

FY2016–2020
5-Year Business Plan
Transformation
toward 2025 Vision

2025 Vision

- Oncology business
- Specialty area
- Regional value
- Expansion of alliances
- Sustainable profit growth

Until FY2015

- Cardiovascular-metabolics area
- Primary care physician focus
- Global products
- In-house
- Sales volume

The Daiichi Sankyo Group defines its **2025 Vision** as striving to become a “**Global Pharma Innovator with competitive advantage in oncology**.”

The **5-year business plan** covers the period from fiscal 2016 to fiscal 2020, which has been positioned as a period for **transformation leading up to the 2025 Vision**. In fiscal 2020, the final year of the plan, we will target revenue of **¥1,100.0 billion**, operating profit of **¥165.0 billion**, and return on equity (ROE) of **more than 8.0%**. Furthermore, in fiscal 2020 we aim to have **three to five late-stage pipelines** that can be launched within the next five years with the potential to generate annual revenue exceeding ¥100.0 billion each at peak.

2025 Vision

Global Pharma Innovator
with Competitive Advantage in Oncology

- To have Specialty area*1 business centered on Oncology business as the core business
- To have enriched regional value products aligned with regional market
- To have innovative products and pipeline changing standard of care (SOC)*2
- To realize shareholders’ value through highly efficient management

*1 Pharmaceuticals mainly prescribed by hospitals and/or specialists
*2 Universally applied best treatment practice in today’s medical science

5-Year Business Plan (FY2016–2020): Transformation toward 2025 Vision

	FY2020 Targets
Revenue	¥1,100.0 billion
Operating Profit	¥165.0 billion
ROE	More than 8.0%
Increases to Value of Late-Stage Pipelines	Late-stage pipeline products that can be launched within the next five years with the potential to generate annual revenue exceeding ¥100.0 billion each at peak 3–5

Strengths of Daiichi Sankyo

Daiichi Sankyo boasts various strengths in three main areas—**science & technology**, characterized by its R&D DNA cultivated over years of operation as a drug discovery-oriented company; superior pharmaceutical technologies for creating innovative pharmaceuticals; and strong ties with leading academic institutions. In terms of our **global organization & talent**, we find strength in our global management system, uniting intellects from around the world, and our robust, global well of talent. Meanwhile, Daiichi Sankyo’s **presence in Japan** is illustrated by its No. 1 ranking in terms of pharmaceutical revenue and of its medical representatives (MRs), and by its four businesses responding to diverse medical needs.

Operating Environment

The operating environment for the pharmaceutical industry is characterized by rising global pressure to limit medical expenses combined with an increase in discussions on cost effectiveness and the growing influence of payers. In developed countries, innovative medicines changing the standard of care (SOC) are becoming increasingly more prominent. At the same time, the differences in market shares of specific drugs by country and region are widening due to differences in regulatory and insurance systems.

Meanwhile, the mortality rate of cancer has become overwhelmingly high among all therapeutic areas, and the needs of patients in this area still remain unmet. Moreover, in terms of global sales of drugs that are effective in treating cancer, the cancer drug market is incredibly large, with annual sales approaching ¥10 trillion. It can therefore be expected that demand will grow going forward centered on oncology and specialty areas (pharmaceuticals primarily prescribed by hospitals and specialists).

2025 Vision

The **2025 Vision** was established and announced in March 2016 to define our vision for Daiichi Sankyo based on its initiatives and success to date, its strengths, and the outlook for the operating environment.

We decided to define our 2025 Vision as striving to become a “**Global Pharma Innovator with competitive advantage in oncology.**”

Specifically, the vision for Daiichi Sankyo in 2025 entails the Company having a specialty area business centered on oncology as its core business, having enriched regional value products aligned with each regional market, and having innovative products and pipeline changing the SOC in each market. At the same time, the Company aims to realize high shareholder value through highly efficient management.

2025 Vision

Global Pharma Innovator with Competitive Advantage in Oncology

- To have Specialty area^{*1} business centered on Oncology business as the core business
- To have enriched regional value products aligned with regional market
- To have innovative products and pipeline changing standard of care (SOC)^{*2}
- To realize shareholders’ value through highly efficient management

*1 Pharmaceuticals mainly prescribed by hospitals and/or specialists
*2 Universally applied best treatment practice in today’s medical science

To realize its 2025 Vision, Daiichi Sankyo will transform from its current business structure, which is focused on such cardiovascular-metabolics areas as hypertension treatments, to become a global company with products and pipeline that change the SOC in specialty areas pertaining to pharmaceuticals prescribed by specialists and centered on oncology. At the same time, we will diverge from our previous approach of pursuing uniform global expansion, adopting instead an approach of expanding our range of regional value products suited to the markets of specific countries. Another transformation will be the abandonment of our emphasis on conducting all areas of operations in-house. Rather, Daiichi Sankyo will utilize alliances to an even greater degree going forward as it pursues sustainable profit growth.

The 5-year business plan is designed to transform Daiichi Sankyo toward its 2025 Vision. Under this plan, we are working to tackle two challenges: “grow beyond FY2017 LOE” and “establish a foundation of sustainable growth.”



Challenge 1: Grow Beyond FY2017 LOE

Daiichi Sankyo aims to overcome declines resulting from the loss of exclusivity (LOE) for mainstay products such as *olmesartan*, an antihypertensive agent. We are targeting revenue of ¥930.0 billion and operating profit of ¥100.0 billion in fiscal 2017.

On this front, *edoxaban*, an anticoagulant that is one of our global mainstay products, is growing smoothly alongside other major products for the Japanese market. Steady growth was also seen for Luitpold Pharmaceuticals, Inc. (LPI), of the United States. In addition, steady progress is being made in enhancing profit generation capabilities through structural reforms.

In April 2017, Daiichi Sankyo set forth its forecast of ¥100.0 billion for operating profit in fiscal 2017, and the Company is moving forward with a concerted effort to grow beyond the LOE for *olmesartan*.

Challenge 2: Establish a Foundation of Sustainable Growth

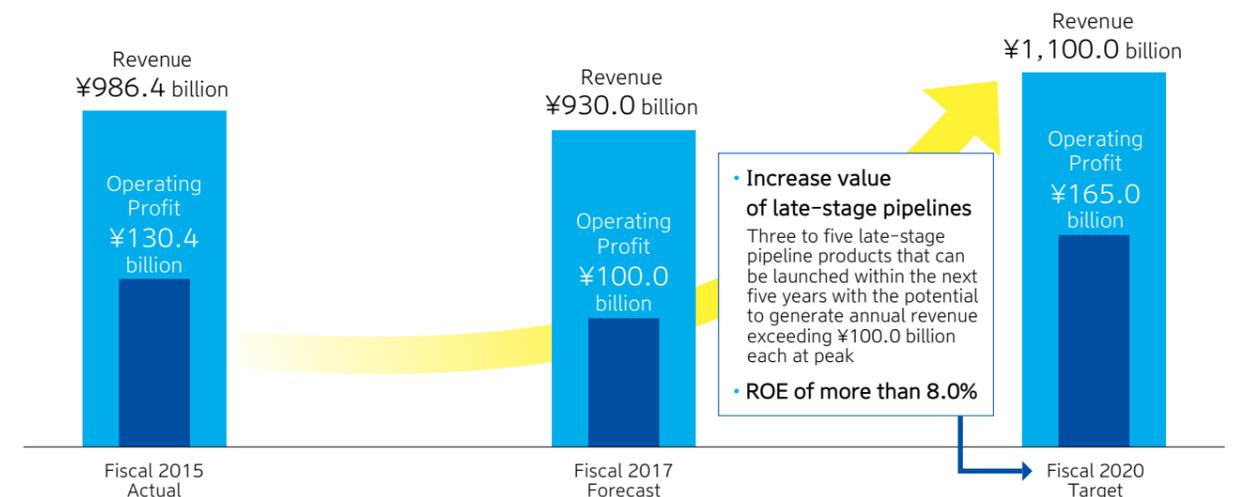
To establish a foundation of sustainable growth, Daiichi Sankyo will target revenue of ¥1,100.0 billion, operating profit of ¥165.0 billion, and return on equity (ROE) of more than 8.0% in fiscal 2020. In addition, in fiscal 2020 we aim to have three to five late-stage pipeline products that can be launched within the next five years with the potential to generate annual revenue exceeding ¥100.0 billion each at peak.

The Company is working toward accomplishing the following six strategic targets in order to establish a foundation of sustainable growth.

On the following pages, you will find information on our progress toward the six strategic targets as well as our growth investment and shareholder returns initiatives.



- Six Strategic Targets for Accomplishing Fiscal 2020 Performance Targets**
- Grow *Edoxaban*
 - Grow as No. 1 Company in Japan
 - Expand U.S. Businesses
 - Establish Oncology Business
 - Continuously Generate Innovative Medicine Changing Standard of Care (SOC)*
 - Enhance Profit Generation Capabilities
- * Universally applied best treatment practice in today’s medical science



Strategic Target *Grow Edoxaban*

Brand name: *LIXIANA* (Japan, Europe, Asia), *SAVAYSA* (U.S.)

1. Thrombosis and Anticoagulants

Blood clots are usually formed to stop bleeding and will eventually dissolve and shrink. However, should a blood clot grow larger, rather than dissolving, and consequently come to clog a vein, it could result in a lack of blood flow to areas of the body beyond the clot, potentially even leading to the death of the tissue therein. This condition is known as thrombosis.

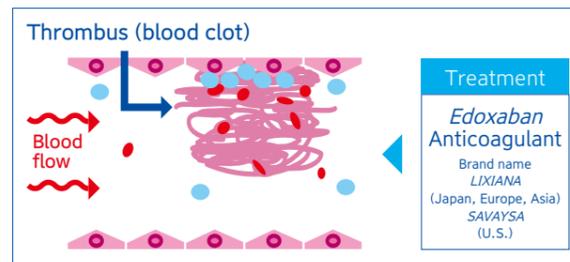
In veins, where blood flow is slow, or in atrial, where blood can gather, blood coagulation can result in the formation of blood clots. Anticoagulants are used to prevent such blood clots from being formed. Some of the representative diseases treated with anticoagulants are as follows.

Major Indications Treated with Anticoagulants

<p>Atrial Fibrillation (AF)</p>	<p>AF is a form of irregular heartbeat in which the heart cannot maintain the proper rhythm, causing blood to become stagnant in the intra-atrial courses and increasing the risk of blood clots forming. Should such a blood clot leave the intra-atrial courses and clog blood flow to the entire body, it could lead to ischemic stroke or systemic embolism.</p>
<p>Venous Thromboembolism (VTE)</p> <ul style="list-style-type: none"> • Deep Vein Thrombosis (DVT) • Pulmonary Embolism (PE) 	<p>DVT is thrombosis in deep veins such as those of the limbs (generally the calf or thigh) or pelvis.</p> <p>PE is a potentially fatal condition in which part of a blood clot formed in a deep vein breaks off, drifts to the lungs, and clogs a pulmonary artery.</p>

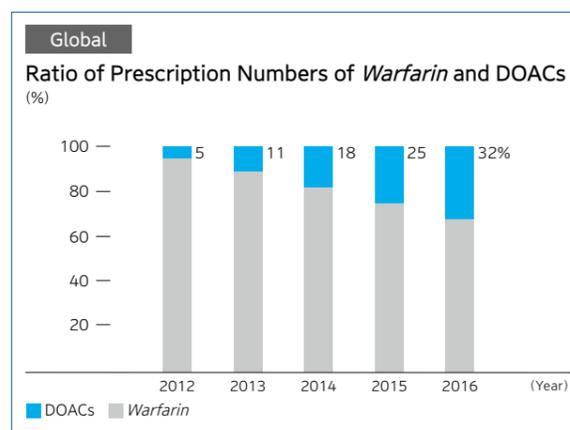
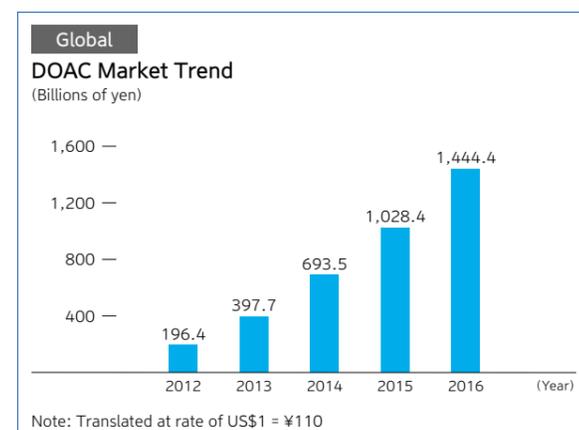
2. Direct Oral Anticoagulants and Characteristics of Edoxaban

Warfarin has long been the standard treatment for blood clot prevention. However, there were many restrictions that needed to be observed when using *warfarin*, such as a need to periodically monitor blood conditions, its various adverse interactions with other drugs, and the dietary restrictions it required. Direct oral anticoagulants (DOACs) such as *edoxaban* were developed to improve upon these shortcomings of *warfarin*. *Edoxaban*, in particular, has superior bleeding safety compared to *warfarin* coupled with the convenience of once daily dose, has significant evidence on its efficacy and safety backed by robust clinical trial results, and addresses needs of atrial fibrillation (AF) patients and venous thromboembolism (VTE) patients.



3. DOAC Market

The DOAC market, which comprises four products—*dabigatran*, *rivaroxaban*, *apixaban*, and *edoxaban*—has grown to a scale of ¥1.4 trillion on a global basis. Looking at the ratio of prescription numbers, DOACs are only used for 32% of cases that would have traditionally been treated with *warfarin*, the current standard treatment. As such, the DOAC market can be expected to grow further in the future.



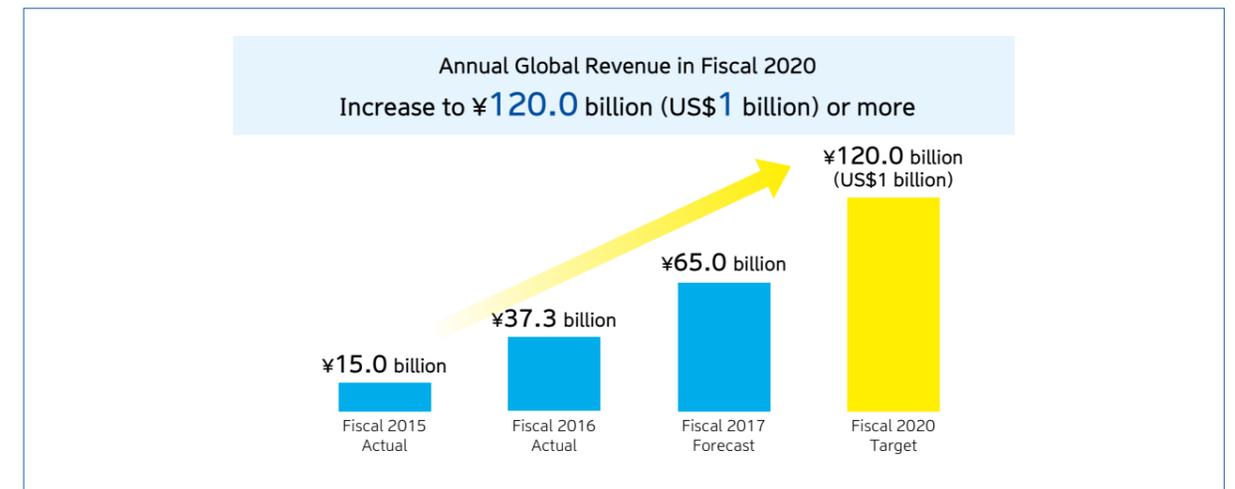
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4. 5-Year Business Plan and its Progress

(1) 5-Year Business Plan

In Japan, we aim to grow *edoxaban* into the No. 1 DOAC in the domestic market by utilizing its superior capabilities and our high-quality marketing capabilities. In Europe, meanwhile, we are currently implementing a sales model that entails finely-tuned response to the needs of individual customers. The markets of other countries are also being explored. In countries and regions in which Daiichi Sankyo lacks its own sales bases, we will advance full-fledged promotional activities through collaboration with ideal partners in each country and region.

