Business Strategies by Process

Drug Discovery

Focus on expanding the pipeline and promoting open innovation

Yoshiharu Hayashi
Executive Officer,
Head of Sohyaku.
Innovative Research Division

Basic policy

The Sohyaku. Innovative Research Division strives every day to continually discover new drugs for the world that address unmet medical needs with the aim of becoming a "pharmaceutical company working with a sense of speed to be the first to deliver original value."

In the area of diseases, the Company is focused on the priority areas of central nervous system diseases and immune-inflammation diseases. At the same time, we are working on additional new areas and modalities for the future and will identify the ones that will become our next pillar of business.

In drug discovery activities, we are aggressively promoting cooperative business through industry-academia-government collaboration and using external drug discovery resources to expand these discovery opportunities, such as identification of novel targets and technologies.

Fiscal 2018 summary and fiscal 2019 initiatives

In fiscal 2018, we sought to rapidly obtain PoC for our drug candidates and focused on strengthening translational research[1]. One of the results is that we selected highly unique indications in several projects, which enabled us to advance the candidates to Phase 1. As we promote the diversification of modalities, we seek to expand our research pipeline to achieve the continuous creation of development candidates.

In addition, with respect to our drug development project, a collaboration with our pharmaceutical development subsidiary in the U.S., Mitsubishi Tanabe Pharma Development America, and in Europe, Mitsubishi Tanabe Pharma Europe, was able to drive the PoC study for its first product as planned after the establishment of our global development system.

Meanwhile, an issue in fiscal 2018 was that we were unable to create drug candidates in priority areas, particularly central nervous system diseases and immuno-inflammation diseases that lead to internal sales, especially in the U.S. following Radicava. It is necessary, more than ever before, to rigorously promote projects from a translational research perspective from the initial stage of research. Another issue was that the results of open innovation in basic research did not effectively lead to pipeline expansion.

In light of these issues, we will continue to steadily promote PoC studies and aggressively expand our pipeline focusing on priority areas in fiscal 2019. Furthermore, our policy is to focus on opening up the research environment. We created an environment where new synergies are easily produced, such as the Shonan Health Innovation Park

(see page 32), and we will collaborate with the best partners inside and outside the Company and incorporate leading-edge technologies. Moreover, we will encourage open discussions on new themes and ideas in the Sohyaku. Innovative Research Division and promote transparency in budget and human resource allocation. In addition, we will strengthen the connection between clinical practice (medical) and basic research (science) by collaborating with the Ikuyaku. Integrated Value Development Division. In cooperation with physicians inside and outside the Company, we will push forward with highly relevant project management that incorporates medical needs and a medical perspective from the early stages of research.

1. "Translational research" involves the connection from basic research to clinical practice. Its purpose is to bridge the excellent results obtained from basic research at universities with the development of innovative pharmaceuticals.

Medium- to long-term perspective

To achieve the goals of the Medium-Term Management Plan 16–20, the Sohyaku. Innovative Research Division should first focus on swift PoC confirmation of drug candidates and pipeline expansion through the continuous creation of drug candidates with a focus on priority areas. Continued discussions on the expansions of the pipeline are to be carried out, not only within the Sohyaku. Innovative Research Division, but also in joint effort with "Drug Discovery Strategy Team" set up in collaboration with the Global Portfolio Management Department and other departments.

The Sohyaku. Innovative Research Division's long-term goal is the "continuous creation of original drug candidates that meet future medical needs." Our strength lies in our drug discovery capabilities. We have a track record of creating the world's first unique pharmaceuticals leveraging our capabilities in chemical synthesis. In addition to conventional small-molecule drug discovery, we are also now expanding new modalities such as nucleic acid drugs and middle molecule drug discovery. Our ideas, creativity and tenacity for creating highly original products are also our strengths.

On the other hand, we need to accelerate drug discovery more than ever. To that end, one thing we should do is to streamline decision-making. In the initial stage of research, we need to emphasize taking on challenges and to not take too much time gathering information for streamlined decision-making. Furthermore, we believe that we can accelerate the entire drug discovery process by incorporating external knowledge and technologies through open innovation and better leveraging external assets. For example, as a new challenge that leverages open innovation, we are conducting drug discovery research on gene therapy in collaboration with Jichi Medical University.

