Japan Business Unit

Satoru Kimura

Head of Japan Business Unit

Satoru Kimura was engaged in work related to domestic sales of pharmaceuticals after entered the company in 1981. He assumed Representative Director, Senior Executive Officer in June 2021, after serving as Vice President of Kyoto branch, Sales & Marketing Division of Japan Company of the company.

Business environment projection and the unit's vision in 2030

Technologies of diagnosis, treatment, and drug discovery are continuously advancing. As digital transformation is accelerating, the environment will change in the next ten years faster than that in the previous ten years. Similarly, the healthcare environment may dramatically change.

However, no matter how much the healthcare environment changes, the basis of our activities is to "contribute to the enrichment of quality of life around the world," which is our purpose. We always aim to be an ethical, trusted, and respectful partner, and continue to contribute to healthcare.

We will strive to contribute to healthcare in Japan as the number one company in Japan by appropriately responding to all the customers' needs including treatment and prevention of diseases and medical cost reduction. For this, we pursue comprehensive business development. This includes the innovative pharmaceuticals business, vaccine business, and the generic business.

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

We believe that one of our strengths in the innovative pharmaceuticals business is trust from healthcare professionals.

We cover a wide range of therapeutic agents such as those for cardiovascular diseases including thromboembolism; lifestyle-related diseases; diseases related to the central nervous system including migraine headache and epilepsy; and diseases related to pain. With the aim of total care focusing on patients, we provide healthcare professionals with useful, thorough, and correct information quickly. As a result, we have continuously been ranked No.1 for MR evaluation conducted by an external organization for years.

In 2020, we launched *Enhertu* in Japan, and expanded our business to the oncology field. We endeavor to provide doctors with thorough information on not only cancer therapy but also any possible subject such as complication and comorbidity so that they can select the best therapy for each patient. This is the sales approach we are pursuing, and it is what we can do as we have a wide range of pharmaceuticals. Trust from healthcare professionals cannot be gained overnight. We will make efforts to further enhance our sales capabilities so that we can provide higher-level information, in a timely manner and in a form required, to respond to a wide range of ever-changing needs based on experience in the primary care field we have built. With such efforts, we strive to be the most trusted healthcare partner also in the oncology field.

We aim to achieve a top level of sales in Japan and continue to grow. To achieve this, it is important that we strive to conduct activities to enhance the value of our products including maintaining drug prices to fit the product value as well as revisions of guidelines through evidence generation and dissemination and application of additional indications and dosage forms. In particular, we will collect, analyze, and evaluate unmet medical needs to strengthen the system of generating and disseminating evidence at an advanced level in the oncology field.

At the same time, facing the threat of infectious disease around the world, we recognize that our vaccine business has a large social responsibility. We strive to fulfill the responsibility of stably providing vaccines we produce. In addition, we will contribute to the society by promoting the development of vaccines that protect against emerging and re-emerging infections and developing a vaccine supply system to respond to future pandemic threats. Today, the generic business plays a role in the improvement of the medical insurance system in Japan. We continue to stably provide high quality generic medicines that not only reduce the economic burden of patients but also have features. These include authorized generics and medicines with formulation, labelling, and packaging innovations that are easy to swallow but hard to swallow accidentally. Furthermore, we will continue to provide pharmaceuticals considering patients and their families as well as healthcare professionals.

Oncology Business Unit

Ken Keller

Head of Oncology Business Unit

Ken Keller is President and CEO of Daiichi Sankyo, Inc. and head of the Global Oncology Business. Since joining Daiichi Sankyo, Inc. in 2014, he has shifted the structure of the U.S. business to focus on launching multiple oncology therapeutics in the coming years. Through his work with Daiichi Sankyo, and prior to that with Amgen Inc., Mr. Keller has more than 30 years of experience in the pharmaceutical industry. He is known for his inclusive leadership approach and his passion for bringing innovative drugs to patients in need.

Business environment projection and the unit's vision in 2030

The Oncology Business Unit (OBU) is committed to achieving Daiichi Sankyo's 2030 Vision to become an "innovative global healthcare company contributing to the sustainable development of society." By aligning our U.S. and European oncology businesses and global oncology functions together under the new OBU in April 2021, we are now one unified team singularly devoted to people with cancer. As we look to become a top leader in oncology – we will do so by launching our three lead ADCs across a dozen indications in 30 countries potentially benefitting more than 50,000 people worldwide by 2025. The field of oncology moves fast; our OBU will allow Daiichi Sankyo to move at the speed in which the oncology field innovates; accelerating our decision making and increasing our agility to respond to the rapid changes we see in standards of care, treatment and diagnoses patterns, and payer dynamics, ultimately making us well positioned to realize the 2030 Vision. Together, and in collaboration with the rest of the organization, the OBU will bring an unprecedented focus to the delivery of our oncology medicines to patients around the world.