Through these initiatives, we succeeded in achieving revenue from *edoxaban* of ¥37.3 billion in fiscal 2016 and are now forecasting revenue of ¥65.0 billion in fiscal 2017. We aim to grow *edoxaban* into a product with annual global revenue of more than ¥120.0 billion (US\$1 billion) in fiscal 2020, which is to be generated mainly in Japan and Europe.



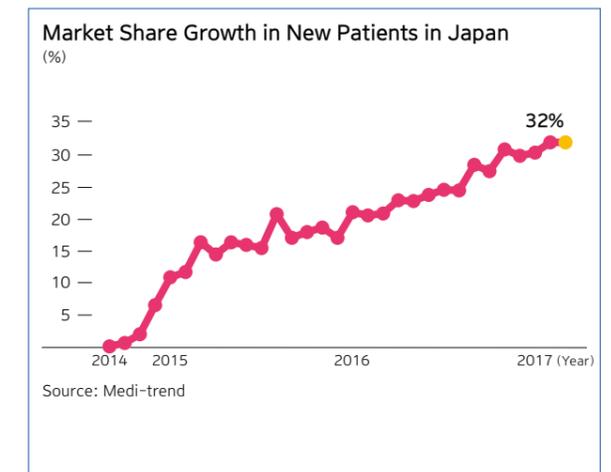
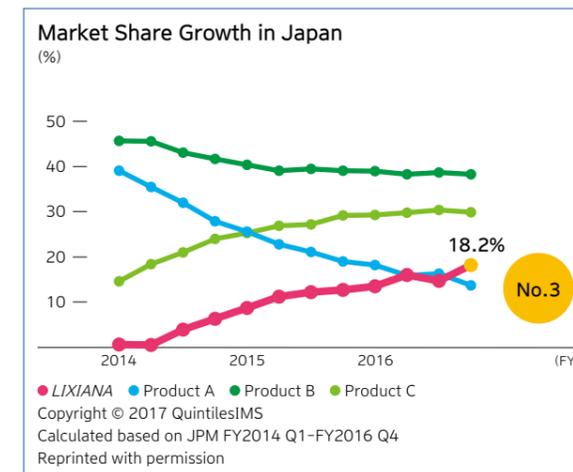
(2) Progress to Date

a. Revenue Growth

Annual global revenue from *edoxaban* has been showing impressive growth, with figures of ¥15.0 billion for fiscal 2015 and ¥37.3 billion for fiscal 2016.

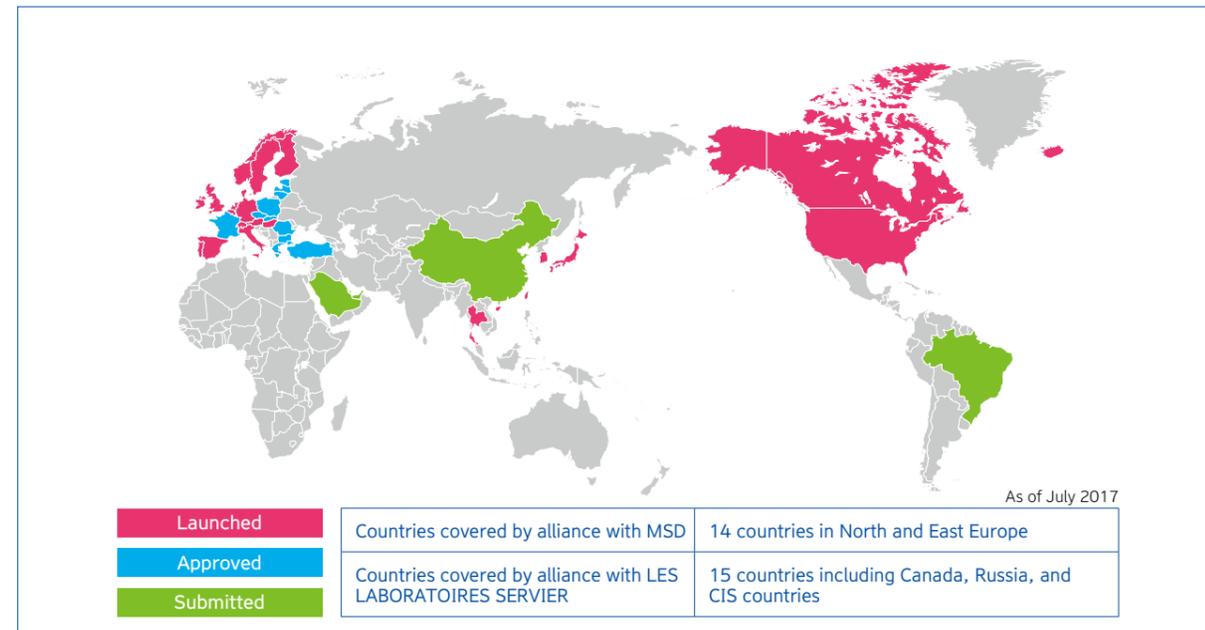
The Japanese DOAC market is growing smoothly, and had reached a scale of more than ¥170.0 billion in 2016. *LIXIANA* boasts a revenue share of 18.2% and was No.3 in this market in the fourth quarter of fiscal 2016 and is quickly encroaching on the position of the two products that were launched prior to it. Furthermore, *LIXIANA* was being prescribed to 32% of new patients in Japan in March 2017, which is a leading indicator of growth.

We are also witnessing favorable revenue growth in Germany and other regions, with *LIXIANA* holding a 7.2% share of the German market in March 2017 along with a 15.6% share of the South Korean market, which is particularly impressive given that it was only launched in this market in February 2016.



b. Launches in New Countries

Edoxaban has already been approved and launched in more than 20 countries, and we are in the process of applying for approval in China, Brazil, and Saudi Arabia, among other countries. In terms of sales scale, this will mean that *edoxaban* is approved and available in countries that make up 95% of the global DOAC market when all of these application processes have been completed. In addition, we have established marketing alliances with Merck Sharp & Dohme Corp. (MSD), a European subsidiary of Merck & Co., Inc., for sales in North and East Europe and with LES LABORATOIRES SERVIER for sales in Canada, Russia, and countries belonging to the Commonwealth of Independent States (CIS).



c. Life-Cycle Management Initiatives

Maximizing the growth potential of *edoxaban* will require that Daiichi Sankyo generate new scientific evidence to further enhance the appeal of this product. Currently, we are engaged in the following *Edoxaban* Clinical Research Program. Those trials circled in red began in or after fiscal 2016.

The Randomized Controlled Trials*1

Study Name	Clinical Setting (Comparator)	Primary Completion
ENSURE-AF	Cardioversion (enoxaparin / warfarin)	Presented at ESC 2016
ENTRUST-AF PCI	PCI (VKA)	November 2018
ELIMINATE-AF	Cardiac ablation (VKA)	December 2018
ENVISAGE-TAVIAF	Transcatheter aortic valve implantation (VKA)	May 2020
ELDERCARE-AF	80 years or older who are ineligible for current OAC therapy (placebo)	December 2019
Hokusai VTE	VTE associated with cancer (dalteparin*2)	December 2017

Non-Interventional Studies and Registries

Study Name	Clinical Setting
ETNA-AF Global	<i>Edoxaban</i> treatment in routine clinical practice in AF
ETNA-VTE Global	<i>Edoxaban</i> treatment in routine clinical practice in VTE
EMIT-AF/VTE	<i>Edoxaban</i> management in diagnostic and therapeutic procedures-AF/VTE
PREFER in AF	Prolongation PREFER in AF, European registry
ANAFIE	All Nippon in AF elderly registry in Japan
Cancer-VTE	Multicenter prospective registry in cancer patients in VTE patients in Japan

*1 Randomized controlled trial: A type of intervention study aimed at scientifically evaluating the preventative or treatment benefits of a specific drug. Participants are randomly assigned to either the test group or the control group, with the test group being administered the drug to be evaluated while the control group is administered a conventional drug or placebo. The results from the two groups are compared to evaluate the efficacy and safety of the drug.

*2 *Dalteparin* has not been approved for an indication for VTE in Japan.

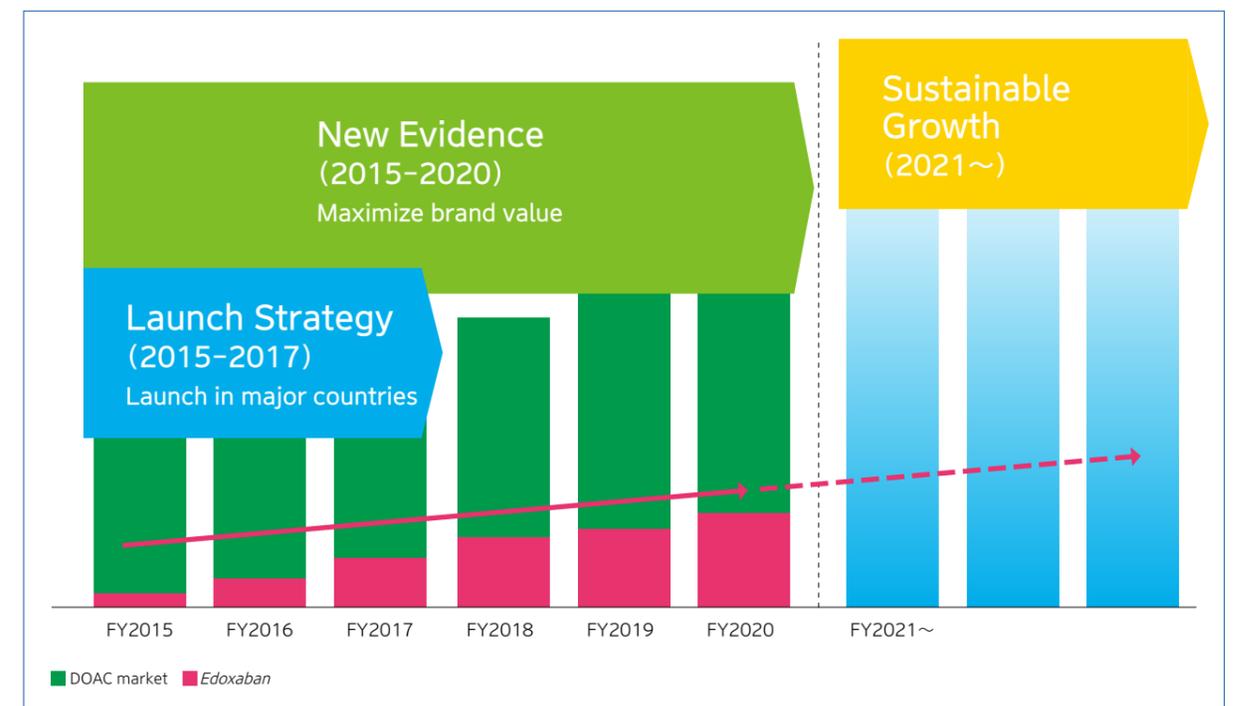
(3) Future Initiatives

Our basic growth strategy for *edoxaban* will be to grow this product in conjunction with the growth of the DOAC market. Fiscal 2017 will be an important year in which we will need to steadily advance a market launch strategy while accelerating the development of new scientific evidence to ensure that *edoxaban* can continue to grow consistently after fiscal 2020.

By accelerating growth in Japan and Europe, we will target annual global revenue from *edoxaban* of ¥65.0 billion in fiscal 2017. If we do not possess sales bases in a specific country or region, we will seek to advance full-fledged promotional activities through collaboration with ideal partners in each area, as we are doing with MSD and LES LABORATOIRES SERVIER.

As we launch *edoxaban* in new markets, we will also take steps with regard to our supply systems to ensure compatibility with the markets in which this product is available and guarantee a stable and continuous supply.

Through these efforts, we will endeavor to grow *edoxaban* into a product with annual global revenue of more than ¥120.0 billion in fiscal 2020.

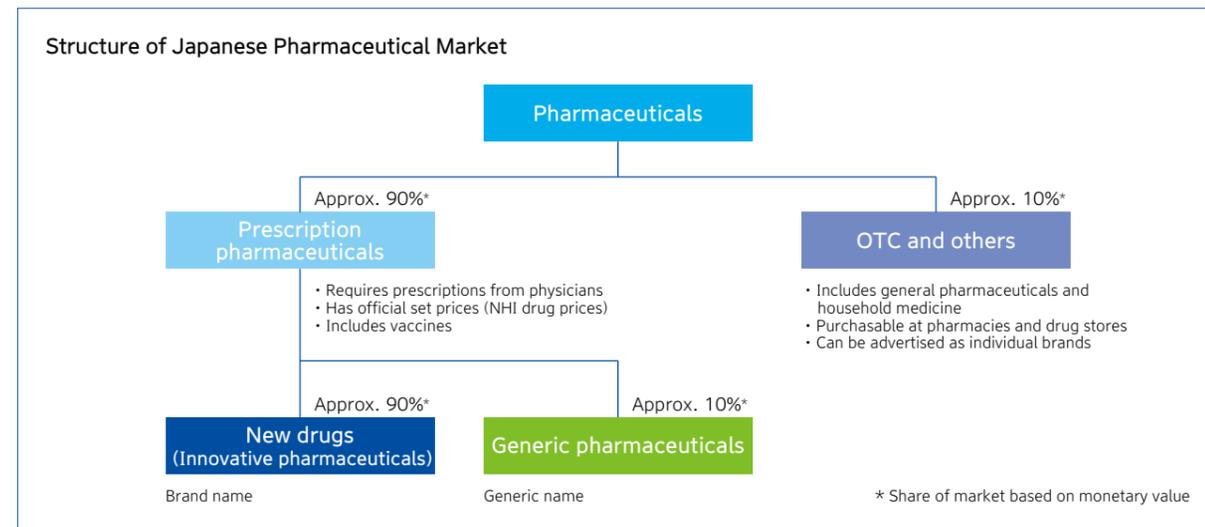


Strategic Target Grow as No. 1 Company in Japan

1. Pharmaceutical Market

In Japan, approximately 90% of the pharmaceutical market is comprised of prescription pharmaceuticals that require prescriptions from physicians with the remainder of the market being accounted for by general pharmaceuticals and other over-the-counter (OTC) drugs that can be freely purchased in pharmacies and drug stores. Moreover, use of generic drugs has been increasing in the prescription pharmaceutical market, and these drugs have recently come to represent 66% of the market on a sales volume basis*.

