Daiichi Sankyo Group's Value Chain and Organization

Daiichi Sankyo Group's value chain primarily encompasses research & development, biologics, pharmaceutical technologies, supply chain, marketing & sales, medical affairs, and quality & safety management. In conjunction with this value chain, we operate our organization independently while utilizing our unique strengths: Science & Technology, Global Organization & Talent, and Presence in Japan.

R&D Unit P.86

The R&D Unit is responsible for continually uncovering the "seeds" of new drugs and cultivating these seeds into innovative pharmaceuticals by refining them, taking them through pre-clinical and clinical trials, and receiving manufacturing and marketing approval.

Pharmaceutical Technology Unit P.88

The Pharmaceutical Technology Unit supplies high-quality investigational drugs, develops manufacturing processes for the drug substances and formulations needed to stably produce high-quality pharmaceuticals, and adds value to products through means such as making them easier to use.

Supply Chain Unit P.89

The Supply Chain Unit leverages our technological prowess to efficiently manufacture high-quality pharmaceuticals while supporting the swift launch of new products, the stable supply and quality assurance of products, and the ongoing pursuit of cost reductions.

R&D → Pharmaceutical Technology → Supply Chain

Biologics

Marketing & Sales

Medical Affairs

Quality & Safety Management

Japan

Innovative Pharmaceuticals Business: Sales & Marketing Unit P.78

The Sales & Marketing Unit leverages Daiichi Sankyo's strong presence as the No. 1 pharmaceutical company in Japan to develop operations focused on innovative pharmaceuticals (new drugs) that are protected by reexamination periods and by patents during exclusivity periods.

Generic Business: Daiichi Sankyo Espha Co., Ltd. P.79

Daiichi Sankyo Espha Co., Ltd., takes advantage of the reputation for reliability we have fostered as an innovative pharmaceutical manufacturer to develop a generic business centered on authorized generics (AGs).

Vaccine Business P.80

Developing a vaccine business that creates the vaccines needed in Japan and making comprehensive contributions to medicine in Japan through a stable supply of high-quality vaccines.

OTC Related Business: Daiichi Sankyo Healthcare Co., Ltd. P.81

Daiichi Sankyo Healthcare Co., Ltd. is engaged in an over-the-counter (OTC) business that contributes to self-medication and self-care in Japan and Asia through the provision of OTC medicines and skincare and oral care products.

Overseas

Biologics Unit P.87

The Biologics Unit is responsible for promoting research and development as well as developing drug technologies in biologics, which are prepared using genes, proteins, cells, viruses, and other substances derived from biological functions and continuously develops innovative biologics.

Quality & Safety Management Unit P.91

The Quality & Safety Management Unit fulfills the mission of ensuring product quality, patient safety, data and application material reliability, creating information that responds to medical needs and promoting regulatory compliance.

Medical Affairs Unit P.90

The Medical Affairs Unit collects, analyzes, evaluates, creates, and distributes information on pharmaceuticals to maximize the value of Daiichi Sankyo products evaluated as contributing to treatment in the medical field.

Daiichi Sankyo, Inc. (DSUSB*) P.82

DSUSB develops innovative pharmaceutical operations in the United States focused on pain, oncology, and other specialty fields.

* Daiichi Sankyo US Business

American Regent, Inc. P.83

American Regent, Inc., offers an iron injection franchise for treating iron-deficiency anemia as well as a generic injection franchise in the United States.

Daiichi Sankyo Europe GmbH P.84

Daiichi Sankyo Europe GmbH provides innovative pharmaceuticals for cardiovascular, oncology, and other specialty fields in 12 European countries.

ASCA* Company P.85

The ASCA Company develops pharmaceutical operations based on regional value in China, Brazil, South Korea, Taiwan, Hong Kong, Thailand, and other parts of the ASCA region.

* Abbreviation for Asia, South & Central America

Global Management Structure (As of June 18, 2019)

Sunao Manabe
CEO

Naoto Tsukaguchi
General Counsel

Corporate Units

Toshiaki Sai
Corporate Strategy & Management Unit (CFO)

Shoji Hirashima
Global Brand Strategy Unit

Stuart Mackey
Business Development Unit

Hironobu Furuta
Corporate Affairs Unit

Business Units

Japan

Satoru Kimura
Sales & Marketing Unit

Katsuhiko Yoshida
Daiichi Sankyo Healthcare Co., Ltd.

United States

Ken Keller
Daiichi Sankyo, Inc.
American Regent, Inc.

Europe

Jan Van Ruymbeke
Daiichi Sankyo Europe GmbH

Asia, South & Central America (ASCA)

Hiroyuki Okuzawa
ASCA Company

Functional Units

Junichi Koga
R&D Unit

Masayuki Yabuta
Biologics Unit

Hiroto Kashiwase
Pharmaceutical Technology Unit

Junichi Fukute
Supply Chain Unit

Yoshikazu Fukuchi
Medical Affairs Unit

Miyuki Arai
Quality & Safety Management Unit

Innovative Pharmaceuticals Business: Sales & Marketing Unit

Business Units (Japan)

Value Chain (Pharmaceutical Technology)

R&D	Supply Chain	Marketing & Sales	
Biologics		Medical Affairs	
Quality & Safety Management			

The Sales & Marketing Unit delivers a wide range of high-quality innovative pharmaceuticals to patients, ranging from *Lixiana* and other primary areas*1 to specialty areas*2 centered on the oncology products. Taking the perspective of total care centered on patients, we aim to meet the needs of each customer and to contribute to healthcare in Japan by providing relevant information correctly, quickly, and carefully to all healthcare professionals who treat patients with diverse symptoms and conditions.

*1 Drugs mainly prescribed by general practitioners
*2 Drugs mainly prescribed by hospitals/specialists

Satoru Kimura Head of Sales & Marketing Unit

Toward a Trusted Medical Partner.

Based on the BRIDGE's* activity concept, which wants to be a bridge between patients, their families and healthcare professionals by emphasizing the connection between people and providing proper information and providing products, we aim to be recognized us as a reliable medical partner by everyone involved in healthcare. In addition to fostering MRs that can respond to a wide range of information needs that change on a daily basis, we are increasing the number of MRs with cancer-related expertise and raising the level of expertise. In addition, each employee strives to improve the correct understanding of dementia and cardiac diseases, and promotes to take training courses for supporters of dementia and to obtain a certification in lifesaving skills.

* Bright Days Together

BRIDGE
Bright Days Together

Progress in Medium-Term Management Planning of Pharmaceutical Sales Units.