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

Achieving our long-term 2030 Vision and contributing to sustainable growth requires us to work collaboratively within the OBU as well across the organization to deliver on Daiichi Sankyo's global purpose to bring life-changing medicines to patients, customers and society overall. Our ADC pipeline has the potential to transform the current standard of care across multiple types of cancer including breast, lung, colorectal, gastric and more. We know the needs of the oncology community continue to rapidly change – from diagnosis patterns to standards of care. We must continue to evolve and adapt – operating with agility and simplicity – to deliver for our patients and customers. This is what we have done with *Enhertu*® and *Turalio*® – leading to their successful growth to date.

We are pleased with the overall adoption of *Enhertu*, as market share continues to grow quarter over quarter. Since our initial launch in December 2019, we have a more robust understanding of how *Enhertu* is being utilized in the real world with experience from approximately 5,000 patients receiving treatment. Our core strategy is to provide a strong support system enabling the appropriate use of *Enhertu* for adult patients with unresectable or metastatic HER2 positive breast cancer who received two or more prior anti-HER2-based regimens in the metastatic setting, and for adult patients with locally advanced or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen and educating healthcare professionals on the management of interstitial lung disease associated with *Enhertu*.

Since launching *Turalio* in 2019, both medical oncologists and orthopedic oncologists have been receptive to using it to treat appropriate patients with tenosynovial giant cell tumor (TGCT). Moving forward, we are concentrating our efforts on educating stakeholders about the disease, given it is a very rare disease and awareness has been very low, in addition to the risks and benefits of *Turalio*. We are also connecting physicians and patients to Sarcoma Centers of Excellence, helping to ensure that these providers are trained and REMS-certified to prescribe *Turalio* to appropriate patients.

It's important to keep in mind that people are at the heart of our business, whether it is the patients, customers or employees. It's our obligation and responsibility to deliver our medicines to patients and we have an incredible team of people within the OBU and across Daiichi Sankyo working collaboratively to make this happen. Together we will achieve our 2030 Vision.

EU Specialty Business Unit

Jan Van Ruymbeke

Head of EU Specialty Business Unit

Jan joined Daiichi Sankyo in 2012 as Managing director, CEO at Daiichi Sankyo Europe GmbH. A medical doctor by education, Jan joined the pharmaceutical industry at Cilag Benelux (a Johnson & Johnson Company) in 1989. After a short period in medical affairs, he moved to marketing and sales. From 1996 he was Janssen-Cilag Hungary's General Manager. At Novartis, from 2000, Jan was county president in South Africa. In 2005 he joined Grunenthal where he worked as General manager Spain and Iberia and as Head of Latin America till joining Daiichi Sankyo in 2012. Throughout his career Jan's focus has been on driving profitable growth by restlessly focusing on customer needs and creating customer centric organizations.

Business environment projection and the unit's vision in 2030

Historically, Daiichi Sankyo in Europe focused on cardiovascular products which enabled us to become true experts in this area. Based on this wealth of experience, capabilities, and customer understanding, we defined our aspiration accordingly: "We want to be recognized as the benchmark for patient and customer centricity through delivering the best customer experience." Our ambitious goal is to exceed our customers' expectations. We want to achieve this by designing and delivering on customer experience collaboratively. Thus, we will be able to increase customer satisfaction, loyalty and advocacy which will be the driver for sustainable growth and contribute to our company's 2030 vision.

From a European perspective we also appreciate the 2030 vision's focus on our role in society. With environmental, social and access aspects becoming increasingly important, we are keen on contributing our part. Elements are the further reduction of our environmental impact, e.g. by using solar energy at our Pfaffenhofen site or by actively shaping a culture that fosters Inclusion & Diversity to make sure everybody can thrive at Daiichi Sankyo.

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

Becoming the benchmark for patient and customer centricity requires us to constantly learn and adapt. We must evolve together with our customers and always be aware of their needs and current and future challenges. This requires us to change our mindset and to constantly ask ourselves whether we are still on the right track. While not everything we do is and will be digital, digital capabilities will nevertheless help us to tackle these challenges.

Digital tools offer enormous opportunities, e.g., based on data analytics we can better tailor our offers. By gaining a deeper understanding of what our customers require to make the right decisions for their patients. we are better able to use the limited time we have with them. The pandemic served as a catalyst for this development. We established a Digital Excellence group in our Specialty business which focusses on exactly this: how can we use digital solutions to better understand and address customers' and patients' needs.

Part of this journey also includes changing to a bespoke omnichannel go-to-market model for us to offer a unified customer experience.

Our cardiovascular portfolio is also an opportunity since it allows us to create synergies at customer level and be recognized as a partner of choice.

In addition, this portfolio approach helps us to be more efficient. While our anticoagulant *Lixiana*® (edoxaban) is advancing in its life cycle, we can put our capabilities and capacities to very good use with *Nilemdo*®/*Nustendi*® (bempedoic acid/ bempedoic acid with ezetimibe). Applying our resources across our cardiovascular portfolio, thus increasing return on investment, allows for reinvestments into other growth areas and future opportunities for further sustainable growth of the entire company.

All of this is only possible with the best people. Only people who are engaged, inspired, and dedicated will be able to deliver the best customer experience to fully realize the potential of our current product portfolio – people with the right mindset, values, and behaviors with an emphasis on commitment to customers and a collaborative and agile way of working, as well as empowerment and diversity. Attracting, retaining, and developing this talent is key for the success of our Specialty business in Europe.