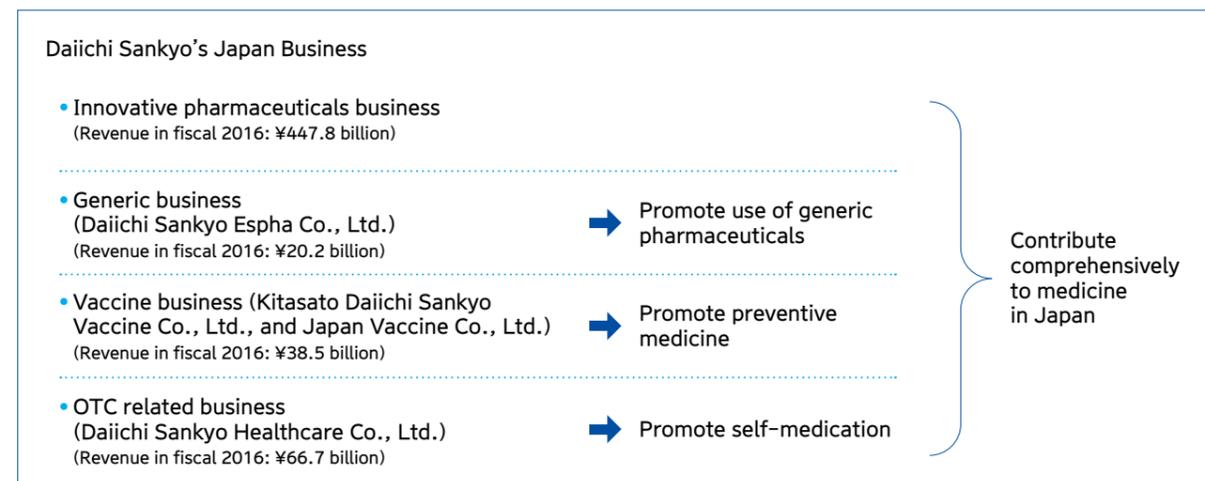
* Generic drugs ÷ (Original drugs for which generic drugs have been released + Generic drugs)



2. Daiichi Sankyo's Four Businesses

We are striving to grow Daiichi Sankyo into the No. 1 company in Japan in both name and substance. To accomplish this objective, the Company will address a wide range of medical needs related to areas such as prevention, self-medication, and treatment by leveraging the strength of its innovative pharmaceuticals* business in combination with its generic business, vaccine business, and OTC related business.

* Pharmaceuticals still protected by the exclusivity period granted by patents



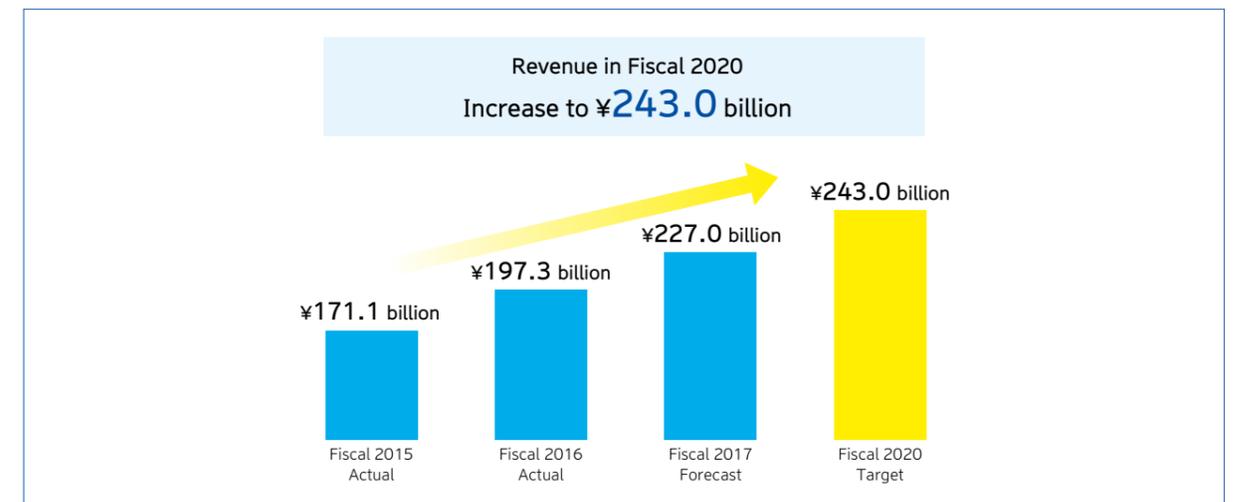
In addition to *LIXIANA*, an anticoagulant developed for the global market, the innovative pharmaceuticals business is developing its operations centered around six major products: *NEXIUM*, an ulcer treatment; *Memary*, an Alzheimer's disease treatment; *PRALIA*, a treatment for osteoporosis; *RANMARK*, a treatment for bone complications caused by bone metastasis from tumors; *Efient*, an antiplatelet agent; and *TENELIA*, a type 2 diabetes mellitus treatment.



3. 5-Year Business Plan and its Progress

(1) 5-Year Business Plan

Under the 5-year business plan, Daiichi Sankyo is working to increase the range of indications for its six major innovative pharmaceutical products for the domestic market. As a result of these efforts, total revenue from these six products amounted to ¥197.3 billion in fiscal 2016 and is forecast to come to ¥227.0 billion in fiscal 2017. By further growing revenues, we will target revenue of more than ¥243.0 billion in fiscal 2020.



(2) Progress to Date

Revenue from the Company's six major innovative pharmaceutical products has been steadily growing, and revenues from these products totaled ¥171.1 billion in fiscal 2015 and ¥197.3 billion in fiscal 2016. Of these, *NEXIUM*, *Memary*, *PRALIA*¹, and *RANMARK* have achieved the No. 1 share of their respective markets and are continuing to grow.

Our efforts to launch new products and acquire licenses for promising products have proven incredibly successful. Our ability to introduce so many in-licensed products is due in part to the high praise partners have for Daiichi Sankyo's sales capabilities. As a result, Daiichi Sankyo ranked No. 1 among Japanese companies in pharmaceutical revenue for the first time in fiscal 2016.

New Product Launches and Product License Acquisitions

- Launched and submitted application for additional indication for *Vimpat* antiepileptic agent
- Received licenses for nine biosimilars from Amgen
- Reinforced AG business of Daiichi Sankyo Espha Co., Ltd.
- Launched *Narurapid* Tablets and *Narusus* Tablets for cancer pain treatment
- Acquired manufacturing and sales approval in Japan for *CANALIA* (*TENELIA* and *CANAGLU* combination tablet), a type 2 diabetes mellitus treatment
- Acquired additional indication related to rheumatoid arthritis for *PRALIA*

Evaluation of MRs

- MRs ranked No. 1 in various external surveys
 - Ranked No. 1 for five consecutive years in survey conducted by ANTERIO Inc.
 - Praised for MR visit activities and as a trustworthy manufacturer in survey conducted by Social Survey Research Information Co., Ltd.
 - Judged to have superior MRs in survey conducted by Mix Online

In the OTC related business, meanwhile, the acquisition of Im Co., Ltd.*2, a direct marketing company, contributed to a 25% year-on-year increase in revenue in fiscal 2016. We also launched a series of *Loxonin S* brand pain-relieving products for external use during this year.

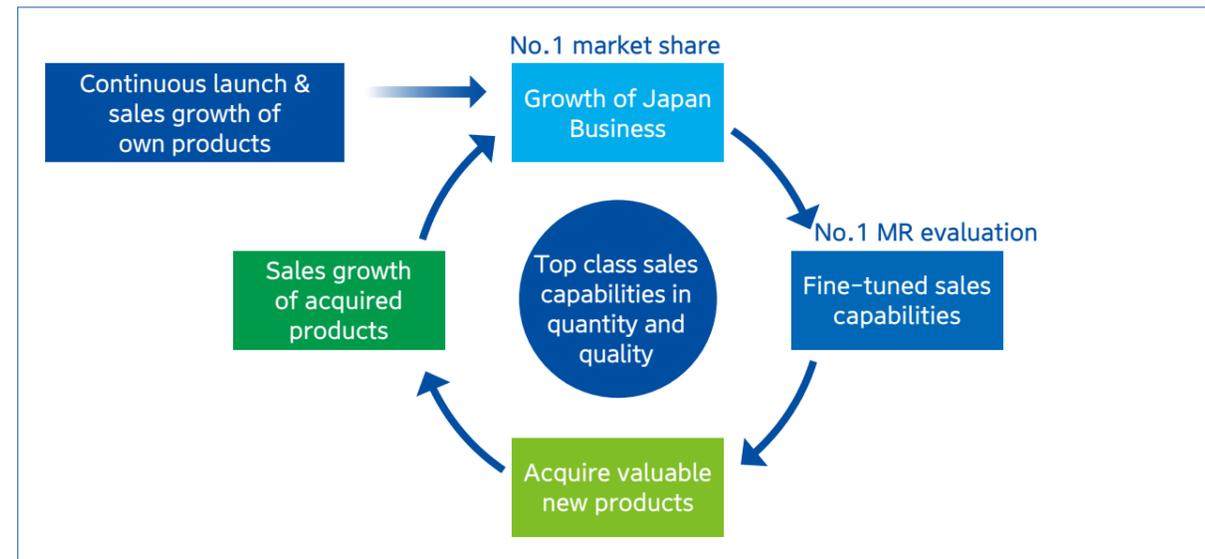
*1 No. 1 in the bone resorption inhibitor market
*2 Acquired in November 2015

(3) Future Initiatives

a. Innovative Pharmaceuticals Business

In the innovative pharmaceuticals business, Daiichi Sankyo will leverage its sales capabilities, which are top-class in terms of both quality and quantity, in order to realize sustainable growth and achieve ¥227.0 billion in total revenue for its six major products in fiscal 2017.

By continually launching and expanding sales of proprietary developed products, we will grow the innovative pharmaceuticals business. At the same time, we will utilize the Company's superb sales capabilities to acquire licenses for promising products developed elsewhere in order to sustain a virtuous cycle driving further growth.



b. Generic Business (Daiichi Sankyo Espha Co., Ltd.)

In the generic business, we have defined our vision of becoming a leader in the domestic generic drug market in order to contribute to national medicine in this era of rapidly aging societies. As a step toward this vision, we aim to be No. 1 in Japan in terms of authorized generic (AG)* lineup and revenue. In fiscal 2017, we plan to launch AGs for *olmesartan* (a proprietary Daiichi Sankyo product), *telmisartan*, and *rosuvastatin*, among other products. We thereby hope to help contribute to medicine in Japan while responding to various pharmaceutical-related needs, particularly those pertaining to AGs.

* Generic drug manufactured by the innovator company and distributed by a generic company under a generic label, pursuant to an agreement between the innovator and the generic company. The same ingredients, additives, and manufacturing processes as the original brand drug are used to create a generic drug of the same quality as the original brand drug.

c. Vaccine Business (Kitasato Daiichi Sankyo Vaccine Co., Ltd., and Japan Vaccine Co., Ltd.)

The vaccine business is advanced through organic collaboration between Kitasato Daiichi Sankyo Vaccine Co., Ltd. (KDSV), which is responsible for the research, development, production, and sales of vaccines, and Japan Vaccine Co., Ltd., which conducts late-phase clinical development and sales. We are committed to contributing to public health in Japan by creating innovative vaccines and reliably supplying high-quality vaccines.

d. OTC Related Business (Daiichi Sankyo Healthcare Co., Ltd.)

In the OTC related business, we strive to become a consumer healthcare company with the ability to achieve dramatic sales growth and sustainable income improvements. This vision is being pursued through growth driven by synergies with Im Co., Ltd., a direct marketing company focused on skincare products, and the expansion of overseas operations centered on entry into the Chinese market.

Strategic Target Expand U.S. Businesses

1. Business Expansion in Pain Franchise (DSI)

(1) Need for Abuse-Deterrent Formulations for Opioid Analgesics in the United States

The United States differs greatly from Japan and other countries in that opioid analgesics, most notably the exceptionally strong morphine and oxycodone, are commonly used to treat pain unrelated to cancer. Accordingly, there is a growing need for drugs to mediate the adverse drug reactions people can experience as a result of opioid use, such as opioid-induced constipation (OIC) symptoms that data suggests are experienced by approximately 40% of patients using opioids*1. Furthermore, the United States is currently in the midst of an opioid epidemic, a serious social issue arising from individuals using opioid analgesics for reasons other than medical purposes or becoming addicted to or overusing these substances. As a result, measures for fighting opioid abuse are popping up at both the federal and state levels. One potential means of combating this epidemic is through abuse-deterrent formulations (ADFs) for opioid analgesics that are designed, for example, to be difficult to crush, inhale or inject. As such, there is strong cry for the development of such ADFs. At the moment, New Drug Applications (NDAs)*2 for opioid analgesics that are not ADFs are subject to review by an advisory committee of the U.S. Food and Drug Administration (FDA), and the current government administration has shown great concern with regard to opioid analgesics. In the future, it can thus be expected that ADFs will replace many opioid analgesics.

*1 Sources: Kalso, et al. Pain. 2004. 112: 373-380.
*2 Application submitted to the U.S. FDA to receive approval to market a new drug

2. 5-Year Business Plan and its Progress

(1) 5-Year Business Plan

Daiichi Sankyo, Inc. (DSI), the United States, is currently in the process of transitioning from its previous product portfolio, which focused on private practices and was exemplified by products such as the antihypertensive agent *Benicar (olmesartan)*, to a portfolio focused on hospitals, specialist, and other specialty care areas. As one facet of this transition, DSI will seek to establish a pain franchise that can generate revenue of more than ¥100.0 billion in the United States by fiscal 2020. In 2015, this company began co-promotions of *MOVANTIK*, an OIC treatment, together with AstraZeneca. We will promote this drug as well as *MorphaBond* and *RoxyBond*, two new ADF opioid analgesics which will be launched in fiscal 2017, to growth our pain business in the United States.