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Enhance Daiichi Sankyo's reputation as a trusted medical partner by improving information provision activities based on the BRIDGE concept	**MRs ranked No. 1 for the seven consecutive year** • Ranked No. 1 in Japan in an overall assessment of MR activities in both the entire market and the hospital and general practice market categories in the survey conducted by an external organization* • In the entire market category, we have maintained the top ranking for seven consecutive years since fiscal 2012 * A survey by ANTERIO Inc. Evaluation of knowledge, information, humanity and responsiveness	**Maintain MR No.1 ranking with high-quality information provision** • Implement MR activities that contribute to the realization of medical care that all involved in medical care thinks by providing corrected information to patients, their families and medical personnel
	All MRs passed the certificate test for the ninth consecutive year • All MRs have passed the certificate test for the ninth consecutive year since fiscal 2010 (Total pass rate in fiscal 2018: 75.9%)	**All MRs pass the certificate test for the tenth consecutive year** • All MRs pass the test through the implementation of high-quality introductory training
Maximize revenue by promoting field and product strategies	**Domestic prescription drug share ranked No.1 for third consecutive year** • Ranked No.1 in Japanese prescription drug share for three consecutive years due to expansion of *Lixiana* and other major products	**Expand major domestic products and early market penetration of new products** • Achieve sustainable growth through further sales expansion of major products, mainly *Lixiana*, and early market penetration of new products
Construct systems and functions in response to environmental changes	**Established sales networks in the specialty care area** • Established a domestic sales networks and information provision system to meet the market introduction of specialty products centered on cancer products, and the launch of new large-scale products such as Tarlige and Minnebro	**Establish an operating structure that can respond to total care** • Establish an operating structure to further increase the level of expertise based on an internal oncology certification system and to respond to the total care of patients waiting for treatment
Promote a multichannel approach	**Utilized multichannel approach to meet individual needs** • In response to the diverse needs of healthcare professionals, a multichannel approach using lectures, web seminars, internet, etc. through MRs gained a high evaluation (which is well retained in the memory of physicians) in the survey* on promotion by external organizations * ANTERIO Inc.	**Provide accurate information to all healthcare professionals** • Build a multi-channel system that enables MRs to conduct activities in accordance with the needs of physicians, pharmacists, nurses, and other healthcare professionals in charge of team medical care, and provide accurate and quick information

Generics Business: Daiichi Sankyo Espha Co., Ltd.

Daiichi Sankyo Espha takes pride in being as an innovator in the domestic generic pharmaceutical industry and provides authorized generics (AGs)*, or a new standard for generics featuring formulation, labelling, and packaging innovations that are easy to swallow but hard to swallow accidentally based on the quality-level and stable supplies of Daiichi Sankyo groups. Through a promotion of the newly launched anticancer AG drug, we will create an environment where those who need generic drugs can use with peace of mind, while addressing various needs, in order to contribute to national medicine.

* Authorized generic (AG): a generic drug manufactured after receiving approval from the brand-name pharmaceutical

Kentaro Murakawa **Daiichi Sankyo Espha Co., Ltd. President**

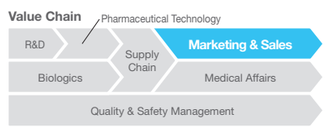
Packaging that reduces the risk of accidental ingestion and can safely carry drugs

Daiichi Sankyo Espha is working on devises for formulation and packaging labels to prevent medical adverse events due to errors in taking drugs. Since there have been cases in which relatively high-risk drugs such as anticancer drugs are accidentally taken by families other than patients, especially small children, we have developed an external case for PTP sheets (named C-guard/child-guard) for the purpose of preventing children from taking the drugs by mistake and preventing drug miscontact and pop-out.

Progress of Daiichi Sankyo Espha's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Strengthen the authorized generic (AG) lineup	**Launched AGs with 3 new active ingredients** • Launched *levofloxacin* intravenous infusion/infusion bag in June 2018 and *gefitinib* tablets and *silodosin* tablets/OD tablets in March 2019 • Expanded our product portfolio to 185 products portfolio with 73 active ingredients (product portfolio for AGs expanded to 25 products with 8 active ingredients)	**Expand product portfolio focused on AGs** • Evolve from "Daiichi Sankyo Espha of AG" to "Daiichi Sankyo Espha of AG with competitive advantage in oncology" • As AG portfolio for anticancer drugs, add 3 active ingredients: bicalutamide tablets/OD tablets, anastrozole tablets, and tamoxifen tablets
Steadily launch AGs and other day-one generics* and gain market shares * Day-one generics: Generic drugs launched on the first day that sales of a generic is possible	**Expanded market share with new products, including AGs** • In addition to AG products launched in fiscal 2017, we also earned the top share in the target market for newly launched AG products • 5th position in the domestic generic pharmaceutical sales ranking	**Promote anticancer AGs** • As AG leading company, expand market share by maximizing trust and expectations from patients, healthcare professionals, and the administration for AG and Daiichi Sankyo Espha through the promotion of anticancer AGs
Step up coordination with partners in Japan and overseas	**Strengthen coordination with partner companies based on changes in the market environment** • Strengthened coordination with contract manufacturers and promoted cost reduction efforts by changing ingredients and streamlining manufacturing	**Promote management efficiency in response to changes in the market environment** • Promote management efficiency through further efforts to reduce cost and reduce costs by strengthening cooperation with contract manufacturers in response to changes in the market environment

Vaccine Business



In April 2019, the functions of Kitasato Daiichi Sankyo Vaccine (KDSV) like manufacturing and production technologies were transferred to Daiichi Sankyo Biotech, and the functions like R&D, quality & safety, and sales & marketing were transferred to Daiichi Sankyo. In addition, a portion of the Japan Vaccine business was transferred to Daiichi Sankyo to integrate dispersed vaccination functions. Daiichi Sankyo, as a manufacturer and distributor of vaccines, is more closely related to healthcare organizations and the government than ever before. By further improving stable supplies and quality levels, we aim to contribute more and more to the healthy lives and well-being of people.

Toshiaki Tojo, Ph.D. **Head of the Vaccine Business**

Technical collaboration on MR-vaccine* manufacture in Vietnam.

KDSV participated in the MR Vaccine Manufacturing Technology Transfer Project in JICA for five years until March 2018, and contributed to the domestic manufacturing and stable supplies in Vietnam by implementing manufacturing technology transfer to Vietnam's Vaccine Public. In October 2018, activities received the 14th JICA President's Award and the 70th Health and Cultural Award. We also donated these awards to Saitama Prefecture's National Midori Fund, where Daiichi Sankyo Biotech is located, to contribute to the conservation of surrounding natural environments. We also contributed to global medical activities by donating to medical institutions implementing medical activities in Vietnam.