ASCA Business Unit

Kiminori Nagao

Head of ASCA Business Unit

Kiminori Nagao assumed President of ASCA Company in April 2021. He has been engaged in work for development of new drugs since joining the company in 1988. As the Vice President of Development Division, his previous job, he promoted development of new drugs globally including Japan and Asia. For two years from 2014, he was in charge of clinical development and regulatory affairs of Asian countries except for Japan.

Business environment projection and the unit's vision in 2030

There are situations that the policies of drug price control are strengthened for products including long-listed products since the national health insurance finances is under pressure in the countries in Asia, South & Central America (ASCA). Such policies include VBP* in China. On the other hand, the oncology market in the ASCA countries is expected to grow significantly. Especially, there is a possibility that China becomes the largest market. We aim to "contribute to the enrichment of quality of life around the world," which is our purpose, by delivering our oncology products to more patients as quickly as possible.

We will strive to grow Daiichi Sankyo's presence globally by continuously launching the new products in the primary care and oncology fields, and by increasing the market share of *Lixiana*. We aim to double our sales and profits in the next ten years to strengthen the business of Daiichi Sankyo in Asia and South & Central America.

* VBP: Volume-Based Purchasing/Procurement. A policy of price reduction on drugs including generic drugs of which the government confirmed equivalence.

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

ASCA Business Unit is responsible for export business for our partners as well as our own business activities of seven group companies in China, Taiwan, South Korea, Thailand, Vietnam, Hong Kong, and Brazil. Every country has a different environment but each of the group companies has secured favorable sales and profits even after patent expiration of the products through their professional promotional activities with strong brand awareness in the primary care business. As a whole, the unit has steadily grown since its establishment in 2010.

Recently, however, as there is a large impact from countries' policies of drug price control, business transformation and continuous launches of new products are required. To respond to this, we have been working hard to establish the system and basis in each country for the oncology business which is expected to be our growth engine and expand our presence. We aim to launch new products in China within two years after their launch in the U.S. by accelerating the development in China. For this, we will reshape the development function in China and enhance our collaboration with related functions. We also aim to expand our footprints to deliver oncology drugs to more patients as quickly as we can.

We will maximumly expand business with a focus on appropriately capturing changes in each of the market; enhancing our strength, relationships between Daiichi Sankyo and stakeholders; and using digital and smart marketing. In addition, we will strengthen the business platform of each group company through measures such as licensing-in the products both in the primary care and oncology fields considering the portfolios as well as improving the efficiency of promotional activities. In China, as there is a significant impact from VBP, a certain degree of the decrease in sales and profits of the products selected for VBP might be unavoidable. We will try to enhance sales and secure profits by selecting appropriate sales channels and customer segments in light of the characteristics of our products and market needs.

During the period under the current 5-year business plan, we continuously focus on primary care business where the products like *Lixiana* are major contributor to the ASCA business. At the same time, we intend to make substantial investment in the oncology business so that it can expand the business in the ASCA regions in 2026 and beyond. Further, we make our best efforts to contribute to Daiichi Sankyo's 2030 vision by continuously uncover unmet needs in each country and responding to those needs.

American Regent Unit

Paul Diolosa

Head of American Regent Unit

Paul assumed the role of President and CEO of American Regent, Inc. in April 2021. Paul has spent the past 13 years committed to implementing significant investments in the company's facilities, equipment, people, and practices, including a state-of-the-art manufacturing expansion with a capacity to help millions of patients. His leadership in modernizing manufacturing operations led to promotions of increasing responsibility since he joined the company in 2008. Prior to joining American Regent, he served as Director of Engineering at Altana Pharmaceuticals for 10 years.

Business environment projection and the unit's vision in 2030

American Regent, Inc. (ARI) employs over 1,150 people in New York, Ohio, Pennsylvania and Altkirch, France. We are a leading injectable medication specialty pharmaceutical company. The company has a long history of supplying a variety of drugs including branded IV iron, high quality injectable generics, and veterinary medicines, primarily to the U.S. marketplace. ARI will continue to strive for year-over-year revenue growth. Growth will be a multi-faceted approach, including continued focus on strong compliance, generic complex development, international expansion, portfolio optimization for CapEx utilization, Animal Health business growth and partnership through business development and M&A. Most importantly, success will be driven by strong compliance, cGMP focus, a culture of teamwork/collaboration, employee focus and care for patients.

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

ARI's product portfolio is comprised of an iron injection franchise with two leading products, *Venofer*® and *Injectafer*®, for the treatment of iron deficiency anemia, a generic injectable franchise with a portfolio of difficult-to-manufacture, sole-sourced, and competitively differentiated products, and a rapidly growing branded Animal Health injectable franchise. Our largest challenge is patent expiration of Injectafer in 2028 with a mitigation strategy of extending through the indication of Heart-FID clinical trials.

Taking advantage of our capabilities to develop difficult-to-manufacture and complex products, we continue to expand our portfolio of competitive products. Our broad portfolio of more than 30 marketed products is constantly evolving to meet our customers' needs and stay ahead of the dynamic generic marketplace.