Arisa Hisanaga
Research Unit/Neuroscience, Sohyaku. Innovative Research Division

Develop reliable assay systems and basic technologies to challenge new themes with high medical needs

I was attracted by this work, drug discovery, that can contribute to the health of people around the world, so I studied brain and nerve functions at the faculty of pharmaceutical sciences during my university days. Since joining the company, I have been consistently engaged in central nervous system projects and primarily responsible for developing assays for compounds.

Before a new drug can be made, the cycle of (1) evaluating the compound and (2) synthesizing the compound based on those results must be repeated to improve the efficacy of the compound. Establishing an assay system that enables us to generate highly recapitulated results is critical to effectively repeat this cycle.

Recently, we created an assay utilizing iPS cell-derived neurons. iPS cells are relatively unstable and it was difficult to obtain highly reproducible results compared to the cells that we have dealt with so far. However, as a result of trial and error based on the advice from other members and my supervisors, I could successfully set up a stable assay, which now contributes significantly to the efficient progress of current drug discovery projects. Moving forward, I'd like to take part in developing functional assays that use patient-derived cells with the aim of discovering pharmaceuticals that can further help patients.

Currently, I'm investigating new projects as a member of the Neuroscience Research Unit. In the field of central nervous system, there are many serious diseases for which treatment has not yet been established despite significant needs from patients, their families, and medical professionals. To address those needs, I'm now conducting validation experiments on new concepts targeting ALS and other neurological diseases. I interact with US doctors and constantly study day after day while assimilating the latest information from domestic and overseas academic conferences and various papers.

I will continue to take on challenging themes that help us develop new pharmaceuticals while enhancing my expertise, and make every effort to improve our own drug discovery infrastructure from a long-term perspective so that I can contribute to the health and happiness of people around the world.

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It is also important to create a better environment for creating such innovations. We will create a more open research environment and promote collaboration with the best partners inside and outside the Company. The relocation of our research laboratory to Shonan Health Innovation Park in the current fiscal year is also viewed as laying the groundwork for pursuing this open innovation.

Furthermore, we also need to change researchers' way of thinking to challenge diseases with high unmet medical needs. We hope to generate new ideas by encouraging researchers who tend to stay in their own shells to break out and expand their perspectives and ideas through opportunities for dialogue and discussion with outsiders. I believe that creating a corporate culture that encourages taking on challenges is a vital mission as Head of the Sohyaku. Innovative Research Division.

Possible risks and countermeasures

Generally speaking, ideas that anticipate future needs, such as what drugs will be needed 10 years from now or ascertaining trends in diseases and technologies are highly important in drug discovery with a long development lead time, and misreading trends could be risky. Research and evaluation of disease trends is being led by three drug discovery units, and technology trends by Modality Laboratories and the US research subsidiary Tanabe Research Laboratories U.S.A. We are proceeding with development for early commercialization of VLP vaccines, a new modality, in collaboration with Medicago and products that combine pharmaceuticals and medical devices in collaboration with NeuroDerm.

On the other hand, there are risks related to the development of new modalities and risks related to regulatory controls and drug price revisions by relevant authorities. With regard to these, we will closely monitor the international situation and industry trends, and take steps to reduce risks through prior consultations with relevant authorities.

Message to shareholders and investors

I think that many of our personnel thrive on adversity, understanding the true nature of problems and finding solutions by themselves. To create pharmaceuticals and medical services that offer new value by leveraging these personnel, we will integrate the individual strengths of each person in the Sohyaku. Innovative Research Division and continue to create original products that meet future medical needs.

Accelerate open innovation by leveraging Shonan Health Innovation Park

As initiatives for Medium-Term Management Plan 16–20 and beyond that toward fiscal 2023, we are reexamining the allocation of management resources, optimizing and streamlining our global management system, and reinforcing each function.

As part of this, to accelerate open innovation in drug discovery research, we decided to use the Shonan Health Innovation Park in Kanagawa Prefecture as one of the research centers starting from May 2019. The Company will swiftly and powerfully take on the challenge of addressing new technologies, new treatments, and new disease areas in this park.