* Measles rubella combination vaccine

Progress of the Vaccine Business's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Stable supply of vaccines Establish a stable supply system Awareness and dissemination of vaccines	**Stable supply of vaccines** • Supplied seasonal influenza vaccine before the influenza season by the effort to reduce lead time utilizing flexible shift production structure **Building a stable supply base** • By improving the production method and establishing a system to increase production, a rapid supply system for MR vaccine is established in the event of an outbreak of measles rubella in response to the national measures for measles rubella	**Stable supply of vaccines** • Supply the necessary and sufficient quantity of seasonal influenza vaccines before the influenza season by continuing measures for production efficiency and ensuring greater numbers of vaccines • Supply MR vaccines in response to demand by utilizing the increased production system implemented in fiscal 2018 **Awareness and dissemination of vaccines** • Support for awareness and dissemination provided by healthcare professionals to ensure that children and families who are vaccinated are reassured
Complete the establishment of a development and production system for pandemic influenza vaccines* and maintain production systems in preparation for future pandemics * Open application project spearheaded by the Ministry of Health, Labour and Welfare to establish a production system and secure venues for supply	**Establishment of a pandemic influenza vaccine production system** • Improved production methods for pandemic outbreaks were established, and the supply system for 40 million people within half a year could not be improved, but the public recruitment project was completed • Conducted a training in preparation for pandemic outbreaks in established manufacturing methods	**Maintenance of a pandemic influenza vaccine production system** • Establishment of a business system to prepare for pandemic outbreaks • Education of personnel and development of action plans in the event of a pandemic
Develop and encourage early market penetration of new influenza vaccines expected to be more effective and new, highly convenient combination vaccines	**Promotion of development themes** • Preparing for launch of nasal spray live attenuated influenza vaccine • Started manufacturing of a convenient trivalent combination vaccine for measles, mumps, and rubella (MMR vaccine) for clinical trials and stability testing	**Promotion of development themes** • Preparation for launch of nasal spray live attenuated influenza vaccine and establishment of supply system • Accelerating development by transferring development of MMR-vaccines from Japan Vaccine to Daiichi Sankyo

OTC Related Business: Daiichi Sankyo Healthcare Co., Ltd.

Business Units (Japan)

Value Chain — Pharmaceutical Technology

R&D | Supply Chain | Marketing & Sales

Biologics | Medical Affairs

Quality & Safety Management

Daiichi Sankyo Healthcare handles a wide range of OTC drugs*, including skin care cosmetics and oral care products. Among the Daiichi Sankyo groups, OTC is a unit that is closer to customers more broadly. By promoting self-medication and self-care through the contact and communication with customers, we will contribute to improving the quality of life (QOL) of many people who wish to be healthier and more attractive.

* OTC drugs available in pharmacies, drug stores, etc.

Katsuhiko Yoshida Daiichi Sankyo Healthcare Co., Ltd. President

"Be more familiar with the use of medicines" A website that uses portals and is more familiar to consumers

With the evolution of digital environments, we provide an easy-to-understand introduction to the company website about signs of familiar symptoms, how to deal with self-care, and points to go to the hospital, in keeping with the era of solving daily questions and shopping on smartphones. We also provide a contact point for people who are unaware of their symptoms and who are encouraged to manage their health. (Drug and Health Information Office as a portal, Health and Beauty School for Women, and *Orekara* for Men) The Store Search page allows you to search the nearest store that handles the desired product, and the Q&A allows you to check the detailed information about the product.

Progress of Daiichi Sankyo Healthcare's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Improve product brand value in the OTC business	**Expansion of key brands** • Expanded key brands, including *Lulu*, *Loxonin S*, and *Transino* • Established a new brand *Breath Labo* (medicinal toothpaste) and added a new line such as *MINON Men* to address a wide range of lifestyle needs	**Accelerate growth of skin care and oral care business** • Accelerate growth of *MINON*, *Transino*, *Clean Dental*, and *Breath Labo* **Continue growth in the OTC business** • Strengthen mainstay brands such as "*Lulu*" and "*Loxonin S*"
Accelerate the growth of the direct marketing business through leveraging synergies with Im Co., Ltd., in the direct marketing business	**Expansion of key brands** • Breakthrough in the second year of launch of the female aging care brand BRIGHTAGE • Launched of Regain Triple Force	**Expansion of direct marketing business** • Maximize the BRIGHTAGE branding power • Challenge to the new area • Further extension of the RICE FORCE
Achieve independent of overseas business	**Expanding the mainstay brand *MINON Amino Moist*** • Expanded the number of sales stores in China • Launched in Hong Kong • Expanded sales during the second year of launch in Taiwan	**Strengthening operations in China, Hong Kong and Taiwan** • Further expansion of the *MINON* brand as a whole • Increase the number of marketed products • Further promote by strengthening inbound efforts
Strengthen operating foundations to ensure responsiveness to market environment changes	**Strengthening the foundation to respond to changes in the needs of customers** • Promoted continuous value creation based on perspectives originating from customers utilizing the functions of the CS* Department and the Product Strategy Department • Increased the number of site visitors by continuous improvement of Daiichi Sankyo Healthcare corporate website * Abbreviation of Customer Satisfaction	**Establishment of business infrastructure to respond to environmental change** • Collect customer's voice and respond in timely manner in various ways • Streamline existing works by using AI and shift manpower to more creative works

Daiichi Sankyo, Inc. (DSUSB*)

* Daiichi Sankyo US Business

Business Units (United States)

Value Chain — Pharmaceutical Technology

R&D | Supply Chain | Marketing & Sales

Biologics | Medical Affairs

Quality & Safety Management

The year 2018 was another successful year of transformation for Daiichi Sankyo, Inc. We have taken great strides toward our goal of becoming a leader in oncology in the U.S. by building new teams with deep and broad cancer expertise. Our new structure will allow us to maximize our in-line medicines as we prepare to launch our oncology portfolio. *Injectafer* stands out as our growth driver with increased sales across all customer types and continues as the #1 iron therapy in oncology clinics by dose volume and the fastest growing iron therapy in the U.S.

Ken Keller Daiichi Sankyo, Inc. President and CEO

Patient advocacy Initiatives

At Daiichi Sankyo, Inc., we believe our business extends beyond the discovery and development of therapies for unmet medical needs. It's our mission to make a positive difference in the communities where we live and work. Our philanthropic initiatives help people identify, prevent and manage illness. In 2018, examples include support for Americares, World Cancer Day, Zufall Mobile Health Van, Myelodysplastic Syndromes Foundation, and the Leukemia & Lymphoma Society.

Daiichi Sankyo, Inc. employees at the 2018 "Light the Night" fundraiser for the Leukemia & Lymphoma Society