The iron injection franchise focuses on two products: Venofer, which is used to treat iron deficiency anemia (IDA) resulting from chronic kidney disease, and Injectafer, which is indicated to treat IDA resulting from chronic kidney disease, as well as from various other causes, but cannot be used in 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 administrations, Injectafer has enjoyed a rapid growth in market share since it was launched. To achieve further growth, Injectafer has increased its voice to meet GI and OB/GYN customer needs and continued awareness among dissatisfied oral iron patients.

These two products boast a combined share of the U.S. iron injection market of more than 70%, making ARI the undisputed leader in this market. With regard to life cycle management and expanded indications, Injectafer is currently enrolling a HEART-FID clinical study. This 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.

ARI manufactures, markets, and supplies generic injectable products in vial and ampule presentations. The company has been launching new products continuously and successfully to achieve sustainable growth. ARI is focused on product development and successful submission of multiple supplemental and new drug applications in FY2021 and beyond, targeting a minimum of 5 filings and 5 product launches per year. The significant capital investment in plant manufacturing capacity to become one of the top suppliers in the U.S. generic injectable market for vials, and we will soon be introducing pre-filled syringes.

ARI's Animal Health franchise is anchored by *Adequan*®. *Adequan*®*i.m*. which is recommended to treat degenerative joint disease (DJD) in horses. *Adequan*® *Canine* is recommended for the control of signs associated with DJD and is the only FDA-approved disease-modifying osteoarthritis drug (DMOAD). Future growth opportunities for this franchise have been secured with the internal acquisition of the Daiichi Sankyo Altkirch API manufacturing facility, currently undergoing investment to increase output. Studies are being planned to provide data to support subcutaneous injection for feline and canine. Successful generation of data will allow for ease of home injection by pet owners, increasing use and patient population. With 190 million cats and dogs in the United States and a 20-50% arthritis rate, there is enormous potential for growth. We will also plan on introducing a Chymase inhibitor injection for rash/itchy skin and Ephisol for improved circulation in horses.

American Regent is proud to be a Daiichi Sankyo company, providing innovative care for patients.

Daiichi Sankyo Healthcare Unit

Katsuhiko Yoshida

Head of Daiichi Sankyo Healthcare Unit

Katsuhiko Yoshida entered Fujisawa Pharmaceutical Co.,Ltd. in 1983.
He assumed Representative Director, President of Daiichi Sankyo Healthcare Co., Ltd. in April 2019, after serving as a Director and head of Corporate Strategy Division of Zepharma, and as a Corporate Officer and Head of Corporate Strategy Division of Daiichi Sankyo Healthcare Co., Ltd..

Business environment projection and the unit's vision in 2030

The way we live and work will be changed within 10 years as population aging is advancing along with the declining birthrate as well as rapid progress of technology typified by AI and IoT. The relationships with other countries including Asian countries are getting closer and closer in business and culture. Today, at the same time, as natural disasters caused by global warming rage, response to the environmental crisis is the whole premise of every corporate activity. Even in the era of drastic changes, our mission—contribution to health and beauty—has never changed at all. We endeavor to help people of every generation increase their quality of life in the era of 100-year lifespan through our creative products and information. In addition, we will make efforts to protect the environment for future generations and contribute to achievement of a sustainable society where life is respected. As a consumer healthcare company based in Japan, we will continue to take on challenges.

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

The strengths of Daiichi Sankyo Healthcare include: firstly, marketing capabilities as a consumer company to capture changes in society to stay ahead of consumers' needs, and secondly, research and development capabilities as a pharmaceutical company to generate creative and trusted products. Armed with these two advantages, we provide three categories of products, namely OTC drugs, products for skin and oral care, and life improver, via three channels comprising of in-store sales including drug stores, in-house mail order through our group company, Im Co. Ltd., and overseas markets including the Chinese market.

To ensure sustainable growth, we set a revenue target of 100.0 billion yen in the 5-year business plan toward 2025. Specifically, we are promoting the following strategies.

1. Domestic in-store sales:
   Aim to win the top share in our targeted OTC markets (excluding sales of tonic drinks) and enlarge our principal brands in the functional skincare and oral care markets.
2. In-house mail order:
   Expand skincare business and strengthen expansion into the life improver field.
3. Overseas business:
   Accelerate the growth of our China business through enhancement of collaboration for cross-border e-commerce and products lines.

For domestic in-store sales, we will foster following brands into a mega-brand: *Lulu*, cold remedy; *Loxonin S*, analgesic for internal and external use; and *Minon*, a series of body cleaning and skincare products for people with sensitive skin, as well as focusing salses development of drugs for skin. For in-house mail order, we plan to enhance the line-up of functional foods and OTC drugs as well as the line-up of *Rice Force* and *Brightage*, both skincare brands, and Regain, a tonic drug. For overseas business, we will further focus on the China market to build our brand equity and increase awareness of the brand there. In addition, we will make efforts not only to develop products but also to create new services through digital transformation so as to provide customers with more useful information.