In addition to pharmaceutical companies and drug discovery ventures, the Shonan Health Innovation Park is occupied by companies that provide drug discovery support services, research and medical devices, and are engaged in AI and IoT business, and the park is working to attract more such companies. Approximately 250 researchers working in the Frontier Research Unit, the Modality Laboratories, and other facilities from the Yokohama Office, the Toda Office (closed in fiscal 2019) will move in to expand collaboration opportunities by building a human network with existing tenants. Above all, we will pursue initiatives based on the theme of achieving radical treatments using genetic drug discovery, which will lead to the provision of new pharmaceuticals and medical services for the prevention and cure of rare and intractable diseases.

Business Strategies by Process　Pipeline

Status of drug candidates (as of July 25, 2019)

Asia: excluding Japan and China

Development code Product name (Generic name)	Category	Indications	Region	Stage Phase 1 2 3 / Filed	Origin
Immuno-inflammation					
MT-5547	Fully human anti-NGF monoclonal antibody	Osteoarthritis	Japan	Phase 2/3	US: Regeneron
MT-1303	S1P receptor functional antagonist	Multiple sclerosis	Europe		In-house
		Crohn's disease	Japan		
MT-7117	Dermatologicals, etc.	Erythropoietic protoporphyria	Global		In-house
MT-2990	Fully human anti-interleukin-33 (IL-33) monoclonal antibody	Endometriosis	Global		In-house
		Seasonal Allergic Rhinitis	–		
Diabetes and kidney					
TA-7284 **Canaglu** (Canagliflozin)	SGLT2 inhibitor	Type 2 diabetes mellitus	Asia		In-house
		Diabetic nephropathy	Japan		
MP-513 **Tenelia** (Teneligliptin)	DPP-4 inhibitor	Type 2 diabetes mellitus	Asia		In-house
			China		
			Europe		
MT-6548 (Vadadustat)	Hypoxia inducible factor prolyl hydroxylase inhibitor	Renal anemia	Japan	19.07	US: Akebia
MT-3995	Selective mineralocorticoid receptor antagonist	Diabetic nephropathy	Europe		In-house
			Japan		
		Non-alcoholic steatohepatitis: NASH	Japan		
Central nervous system					
MCI-186 **Radicut/Radicava** (Edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis: ALS	China	19.04	In-house
			Asia		
MP-214 (Cariprazine)	Dopamine D3/D2 receptor partial agonist	Schizophrenia	Asia		Hungary: Gedeon Richter
MT-5199	Vesicular monoamine transporter type 2 inhibitor	Tardive dyskinesia	Japan	Phase 2/3	US: Neurocrine Biosciences
MT-8554	TRPM8 antagonist	Painful diabetic peripheral neuropathy	Europe		In-house
		Vasomotor symptoms associated with menopause	Global		
ND0612 (Levodopa/Carbidopa)	Continuous SC pump/ patch pump	Parkinson's disease	Global		In-house
ND0701 (Apomorphine)	Continuous SC pump	Parkinson's disease	–		In-house
MT-1186 (Edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis: ALS/Oral suspension	–		In-house
MT-6345	Nervous system	–	–		Japan: Co-developed with Ube Industries
MT-3921	Anti-RGMa antibody	Spinal cord injury	–		Japan: Co-developed with Osaka University

Asia: excluding Japan and China

Development code Product name (Generic name)	Category	Indications	Region	Stage (Phase 1 2 3 / Filed)	Origin
Vaccines					
MT-2355	Combined vaccine	Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants	Japan		Japan: Co-developed with The Research Foundation for Microbial Diseases of Osaka University
MT-2271	Plant-based VLP vaccine	Prophylaxis of seasonal influenza/adults	US, Europe		Canada: Medicago product
		Prophylaxis of seasonal influenza/elderly	US, Europe		
MT-8972	Plant-based VLP vaccine	Prophylaxis of H5N1 influenza	Canada		Canada: Medicago product
MT-7529	Plant-based VLP vaccine	Prophylaxis of H7N9 influenza	–		Canada: Medicago product
MT-5625	Plant-based VLP vaccine	Prophylaxis of rotavirus gastroenteritis	–		Canada: Medicago product
Others					
TAU-284 Talion (Bepotastine)	Selective histamine H1 receptor antagonist, anti-allergic agent	Allergic rhinitis, Urticaria	Asia		Japan: Licensed from Ube Industries
MT-4129	Cardiovascular system, etc.	–	–		In-house