(2) Progress to Date

With revenue of ¥2.0 billion in fiscal 2015 followed by ¥4.2 billion in fiscal 2016, *MOVANTIK* has been steadily growing in sales. We are currently engaged in direct-to-consumer educational campaigns aimed at improving awareness regarding OIC. In addition, DSI received rights in October 2016 from Inspirin Delivery Sciences, LLC, for commercialization in the United States of two opioid analgesics with abuse-deterrent properties—*MorphaBond* and *RoxyBond*. In the global phase 3 ALDAY clinical trials evaluating *mirogabalin* for the treatment of pain associated with fibromyalgia, *mirogabalin* did not meet the primary efficacy endpoint. We will continue to study *mirogabalin* and its potential use in pain syndromes as part of our ongoing global clinical development program.

In light of the opioid analgesic abuse epidemic that is becoming a major social issue in the United States, DSI has announced its Commitments in Pain Care. Detailed on the next page, these Commitments describe DSI's stance toward helping patients manage their pain and addressing the opioid analgesic abuse epidemic.

We are committed to:

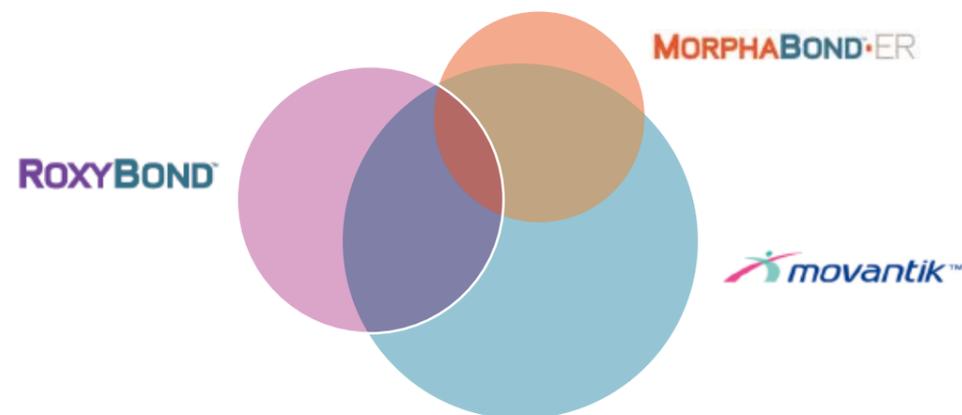


- The well-being and proper treatment of patients who suffer from pain and to providing prescription medicines to treat their pain and other related conditions.
- Educating healthcare providers, patients, families and caregivers on the appropriate use of pain medicines, and recognizing and preventing their potential for diversion, misuse, abuse, addiction, and overdose.
- Being a part of the solution to prescription drug abuse.
- Monitoring prescribing and distribution patterns for signs of inappropriate prescribing or diversion of these medications.
- Ensuring that our employees are reliable, trustworthy sources of information about pain treatments, and that our communications about pain medicines will be truthful, accurate, and respect the seriousness of the condition being treated, as well as the potential risks associated with these medicines.
- Ethical and socially responsible business practices at all times, conducting our business fairly, honestly, with integrity, and in accordance with our Standards of Business Conduct.

(3) Future Initiatives

The growth of *MOVANTIK* will be accelerated in fiscal 2017. OIC is still a condition that physicians and patients are not well aware of, meaning that the market will need to be educated. We will therefore seek to invigorate this market by stepping up education activities regarding this condition. In addition, *MorphaBond* and *RoxyBond*, the ADF opioid analgesics licensed from Inspirion, will be launched in the U.S. market in fiscal 2017. Both of these products feature SentryBond™, Inspirion’s unique, patent-protected abuse-deterrent technology. *MorphaBond* is an extended-release morphine tablet meant for treating chronic pain while *RoxyBond* is a fast-acting oxycodone formulation designed to treat acute pain. DSI will work to grow both drugs into prominent products in their respective markets. Moreover, there is a great deal of overlap between the physician groups that would prescribe these two drugs and those who prescribe *MOVANTIK*, a fact that will enable us to advance efficient marketing activities.

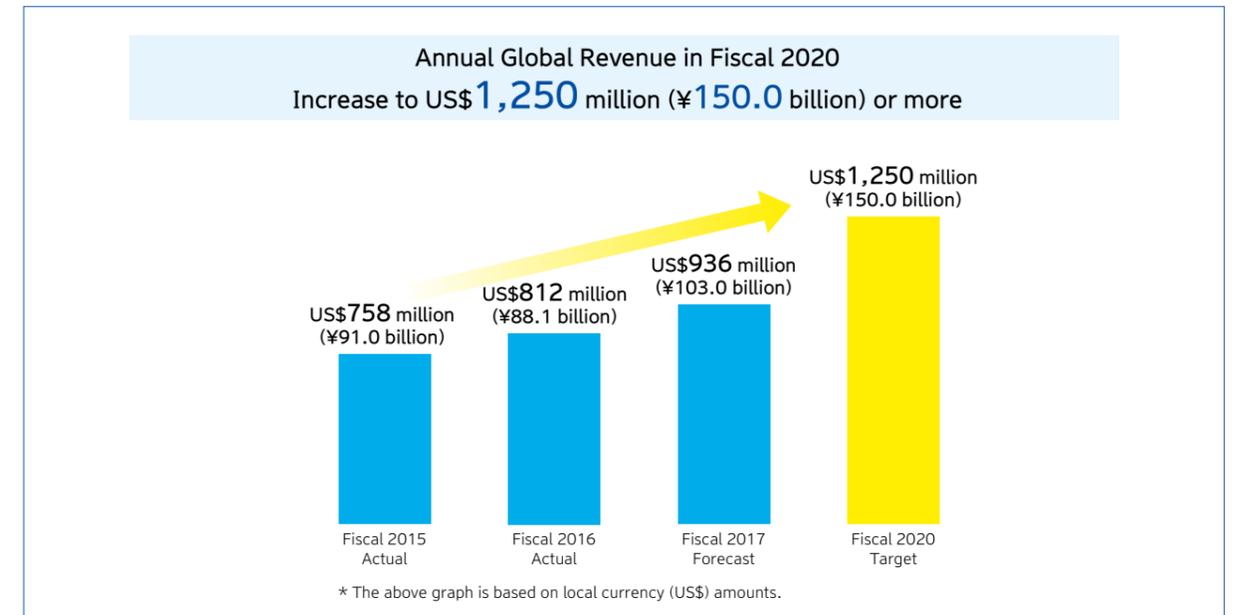
Many target physicians for *MorphaBond* and *RoxyBond* are overlapped with target physicians for *Movantik*



3. Growth of Luitpold Business

(1) 5-Year Business Plan and its Progress

The revenue of Luitpold Pharmaceuticals, Inc. (LPI), has been growing smoothly, totaling US\$758 million in fiscal 2015 and US\$812 million in fiscal 2016. By growing and expanding its iron injection franchise and its generic injectable franchise, LPI will target annual global revenue of US\$1,250 million (¥150.0 billion) in fiscal 2020.



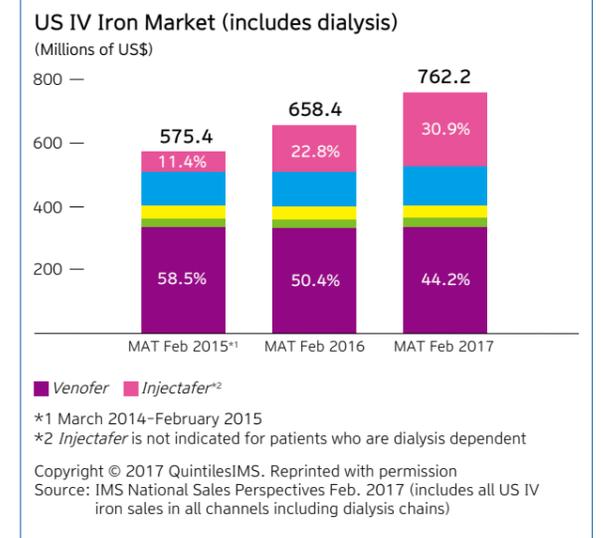
(2) Iron Injection Franchise

a. Iron Deficiency Anemia and Iron Injections

Hemoglobin located inside red blood cells is responsible for carrying oxygen to other parts of the body. Iron is vital to the functioning of hemoglobin, and a lack of iron within the body can lead to a condition known as iron deficiency anemia (IDA). Other causes of IDA include cancer and chronic kidney disease, among various other diseases. It has been common for IDA to be treated via oral iron supplements in the past. However, such supplements required extended periods of use to be effective and the actual amount of iron absorbed by the body was low. These and other issues led to attention being turned toward high-dose iron injections in Europe and the United States.

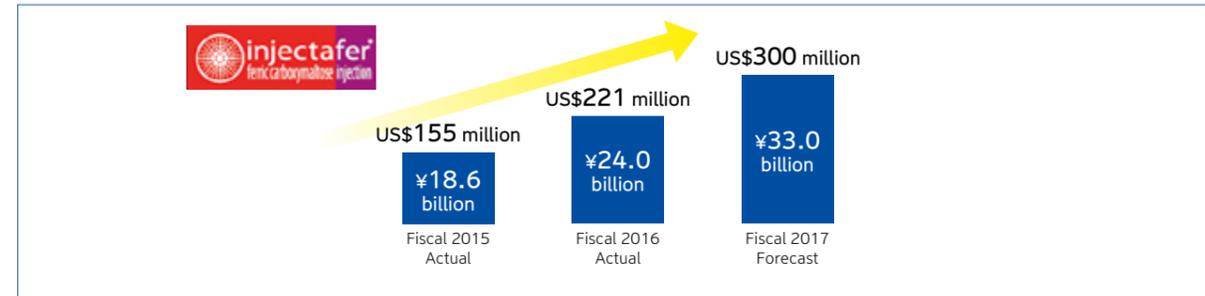
The U.S. iron injection market continues to grow with each coming year, and its scale recently reached US\$762 million in MAT-based February 2017.

LPI provides two types of iron injections: *Venofer*, which is used to treat IDA resulted from chronic kidney disease, and *Injectafer*, which can treat IDA resulted from chronic kidney disease as well as from various other causes, but cannot be used by patients undergoing dialysis. Due to its ability to treat a wide range of conditions and the convenience of being able to completely dose patients in only two applications, *Injectafer* has enjoyed rapid growth in its share since launch. These two products boast a combined share of the U.S. iron injection market of more than 70%, making LPI the undisputed leader in this market.

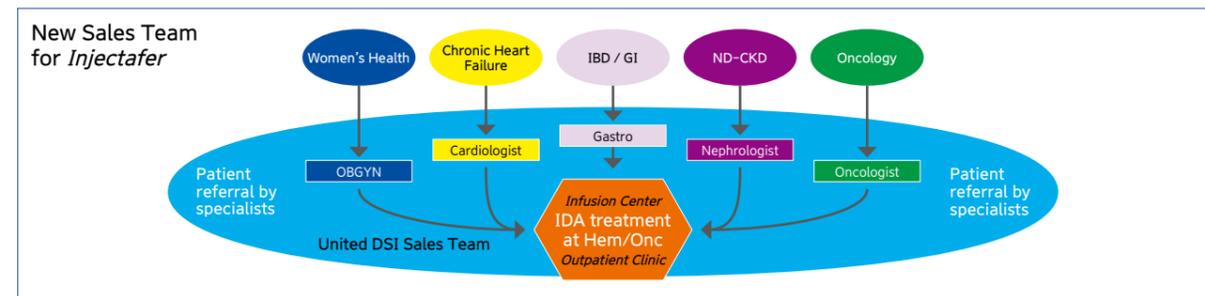


b. Progress to Date and Future Initiatives

With revenue of US\$155 million in fiscal 2015 and US\$221 million in fiscal 2016, *Injectafer* is growing at an impressive rate, and we hope to take advantage of this momentum to achieve revenue of US\$300 million (¥33.0 billion) in fiscal 2017.



In January 2017, we transferred the *Injectafer* sales team of LPI to DSI, integrating this team into DSI's own sales team. The goal of this move was to accelerate the growth of *Injectafer*, and the integrated sales team has already commenced promotions to this effect. Now able to leverage the strengths of both companies, the sales team is implementing promotion measures that target gastroenterology and obstetrics and gynecology specialists who treat IDA in addition to the traditional sales targets of cancer and hematology and oncology specialists. Furthermore, we commenced a phase 3 study in March 2017 evaluating *Injectafer* for treatment for heart failure patients with iron deficiency, with the aim of maximizing the value of this product.



(3) Generic Injectable Franchise

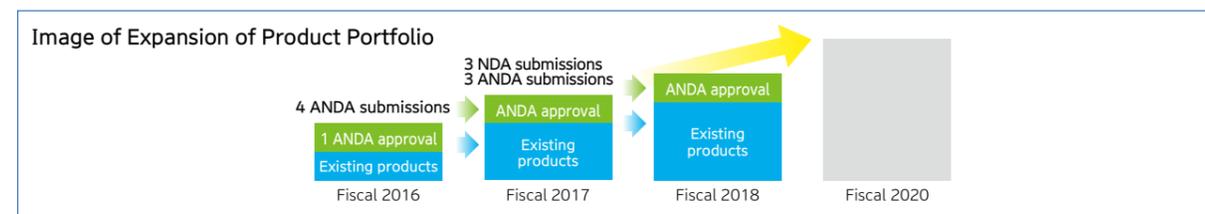
a. U.S. Generic Injectable Market

The U.S. generic injectable market is a highly dynamic market in which prices and demand fluctuate greatly. As such, achieving continuous growth requires the ongoing introduction of new products. LPI supplies this market with a lineup of more than 50 products focused on small volume vials and ampules.

b. Progress to Date and Future Initiatives

With the aim of expanding its product portfolio, LPI submitted four Abbreviated New Drug Applications (ANDAs)^{*1} in fiscal 2016, of which one has received approval. In fiscal 2017, we plan to submit three NDAs^{*2} and three ANDAs. LPI is also conducting capital investments for augmenting its production capacity in order to increase its ability to respond swiftly to market changes. These investments are being utilized to propel LPI toward the position of top supplier in the U.S. generic injectable market.

*1 Abbreviated New Drug Application (ANDA): Application submitted by a generic product manufacturer to the U.S. FDA to receive approval to market a generic product
 *2 New Drug Application (NDA): Application submitted to the U.S. FDA to receive approval to market a new drug



Strategic Target Establish Oncology Business

1. 5-Year Business Plan

We will establish an oncology business by launching several drugs currently in late-stage development. Concurrently, we will accelerate early-stage pipeline development and evaluate further enrichment of our oncology pipeline through the acquisition of external assets. Through the acceleration of oncology research and development, we aim to grow oncology business revenue to more than ¥40.0 billion in fiscal 2020 and ¥300.0 billion in fiscal 2025, when this business will function as a core business.



2. Initiatives to Date

(1) New Start as a Cancer Enterprise

Daiichi Sankyo has strong scientific and technological prowess rooted in its history and backed by its global network. In recent years, the speed of research and development has been accelerating on a global scale. Seeking to achieve a level of speed that surpasses the global standard, we integrated our oncology R&D organizations in April 2016. To lead the resulting organization, we appointed Antoine Yver, an individual that had previously headed up oncology development at a global mega-pharma corporation and that has recently become known for his breadth of experience and accomplished background in the field of global cancer treatment development. Guided by Yver, the Company's oncology R&D organization cut a new start as the Daiichi Sankyo Cancer Enterprise. Daiichi Sankyo has defined its focus franchises as antibody-drug conjugates (ADCs) and acute myeloid leukemia (AML). We have also set forth our policy of actively forming outside alliances to strengthen these franchises.