Daiichi Sankyo, Inc. 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Build and grow oncology capabilities	**Building awareness of our portfolio** ***Injectafer*** • With new initiatives, *Injectafer* grew not only within the hematology/oncology market – where it is still the market leader – but also overall in new areas of patient need. • In 2018 we launched our first direct-to-patient promotional campaign driving thousands of new potential patients to speak with their HCPs about Iron Deficiency Anemia (IDA), including our Get Iron Informed campaign with celebrity IDA patient. **Oncology** • Our medical teams have been incredibly responsive to healthcare providers seeking to learn about the mechanisms-of-action and data released to date for our oncology portfolio. • We have also recruited top talent into the organization to launch our new cancer therapies once approved, many with more than a decade of experience with leading oncology companies.	**2019 Is our inflection point** ***Injectafer*** • We plan to grow *Injectafer* even further by building our share of voice to meet GI and Ob/Gyn customers' needs. **Oncology** • Upon approval, we will launch *pexidartinib* offering certain TGCT patients with the first systemic therapy for this progressive and often debilitating disease. • With the planned filing of [fam] *trastuzumab deruxtecan* (*DS-8201*) BLA in 2019, we will prepare to successfully launch this medicine into the breast cancer space with our new collaborator, AstraZeneca. • We will focus on securing payer coverage and implement patient reimbursement support services for all of our medicines.
Grow pain business	**Tackling challenges head on** • For *MorphaBond* and *Movantik* we maintained formulary coverage and access. • Our team remained resilient and adaptable to address challenges and to ensure all appropriate patients have access to our pain portfolio. • With the continued dialogue with the U.S. FDA regarding *RoxyBond*, our commercial organization continued focus on growing *Movantik* and *MorphaBond* ER.	**Offer abuse deterrent options** • We will seek growth of both *Movantik* and *MorphaBond*. • In 2019 we plan to launch *RoxyBond* to offer an abuse deterrent formulation of a widely prescribed opioid and seek to be part of the solution to opioid misuse and abuse.
Maximize profit for mature products through LOE* timeframe *Loss of exclusivity	**Balancing investments** • We maximized revenue for *Welchol* despite generic entry. • We have implemented innovative programs that reduce costs dedicated to our mature products while also ensuring our customers' needs are met.	**Maintain access and shift resources** • We will continue to ensure patients have access to our mature medication while continuing to shift resources to our new portfolio.

American Regent, Inc.

Business Units (United States)

Value Chain: Pharmaceutical Technology — R&D, Supply Chain, Marketing & Sales, Biologics, Medical Affairs, Quality & Safety Management

American Regent, Inc. is a developer, manufacturer, and distributor of diversified pharmaceutical products. We have a long history of supplying high quality injectable generics, branded IV iron, and veterinary medicine drugs to the US marketplace. Our growing business generates over $1 Billion dollars in revenue and is a highly profitable unit within Daiichi Sankyo. Taking advantage of our capabilities to develop difficult-to-manufacture and complex generics, we continue to launch competitive products. Our broad portfolio of more than 30 marketed products is constantly evolving to meet our customers needs.

Ken Keller **American Regent, Inc. President and CEO**

Communication with community

At American Regent, Inc., we strive to make a positive impact in our communities. In FY2018, our company and our employees participated in numerous events to make a difference in the neighborhoods in which we work and live. Such examples include participating in Habitat for Humanity, which provide adequate and affordable housing, the Take Steps–Crohn's and Colitis Foundation walk, and our annual Holiday Adopt an Angel program.

American Regent, Inc. employees at "Habitat for Humanity"

American Regent 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Build *Injectafer* into flagship product and market leader	**Secured market leader position** • Our IV iron franchise is the #1 leader in the United States market, dominating market share with over 70% of all dollars in this category. Our two products, *Injectafer* and *Venofer*, are highly valued by our customers. We are focused on both protecting this business and expanding the appropriate use of IV iron into new therapeutic areas of iron deficiency in Heart Failure patients, as well as growing penetration into IDA in women's health and gastroenterology. **Achieved revenue target** • *Injectafer* achieved a record revenue level of $399 million, an increase of 29% over the previous year. Continued collaboration between American Regent, Inc. and DSUSB was a main driver of the growth of *Injectafer* in spite of increasing competitive pressure.	**Continue market leadership for *injectafer*** • *Injectafer* revenue target in FY2019 is $418 million, +$20M versus prior year despite increasing competitive threats. Growth drivers are; - Increased share of voice to meet GI and OB/GYN customer needs - Continued awareness among dissatisfied oral iron patients **Accelerate life cycle management** • HEART-FID clinical study is ongoing. Study will assess the efficacy and safety of iron therapy using *Injectafer* relative to *placebo* in treating patients with heart failure, iron deficiency, and a reduced ejection fraction.
Expand generic injectable portfolio with a variety of products to support customer needs	**Bring new products to market** • American Regent successfully launched 7 new products in FY2018: *Neostigmine, Sterile Water, Hydroxyprogesterone Caproate, Fomepizole, Testosterone Cypronate, Aminocaproic Acid* and *Droperidol*. **Achieved revenue target** • FY2018 actual American Regent generic injectable portfolio revenue exceeded budget and continued to deliver year on year growth.	**Expand generics portfolio** • American Regent plans to launch between 6 and 8 new products in FY2019. These product launches, coupled with American Regent's existing portfolio, will help to drive growth in the face of increasing competition in some key categories. • Continued focus and investment in product development and NDA/ANDA /505B2 filing efforts along with enhanced contracting strategies with GPOs and new evolving players entering the market will help to increase revenue going forward. **Capital expansion investment underway** • American Regent's capital expansion investment of approximately $200M across three manufacturing sites is underway and on-track. When completed, this investment will provide robust, state of the art manufacturing capabilities that will enable us to continue to meet the needs of our patients and customers.

Daiichi Sankyo Europe GmbH

Business Units (Europe)

Value Chain: Pharmaceutical Technology — R&D, Supply Chain, Marketing & Sales, Biologics, Medical Affairs, Quality & Safety Management

FY2018 was a very successful year for Europe. *LIXIANA*® is continuously increasing its market share and we in-licensed *bempedoic acid* for patients who need additional LDL cholesterol lowering after maximum tolerated statin therapy. If authorized the new product will be a synergistic addition to our cardiovascular portfolio.
We also established an effective commercial oncology organization to successfully launch our oncology products in Europe.
For both business areas we continue to work on our aspiration to become the benchmark for customer centricity and have implemented many projects and processes to achieve this goal.

Jan Van Ruymbeke, MD. **Daiichi Sankyo Europe GmbH Managing Director, CEO**

Mycancertherapy.eu: Video portal for patients with cancer

Mycancertherapy.eu provides information in 16 different languages. It aims to help patients overcome barriers – often due to medical jargon, foreign language and a sense of being overwhelmed after a cancer diagnosis – in understanding their therapy journey.
Leading HCPs answer the most frequent patient questions in their native tongue on the main aspects of cancer treatment, including side-effects or types of treatment. The website supports physicians in patient education as it enables patients to have the most important information about cancer explained to them by experts at home.

website: Mycancertherapy.eu

Daiichi Sankyo Europe 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Maximize *LIXIANA's* potential	**Increasing market share** • Since 2015 we launched *LIXIANA*® in all our European affiliates except for France and keep growing market shares. • As a result, our EU market share in March 2019 is more than 12% (exit share in DOT – days of treatment – for the month). • To leverage our cardiovascular success and heritage we have in-licensed *bempedoic* acid for patients who need additional LDL cholesterol lowering.	**Brand refinement** • We have defined a new single-minded proposition for *LIXIANA*®: "Your choice for the elderly NVAF patients" is rolled-out across all European markets. • FY2019 is also the year we prepare for the launch of *bempedoic acid* foreseen in Q2 of FY2020. Launch preparations will build on the capabilities, synergies and learnings from the *LIXIANA*® introduction.
Establish oncology business	**Thorough preparation for launches** • The European commercial organization is set up well to successfully launch our oncology products. • We have hired talented professionals for medical, market access, marketing, field force and other functions. • Our focus on customer centricity enables us to cater to the needs of the full set of stakeholders who contribute to patient care, among them oncologists and hematologists.	**Launching with excellence** • Our focus this year is the successful launch of *VANFLYTA*® in early 2020. Together with our partner AstraZeneca we are also preparing for the launch of *DS-8201*.
Develop organization to further evolve into specialty care provider	**Adapt to upcoming oncology portfolio** • With the build-out of our oncology division over the last years, we have set the ground for future launches. • At the same time we have further adapted our customer-facing roles to the needs of a specialty care environment.	**Focus on patients' and customers' needs** • We are constantly evolving our organization to adapt to the changing healthcare environment. • In FY2019, we keep focusing on how to best meet patients' needs as well as provide our stakeholders – e.g. HCPs, payers – with solutions for their requirements in both the cardiovascular and oncology field.