Major out-licensed products

Development code Product name (Generic name)	Category	Indications	Region	Stage (Phase 1 2 3 / Filed)	licensee
Diabetes and kidney					
TA-7284 INVOKANA (Canagliflozin)	SGLT2 inhibitor	Diabetic nephropathy	US	19.03	US: Janssen Pharmaceuticals
Central nervous system					
MT-210	5-HT2A/Sigma 2 receptor antagonist	Schizophrenia	US, Europe		US: Minerva Neurosciences
Others					
MT-4580 Orkedia (Evocalcet)	Ca sensing receptor agonist	Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism	Japan	19.04	Japan: Licensed to Kyowa Kirin

Business Strategies by Process

Drug Fostering and Evolution

Maximize and optimize pharmaceutical value in global development

Yoshihiro Kobayashi

Member of the Board, Managing Executive Officer,
Head of Ikuyaku. Integrated Value Development Division

Basic policy

The Ikuyaku. Integrated Value Development Division features the development section that plans and manages clinical trials for pharmaceuticals, the medical affairs section that is responsible for medical activities such as the acquisition and dissemination of various information required in medical settings, and the pharmacovigilance (PV) section that conducts surveys and writes reports on safety information and drug side effects and also oversees a wide range of functions including the data science section that makes use of clinical trials, PV data, and RWD[1] to extract scientifically and socially useful information. With these various specialized sections collaborating together, we strive to maximize product value in various stages, from late development to post-marketing, centered on our priority disease areas of immuno-inflammation, diabetes and kidney, central nervous system, and vaccines.

1. The acronym for Real World Data, which refers to data that is based on actual medical care practices, such as medical fee data (health insurance claim receipts) and medical exam data, or the databases of these.

Fiscal 2018 summary and fiscal 2019 initiatives

In fiscal 2018, this division pursued initiatives based on the themes of "Late-stage drug development in Japan and Asia," "Medical activities for diabetes centered on Canaglu and Tenelia," and the "Global promotion of PV activities."

Notably, in "Late-stage drug development in Japan and Asia," development of MT-6548, MT-5547, MT-5199, TA-7284 (diabetic nephropathy), and MP-513 (China) proceeded without a hitch. Of these, MT-6548 and MP-513 (China) achieved the primary endpoints anticipated in Phase 3 and are moving steadily ahead to launch as new drugs. In addition, we gave academic presentations and presented papers on the results of various clinical studies and post-marketing surveillance in collaboration with the medical affairs and PV sections. Among these, an interim report we presented on the results of Radicut use in ALS received the Excellence Award from the Japanese Society of Neurological Therapeutics.

In fiscal 2019, we will focus on "Pipeline enhancement and selection," "Acceleration of development," and "Streamlining operations" as priority issues. In our development work, we will apply for approval of MT-6548 in Japan, which obtained Phase 3 results in fiscal 2018, and approval of MP-513 in China, and move forward with other drug candidates according to plan. Since MT-8554 and MT-7117, which originated in-house, will enter the global late-stage development phase as drug candidates, in the development of these and Radicava oral suspension (MT-1186) in Japan and Asia, we will promptly cooperate with medical and PV activities to promote integrated global

activities. As for diabetes and kidney disease, Janssen Pharmaceuticals, a U.S. company, presented the excellent results of a clinical study of diabetic nephropathy (CREDENCE study[2]) at an international conference in April 2019. Consequently, we will strengthen our development and medical activities in Japan to quickly deliver these results in Japan as well.

2. Acronym for Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation.

Medium- to long-term perspective

New modalities such as regenerative medicine, gene therapy, and digital medicine are emerging in the medical world. Moreover, past rules and methods are changing, for example, "global development" now occurs simultaneously at locations around the world, and RWD and AI being used. In anticipation of these changes, as a global research-driven pharmaceutical company, we will continue to work with Sohyaku. Innovative Research Division and overseas affiliates to provide society with new drugs that patients around the world are eagerly waiting for, and we will continue to increase their value.

In maximizing and optimizing the value of pharmaceuticals, drug applications and approvals are only "waypoints." We are carrying out our activities with greater determination to further enhance and optimize their value, including development activities such as adding indications, medical activities by providing medical information for clinical questions[3], and PV activities such as collecting post-marketing safety information. We have built a system which enables the development, medical affairs, PV, and data science sections to promote strategies through this division, and with this we are steadily accumulating a wide range of knowledge and experience. Moving forward, we will continue to leverage all of these to maximize and optimize the value of pharmaceuticals not only in Japan and Asia, but globally. Furthermore, we seek to enhance our expertise and streamline operations by strengthening not only the expertise of each department's operations, but also collaboration in disease areas including priority diseases.