In April 2017, we established a new organization tasked with enhancing our global marketing capabilities in the oncology field. This organization will be led by Thierry Gruson, an individual that has played a role as a global leader in the immuno-oncology drug field, overseeing the marketing strategies of countless global products.

Under the guidance of these two leaders, we will accelerate the research and development of oncology drugs discovered by Daiichi Sankyo.

Daiichi Sankyo's Two Oncology Field Franchises

- ADC Franchise**
Development of proprietary technologies and application of developed technologies
- AML Franchise**
Development of numerous new drugs

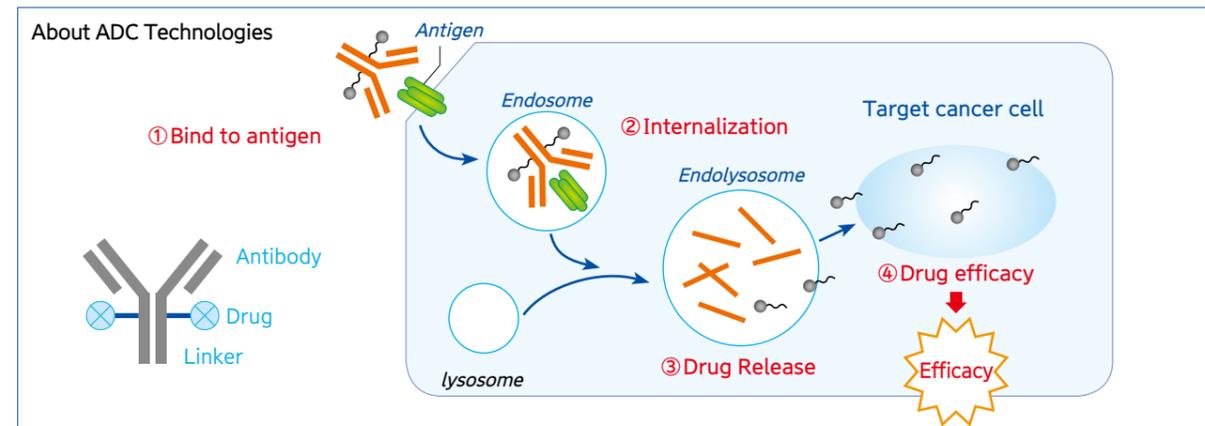
(2) ADC (antibody-drug conjugates) Franchise

a. ADC Technologies

In the past, over an extended period of time, cancer treatments predominantly consisted of small molecule drugs known as chemotherapy drugs that work by acting on cell proliferation to eradicate cancer cells. However, chemotherapy drugs presented troubles due to side effects, namely that they exhibited significant levels of cytotoxicity to normal cells. It was for this reason that the development of molecular targeted drugs, which only act on specific cancer cells, began in the 1990s. Development ventures that, for example, attempted to use antibodies that bind to proteins that are specifically expressed on the surface of cancer cells as anticancer drugs have been advancing since then. Today, quite a few antibody drugs have already been put on the market, where they have grown into major cancer treatments.

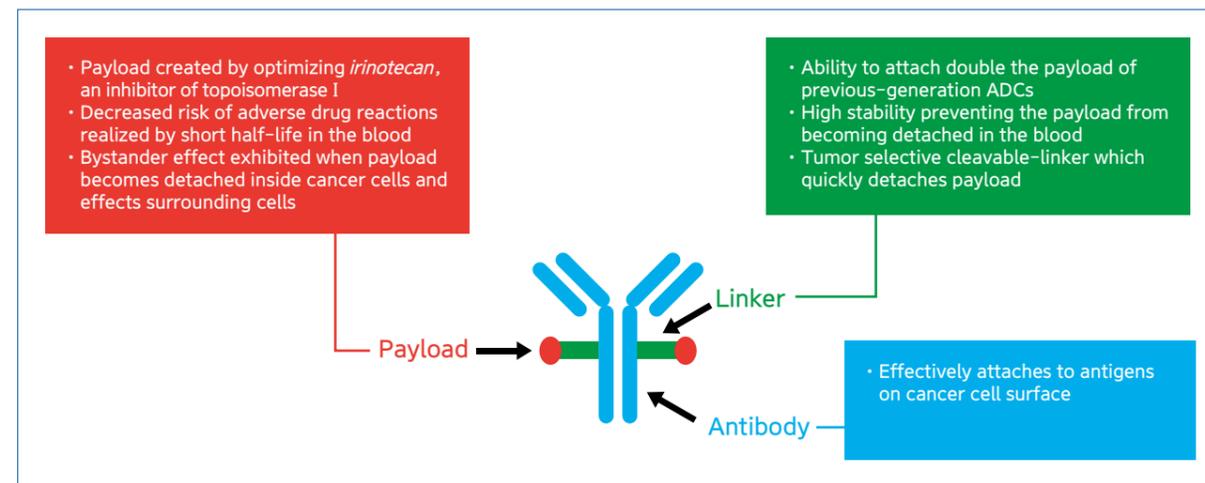
ADCs are made by bonding an antibody and a chemotherapy drug to discover a new therapy. Development on this drug technology is advancing in the hopes that chemotherapy drugs will only affect the cancer cells by specifically sending chemotherapy drugs into cancer cell.

First-generation ADCs have already been commercialized. However, the amount of the chemotherapy that can be loaded onto a single antibody molecule is still relatively low. Moreover, as the synthetic linkers used may be unstable, the chemotherapy portion can become detached, leading to the onset of adverse drug reactions. As such, ADC technologies are still evolving, and many companies are currently working to develop next-generation ADC technologies.



b. Characteristics of Daiichi Sankyo's ADC Technologies

Daiichi Sankyo's ADCs feature an optimal payload derived from *irinotecan*, a chemotherapy drug that inhibits topoisomerase I, which stimulates DNA synthesis. They also utilize proprietary technologies characterized by a structure of unique linkers connecting the drug and the antibody.



c. Future Initiatives

Daiichi Sankyo's ADC technologies allow for the linker and the payload to be combined with various antibodies. By capitalizing on this characteristic, we aim to maximize the value of these technologies through internal efforts and possibly through external collaboration.

In addition, the Company has resolved to devote ¥15.0 billion to its first wave of capital investments, eyeing the future increase and acceleration of ADC project development as well as the commercial production activities to be conducted. Such investments will be continued going forward in order to expand the scale of production.

(3) DS-8201

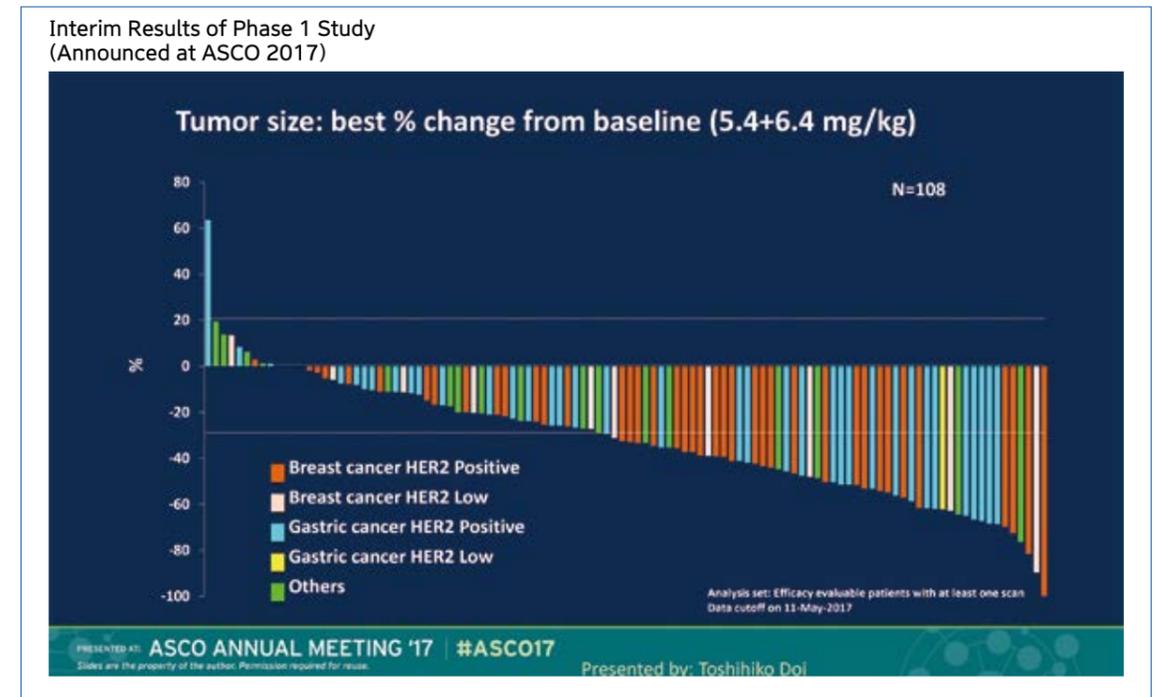
a. Progress to Date

DS-8201 is an ADC created using anti-HER2 antibodies to represent the first compound utilizing Daiichi Sankyo's proprietary ADC technologies to be advanced to the clinical phase, with a phase 1 study which commenced in August 2015. In clinical trials, it was discovered that there were several cases in which DS-8201 exhibits relatively high response in patients suffering from breast cancer or gastric cancer for which standard treatments, such as *T-DM1* (*trastuzumab emtansine*) or *trastuzumab*, are not effective and for which other treatment options do not exist. As of now, no serious adverse drug reactions have appeared that threaten the continuation of clinical trials.

Interim trial results were announced to the European Society for Medical Oncology in October 2016 (ESMO 2016). This announcement garnered much attention, being recognized as a highlight presentation of the academic meeting. DS-8201 then received Fast Track Designation for HER2 positive metastatic breast cancer from the U.S. FDA in November 2016.

Later, at the Annual Meeting of the American Society of Clinical Oncology held in June 2017 (ASCO 2017), Daiichi Sankyo made an announcement on the interim results of trials on 108 patients to which DS-8201 had been administered that included data collected after the announcement to ESMO 2016.

The graph below shows data on the 108 HER2 positive metastatic cancer patients that DS-8201 had been administered to. Each bar represents one patient. The lower a bar stretches down, the more cancer tumors had shrunken. Patients are arranged in order of the degree to which tumors shrank, with those showing the greatest rate of shrinkage on the right.



In terms of efficacy, an overall response rate*1 of 40.2% and a disease control rate*2 of 91.8% were achieved among 97 condition confirmed patients out of 108 enrolled patients. In 30 patients who failed SOC of breast cancer, *T-DM1* (*Kadcyla*) and *pertuzumab* (*Perjeta*), overall response rate was 46.7% and disease control rate was 100%.

*1 Ratio of patients in which tumors had shrunken by more than 30% or completely disappeared

*2 Ratio of patients exhibiting an overall response in which tumors are remaining at a consistent size (less than 30% shrinkage and 20% growth)

Interim Results of Phase 1 Study (Announced at ASCO 2017)

Confirmed Overall Response Rate (5.4+6.4 mg/kg)

	ORR n (%)	DCR n (%)
Total	39/97 (40.2)	89/97 (91.8)
Breast Cancer	19/45 (42.2)	44/45 (97.8)
BC Prior <i>T-DM1</i>	16/35 (45.7)	35/35 (100.0)
BC Prior <i>T-DM1</i> + <i>Pertuzumab</i>	14/30 (46.7)	30/30 (100.0)
Gastric Cancer	16/36 (44.4)	32/36 (88.9)
GC Prior <i>CPT-11</i>	8/18 (44.4)	17/18 (94.4)

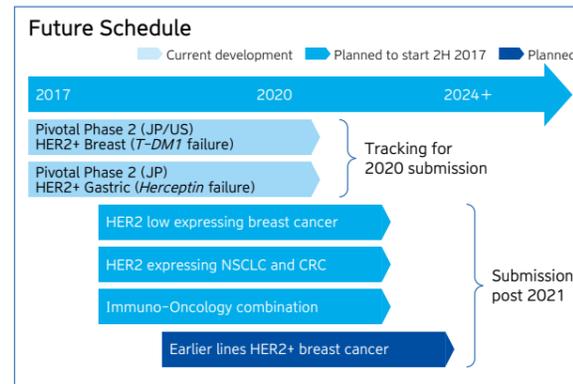
Analysis set: Efficacy evaluable patients for confirmed overall response
Data was analyzed based on the data cutoff on May 11, 2017

b. Future Initiatives

The interim results for the phase 1 study currently under way have indicated the safety and efficacy of *DS-8201*. Daiichi Sankyo is thus preparing to commence a pivotal study (a primary verification test for evaluating the safety and efficacy of an under-development drug) to evaluate the safety and efficacy of *DS-8201* in treating HER2 positive metastatic breast cancer and HER2 positive gastric cancer.

We also plan to commence studies evaluating *DS-8201* as a treatment for HER2 low expression breast cancer and HER2 expressing non-small-cell lung cancer (NSCLC) and colorectal cancer (CRC), for use in combination with immuno-oncology drugs, and as a first-line treatment for breast cancer.

We hope to be able to deliver *DS-8201* to patients as soon as possible, and are accelerating development with the target of commencing filing applications in 2020 for market approvals. Furthermore, to maximize the value of *DS-8201*, we are investigating the effectiveness of combination therapy with immuno-oncology medicines, such as immune checkpoint inhibitor.



(4) U3-1402

a. Progress to Date

U3-1402 is an ADC that utilizes the Company's proprietary ADC technologies together with *Patritumab*, an anti-HER3 antibody. In December 2016, a phase 1/2 clinical study was commenced in Japan targeting HER3 positive unresectable and metastatic breast cancer for which unmet medical needs are substantial. At the Annual Meeting of the American Association for Cancer Research held in April 2017, we announced the results of a pre-clinical study on *U3-1402*. In this study, it was confirmed that cancer cells pretreated with *erlotinib*, a standard treatment for non-small-cell lung cancer accompanied by epidermal growth factor receptor mutation, show high expression of HER3. *U3-1402* demonstrated a stronger antitumor effect than *erlotinib* in such pretreated cells that had been transplanted into test mice. *U3-1402* is therefore anticipated to prove effective for treating patients for which *erlotinib* lacks efficacy.

b. Future Initiatives

In the third quarter of fiscal 2017, we plan to commence a phase 1 study evaluating *U3-1402* in patients with non-small-cell lung cancer accompanied by epidermal growth factor receptor mutation.