ASCA* Company

* Asia, South & Central America

Business Units (Asia, South and Central America)

The keywords concerning the growth of ASCA Company are “China”, “*LIXIANA*”, “Business Development” and “Oncology business”. In China, we aim to ensure growth and improve profitability by strengthening the business structure. For *LIXIANA*, we will take full advantage of the customer relationship that we have established for *Olmesartan* and synergze both products. Regarding Business Development, we will explore new markets by in-licensing local products and establishing DS own companies. We will also build a business infrastructure and prepare for launch in China, Brazil, and other countries with a large market for oncology products in order to quickly deliver promising new drugs in the future.

Hiroyuki Okuzawa **ASCA Company President**

More women playing active roles in ASCA Company

ASCA Company has affiliates in Asia and South and Central America, and is operating its business there. ASCA Company, whose operation is supported by approximately 2,100 employees, has improved women’s empowerment; women comprise more than 50% of its workforce, and women occupy more than 40% of managerial positions. For example, in Daiichi Sankyo Taiwan, the President is a woman, and in addition, half of the senior members are women. We will make medical contributions matched to the specific needs of each country by promoting management based on Diversity and Inclusion, including women’s empowerment.

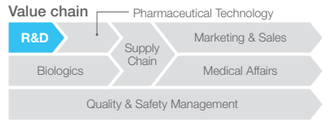
Daiichi Sankyo Taiwan senior members
President Sheron Lin (third from left)

Progress of ASCA Company’s 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Maintain and expand sales of existing products and quickly develop, launch, and expand sales of new products	**Achieved revenue of ¥87.7 billion (up 9.0% year on year)** • Existing mainstay products including *OLMETEC* and *CRAVIT* steadily grew in each country where they are marketed. In China, the revenue increased by 9% compared with the previous year, and challenges for optimizing alliance models with partners were extracted and countermeasures were implemented • *LIXIANA* grew to DOAC market share No.1 per month in South Korea, and Taiwan also continued to expand market share. In addition, it was launched in Brazil, and launched in Saudi Arabia and Indonesia through partners • Launched *SEVIKAR* in China and *EFIENT* in Taiwan	**Achieve revenue ¥100 billion (up 14.1% year on year)** • Implement strategies that maximize the potential of the Chinese business (expanding own marketing territories to increase profitability) • Expand further revenue of *LIXIANA* in each country and implement initiatives in collaboration with various functions such as Marketing and Medical Affairs for launch and expansion in China • Launch *LOXONIN TAPE* in Brazil
Enhance portfolio of products matched to the specific needs of respective regions and countries	**Expanded the product pipelines** • Launched *LATUDA*[*1] in Brazil • In-licensed *PENTHROX*[*2] in China, Thailand and Vietnam • Started a promotion for *Omacor*[*3] in South Korea • Obtained a marketing approval for *LIXIANA* in China *1 Antipsychotic agent in-licensed from Sumitomo Dainippon Pharma *2 Non-opioid pain agent in-licensed from Medical Developments International *3 Treatment for dyslipidemia that has signed a co-promotion agreement with Kuhnil	**Enrich product portfolio** • Promote preparations for commercialization of *PENTHROX* • Out-license *LIXIANA* in countries where we do not have affiliates and create business development opportunities
Strengthen business foundation and implement measures targeting growth markets in fiscal 2021 and beyond	**Considered a plan to establish new own sales companies** • Considered establishment of bases in countries and regions that do not have our group‘s own sales companies in line with the enrichment of the oncology pipeline	**Further strengthen business foundation** • Design functions and organizations and promote talent acquisition for oncology business • Continue to consider establishing own sales companies in ASEAN countries, Oceania, and Latin America in order to expand the oncology business and existing products such as *LIXIANA*

R&D Unit

Functional Units



The R&D Unit developed “R&D2025” Vision at the end of 2017, which includes seven new compounds launches in the oncology area and five new compounds launches in the Specialty Medicine area by 2025, and has made every effort to achieve this vision. We will accelerate the development of *DS-8201* through co-development with AstraZeneca, and will make use of that experiences to development of the entire oncology area. We will also build new pillars to support us next to the oncology area by challenging the therapeutic applications of innovative and diverse modalities such as nucleic acid drugs and cell therapies, leading to generate innovative pharmaceuticals which will change SOC*.

* Standard of Care. The best and widely used treatment in modern medical.

Junichi Koga, Ph.D. **Head of R&D Unit**

“COMPASS” navigator for drug discovery required by patients

The R&D division conducts activities called COMPASS, which links the R&D field to the medical field. The activity name, COMAPSS, is derived from the “Compassion for Patients Strategy” and is meant to be a “compass” for drug discovery based on patient needs. COMPASS develops three initiatives with the concepts of A (Alliance): know from activities in collaboration with patients’ organizations; B (Bedside): realize medical needs from experiences in healthcare settings; and C (Communication): learn from lectures and dialogue style conferences. We aim to achieve “patient-oriented drug discovery” through opinion exchanges with patient organizations and healthcare professionals, lectures, and hospital training to see the field of medical care.