3. Clinical questions and issues. There are of various types including those related to clinical condition, evaluation, treatment, risk, and prevention.

Message to shareholders and investors

One risk that is becoming apparent is the global rise in R&D costs. On the other hand, market conditions for pharmaceuticals have become increasingly harsh due to the promotion of cost control measures in Japan and other countries. We need to consider how quickly we can deliver treatment agents and treatment methods that society urgently requires without being bound by past methods.

This division will create new methods that are focused on patient-centered healthcare. I would like to create a system that enables the efficient turning of the PDCA cycle and lets us quickly determine and select those things that are certain from those that are not. For example, Japan is expected to be the first country in the world to approve and launch MT-6548, which is now under development, and post-marketing safety information that we collect will be disseminated worldwide in the future. It is important to quickly collect and analyze safety information immediately after sales and appropriately disseminate it worldwide. Since it is important that we strengthen our global system in the United States and worldwide, we will train employees to have a broad and multifaceted perspective. Recognizing that we are globally connected wherever we are, we will act based on our key message of "Think globally, Act locally."

Along with changes in the business environment, each department of this division will increasingly require a high level of specialization. In addition to drug development activities in Japan and Asia, we will work closely with the functions of each department to expand the Group's business presence around the world.

Business Strategies by Process

Supply Chain

Promote rebuilding of supply chain system to adapt to changes in the business environment

Ryosuke Tanabe
Executive Officer,
Head of Production Technology &
Supply Chain Management Division

Basic policy

The Production Technology & Supply Chain Management Division was established in April 2018 with the integration of the CMC[1] Division and the Production Division. It plays a role in facilitating and flexibly promoting *monozukuri* (manufacturing with production technology and supply chain management), from the manufacture of investigational drug products used in clinical trials to product design for launch, commercial product procurement, production and supply.

In fiscal 2019, we will steadily promote development projects and maximize product value through product design from the customer's point of view. At the same time, we will restructure our Japan-centered *monozukuri* system into a system capable of adapting to our U.S.-centered business development.

1. CMC: The acronym for Chemistry, Manufacturing and Control ("the chemistry, manufacturing and quality control of drug ingredients and pharmaceuticals"). Comprehensive research that supports pharmaceutical manufacturing and quality.

Fiscal 2018 summary and fiscal 2019 initiatives

In fiscal 2018, when our division was established, we formulated a plan for restructuring our production and technology bases under our "Strategic Future Vision for Production, SCM[2], and CMC." In fiscal 2019, the steady implementation of this restructuring plan will be a priority issue.

For example, this restructuring plan will include factors such as further strengthening of our capabilities in the field of global supply chain management. Leveraging the experience and know-how gained from Radicava, we will create a system that enables rapid supply of globally developed products such as MT-1186, ND0612, MT-8554, and MT-7117, from investigational drug products to commercial product supply.

In addition, we will leverage the characteristics of our domestic production bases to achieve an efficient production system. Based on the product life cycle, the Onoda Office will be responsible for everything from the manufacture of investigational drugs to the timing of their introduction and growth, while the Yoshitomi Office will promote the reallocation of production items following the restructuring of production bases, and will changeover to a system that supports *monozukuri* from growth period onward, and provides efficient and stable supply.

Furthermore, we will rebuild our production technology to create unique value and deliver it globally. To achieve a seamless connection between CMC and production functions, a new research building, CMC Innovative Laboratories (CIL), will be constructed at the site of the Onoda Office and develop it as a *monozukuri*

base. In addition, technology and know-how not located in-house will be acquired through partnering including collaboration with industry, academia, and government.

2. SCM: Acronym for Supply Chain Management. A business management method for optimizing the entire process from raw material procurement to manufacturing and supply to consumers.

Medium- to long-term strategy

The mission of our division is to grasp the needs of the market, rapidly create the products that are needed, and stably deliver products of both reliable quality and reasonable cost to customers around the world based on our high technological capabilities.