Molecular Subtypes of Breast Cancer with HER2 ADC & HER3 ADC Targets

	Growth Speed	Hormone-Receptor Positive*	Hormone-Receptor Negative	ADC Target
HER2 Negative	Low	Luminal A	Triple-negative	HER3 ADC <i>U3-1402</i>
	High	Luminal B (HER2 negative)		
HER2 Positive	—	Luminal B (HER2 positive)	HER2 type	HER2 ADC <i>DS-8201</i>

* Estrogen-receptor and/or progesterone-receptor positive

Subtype	Characteristics
Luminal A	Hormone-receptor positive / HER2 negative / High growth speed
Luminal B (HER2 negative)	Hormone-receptor positive / HER2 negative / Low growth speed
Luminal B (HER2 positive)	Hormone-receptor positive / HER2 positive
HER2 type	Hormone-receptor negative / HER2 positive
Triple-negative	Hormone-receptor negative / HER2 negative

About the HER Family

The HER Family (Human epidermal growth factor receptors)

The human epidermal growth factor receptor (HER) family consists of four receptors: HER1, HER2, HER3, and HER4. These receptors are involved in the regulation of cell multiplication and differentiation in normal cells. However, HER family receptors have been found to be overexpressed, amplified, or mutated in several types of cancer and are thus an important target to be focused on in treating cancer. Compounds and antibodies that inhibit HER1, also known as epidermal growth factor receptor, are used to treat lung, colorectal, and other cancers. Antibodies that target HER2 are used to treat breast cancer and gastric cancer. HER3, meanwhile, has been reported to be highly expressed in breast and lung cancer and is thus garnering attention as a new target for cancer treatment. Currently, no link between HER4 and cancer has been confirmed.

(5) Future Initiatives for Other ADCs

Daiichi Sankyo's ADC technologies are applicable to a wide variety of antibodies. For example, we are currently engaged in pre-clinical research on *DS-1062*, an anti-TROP2 ADC, and *DS-7300*, an anti-B7-H3 ADC. We also have several other ADCs in the pre-clinical phase. Daiichi Sankyo is always examining possibilities for collaboration with other companies to increase the range of antibodies it can apply its ADC technologies to.

Project Code	Antibody Target	Indication	Research	Pre-Clinical Development	Phase 1 Clinical Studies
<i>DS-8201</i>	HER2	Breast cancer Gastric cancer	█	█	█
<i>U3-1402</i>	HER3	Breast cancer Non-small-cell lung cancer	█	█	█
<i>DS-1062</i>	TROP2	Solid tumors	█	█	
<i>DS-7300</i>	B7-H3	Solid tumors	█	█	

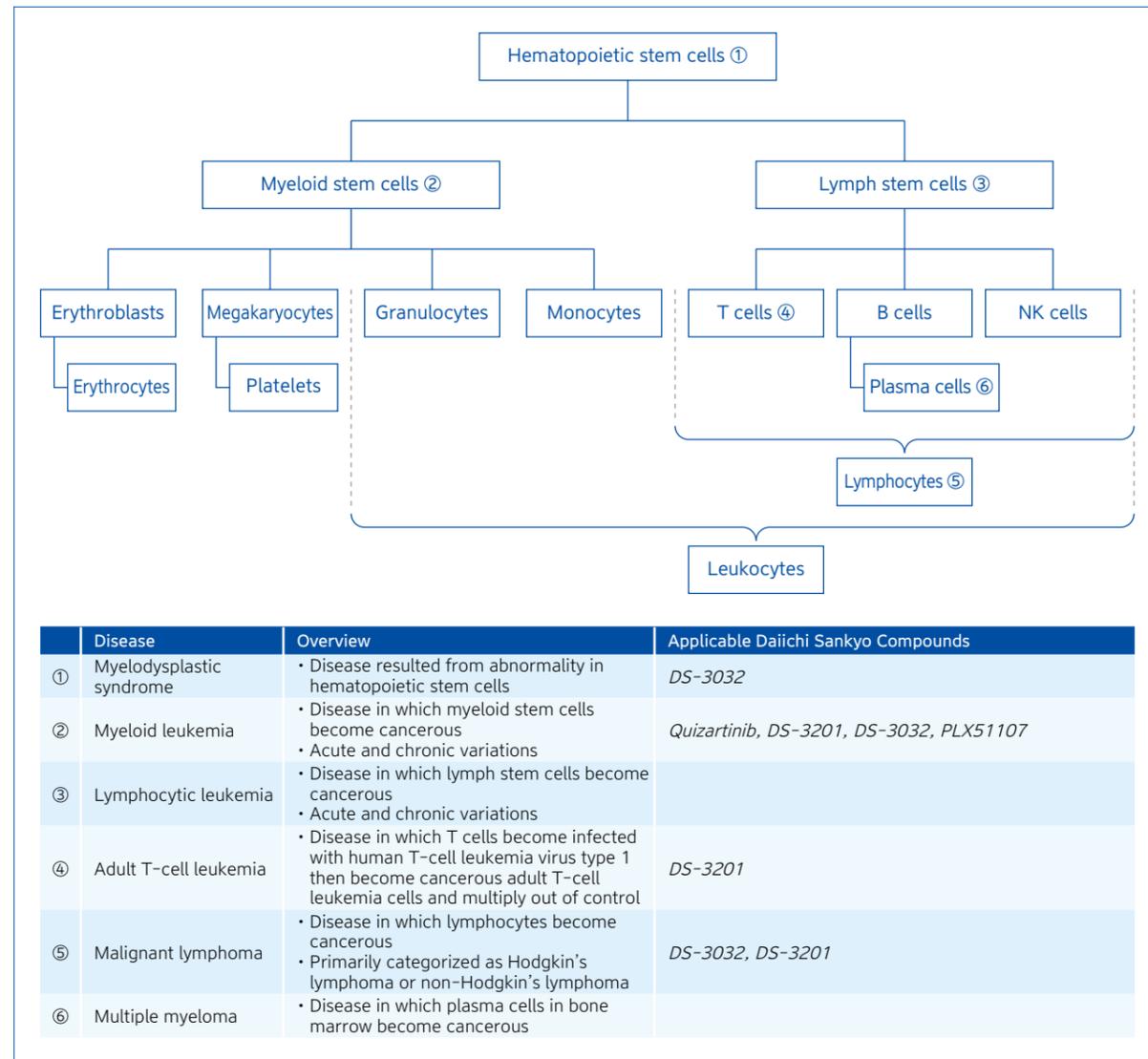
As of July 2017

(6) AML (acute myeloid leukemia) Franchise

a. About AML

Leukemia is a disease in which hematopoietic stem cells in bone marrow multiply at an abnormal rate when undergoing differentiation and development into white blood cells and platelets and then become cancerous. Acute myeloid leukemia (AML) is a form of myeloid leukemia that progresses extremely rapidly. The cause of AML is not completely clear. However, it is well known that this disease can become life-threatening as the amount of normally functioning white blood cells, red blood cells, and platelets declines in conjunction with the spread of the disease. Although, since 2000, numerous new drugs have been approved for other forms of hematological tumors, such as non-Hodgkin's lymphoma and multiple myeloma, only one drug has been approved for the treatment of AML, and that drug was not approved until 2017. It has been reported that only 26% of AML patients survive for five years*. Accordingly, there are significant unmet medical needs in relation to AML.

* Source: Leukemia & Lymphoma Society, NCCN Guidelines, Brunet-S, et al., J. Clin. Oncol. 2012; 30: 735-741, Dohner-H, et al., NEJM 2015; 373: 1136-1152

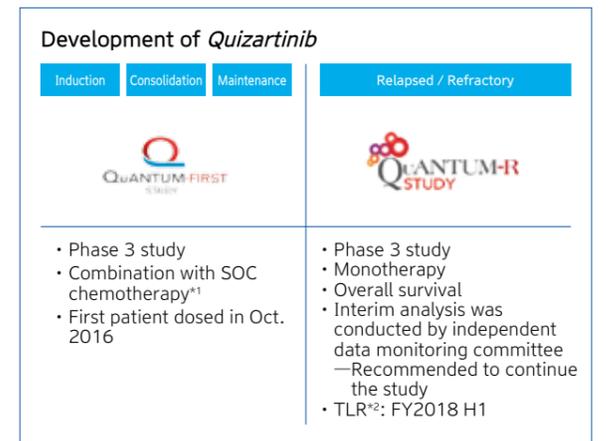


(7) Quizartinib

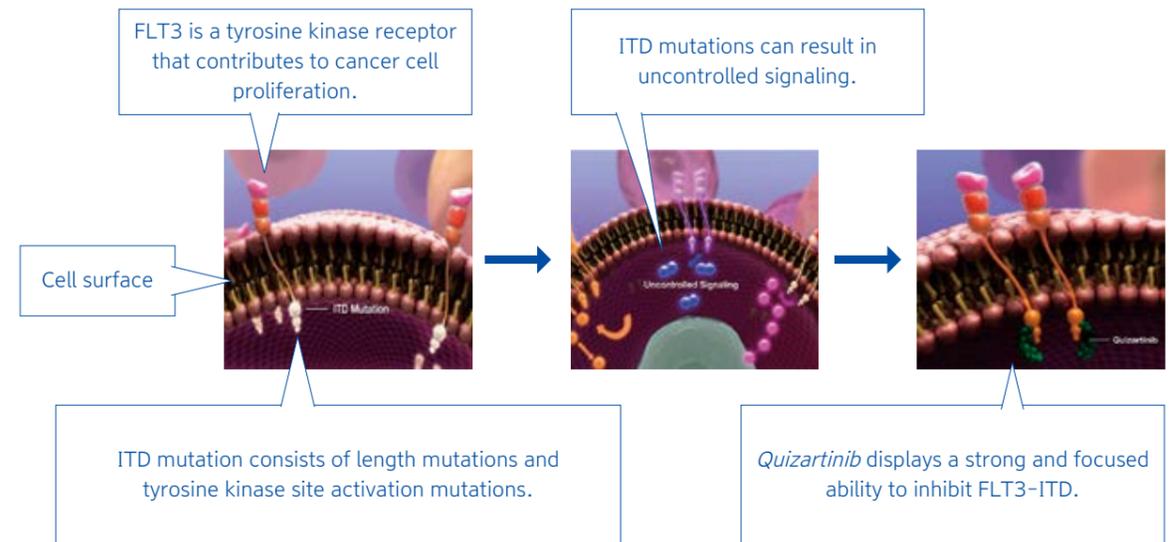
There exists a subtype of AML in which internal tandem duplication (ITD) mutations (genetic mutations) occur in FLT3 (a tyrosine kinase receptor that contributes to cancer cell proliferation). This subtype of AML, called FLT3-ITD-positive AML, has a particularly high degree of malignancy and extremely poor prognosis, with a rate of recurrence two years after bone marrow transplants that is three times higher than that of other forms of AML*. Quizartinib is a tyrosine kinase inhibitor that displays a strong and focused ability to inhibit FLT3-ITD.

Currently, we are advancing a phase 3 study for quizartinib on relapsed and refractory FLT3-ITD-positive AML patients with overall survival periods as its primary endpoint. In April 2017, an independent data monitoring committee conducted an interim analysis of this study, and the continuation of the study was approved. We expect to be able to release results from this study during the first half of fiscal 2018. In addition, a phase 3 study was commenced in October 2016 in combination therapy with chemotherapeutic agents in the induction, consolidation, and maintenance methods that are first-line treatments for AML.

* Source: Leukemia & Lymphoma Society, NCCN Guidelines, Brunet-S, et al., J. Clin. Oncol. 2012; 30: 735-741, Dohner-H, et al., NEJM 2015; 373: 1136-1152



*1 Induction (Cytarabine + Anthracycline + Quizartinib for 1-2 cycles)
Consolidation (High dose Cytarabine + Quizartinib up to 4 cycles and/or HSCT)
Maintenance (Quizartinib or placebo up to 12 cycles)
*2 Topline results



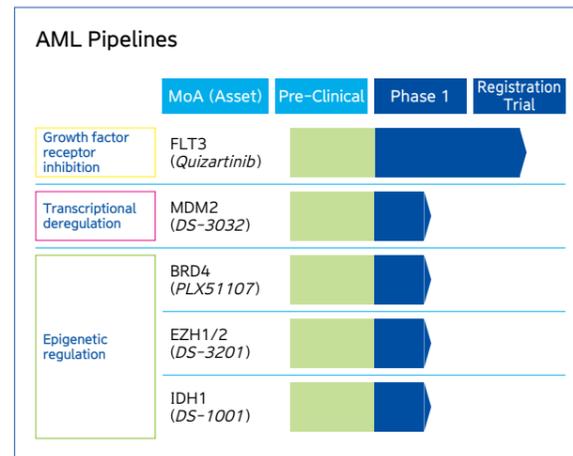
(8) AML Pipelines Other than Quizartinib

Aside from FLT3-ITD, there are several other target candidates to be focused on in developing AML treatments.

DS-3032 is an MDM2 inhibitor targeting transcriptional deregulation. Currently, a phase 1 study is under way in the United States to test *DS-3032* for treatment of relapsed and refractory AML patients and of patients with high-risk myelodysplastic syndromes. The results of this trial were announced to the American Society of Hematology in December 2016. Efficacy was confirmed in a preliminary evaluation of effectiveness, and we are currently planning the next phase of clinical trials.

In addition, phase 1 studies were started for *PLX51107*, a BRD4 inhibitor targeting epigenetic regulation (regulation of the transcription or expression of genes), in February 2016; *DS-3201*, an inhibitor of EZH1 and EZH2, in March 2016; and *DS-1001*, a mutated IDH1 inhibitor, in January 2017.

Daiichi Sankyo is working to expand its AML franchise to include a diverse range of pipelines. We are thoroughly committed to making contributions to the realization of multifaceted, comprehensive treatments for overcoming AML through these efforts.



(9) Progress of Other Late-Stage Pipelines

a. Pexidartinib

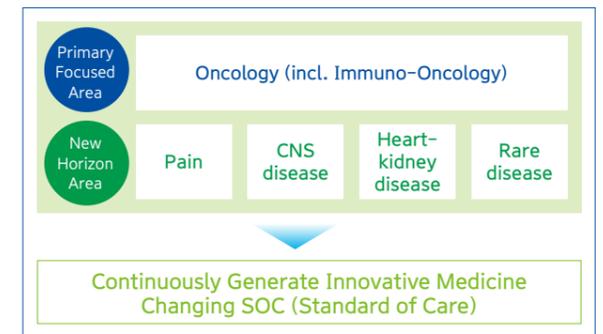
Pexidartinib is a tyrosine kinase inhibitor that specifically targets CSF-1R, Kit, and FLT3-ITD. We have been moving forward with a phase 3 study of this drug for treatment of tenosynovial giant cell tumor since 2015, and we anticipate to obtain results in the first half of fiscal 2017.