The initiative for a sustainable society is one of important challenges in the 5-year business plan. For the initiative, we will implement own measures such as enhancement of environmentally-friendly plastic packages as a consumer company, not to mention that we will involve ourselves in the activities as a member of Daiichi Sankyo. At the same time, as a public organ, we will fulfill roles such as facilitating mutual growth between the company and employees through work, ensuring transparency, and respecting diversity.

Research & Development Unit

Ken Takeshita

Head of Research & Development Unit

Ken Takeshita was engaged in research at the University of Tokyo and other universities after earning a bachelor's degree in molecular biology from Harvard University and his medical degree from Yale University.
He then joined the pharmaceutical industry and led drug development programs including anti-cancer drugs at several global pharmaceutical companies.
He served as Global Head of Development as well as interim Head of Research at Kite Pharma since 2019.
He was appointed as Daiichi Sankyo's Global Head of R&D as of April 2021.

Business environment projection and the unit's vision in 2030

The most important near-term mission of Global R&D unit is to further strengthen the global R&D organization for oncology and maximize the value of the oncology pipeline focusing on 3ADCs. Although the competition in oncology is fierce, there is a large market for oncology drugs in Japan, the U.S., Europe and Asia, and these markets are expected to grow steadily. By launching products that leverage our strengths in ADC technology with promising targets, such as HER2 and TROP2, we will realize our vision of "Global Top 10 in Oncology" by 2030.

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

To become one of the top 10 global companies, we will further refine our global development capabilities in oncology. First, we will systematically build global development footprints in order to efficiently conduct global clinical trials for 3ADCs, centered on *Enhertu*, which has been approved under the accelerated approval pathways in Japan, U.S. and EU. To date, we have achieved the first step in expanding our Europe development footprint. Furthermore, we will expand our development footprint in China and other countries for the global development of *HER3-DXd*. In the future, we will expand our development footprint in major regions around the world in a stepwise manner, anticipating the future pipeline following the 3ADCs, including DXd-ADC family, such as *DS-7300*. With the aim of becoming an unified global organization, we will further enhance our operational efficiency and contribute to the enrichment of quality of life around the world by promptly delivering our innovative pharmaceuticals.

In the oncology area, the standard of care is changing rapidly, and the competition in development is becoming even more intense. We will leverage our strategic partnership with external parties to accomplish global development and deliver our new drugs to patients worldwide. To maximize the value of our 3ADCs, we have been strengthening our internal development capabilities while leveraging our partnerships, including the development platform of our partner AstraZeneca for *Enhertu* and *Dato-DXd*, and our strategic CRO coalition with Syneos. We will continue to strengthen our agile global development organization that can flexibly respond to changes in the environment.

We recognize that R&D in non-oncology is also critical for our sustainable growth. It took us ten years to commercialize oncology drugs based on our DXd-ADC technology. As the mission of our research organization, we are actively investigating various modalities and advanced technologies that focus on areas beyond oncology to identify the next pillar for Daiichi Sankyo's growth following the DXd-ADC family. Toward 2030, we will create new pillars of growth by maximizing advantages of our oncology R&D, such as the DXd-ADC family and next-generation ADCs, while also engaging in R&D activities utilizing next-generation modality technologies, such as oligonucleotide therapeutics and gene therapy. We aim to generate innovative medicine that truly transforms standards of care in the rare disease, CNS and other areas where unmet medical needs are high, utilizing advances in translational science and precision medicine to enhance our ability to succeed.

The central nervous system area is a challenging disease area with high hurdles for drug discovery. However, our multimodality strategy, which is one of the strengths of our research, has a potential to create breakthrough new drugs in this area that can transform patients' lives by pursuing targets deemed unreachable in the past. We have an environment that allows us to pursue unique research activities based on out-of-box thinking and our unique medicinal chemistry capabilities, advanced technology platforms and unique applications of translational science and precision medicine. By maximizing 3ADCs and strengthening our global R&D organization, we strive to build a new pillar that will drive our sustainable growth.

Biologics Unit

Masayuki Yabuta

Head of Biologics Unit

Masayuki Yabuta joined Pharmaceutical Division in Suntory Co., Ltd., in 1985 and has been widely engaged in the production of biologics: developing culture process of biologics, designing a manufacturing plant at the Tatebayashi Plant facility, developing a production method of an enzyme used for HANP production, handling a R&D project with use of overseas Contract Manufacturing Organization (CMO), and so on. He joined the Biologics Technology Research Laboratories in the Pharmaceutical Technology Division of Daiichi Sankyo in 2010. He was appointed as Head of the Biologics Division in 2017 and has held his current position since 2020.

