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In the case of any discrepancy between the translation and the Japanese original, the latter shall prevail.

(Translation)

August 19, 2024

To Shareholders,

Company Name: Renaissance Inc.

Representative: Keisuke Furuta, President & CEO

(Code: 4889 TSE Growth)

For inquiries, please contact Administration Dept.

Announcement of Initiation of clinical performance trial of artificial intelligence (AI) to predict insulin dosage for diabetes patients.

The Company are pleased to announce the start of a clinical performance trial of “Diabetes Treatment Support Program Medical Device”. The trial is a validation clinical trial for regulatory approval and will be conducted at five medical institutions in Japan, including Tohoku University (Principal investigator is Professor Hideki Katagiri, Department of Diabetes and Metabolism, Tohoku University Graduate School of Medicine).

This project has been Adopted as an AMED’s Research program for Innovation in Medical Engineering (Project for diabetes treatment support system) for the FY2022.

Insulin injection therapy is necessary to strictly control blood glucose levels in diabetic patients and to prevent diabetic complications. However, because the safe dose range of insulin is narrow and overdosing causes hypoglycemia, the optimal type and dosage must be selected for each patient, and diabetologists set the dosage based on tacit knowledge and other factors based on experience. On the other hand, since diabetes specialists account for less than 2% of all physicians and are unevenly distributed geographically, diabetes patients are not always attended by a diabetes specialist, but rather often see a nonspecialist, creating a significant burden for nonspecialists.

In order to reduce the burden on healthcare professionals engaged in diabetes care with fewer human resources and improve patients' quality of life, the company have been working with Tohoku University and NEC Corporation (NEC) to develop a programmed medical device (software) utilizing AI to assist non-specialists in performing specialist-level insulin therapy, (NEC) and NEC Solution Innovator to develop a programmed medical device (software) that uses AI to assist non-specialists in administering specialist-level insulin therapy. “DM-SAiL” is capable of predicting the judgment of a diabetes specialist with an error accuracy of less than 2 insulin units. In order to enable the developed AI to be used in the medical field, it is necessary to verify whether it performs as expected in a clinical setting using actual human clinical data, and this clinical performance trial will be conducted for this purpose. Based on the performance confirmed in the clinical performance trial, an application for manufacturing and marketing as a programmed medical device (pharmaceutical application) is submitted to the Ministry of Health, Labour and Welfare.

This AI is capable of predicting insulin dosage for hospitalized diabetic patients with the same accuracy as a specialist, and predicts the necessary insulin dosage from blood glucose levels measured by simple blood glucose monitoring. If it can be put into practical use, it is expected to reduce the progression of chronic diabetic complications and adverse events during hospitalization (e.g., death, new onset of infection or respiratory failure, etc.). Non-specialists, who spend time on their own specialized work (e.g., surgery, treatment of other diseases, etc.)

to care for diabetic inpatients, will be able to reduce some of their work hours with this AI. For patients, it is expected that favorable blood glucose levels will lead to a reduction in the progression of chronic diabetic complications.

This matter will have no impact on the forecast of business results for the fiscal year ending March 31, 2025.