Tenosynovial giant cell tumor is a type of benign tumor that occurs in larger joints, such as the knee, and can become a serious obstacle impeding people's daily lives. Currently, there exists no treatment method outside of surgery. Moreover, the rate of recurrence is high, and there is sometimes no other choice but to amputate a patient's limb. As such, there is strong demand for new treatment methods for tenosynovial giant cell tumor. *Pexidartinib* was granted Breakthrough Therapy Designation by the U.S. FDA based on results from an extension cohort in a phase 1 study.



Strategic Target Continuously Generate Innovative Medicine Changing Standard of Care (SOC)

The standard of care (SOC) is the universally applied best treatment practice in today's medical science. Our target therapeutic areas for research and development include **oncology**, which will be positioned as a primary focused area, as well as **pain, central nervous system diseases, heart and kidney disease, and rare diseases**, which we define as new horizon area. Research and development of treatments in these areas will be accelerated going forward. We will strive to continuously generate innovative medicine changing SOC by taking advantage of partnering, open innovation*1, and translational research*2.



In the pages that follow, we will explain several examples of collaborative efforts with external organizations.

*1 Open innovation: Development method in which external development capabilities and ideas are used to overcome internal development challenges and create innovative new value
 *2 Translational research: Integrated research process encompassing development of new medical innovations, testing in clinical settings to verify safety and efficacy, and application in everyday medical practice

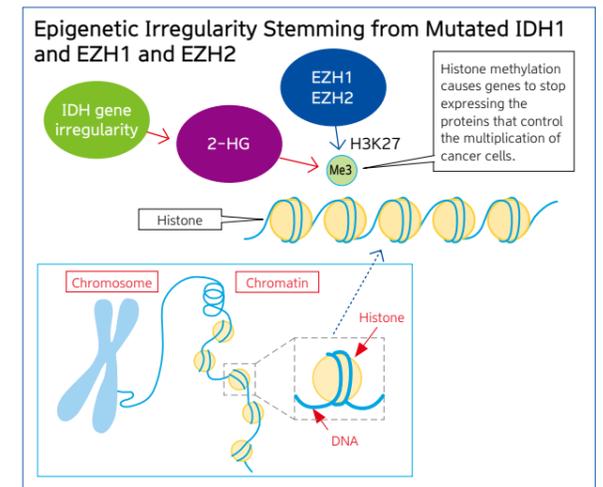
1. Oncology

(1) Comprehensive Collaboration with the National Cancer Center

Daiichi Sankyo entered into a comprehensive research alliance agreement with the National Cancer Center in May 2012, under which it has been engaged in joint drug-discovery efforts for developing revolutionary cancer treatments. The successes created through this collaboration include two compounds related to epigenetics (frameworks related to the regulation of the transcription or expression of genes) for which clinical trials are under way.

a. DS-3201 (EZH1/2 Inhibitor)

DS-3201 is a compound that inhibits EZH1 and EZH2. Malignant lymphoma is commonly known to have poor prognosis. One cause of this is thought to be the fact that the cancer stem cells, which have the ability to regenerate cancer cells, survive after treatment. However, cancer stem cells require histone methylation enzymes EZH1 and EZH2 to sustain themselves. Accordingly, by inhibiting these enzymes, it may be possible to eradicate cancer stem cells and breakdown a cancer's resistance to treatments, effectively preventing recurrence. *DS-3201* is a drug with potency in inhibiting both EZH1 and EZH2, and a phase 1 study is currently being implemented to evaluate *DS-3201* as a treatment for malignant lymphoma.



b. DS-1001 (IDH1 Inhibitor)

Mutations are seen in mutated isocitrate dehydrogenase IDH1 with relatively high frequency in malignant brain tumors, AML, cholangiocarcinoma, chondrosarcoma, and other malignant tumors. In March 2017, Daiichi Sankyo commenced a phase 1 clinical study to evaluate *DS-1001*, a drug that selectively inhibits mutated IDH1, as a treatment for malignant brain tumors (gliomas). When gliomas are accompanied by IDH1 mutations, they tend to reoccur frequently, elongating treatment periods. *DS-1001* is anticipated to become a treatment that is capable of addressing unmet medical needs related to this condition.

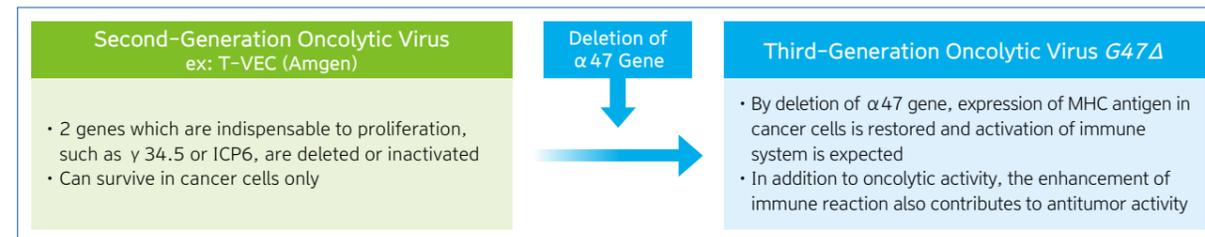
c. Potential for Treatment of AML

EZH1 and EZH2 and IDH1 are promising targets for the treatment of AML. *DS-3201* is therefore a pipeline that is anticipated to play a central role in Daiichi Sankyo's AML franchise. A phase 1 study was thus started in April 2017 to evaluate the ability of *DS-3201* to treat AML. We are also examining the potential for *DS-1001* to be used as an AML treatment.

(2) Joint Research with the Institute of Medical Science of the University of Tokyo (DS-1647: G47Δ Oncolytic Virus)

Developed together with Professor Tomoki Todo of the Institute of Medical Science of the University of Tokyo, G47Δ is a third-generation strand of oncolytic herpes simplex virus 1 (HSV1) created by using genetic modification technologies to modify HSV1 so that it only multiplies in cancer cells. This second-generation oncolytic virus was made by deleting or rendering inactive two genes (γ34.5 and ICP6) necessary for multiplication inside normal cells, making it only possible for the virus to multiply inside of cancer cells. In addition to these two genes, α47* was deleted from the third-generation virus to ensure that it only multiplies in cancer cells while also enhancing its antitumor immunity. An investigator initiated clinical phase 2 study targeting malignant gliomas was commenced in 2015. Furthermore, this drug received designation under the SAKIGAKE Designation System for medical equipment, in vitro diagnostic, and regenerative medicine products in February 2016. G47Δ was also designated as an orphan drug under the Orphan Drug/Medical Device Designation System by the Ministry of Health, Labour and Welfare in July 2017. Together with Professor Todo, Daiichi Sankyo is developing treatment methods using G47Δ for malignant gliomas and various other forms of cancer tumors.

* Proteins coded with the α47 gene limit the expression of MHC Class I on the surface of host cells, restrict provision of virus proteins, and evade the immunity surveillance of host cells. Accordingly, by deleting α47 from the HSV1 virus, expression of MHC Class I on host cells can be maintained, giving the potential for strong stimulation of antitumor immunity cells.



(3) Partnership for Oncology Field Cell Therapy Pipeline with Kite Pharma

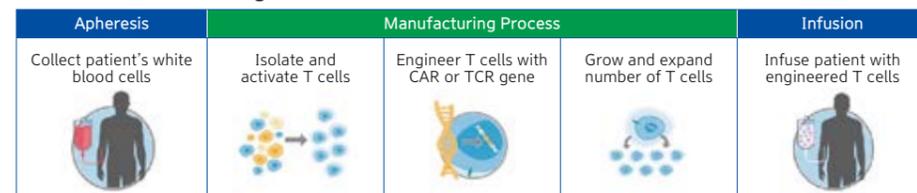
In January 2017, Daiichi Sankyo entered into a strategic partnership with Kite Pharma, Inc., the United States, in relation to its oncology field cell therapy R&D pipeline. This partnership grants the Company exclusive rights for development, manufacturing, and commercialization in Japan of Kite Pharma's KTE-C19 (a cell therapy that uses Kite Pharma's genetically modified T cells). The agreement also includes optional licensing rights for certain of Kite Pharma's other product candidates, some of which will progress into the clinical development stage over the next three years.

Cell Therapy Category	Definition	Applicable Daiichi Sankyo Compounds
Autologous	Made by cultivating and modifying cells taken from the patient	• KTE-C19
Allogeneic	Made by cultivating and modifying cells taken from a person other than the patient	• DS-8100 (Heartcel™) • iPS cell-derived cardiomyocyte sheet

KTE-C19 is a form of chimeric antigen receptor T (CAR-T), which is a cell therapy directed against CD19, an antigen expressed on the surface of B-cell malignant lymphoma cells. Applied via intravenous injection, this therapy is anticipated to demonstrate efficacy against recurrent and refractory malignant lymphoma. KTE-C19 has been granted Breakthrough Therapy Designation by the U.S. FDA, and started rolling submission in the United States in December 2016 and was completed in March 2017. In Europe, KTE-C19 has received Priority Medicines (PRIME) Designation from the European Medicines Agency and aim to file application for approval during fiscal 2017.

In Japan, we are engaging in discussions with the relevant authorities as part of preparations for commencing clinical trials. The diagram below details the steps leading up to the administration of genetically modified T cells to patients. White blood cells extracted from patients are sent to a cell processing facility, where a viral vector is used to introduce the chimeric antigen receptor gene into the T cells taken from the patient to make KTE-C19. The engineered cells are then administered to the patient intravenously for treatment.

Process of Administering KTE-C19 to Patients



(4) Other Cancer-Related Research Alliances

The following table shows cancer-related research alliances with research institutions that took place in fiscal 2016.

Start of Alliance	Partner	Alliance Details
May 2016	Astellas Pharma Inc., Takeda Pharmaceutical Company Limited	Establish basis of biomarker data
September 2016	Zymeworks Inc.	Joint discovery research and cross-licensing related to bi-specific antibodies
October 2016	AgonOx, Inc	Joint immuno-oncology research
October 2016	Dana-Farber Cancer Institute, Inc.	Pre-clinical research collaboration focused on lung cancer
December 2016	DarwinHealth, Inc.	Research alliance for establishing oncology field development strategies and prioritizing investigational compounds
December 2016	Sysmex Corporation, Astellas Pharma Inc.	Creation of a method for analyzing circulating tumor cells
March 2017	National Institutes of Biomedical Innovation, Health and Nutrition, Mitsubishi UFJ Capital Co., Ltd.	Open innovation research on new cancer immunotherapy

2. Pain

(1) Drug Discovery and Licensing Agreement with Heptares

In March 2017, Daiichi Sankyo entered into a drug discovery and research technology licensing agreement with Heptares Therapeutics Limited of the United Kingdom focused on G protein-coupled receptor (GPCR), which plays a role in alleviating pain. GPCR is known to contribute to various types of pain, and pharmaceuticals controlling the functioning of GPCR can be expected to be effective at alleviating pain. Through this agreement, Heptares Therapeutics' crystallization technology will be utilized to gain information on the structure of proteins in order to predict the type of compounds that will affect proteins. We anticipate that this process will allow for rational pharmaceutical design and thereby help accelerate the speed and increase the success of drug discovery ventures. Together with Heptares Therapeutics, Daiichi Sankyo will seek out new compounds and evaluate their safety and efficacy through animal experiments in a drive to jointly develop new pain treatments.

3. Central Nervous System Diseases

(1) Alliance with University of California San Francisco Institute for Neurodegenerative Diseases

Since April 2014, Daiichi Sankyo has been jointly researching drugs and diagnostic agents for various neurodegenerative diseases together with the University of California San Francisco Institute for Neurodegenerative Diseases (UCSF-IND). Established in 1999, the UCSF-IND is a world-leading academic research institution specializing in neurodegenerative diseases. Led by the institute's director, Professor Stanley B. Prusiner, a Nobel laureate, the UCSF-IND is utilizing the experience and insight it has gained through years of research in the field of prions (infectious agents composed of proteins) to advance research and development of drugs and diagnostic agents for various neurodegenerative diseases.

4. Heart and Kidney Disease

(1) In-Licensing Agreement with Celixir

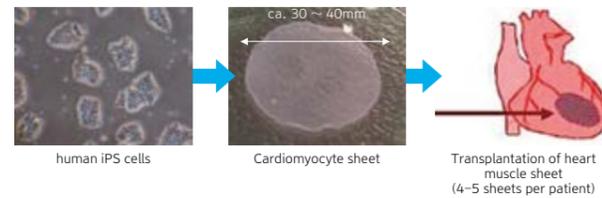
(DS-8100: Heartcel Cell Therapy)

In May 2016, we concluded an in-licensing agreement with U.K.-based Cell Therapy Ltd. (Celixir at present), where Nobel laureate Professor Martin Evans work as chief science officer, for Heartcel, an allogeneic cell (cell from a person other than the patient) therapeutic agent for ischemic heart failure currently in development. Under this agreement, Daiichi Sankyo will be responsible for development and sales of Heartcel in Japan. Preparations for development are currently being made.

Compound	Production Method
DS-8100 (Heartcel)	Derived from somatic stem cells (which possess pluripotency) isolated from healthy individuals that, based on cultivation under certain conditions, have been modified to show a treatment effect on cardiac disorders; unlike iPS cells, gene transfers do not take place
iPS cell-derived cardiomyocyte sheet	Heart muscle cells (iPS cardiomyocyte) made using human iPS cells; by introducing specific genes into somatic cells (which do not possess pluripotency), cells are reset to a state in which they had pluripotency (pluripotent stem cells); made through gene transfers

(2) Collaboration with Venture Company Originating from Osaka University (iPS Cell-Derived Cardiomyocyte Sheet)

In August 2017, Daiichi Sankyo concluded an agreement that will entail investment in Cuorips Inc., a venture company originating from Osaka University, and the acquisition of global sales rights for the induced pluripotent stem cell (iPS cell)-derived cardiomyocyte sheet developed by this company. This product is made using iPS cells, which can multiply almost indefinitely and have the ability to be differentiated into various tissue and organ cells. These cells are thus anticipated to be highly viable for use in cell therapy going forward. The iPS cell-derived cardiomyocyte sheet is an allogeneic cell therapeutic product (a product made by cultivating and modifying cells taken from a person other than the patient) comprised of human iPS cells that have been differentiated into cardiomyocyte cells and then processed into sheets. This product is expected to be beneficial for treating severe heart failure, a condition for which no viable treatment exists aside from the transplantation of a human heart or artificial heart. It should be possible to improve heart functioning and recovery from heart failure by implanting this product into the heart of a patient suffering from severe heart failure.



Daiichi Sankyo is researching the iPS cell-derived cardiomyocyte and potential manufacturing methods, and is currently developing efficient production technologies for this product with a view toward practical application. Going forward, we will advance discussions with Cuorips with the aim of engaging in joint development so that we can work together to be the first in the world to commercialize severe heart failure treatments using iPS cell-derived cardiomyocyte sheets.