Business environment projection and the unit's vision in 2030

Biopharmaceuticals including antibody drugs have been growing due to their remarkable efficacy. In fact, biopharmaceuticals occupy more than half of the top 10 sales products in the global pharmaceutical market. Accordingly, we expect that antibody drugs including *Enhertu* will continue to lead the pharmaceutical market as an advanced medical treatment. Furthermore, in recent years, more and more innovative therapies are being developed for diseases that had no treatment yet, thanks to the advanced development of new modalities such as nucleic acid drugs, gene therapy, and cell therapy. Daiichi Sankyo also has been focusing on such fields. Over the next 10 years, it is critical for us not only to maximize the 3ADCs but also to develop next generation biopharmaceuticals that follow 3ADCs as new pillars, including DXd-ADCs, antibody related drugs, and new modalities. In addition, the global COVID-19 pandemic has reminded us of the importance of vaccine development. To respond to this, we will also focus on the development of vaccines by using our biotechnology platform. This will allow us to further promote our purpose, "To contribute to the enrichment of quality of life around the world."

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

The manufacture of biopharmaceuticals includes biological process, which produces complex molecules. This means that each phase of development until commercialization requires a high level of biotechnology. As the molecular structure of biopharmaceuticals greatly affects manufacturing efficiency, it is important to consider the productivity as a drug product at the discovery phase. We believe that creating modalities with excellent efficacy, and also conducting technology research on molecular design and manufacturing methods pursuing good productivity and reasonable cost will become more important.

The Biologics Unit intends to accelerate the product development of biopharmaceuticals by developing our own competitive biotechnology, with which, designing candidate biological products together with the Research & Development Unit, and constructing manufacturing methods in collaboration with the Pharmaceutical Technology and Supply Chain Units. Specifically, while further enhancing the already cultivated technology of antibody design, production cell development and mass production, we will support maximization of the 3ADCs and DXd-ADC from technology standpoint, and at the same time, apply the technology to the next generation antibody therapeutics, gene therapy, mRNA vaccines ,cell therapy and so on. We will take responsibility from molecular design through process development of biopharmaceuticals. Going forward, we aim to contribute to Daiichi Sankyo's sustainable growth from a biotechnology standpoint by creating a unique modality that is expected to be the next pillar following DXd-ADC.

In order to realize these goals, development of new technologies and human resources are essential. In doing so, it is especially important to develop technology with a broad perspective from molecule design to commercialization, and an organization structure is needed where the drug design and production design functions collaborate closely. In addition, it is important to increase the depth of biological researchers and technical experts throughout the entire Daiichi Sankyo Group. We strive to be the unit as well as corporation with world-class biotechnology by mutually connecting and collaborating biotech talents from the entire Group including other units and overseas companies through engaging common tasks and developing human resources while advancing our technology throughout the Group.

Pharmaceutical Technology Unit

Hiroto Kashiwase

Head of Pharmaceutical Technology Unit

After joining Sankyo Co., Ltd. in 1989, Hiroto Kashiwase has engaged in research of antiviral agents for twelve years. He earned experience in Corporate strategy and managemen at the headquarters and contributed to the merging into Daiichi Sankyo. After the merger, he was involved in work related to pharmaceutical technology at CMC Planning Department, DAIICHI SANKYO, INC., Luitpold Pharmaceuticals, Inc. (currently, American Regent, Inc.). He assumed the Head of Pharmaceutical Technology Division in June 2019.

Business environment projection and the unit's vision in 2030

Toward 2030, Daiichi Sankyo has an aim of having a solid position in the global oncology market and a new growth pillar of profits. To achieve this, we need to continuously develop products and modalities that are expected to be the next growth pillars following 3ADCs. The Pharmaceutical Technology Unit plays a role to establish pharmaceutical technologies for commercializing new drugs developed by Research & Development. We will strive to establish technologies for various candidate modalities including next generation antibodies following DXd-ADC, gene therapy, cell therapy, LNP*1, and DTx*2. We will make the most of our knowledge and experience to manufacture and supply investigational drugs in at timely manner, as well as developing stable manufacturing processes to achieve high-quality products. These manufacturing and analysis technologies are transferred to supply chain functions including overseas CMOs.

Another important role we play is to design formulations and packaging that are easy for patients and healthcare professionals to use, and develop relevant manufacturing methods. We have been promoting the development of products and technologies by using the information on healthcare professionals' needs collected by our marketing personnel. In particular, such information has helped develop orally disintegrating (OD) tablets and extended-release formulations of oral narcotic drugs with abuse deterrence. In 2030, also on the oncology and DXd-ADC fields, we will be contributing to our purpose, "The enrichment of quality of life," through craftsperson-ship based on the Patient Centric Mindset.

Daiichi Sankyo aims to promote ESG management to ensure sustainable operations and growth. From this perspective, pharmaceutical technology unit especially focuses on environmental matters and strives to promote technological approaches such as improvement of manufacturing processes and analytical methods, selection of materials, to reduce waste and energy.

*1: Lipid Nano Particle, *2: Digital Therapeutics

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

Pharmaceutical Technology Unit is required to respond to all of the modalities identified by the Research & Development Unit promptly and flexibly, as we are in charge of the development of manufacturing and evaluation methods for all of the items developed by the company. To achieve this, it is essential to make the most of our experience and intangible assets accumulated through the development of small molecules and ADCs in addition to obtaining new technologies and knowledge. The use of IT tools is a key to success. We will improve business efficiency by using IT tools with the aim of establishing a system where complex business operations can be performed promptly and stably. With IT tools, we will promote research with simulation and modeling, adjust manufacturing and supply of investigational drugs based on accurate and real-time demand information, accumulate and use the regulatory knowledge on various modalities and countries, and strengthening communications globally and locally. In addition to efficiency improvement, we will promote automation with robotics which will enable accumulation of a large volume of data, and use it for new research so that we can sophisticate and deepen new modalities by using our strengths: "Capabilities for deep understanding of the manufacturing processes" and "Capabilities for developing manufacturing process that can control drug quality."

