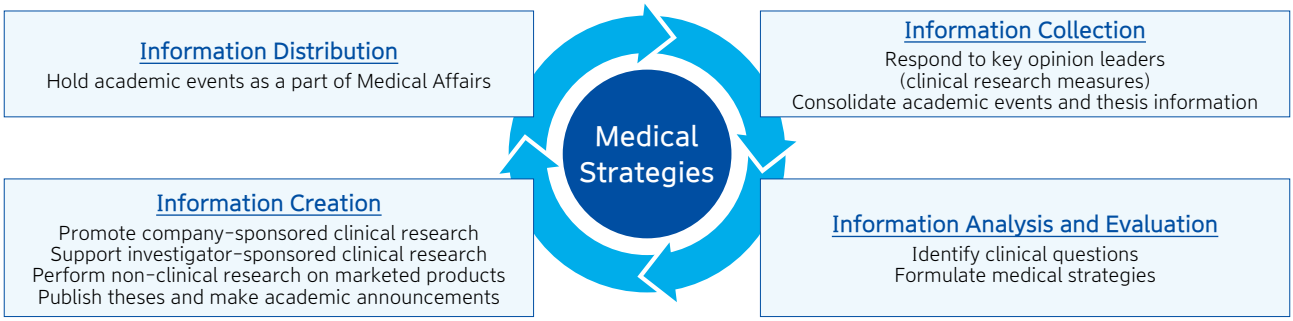
Initiatives for Fiscal 2017

- Create and distribute information based on the enhancement of Medical Strategies for *edoxaban* (domestically and globally)
- Create and distribute information based on the enhancement of Medical Strategies for *prasugrel* and other priority drugs
- Execute measures for reinforcing domestic functions and systems and construct and institute global systems
- Enhance medical intelligence*

  * Meaningful (valuable) information that has been created by collecting, integrating, evaluating, and analyzing medical information
- Continue to be ranked No. 1 in inquiry responses by pharmacists working in pharmacies utilizing health insurance plans
- Examine the possibility of introducing artificial intelligence (AI) technologies to reinforce inquiry response functions

Value Linkage Based on Medical Strategies

Daiichi Sankyo collects, analyzes, and evaluates information to identify clinical questions and then formulates medical strategies for creating and distributing information. Based on these strategies, the Company enhances and steps up coordination between functions related to processes spanning from collection to distribution of information in order to create the value linkage that is essential to medical affairs activities.



Examples of CSR Activities
- Communication with healthcare professionals and patients ····· Page 80