COMPASS C activity landscape

Progress of the R&D Unit’s 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Become a leader of Antibody-drug conjugates	***DS-8201*(HER2-ADC)** • HER2 positive metastatic breast cancer 3rd line - Completed pivotal phase 2 study enrollment - Initiated phase 3 study • Initiated HER2 positive metastatic breast cancer 2nd-line vs T-DM1 phase 3 study • Initiated HER2 low breast cancer phase 3 study • Initiated lung cancer phase 2 study • Initiated phase 1 study of combination with immune checkpoint inhibitor	***DS-8201*(HER2-ADC)** • Submit BLA/NDA (US/Japan): HER2 positive metastatic breast cancer 3rd-line • Complete pivotal phase 2 study for gastric cancer (JP) • Initiate phase 2 study for gastric cancer (US/EU) **Other ADC franchises** • Prosecute *U3-1402* (HER3-ADC) phase 1 study • Prosecute *DS-1062* (TROP2-ADC) phase 1 Study • Initiate phase 1 studies for *DS-7300* (B7-H3-ADC) and *DS-6157* (GPR20-ADC)
Establish a hematology cancer franchise	***Quizartinib* (FLT3 inhibitor)** • Submitted NDA (JP/US/EU): relapsed/refractory AML • Designated as breakthrough therapy (US) and as orphan drug (JP)	***Quizartinib* (FLT3 inhibitor)** • Obtain approval (JP/US/EU): relapsed/refractory AML • [Obtained approval in June (JP), recieved complete response letter (CRL) in June (US)]
Become a leader in breakthrough science in the oncology area	• Submitted NDA of *pexidartinib* (US/EU): tenosynovial giant cell tumor • Initiated phase 2 study of *Axi-Cel*® (CAR-T) (JP) and designated as orphan drug (JP) • Initiated phase 1 study of *DS-1205* (AXL inhibitor) • Completed phase 2 study of *DS-1647* (G47Δ) (JP)	• Obtain approval for *pexidartinib* (US): tenosynovial giant cell tumor • Submit NDA of *DS-1647* (G47Δ) (JP): Glioblastoma • Prosecute phase 1 study of *DS-3201* (EZH1/2 Inhibitor) [SAKIGAKE designation in April (JP)]
Maximize near-term revenue and grow future franchises in the specialty medicine area	**Maximize near-term revenue** • Obtained approval of *esaxerenone* (JP): hypertension • Obtained approval of *mirogabalin* (JP): peripheral neuropathic pain • Submitted NDA of *Inavir nebulizer* (JP): influenza virus infections	**Maximize near-term revenue** • Prosecute phase 3 study of *mirogabalin* central neuropathic pain (JP) • Obtain approval of *Inavir nebulizer* (JP): influenza virus infections **Grow future franchises** • Prosecute phase 1/2 study of *DS-5141* (JP)

Biologics Unit

Functional Units

Value chain — Pharmaceutical Technology

R&D	Supply Chain	Marketing & Sales
Biologics		Medical Affairs
Quality & Safety Management		

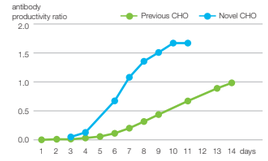
The Biologics Division is responsible for promoting the development of Daiichi Sankyo biologics from the viewpoint of technologies; by rapidly developing the required technologies, from molecular designing to commercial manufacturing of biopharmaceuticals that are diversifying, including antibody pharmaceuticals and other proteinaceous pharmaceuticals, biological materials such as therapeutic cells, synthetic oligo nucleic acids and peptides. In addition, we aim to become a hub for the development of advanced biotechnology and the development and supply of in-house biotech human resources, and to be a driving force for sustainable company growth.

Masayuki Yabuta, Ph.D. **Head of Biologics Unit**

To develop highly productive expression systems in novel CHO cell line*1

In the manufacture of antibody drugs, long-term cell culture is one of the high cost factors of antibody drugs. Daiichi Sankyo has participated in the Manufacturing Technology Association of Biologics, so-called MAB, supported by the(AMED*2 and MITI*3), and successfully obtained novel CHO cell line with high growth performance. In addition, a new CHO cell expression system developed by combination with an in-house developed vector showed about three times higher antibody productivity than the previous system. In the future, we will achieve rapid and low-cost manufacturing by applying it to the production of biopharmaceuticals, and we hope that this cell will be widely used in other companies by the collaboration with MAB

Three times higher antibody productivity (ratio to previous system)



*1 Cell lines derived from Chinese hamster ovary cells. It is widely used in the manufacture of antibody drugs.
*2 Japan Agency of Medical Research and Development *3 the Ministry of Economy, Trade, and Industry

Progress of the R&D Unit's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Contribute to accelerating the launch of *DS-8201* and other ADC franchise drugs	**Establish commercial manufacturing process of antibodies for *DS-8201*** • Established antibody manufacturing process for commercialization • Completed technology transfer to group companies responsible for commercial manufacturing • Started discussion on manufacturing process for large-scale manufacturing	**Establish commercial manufacturing process for *DS-8201*and ADCs** • Conduct actions for NDA of *DS-8201* • Continue discussion on manufacturing process for large-scale manufacturing • Develop manufacturing process for antibody part of ADC franchise
Develop manufacturing technologies and accelerate clinical development for biologics	**Develop cutting-edge technologies and apply them to development candidates** • Developed in-house manufacturing technology (cell, culture medium, purification method, etc.) • Developed new biologics by in-house technology and developed manufacturing process	**Develop cutting-edge technologies and apply them to development candidates.** • Develop antibody manufacturing process by using novel CHO cells. • Establish strategic antibody manufacturing alliance including group companies for clinical/commercial provision • Utilize in-house technology for the manufacture of various modalities
Discover innovative forms of modality* *The foundation of drug development and therapeutic approaches such as protein drugs, nucleic acid medicine, cell medicine and regenerative medicine including low molecular compounds, peptide (middle molecule)	**Create new modalities** • Determined the development of nucleic acid pharmaceuticals with DDS (Drug Delivery System) functions • Determined the development of original protein scaffold as pharmaceuticals. • Expanded collaboration with Zymeworks on bispecific antibodies • Determined the development of lipid nanoparticle-mRNA (LNP-mRNA) for the novel immunotherapy against HPV-associated neoplasia/cancers.	**Create new modalities** • Expand and optimize various modalities such as glycoengineered antibodies, cyclic peptides, and protein scaffolds and extend the application area • Build basic infrastructure for gene therapy research • Promote development of LNP-mRNA vaccines/ immunotherapies
Construct and strengthen technologies and human resource infrastructure that support commercial-ization of biologics including cell therapies	**Promote cell therapy projects and R&D** • Conducted various actions for NDA of *DS-1647* (G47Δ) by collaborating with partners • Conducted technology transfer of cell manufacturing methods in *Axi-Cel*® (CAR-T) projects	**Promote cell therapy projects and R&D** • Take actions for NDAs of *DS-1647* (G47Δ) and *Axi-Cel*® (CAR-T) • Promote joint research with Tokyo Industrial University on the preparation methods of iPS cell-derived insulin-producing cells **Build and strengthen technology and human resource infrastructure** • Develop biologics technologies and establish supply systems that make full use of in-group functions

Pharmaceutical Technology unit

Functional Units

Value chain — Pharmaceutical Technology

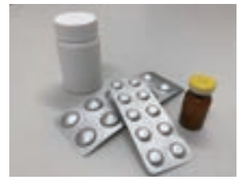
R&D	Supply Chain	Marketing & Sales
Biologics		Medical Affairs
Quality & Safety Management		

The Pharmaceutical Technology Unit develops investigational drug products from new drug candidates through drug substance, drug product and analytical & quality evaluation research activities as well as CMC regulatory affaires related activities. We are also responbsible for establishment of a robust commercial manufacturing processes that consistently provides high quality products. After commercial launch of products, we continue to improve manufacturing processes and formulations through the product life cycle, such as making drug prodcuts easier to administer, and implementing anti-counterfeiting drug measure. With regard to *DS-8201*, we re-organize the unit structure for expanding manufacturing capacity of investigational drug products so that we can support growing clinical studies and extended study drurations. At the same time, we are supporting for establishement of commercial manufacturing facilities in order to deliver *DS-8201* to the patients as early as possible.