5. Rare Diseases

(1) Joint Development with Orphan Disease Treatment Institute (DS-5141: Nucleic Acid Drug)

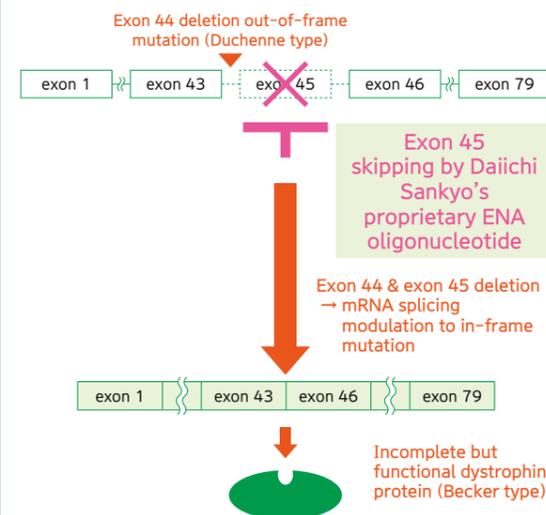
DS-5141 is a treatment drug for Duchenne muscular dystrophy (DMD) that is being developed together with Orphan Disease Treatment Institute Co., Ltd.*, and that went into phase 1/2 studies in Japan in February 2016. This is the first for the drug which has been submitted to clinical trials. DMD is a disease that has the same rate of occurrence in people from all ethnic backgrounds and is known to occur in roughly one out of every 3,500 boys. Many of the people affected by this incredibly serious and rare X-linked recessive condition (a genetic condition that expresses difference in sex) do not survive past their 20s or 30s. DMD prevents the production of dystrophin proteins in muscle cells, and can therefore lead to a decline in motor functions, respiratory failure, or cardiomyopathy. DS-5141 is a nucleic acid drug that helps combat this condition by stimulating the production of imperfect but still functional dystrophin proteins. Moreover, the drug utilizes our ENA nucleic acid modification technology and has demonstrated exceptionally high efficacy in animal experiments.

ENA is an ethylene-bridged nucleic acid in which ethylene is bridged at the furanose sugar ring at 2'-O and 4'-C ends. ENA and other ENA oligonucleotides, which are short-chain nucleic acids, demonstrate high binding force with complementary DNA and RNA as well as superior thermal stability and nuclease resistance.

DS-5141 was granted SAKIGAKE Designation by the Ministry of Health, Labour and Welfare in April 2017. We are advancing development of DS-5141b in close coordination with specialists with the hopes of quickly delivering this drug to patients awaiting an effective treatment.

* Orphan Disease Treatment Institute: A company that was established in 2013 through joint investment by Innovation Network Corporation of Japan, a fund operated by Mitsubishi UFJ Capital Co., Ltd., and Daiichi Sankyo

Mechanism of Duchenne Muscular Dystrophy and Concept of ENA® Oligonucleotide-Induced Exon Skipping



- Exons are the base sequences of genes, which possess the information necessary for synthesizing proteins. Proteins are created when exons are linked and translated.
- If, for example, a DMD patient lacks exon 44, the gene information will not be able to be read properly and proteins will not be made.
- Exon skipping entails skipping exons to create imperfect versions of the target protein. In the example above, exon 45 would be skipped to link exon 43 and 46.

Strategic Target Enhance Profit Generation Capabilities

1. 5-Year Business Plan and its Progress

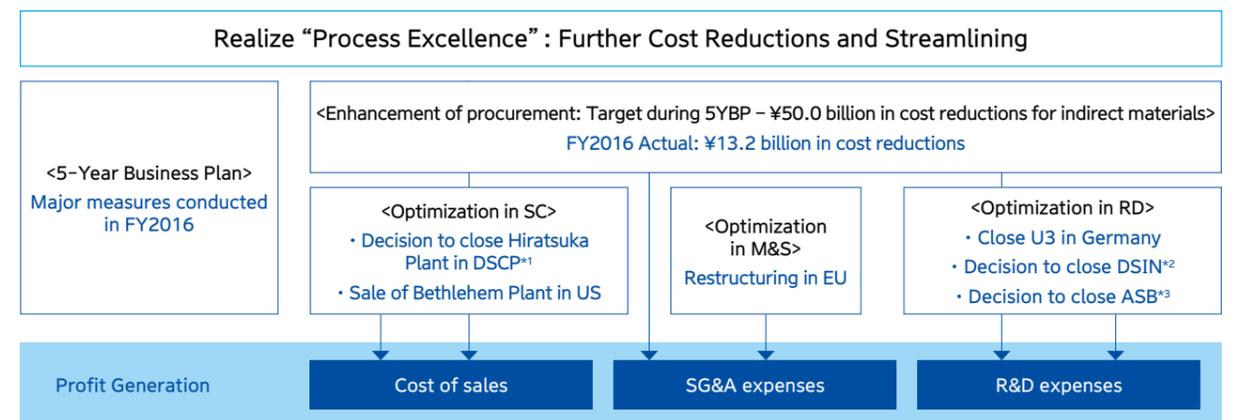
(1) 5-Year Business Plan

The Daiichi Sankyo Group is transforming on various fronts to realize its 2025 Vision of striving to become a “Global Pharma Innovator with competitive advantage in oncology.”

A specific goal toward realizing this vision is to enhance profit generation capabilities, which will be accomplished by optimizing operating structures, repositioning bases, and taking other steps to revise processes and costs. Through these efforts, we aim to achieve what we call “process excellence.” Various initiatives are being accelerated to this end.

By enhancing profit generation capabilities, we aim to grow beyond the LOE for *olmesartan* and achieve operating profit of ¥165.0 billion in fiscal 2020. A particular focus will be the procurement of indirect materials*, an area in which we will be optimizing procurement processes in pursuit of aggregate reductions of ¥50.0 billion over the period of the 5-year business plan.

* Excludes direct materials (raw materials, other materials, and procured articles)



*1 DSCP: Daiichi Sankyo Chemical Pharma Co., Ltd. in Japan
 *2 DSIN: Daiichi Sankyo India Pharma Private Ltd.
 *3 ASB: Asubio Pharma Co., Ltd., in Japan

(2) Progress to Date

Various initiatives are being advanced with the aim of optimizing all business. In fiscal 2016, one such initiative was the reorganization of our European marketing system, which was conducted centered on France. In addition, we resolved to close the Hiratsuka Plant of Daiichi Sankyo Propharma Co., Ltd., in Japan and sold the Bethlehem Plant of DSI in the United States in order to further optimize our global production systems.

Measures for optimizing our R&D system included finalizing the closures of U3 Pharma GmbH in Germany, Daiichi Sankyo India Pharma Private Ltd. in India, and Asubio Pharma Co., Ltd., in Japan. In this manner, we pursued selection and concentration across the Daiichi Sankyo Group.

With regard to raw materials and other direct materials, we advanced price negotiations based on global procurement volumes, examined low-cost production processes from a technical standpoint, and implemented other activities for reducing manufacturing costs in all areas. These initiatives led to manufacturing cost reductions of more than ¥10.0 billion in fiscal 2016.

In addition, we pursued our indirect material procurement cost reduction target of an aggregate ¥50.0 billion reduction over the period of the 5-year business plan with a focus on optimizing procurement processes. Specific measures included promoting global management of contract resource outsourcing expenses, transportation expenses, IT expenses, capital investments, and other outlays. As a result, we succeeded in reducing indirect material procurement costs ¥13.2 billion in fiscal 2016.

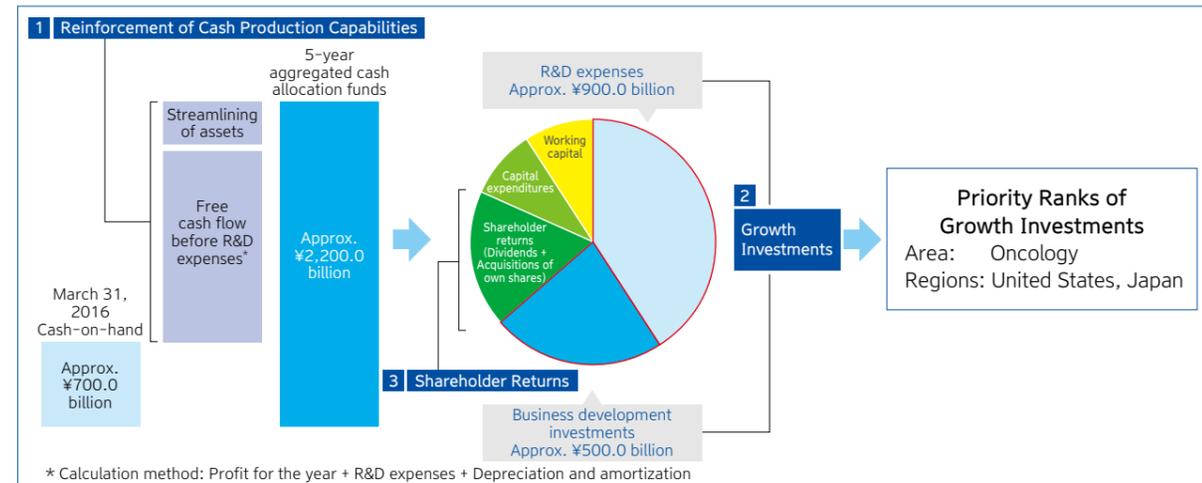
(3) Future Initiatives

Daiichi Sankyo's drive to enhance profit generation capabilities will continue, and aggressive promotion of process excellence will be a major part of this undertaking. As part of these efforts, we will pursue optimization across all businesses along with massive, groupwide cost reductions and efficiency improvements, which will primarily be accomplished through the reinforcement of procurement functions.

Growth Investments and Shareholder Returns

Under the 5-year business plan, our policy will be to prioritize growth investments while also enhancing shareholder returns.

On March 31, 2016, cash-on-hand totaled roughly ¥700.0 billion. Our activities over the five years of the plan will be funded by this cash as well as the approximately ¥2,200.0 billion to be generated in the form of free cash flow before R&D expenses (Profit before R&D expenses, depreciation and amortization) and cash recovered through asset downsizing. As for specific allocations, we plan to conduct growth investments of ¥900.0 billion in R&D expenses and ¥500.0 billion in business development. The remainder of the funds will be used for shareholder returns, capital expenditure, and working capital.



1. Reinforcement of Cash Production Capabilities

(1) Free Cash Flow before R&D Expenses

Free cash flow before R&D expenses will be increased by achieving process excellence throughout the Daiichi Sankyo Group.

(2) Asset Streamlining

Proactive asset streamlining will be practiced to generate additional cash flows.

a. Shortening of the Cash Conversion Cycle

Optimizing inventories is a goal we will aggressively pursue on a global basis in order to shorten the cash conversion cycle. By categorizing all items, we will implement exhaustive inventory management measures, with specific measures being deployed on a global and regional basis to establish systems for supporting such management. At the same time, we will also work to maintain stable supplies while achieving industry-leading levels of inventory management.

b. Liquidation of Non-Core Assets and Optimization of Capital Expenditure

We aim to liquidate non-core assets at the most ideal timing. With regard to real estate held by the Company, this judgment will be made by considering necessity to business activities, ability to be replaced, evaluations of life-cycle costs (maintenance costs needed to maintain functions subject to deterioration and renovation costs required to improve necessary performance aspects) and business continuity plans (BCPs), and market conditions.

c. Reduction of Cross-Shareholding Shares

The Company engages in cross-shareholdings of listed stocks when such holdings are judged to contribute to the maintaining and strengthening of long-term business relationships and subsequently to the improvement of corporate value. However, we seek to reduce the total amount of cross-shareholding shares to a level that is appropriate from the perspective of capital efficiency.

(1) Increase in free cash flow before R&D expenses

(2) Streamlining of assets

Current assets	a. Shorten CCC*
Fixed assets	b. Liquidate non-core assets Optimize capital expenditure
Securities	c. Reduce cross-shareholding shares

* CCC: Cash conversion cycle

2. Growth Investments

Daiichi Sankyo will actively make growth investments to achieve the goals of the 5-year business plan. The Company is planning growth investments of ¥900.0 billion in R&D expenses and ¥500.0 billion in business development. In conducting these investments, our top priority will be to acquire oncology products and pipelines, and the United States and Japan will be defined as priority regions. Investment will be made as appropriate based on these policies.

3. Shareholder Returns

Our policy for shareholder returns will be to seek a total return ratio* of 100% or more over the period of the 5-year business plan and issue annual ordinary dividends of more than ¥70 per share. While continuing stable dividend payments, we will conduct flexible acquisitions of treasury shares.

* Total return ratio = (Total dividends + Total acquisition costs of own shares) / Profit attributable to owners of the Company

Shareholder Returns Policy during 5YBP*

- Total return ratio: **100% or more**
- Annual ordinary dividend: **More than ¥70**
- Flexible acquisition of own shares

* 5YBP: 5-year business plan (FY2016-FY2020)

4. Progress to Date

(1) Capital Investments

Efficient investments were carried out based on the priority ranks of each business. In addition, capital investments totaling ¥15.0 billion were approved for bolstering ADC production systems in order to facilitate the establishment of an oncology business.

(2) Reduction of Cross-Shareholding Shares

In fiscal 2016, the Company sold its holdings of 14 different stocks for a total amount of ¥17.3 billion. Going forward, the Board of Directors will periodically evaluate the rationale of listed shareholdings. The decision whether or not to sell those holdings that are deemed to lack meaning will be made based on a comprehensive evaluation of factors including impact on the market, and those that are to be sold will be done so sequentially.

(3) Issuance of Super-Long-Term Unsecured Corporate Bonds

Taking advantage of the continuation of low interest rates, Daiichi Sankyo issued super-long-term unsecured corporate bonds with maturity periods of 20 and 30 years in July 2016. These bonds were the first of their kind to come from the healthcare sector in Japan. Through these bonds, we procured ¥100.0 billion worth of funds with low, stable, long-term costs. Both the 20- and 30-year bonds have fixed interest rates. Those rates are 0.81% and 1.20%, respectively.

(4) Shareholder Returns

Daiichi Sankyo is targeting a total return ratio of 100% or more over the period of the 5-year business plan. In fiscal 2016, this ratio was 180.7% on a single-year basis.

Standard dividend payments were raised to ¥70 per share in fiscal 2016, from the ¥60 per share in fiscal 2015 and earlier. We plan to issue standard dividend payments of ¥70 in fiscal 2017 as well.

In addition, Daiichi Sankyo acquired approximately 20,650,000 of its own shares for approximately ¥50.0 billion on the open market in fiscal 2015 and then acquired an additional 20,250,000 for another ¥50.0 billion in fiscal 2016.

In order to achieve sustainable growth in corporate value, Daiichi Sankyo will continue to conduct investments essential for implementing its growth strategies while returning profit to shareholders.

	FY2015 Results	FY2016 Results	FY2017 Plan	(Target during 5YBP)
Total return ratio	118.9%	180.7%		100% or more
Dividend	Ordinary dividend	¥60	¥70	more than ¥70
	Anniversary dividend	¥10	—	—
Acquisition of own shares	¥50.0 billion	¥50.0 billion	Flexible	Flexible