Supply Chain Unit

Junichi Fukute

Head of Supply Chain Unit

Joined the Company in 1981. Engaged in manufacturing of API (Active Pharmaceutical Ingredient) for 20 years at Odawara Plant and Onahama Plant. Took charge of the project to establish a plant for Loxonin API while working at Odawara Plant. Vice President, Supply Chain Strategy Department in 2005, Vice President, Procurement Department in 2007, Vice President, Supply Chain Technology Department in 2011, Vice President, Corporate Business Management Department in 2012, and Vice President, Supply Chain Planning Department in 2014. Corporate Officer in 2016, He assumed the Head of Supply Chain Division since April 2019.

Business environment projection and the unit's vision in 2030

In response to an increase in demand for 3ADCs, including *Enhertu* and the steady progress of the clinical studies of subsequent DXd-ADCs family, Supply Chain Unit will continue to pursue maximization of our supply capacity and stable supply of ADC products. At the same time, Supply Chain Unit will successfully establish a production and supply system in accordance with the identification and selection of the promising modalities that will become post-DXd-ADC growth drivers of Daiichi Sankyo.

However, in the process of innovation focused on ADC products and post DXd-ADC modalities, we remain consistent with QCD (Q: Quality, C: Cost, D: Delivery) as our base. In addition to QCD, we will position Resilience as an important factor and improve it to address COVID-19 and prepare for future pandemic of new infectious diseases and an increase of risk of large-scale natural disasters (large earthquakes, typhoons, torrential rains).

Moreover, Supply Chain Unit will aim to achieve a decarbonized society, a circular economy and a society co-existing with nature to address social and environmental issues under the current 5-year business plan and contribute to the realization of a sustainable society by committing to various initiatives for logistics, packaging and facilities such as promotion of use of solar power systems, energy saving and energy generation, biomass plastics.

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

For maximization of our supply capacity and stable supply of ADC products, Supply Chain Unit have consistently advanced streamlining of the production system to achieve a seamless system from production of investigational drugs to commercial production in order to ensure a stable supply of high quality products. We will continue to actively invest in production bases all over the world and to promote enhancement of our production capacity and securement of production lines of CMOs to establish a robust global production and supply structure.

Then, for establishment of a production and supply system for the post DXd-ADC modalities, Supply Chain Unit will advance development of a self-manufacturing policy and production system establishment scheme based on individual products' characteristics.

In order to maintain and reinforce our strength, represented by "a global manufacturing and supply system enabling launch and stable supply of products suitable for the market in each country," we are advancing transformation by investing our human resources and facilities in manufacturing biopharmaceuticals. In addition, we will promote to increase the mobility of human resources on a global level while advancing development and acquisition of professional talent.

For contribution to the principle of QCD and improvement of Resilience, Supply Chain Unit are emphasizing a mid-to-long term perspective taking global balance into consideration for the purpose of generating profit as well as working on the sophistication of our global supply chain management system that accurately forecasts demand that changes from day to day depending on the progress of development or sales. Particularly, for supply of DXd-ADCs, we have pursued diversification of risks by evaluating production bases based on the two levels – in Japan and overseas and within Daiichi Sankyo and CMOs. We will further reinforce the system "capable of providing a long-term stable supply of high-quality pharmaceutical products around the world in the event of an emergency such as a natural disaster." In addition, in order to achieve Data driven management through DX, we will steadily promote various measures (efficient, quality improved and predictive maintenance of ADC manufacturing) to achieve the smart factory that actively utilizes advanced digital technologies. Through these, we will improve Resilience.

Quality Assurance & Regulatory Affairs Unit

Miyuki Arai

Head of Quality Assurance & Regulatory Affairs Unit

After joining Daiichi Sankyo in 1985, Miyuki Arai was engaged in efficacy and pharmacological research of cancer immuno-therapeutic agents for eight years at a research laboratory. Since 1993, she has been working for more than 20 years in regulatory affairs, including management of marketing authorization holders, development and post-approval regulatory affairs, safety and package insert matters and legality review of advertisement, etc. She was appointed as the Head of Pharmacovigilance Department in 2015, the Head of Safety and Risk Management Department in 2017, and the current position in April 2019.

Business environment projection and the unit's vision in 2030

Quality assurance of product reliability and regulatory compliance are essential for the realization of the global top 10 in the oncology area and total healthcare services that provide optimal modalities to patients. In addition, given the prospects of environmental changes such as the aging society and entry into the healthcare business from other industries, it will be necessary to provide diversifying healthcare and therapeutic solutions to respond to various medical needs. We, QARA unit, aim to be an organization which contributes to business throughout the product lifecycle by securing reliability in an agile manner by the most efficient process, and by planning/executing seamless regulatory strategies with the relevant departments.