Hiroto Kashiwase, DVM, Ph.D. **Global Head of Pharmaceutical Technology Unit**

Strengthening the supply system for investigational drug products

The Pharmaceutical Technology Unit develops new technologies and new application, such as ultra-low temperature cold chain technology, in order to deliver drug candidates, which consist of various modalities, as investigational drug products for clinical trials. We are working to deliver investigational drug products as soon as possible to patients who are waiting for a new treatment approach. We are also doing our best to address the demands from physicians and patients for compassionate use of investigational drug products, as well as supporting the ongoing extended access for patients after the completion of clinical trial. In addition, we are establishing a robust system for stable supply of investigational drug products.



Investigational drugs used in clinical trials

Progress of the Pharmaceutical Technology Unit's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Accelerate and improve the efficiency of oncology development	**Steadily performed application-related work and technology transfer** • Implemented process validation and prepared application dossiers in order to achieve acceleration of *DS-8201* application • Implemented technology transfer for commercial manufacturing facilities for launch of *DS-8201* • Determined commercial manufacturing conditions for *quizartinib* and *pexidartinib*, which achieve good quality and productivity • Prepared application dossiers for *quizartinib* and *pexidartinib*	**Initiatives for *DS-8201*** • Prepare for BLA/NDA submission in Japan and the US and respond to inquiries from regulatory reviews • Establish manufacturing and supply system for investigational drug products and commercial products considering collaboration with AstraZeneca, **Develop other oncology drugs** • Ensure supply investigational drug products to support accelerated development even with rapid changes in the demands of investigational oncology products and comparator
Enhance fundamental technologies of biologics (ADCs)	**Enhance and deploy ADC-related technologies** • Developed new formulations by using ADC-platform technologies (e.g., *DS-6157* and *DS-6000*) • Developed ADC analysis technology that enables precise control of impurities **Prepare for the next generation ADCs** • Developed efficiently next-generation ADCs based on the experience of existing ADCs	**Promotion of next-generation ADC development** • Develop high-speed analytical technology that shortens the research and development period for biopharmaceuticals • Establish investigational product manufacturing and supply system for next-generation ADCs
Develop high-value-added products, reduce costs, and establish new manufacturing processes	**Develop high-value-added products** • Prepared application dossiers for *Inavir nebulizer** formulation • Designed of a package capable of preventing exposure to oncology drugs * Devices for nebulizing drug solutions through the mouth and nose	**Develop technologies that address a variety of modalities** • Establish ultra-low-temperature cold chain* that supports cell therapy and regenerative medicine • Establish manufacturing process of nucleic acid drugs to reduce cost * Logistics method that maintains uninterrupted low temperatures between manufacturing , transportation and consumer activities

Supply Chain Unit

The Supply Chain Unit is rapidly transforming its organizational functions with the aim of a “supply chain with competitive advantages in oncology and biotechnology”. In particular, for the launch of *DS-8201*, we are strengthening our stable production and supply system by investments in biopharmaceuticals manufacturing facilities, addition of contract manufacturers worldwide and continuing development of biotech personnel capabilities. In the meantime, we are working to achieve stable supply and reduce product cost in response to the growing demand in *edoxaban*, which supports our growth. We will continue to contribute to the creation of group profits by transforming and strengthening supply chain functions.

Junichi Fukute **Head of Supply Chain Unit**

Toward a production system that utilizes environmentally friendly equipment

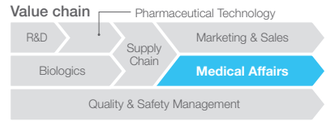
Daiichi Sankyo Propharma Co., Ltd., a subsidiary company belongs to the Supply Chain Unit, has used an environmentally focused gas co-generation system since 2012 after the earthquake, and efficiently uses energy such as heat and steam generated by its operation. Furthermore, this system can supply power even in an emergency such as power failure. In FY2018, this system contributed to the reduction of environmental impact by reducing approximately 2,000t of CO_2. The effect is on the rise year by year, and we aim to make a more environmentally focused production system by using it continuously.

A power generator that takes development environments into account

Progress of Supply Chain Unit’s 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Transform and rebuild supply chain structures adapted to changes in the product mix	**Established a manufacturing system for anticancer drugs and biologics** • Established manufacturing facilities for drug substances and formulations in accordance with the development plan of the ADC franchise • Secured and developed human resources in accordance with the human resources developing roadmap in biologics field • Promoted preparations/considerations on initiatives for a stable supply globally in accordance with the mid-to-long term supply plan	**Strengthen a manufacturing system for anticancer drugs and biologics** • Strengthen the global manufacturing and supply system for anticancer drugs and biologics, including investigational drugs • Secure manufacturing and analysis personnel based on the human resources developing roadmap in biologics field • Promote capital investment plan based on our future vision • Establish new logistics functions in response to environmental changes
Construct a supply system in response to the growth of existing and new products and respond to new technologies	**Established a global supply system for *edoxaban*** • Established a stable supply system by reviewing mid-to-long term supply system in response to the expansion of approved countries	**Establish and promote a supply system in accordance with development and launch schedules** • Prepare for launch of new products on schedule and achieve a stable supply after launch • Achieve a stable supply of *edoxaban* in response to growing demand in Japan and Europe
	Established a manufacturing and supply system for cutting-edge pharmaceutical products • Promoted an establishment of production system and cold chain* tailored to individual product characteristics of regenerative medical products, such as *Axi-Cel*® (CAR-T) and *DS-1647* (*G47Δ*) * A logistics that maintains uninterrupted low temperatures from manufacturing to consumers	**Establish a reliable supply system for ADC and cutting-edge pharmaceutical products and study mid-to-long term stable supply measures** • Promote mid-to-long term stable supply measures to increase production of *DS-8201* • Establish a manufacturing and supply system for *Axi-Cel*® and *DS-1647* (*G47Δ*)
Promote cost reduction activities and attain results globally	**Reinforcing continuous profit generation by cost reductions** • Achieved manufacturing cost reduction as planned by cost reduction approaches from various viewpoints including procurement and manufacturing process	**Contribute to the group profits by promoting cost reduction measures** • Promote cost reduction of *edoxaban* drug substance by adding new supply sources • Optimize capital investments, Reduce procurement costs for facility.