As typified by the three growth drivers, we need to shift not only investigational drugs, but also our product supply system to the U.S. to accompany the shift of development and sales areas to the U.S. Along with these changes, the functions of our division must be changed, and therefore we will build the systems that we need in the future.

To contribute to the company's global growth, we will also focus on the early development of human resources who can properly build and manage supply chains, who can manage positive relationships with various stakeholders, and who can properly respond to new modalities and markets.

A message to shareholders and investors

While raw materials suppliers, manufacturing sites, and sales regions of pharmaceuticals have globalized, global products have to be supplied according to different regulations and local requirements for each country, so it is increasingly difficult to demonstrate economies of scale by manufacturing one product together from a supply chain perspective.

In addition, manufacturing sites with special raw materials and technologies required for new modalities are limited, and there may be risks that could affect stable supply due to unexpected natural disasters and accidents. As countermeasures to these risks, we have developed rules and manuals for responding to crises with a view to business continuity, and have identified specific risks for each key business in the supply chain.

Because the market, patient needs, and required technologies are constantly changing, we will strengthen *monozukuri* from the customer's point of view and create a supply chain system that adapts to changes in the business environment so as to achieve "reliable products and sustainable supply," one of our material issues.

Takashi Nishii
Technology Department, Yoshitomi Plant
Mitsubishi Tanabe Pharma Factory Ltd.

Viewing the reorganization as an opportunity, we will introduce new technologies while ensuring quality

The Group is currently reorganizing its bases with the aim of establishing a global new drug supply system and switching to a flexible and efficient production system that is resistant to environmental changes. Accordingly, I'm in charge of transferring manufacturing technology between factories and outside the Company, and every day I feel how difficult it is to transfer manufacturing technology and continue to manufacture products of the same quality as if it were nothing. Complex factors such as raw materials, machinery, and manufacturing environment may affect quality, even in the same process and procedure. Moreover, the transfer of manufacturing technology substantially changes manufacturing conditions, so high technology is required to ensure the same quality.

For example, when the technology used to manufacture a tablet at our plant was transferred to a new plant, the brand name printed on the tablet was changed to appear on both sides instead of just one, and as a result, many technical issues needed to be solved. Therefore, working closely with the manufacturing division, we reviewed the process from the beginning and conducted repeated trial and error, such as changing the method used to polish the tablet surface. As a result, we not only ensured quality, but were able to achieve significant reductions in work time and defect rate. In a situation that requires close collaboration with other departments and related companies, we reaffirmed the importance of leading the project by having our technical staff carefully examine a wide range of information. Furthermore, viewing each change as an opportunity to achieve a higher quality, lower cost, and more stable supply than before, we review data analysis at the time of the manufacturing technology transfer. At the same time, we are actively introducing new technologies such as non-destructive and non-contact analysis technologies and continuous monitoring methods.

Also, to improve my expertise and acquire further problem-solving skills, I'm registered as a visiting researcher at a university under a work-study program. I will further enhance cooperation between the production and research divisions while combining the experience gained at the Company and the knowledge learned at the university so that we can manufacture and provide even safer and more secure pharmaceutical drugs than before.

Business Strategies by Process

Marketing

Providing high value-added information through consulting and solutions

Yasutoshi Kawakami

Executive Officer,
Head of Sale &
Marketing Division

Basic policy

The pharmaceutical market in Japan continues to face a tough environment due to drastic reform of the drug price system. Furthermore, with the introduction of "Sales Information Provision Activity Guidelines," regulations concerning MR activities have been tightened. Under these market conditions, the Sales & Marketing Division will prop up the Company's growth foundation with the goal of maintaining revenue of ¥300.0 billion in Japan.

In fiscal 2019, we will take area marketing and digital marketing to new levels and strengthen prescription proposal capabilities, which were priority policies in fiscal 2018. We will also maximize our presence in existing areas and prepare to launch new drugs.

Fiscal 2018 summary and fiscal 2019 initiatives

One of our achievements in fiscal 2018 was to raise our market share through area marketing. Area marketing planners (AMPs), who are deployed in all sales offices, played a central role to boost the market share of Canaglu, Tenelia, and Canalia for diabetes and kidney diseases by drawing up and executing strategies for each area. In digital marketing, in response to the growing number of multichannel customers, doctor assessments have dramatically boosted our ranking[1] from No. 20 last year to No. 8 this year thanks to our healthcare professional website Medical View Point and MR activities that effectively used digital marketing tools. Finally, with regard to strengthening our prescription proposal capabilities, in the area of immuno-inflammation, Remicade, Simponi, and Stelara maintained the No. 1 market share[2] and MR activity evaluations boosted the Company from No. 7 last year to No. 6 this year in the area of diabetes[3].

