[Translation]

December 8, 2022

Key Questions and Answers at the Q2 FY2023 Financial Result Briefing

Q1: How are the results of the clinical trial of the PAI-1 inhibitor (RS5614) for COVID-19 pneumonia? Also, when will it be launched?

A1: The enrollment of the patients for the Ph2b trial was completed at the end of October 2022. We are currently consolidating the medical data, and the study report will be prepared in March 2023. The timing of the market launch will depend on the results, but once the efficacy is confirmed, we would like to take advantage of all possible institutions to deliver the product to the medical field as soon as possible.

Q2: While COVID-19 is becoming less severe and converging, the option agreement with Daiichi Sankyo Company, Limited (Daiichi Sankyo) for RS5614 has been extended. Please tell us about its aims.
Also, you mentioned that you are also looking into interstitial pneumonia. Please inform us the details.

A2: We have granted to Daiichi Sankyo the preferential negotiating rights with the option right to license the development and commercialization of RS5614 for lung diseases. There are various causes of interstitial pneumonia, including infections such as a novel coronavirus, anticancer agents, and even immune abnormalities such as systemic sclerosis, and RS5614 is potentially effective against interstitial pneumonia regardless of the cause. We have agreed to further extend the agreement with a view to work on the usefulness of this medicine for interstitial pneumonia arising from causes other than the novel coronavirus.

Q3: What is the timing of the launch of the lung cancer drug?

A3: We are preparing for a Ph2 study for non-small cell lung cancer in collaboration with Hiroshima University. We need to conduct a confirmatory study (Ph3 study) later based on the results of the Ph2 study, so the timing of the launch is undecided at this time.

Q4: Is RS5614 effective against all cancers?

A4: It may not be effective against all cancers. The cancers with high expression of PAI-1 (therapeutic target molecule of RS5614) have a poor prognosis in several types of cancer, and in fact, non-clinical studies (basic research) conducted using RS5614 have confirmed its efficacy in several types of cancer. The clinical trials are

currently underway for chronic myeloid leukemia and malignant melanoma. We plan to expand the indications to non-small cell lung cancer and angiosarcoma.

Q5: When will the disposable ultrafine endoscope be launched?

A5: A regulatory filing for the fiberscope was submitted in August 2022, so we expect it to be approved and used in the medical field within the next fiscal year. We have also completed the basic design of a guide catheter that enhances the operability of the ultrafine endoscope, and plan to submit the regulatory filing in the next fiscal year. With the approval of both the fiberscope and the guide catheter, we anticipate the full-scale use of the disposable ultrafine endoscope in the medical field.

Q6: You mention that you intend to expand your pipeline in the area of artificial intelligence (AI). How do you plan to acquire and develop new seeds?

A6: We promote the development of software as a medical device (AI) that can solve various issues (diagnosis and treatment) in the medical field. Each medical department has its own medical challenges, so there are many potential medical AI seeds. We have received new proposals from university hospitals and other medical institutions (physicians) for several seeds at this point, but we are unable to respond to all of them due to limitations in our resources. Currently, we are developing about 10 pipelines, including those that we explained at the financial result meeting.

Q7: What is your business model for medical AI?

A7: The artificial intelligence (AI) we develop is basically software as a medical device (SaMD) to be used in the cloud, rather than to be installed in medical devices. To manufacture and sell such SaMD, it is necessary to obtain a medical devices marketing license based on the "Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Device" but we do not have such license. Therefore, we will commercialize the products by licensing them to healthcare companies and such companies will be responsible for sales and marketing.

Q8: What is your future development policy for the pipeline (diseases, modalities, etc.)?

A8: We work to solve issues of medical or social importance, such as aging-related diseases (cancer, diabetes, respiratory diseases, cardiovascular diseases), diseases of women and children, and novel coronavirus infection, and we intend to continue to focus on these areas. As for pharmaceuticals, our development efforts focus on clinical development in oncology, respiratory diseases, and psychiatric diseases. In particular, we will develop the PAI-1 inhibitor, our flagship medicine, for multiple types of cancer and aging-related diseases such as lung diseases. We do not focus on a specific modality, but develop various modalities (pharmaceuticals, medical devices, and artificial intelligence (AI)) to solve medical issues, and we believe that the development of biopharmaceuticals and SaMD (AI) will be most important in the future.

Q9: You have executed a partnership agreement with Tohoku University on an open innovation and have established a research facility (TREx) within the university. Please explain the outcome of TREx so far.

A9: It would be inefficient and practically difficult for us to provide all the necessary infrastructure (system, facilities, technology, and human resources) for research and development in-house across the diverse medical fields and modalities we practice. Tohoku University Graduate School of Medicine has the "Life Science Open Innovation Platform" called the Medicinal Hub, where cutting-edge researchers, physicians from various medical fields, companies from different industries, and government agencies form an ecosystem. With the signing of the partnership agreement with Tohoku University, the infrastructure necessary for our research and development has been efficiently established in January 2022, enabling us to accelerate research activities and acquire new seeds. More than half of our new development pipeline is the result of collaborative research with Tohoku University, and the number of new seeds has also increased in a short period of time since the start of TREx. In addition to pharmaceuticals (systemic sclerosis, angiosarocoma) we have steadily acquired several new pipelines of software as a medical device (AI). We currently discuss similar collaboration with other universities, which will lead to further acceleration of research and acquisition of new seeds.

Q10: You have received grants from the Japan Agency for Medical Research and Development (AMED). What are the reasons for the successful adoption?

A10: Not only our company, but many other biotech companies in Japan take advantage of funding from AMED. Otherwise, it would be difficult to manage a biotech with high R&D expenses. We apply for many public grants to make efficient use of the investment received from our shareholders.