Medical Affairs Unit

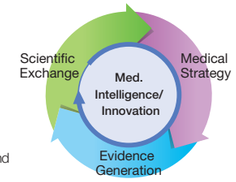


The Medical Affairs (MA) Unit will accelerate activity which has been working since fiscal 2018 to further prepare the MA system for the launch of new oncology products. In particular, for *DS-8201*, we will establish a collaborative relationship with its strategic partners, AstraZeneca, to ensure that high-quality evidence is delivered to healthcare professionals and patients as soon as possible. In Japan, new products other than oncology have been launched, and we aim to build evidence to answer clinical questions in the medical community. In addition, we are enriching product information functions and enhancing the quality of the response to our client.

Yoshikazu Fukuchi **Head of Medical Affairs Unit**

Initiatives for the dissemination of latest information to healthcare professionals and patients in the oncology field

Novel cancer drugs provide new benefits to patients who failed conventional therapies, but they also could carry a variety of side effect risk. We will provide benefits to patients by finding new knowledge on efficacy and safety from various clinical studies and disseminating them to healthcare professionals and patients as soon as possible. To this enel, we will strengthen our MSL* functions and also strengthen and maximize oncology and pipeline knowledge of our call-centers.



* 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

Progress of Medical Affairs (MA) Unit’s 5-year business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Generate and disseminate scientific evidence on *edoxaban*	**Generate scientific evidence on *edoxaban*** • Presented ELIMINATE trial * results at scientific conferences • Presented patient background data from a large-scale registry study in Japan at scientific conferences * Study in patients with atrial fibrillation who underwent catheter ablation	**Accelerate dissemination of *edoxaban* evidence** • Disseminate information from multiple Japanese and foreign clinical studies through presentations at scientific conferences and publications • Promote research toward the end of various clinical research
Generate and disseminate scientific evidence in the oncology field	**Established launch readiness for oncology products** • Established a medical plan* to prepare for the launch of *quizartinib* and *DS-8201* • Deployed oncology MSL in Japan * Evidence generation and dissemination plan to contribute to medical practice	**Generate and disseminate scientific evidence in the oncology field** • Establish a new Oncology Medical Science Department • Implement a medical plan for *quizartinib* and create evidence through a investigator-initiated study of *DS-8201*
Generate and disseminate scientific evidence on other priority products	**MA activities for *esaxerenone* and *mirogabalin*** • Developed activity plan for creation and dissemination of evidence for new products • Data lock for *prasugrel* PENDULUM study* * Investigation of thrombotic events, bleeding events, and platelet aggregation inhibition by antiplatelet therapy in patients undergoing PCI	**Generate and disseminate evidence on other priority products** • Start clinical research studies of *esaxerenone* and *mirogabalin* • Present at a conference and publish paper on the results of a PENDULUM study • Information gathering through advisory meetings
Sophisticate MA operation in response to environmental changes	**Reinforce infrastructures for the global MA operation** • Realized stable operation of the global MA (GMA) activities • Developed GMA future plans and started initiatives to achieve MA Unit 2025 Vision	**Reinforce the Global MA activities in the oncology field** • Further strengthen GMA functions, mainly in the oncology field • Sophisticate information generation and dissemination activities through deepening collaboration with relevant departments, such as R&D and market access
Improve customer satisfaction, enhance medical information, and entrench practice of utilizing Voice of Customer (VOC)	**Ranked No.1 for 4 consecutive years** • Our call center was ranked No.1 among pharmacists in health insurance pharmacies for 4 consecutive years based on a survey conducted by outside research company on DI centers • Started inquiry response operations activities using AI for the first time in industry • Established a dedicated line for inquiries about oncology field	**Create more sophisticated medical Information’s functions** • Aim to continue to be ranked No.1 among pharmacists in health insurance pharmacies for 5 consecutive years and also aim to be ranked No.1 among pharmacist in hospitals • Comply with Guidelines for Sales Information Provision Activities • Propose clinical questions by gathering, analyzing, and evaluating the voice of customers

Quality & Safety Management Unit

The Quality & Safety Management Unit is responsible for quality assurance and safety management of pharmaceuticals throughout the life cycle using global standards. We will establish a safety management system to ensure the reliability of not only small molecule pharmaceuticals but also antibodies and new modality products, as well as a safety management system that can respond to the shift toward the cancer area. In addition, by ensuring to monitor adverse reactions and disseminate various information on proper use and safety management that enable to contribute to patient's safety and security, we will be able to treat patients with high risk of side effects, and aim to suppress adverse reactions and diseases to become severe.

Miyuki Arai **Head of the Quality & Safety Management Unit**

Aiming to promote further diversity

In fiscal 2019, the percentage of women in The Quality & Safety division's 305 employees is 42% and the percentage of women in management positions is 28%. Many employees have returned to work after maternity leave. We have a team system that allows us to follow each other, so we are able to flexibly utilizes flex-time, home-based work, and short working hour system to make balance of both work and private including childcare and nursing care. We also provide career change opportunities for senior employees to work that leverages their past experiences. We aim to promote further diversity in the future in order to foster a corporate culture in which everyone can work lively and be active in a variety of ways.

Progress of the Quality & Safety Management Unit's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Continue the post-marketing surveillance on *LIXIANA* and *Effient* to create additional evidence	**Prosecuted post-marketing surveillance on mainstay products and created additional evidence** • Published *LIXIANA*'s latest evidence and shared with healthcare professionals • Presented data on *Effient*'s large-scale real-world data on dosages suitable for the Japanese at the late breaking session of the Japanese Circulation Society for two consecutive years	**Promote post-marketing surveillance on mainstay products and create additional evidence** • Continue to prosecute large-scale studies on *LIXIANA* and *Effient* and present efficacy and safety information at major academic conferences, etc. • Start specific use results survey for new products such as *Tarlige* and *Minnebro* and plan database survey
Introduce quality risk analysis and evaluation systems for new fields and new technologies	**Established a quality assurance system for products in new areas** • Ensured the reliability of manufacturing sites for *DS-8201* and prepared for regulatory inspections • Supported problem solution at the contract manufactures for NDA of *DS-1647* (*G47Δ*) • Established a quality-assurance system for commercialization of *Axi-Cel*® (CAR-T) and clarified challenges and risks	**Establish a quality assurance system for products in new areas** • Promote reliability assurance of *DS-8201* BLA/NDA data and response to regulatory inspections, and establish a manufacturing site control system including CMO* • Complete NDA of *DS-1647* (*G47Δ*) and *Axi-Cel*® (CAR-T) as planned and respond to regulatory review * CMO: Contract Manufacturing Organization
Strengthen safety monitoring measures and verify the effectiveness of safety measures	**Reinforced safety measures for new and mainstay products** • Practiced integrated risk management and thorough safety measures in the global clinical trial of *DS-8201* • Built a framework that facilitates prompt communication with healthcare professionals on the safety information of oncology products • Improved productivity by automating routine tasks with RPA* implementation *Robotics Process Automation	**Reinforce safety measures for new and mainstay products** • Continue *DS-8201* clinical trial safety measures, prepare package inserts and RMP* for approval, and establish a system to collect and provide information after launch • Contribute to the safety and security of patients by promoting a framework that facilitates prompt communication with healthcare professionals on the safety information of oncology products * RMP: Risk Management Plan