We also strongly desire to be an organization that leads a Quality First culture, in which every single employee recognizes the responsibility for quality, the executives proactively promote quality improvement activities through quality management review, and the entire company provides a stable supply of top-quality pharmaceutical products and highest quality medical information.

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

Until now, new products have been expanded to other regions after approved in Japan, the U.S. and Europe, and DS head office has taken the initiative in quality assurance for products and maintenance of approval in cooperation with DS group companies. Going forward, we need to handle more reliably, efficiently, and speedily so as to correspond to the acceleration of global expansion and numerous changes application plans toward maximizing the 3ADCs.

As for the quality assurance system, we will establish a globally unified quality management system for R&D, medical affairs, and pharmacovigilance areas, strategically manage quality issues and implement the PDCA cycle to ensure the reliability of medical information on a global basis. In the GMP area, the management of increasing overseas CMOs will be shared among three regions, Japan, the U.S. and Europe, and promote early detection and resolution of quality events/issues and technology transfer. As the same time, we will strengthen quality governance by comprehensively managing and horizontally deploying such information by DS head office. Furthermore, we will contribute to the stable supply of top-quality pharmaceutical products by introducing a global electronic system that enables real-time identification of process bottlenecks and continuous improvements, and expanding this system to include group companies in the future and making it a more robust quality management system.

As measures to enhance the regulatory affairs, we will visualize the regulatory status of products in each region, establish a process for collection and impact analysis of frequently updated regulatory information. In addition, for the purpose of efficient, effective and comprehensive plan and implementation of the regulatory submission strategy while taking into consideration each country's regulatory requirements, we will not only collaborate with the change management office, but also prepare to establish a seamless collaboration system that breaks down barriers between 3 regulatory affairs departments from development to post-marketing.

In providing optimal modalities to patients, we need to challenge in inexperienced areas, and find out how to leverage our knowledge. We will strive to develop and acquire specialists of our products and establish systems for quality assurance and regulatory affairs.

Clinical Safety & Pharmacovigilance Unit

Kento Wada

Head of Clinical Safety & Pharmacovigilance Unit

Kento Wada entered Suntory Limited in 1991 and was responsible for work including new drug development, project management in Japan and the U.S., the launch of subsidiaries in the U.S., and business planning. After transferring to Daiichi Sankyo in 2010, he was engaged in global safety management. In 2015, he planned and promoted the establishment of the Medical Affairs Division in Japan. He assumed the Head of Clinical Safety & Pharmacovigilance Division in April 2020 after serving as Vice President, Pharma-covigilance Department and Vice President, Post Marketing Study Department.

Business environment projection and the unit's vision in 2030

A good drug must have a high-level quality combined with provision of appropriate information. Any drug carries a risk of adverse events, no matter how effective it is. Daiichi Sankyo strives to minimize patient safety risks by promoting appropriate usage of drugs. For this, we always objectively analyze safety information collected around the world and provide healthcare professionals with necessary information including that on prevention, suppression of aggravation, and measures for adverse events in a timely manner.

Toward 2030, we strive to provide patients with new modality products, which is our new business pillar, while working on the global expansion of oncology drugs including 3ADCs. This will enrich safety information, and at the same time, global risk management will become more diverse and complex. In addition, the speed of development, application, approval will be accelerated, and therefore, timely risk management in development will become more important. Similarly, increasing early approvals will raise the importance of risk management for post-marketing. As well as the above, it is important to maintain and manage safety also for non-oncology products including existing launched products. We need to have more sophisticated and efficient business operations as each country is tightening the required level of safety management.

The 2030 Vision of the Clinical Safety & Pharmacovigilance Unit is "Be a Global unit which contributes to ensuring patient safety by providing a high quality safety information in a timely manner for all products including expanding oncology products and new modality from development to post-marketing." We will strive to conduct proactive safety monitoring and risk management to ensure patient safety throughout the life cycle from development to post-marketing.

Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

We will implement four major strategies to achieve the 2030 Vision. First, we will endeavor to conduct a high level of safety management while responding to diverse and complex risk management. For this, we will identify the best analysis methods and tools and strengthen the function for safety analysis that helps us quickly perform proactive risk analysis and take safety measures in a timely manner. We will also use epidemiological methods to implement advanced safety measures. In particular, we will use data from actual clinical data to understand drug utilization in the real world and check the effectiveness of safety measures. Second, to respond to growing safety information, we will integrate the global process and management of case evaluation so as to increase operational efficiency. Third, we will strengthen the unit's global governance to make global decisions faster on various matters, as well as enhance collaboration with related departments in the development and post-marketing phases. This will help us establish a system with which we can understand challenges and timely and appropriate decision making from both global and local perspectives. Finally, to secure global human resources who can flexibly respond to changes and will be responsible for the next generation, we will facilitate personnel exchanges while enhancing internal human development and promoting personnel acquisition outside the company.

We will strive to contribute to ensuring patient safety by achieving these four strategies and providing a high quality safety information in a timely manner.