Business Strategies by Process

Drug Fostering and Evolution

Maximize and optimize pharmaceutical value in global development

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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.