In light of the impact of the Sales Information Provision Activity Guidelines and Promotion of Working Style Reforms for Healthcare Professionals, in fiscal 2019, we recognize the need to provide appropriate high value-added information in a shorter timeframe than before. In the area of immuno-inflammation, in May of this year, we launched a new Simponi autoinjector formulation that improves patient safety and effectiveness and we are working hard to achieve its rapid market penetration. In the areas of diabetes and kidney disease, the CREDENCE study, which is the global evidence for Canaglu presented at international conferences, is being appropriately disseminated to healthcare professionals. We expect this preparatory marketing effort to facilitate sales of the HIF-PH inhibitor Vadadustat (MT-6548), which is scheduled for release in fiscal 2020.

We will also expand our points of contact in digital

marketing to ensure that these information provision activities are carried out. In order to seamlessly respond to diversifying needs, we will evolve to omnichannel, which merges digital and real world data (face-to-face information provision), and perform our industry-leading digital marketing. Further, by increasing the expertise of each MR, we will further boost our MR activities. This will be done in two ways, by accelerating consulting sales, which recommend the optimal treatment taking into account the disease's progression, and solution sales, which meet the needs of each region through the creation of regional networks such as medical facilities and nursing homes.

1. MCI Multimedia Whitepaper 2016 Winter Edition, 2018 Summer Edition.
2. IQVIA Data
3. Macromill CareNet fiscal 2018 Survey.

Medium- to long-term perspective

The greatest mission of this division from a medium- to long-term perspective is to develop growth and revenue strategies for sustainable growth.

With regard to our growth strategy, we will further increase our presence in priority areas in anticipation of the development pipeline.

Our revenue strategy will be to help secure funds for growth investments by promoting reforms to achieve an optimal organizational structure and advancing operational productivity reforms that actively utilize robotic process automation (RPA) to reform working styles and strengthen competitiveness.

Message to shareholders and investors

The business environment has changed dramatically in recent years and risks related to sales activities include drastic reform of the drug price system, promotion of generic drug and biosimilar use, and stricter regulations on visits and sales promotions to medical institutions. To deal with this sudden change, we need to create an organization in which employees have a clear awareness of goals and can quickly take on the necessary challenges. I also believe that creating this organizational culture is an important function. We want to continue to contribute to the health of as many patients as possible and to be a company trusted by society by promoting "the appropriate use of products," a material issue, strengthening our presence in priority areas, one of our strengths, and promoting information provision activities that meet market needs.

Mio Sogo
Product Marketing Department, Sales & Marketing Division Pediatrics West Japan Promotion Group Team Leader

Creating a system that provides up-to-date information that matches the needs of pediatricians

Since joining the Company, I have been involved in information provision activities as an MR. After that, I was assigned to a corporate division where I examined sales policies for vaccines and created sales promotion materials. Leveraging this experience, I'm now affiliated with an MR Group specializing in pediatrics that was established in October 2018. In addition to visiting pediatricians, as a leader of a team with six members including myself, I also support these members.

Our mission is to establish an overwhelming presence in the pediatrics field by gaining the trust of not only pediatricians, but also healthcare professionals and patients. In the pediatrics field, the latest information is most important, so it is necessary to constantly raise one's expertise. Various efforts are made when providing information, so we constantly work with feelings of tension, responsibility, and good faith.

Many female employees balance work with childcare, and working style reforms are also an important mission of our team leaders. In addition to existing sales styles, we are actively pursuing efforts to establish efficient and effective approaches. One of these was the introduction of ZEUS, an email system that sends information to doctors. This system enables information to be customized to suit each pediatrician that's in charge and provide more needed information. We are also taking steps to streamline communication by leveraging IT tools to hold meetings with team members working remotely in their respective areas of responsibility.

Supporting the health of children is also about creating Japan's future. Moreover, the vaccine business that we are rolling out in the field of pediatrics contributes to society by controlling medical costs from the standpoint of disease prevention, and I am proud and satisfied to be able to play a part in this socially significant business.