(Translation)

October 21, 2024

To Shareholders,

Company Name: Renascience Inc.
Representative: Keisuke Furuta, President & CEO
(Code: 4889 TSE Growth)
For inquiries, please contact Administration Dept.

Notice of start of clinical performance testing of artificial intelligence (AI) to predict total water removal volume in maintenance hemodialysis patients

We are pleased to announce that we will begin clinical performance testing*1 of our "Maintenance Hemodialysis Medical Support AI". This is a verification clinical trial for pharmaceutical approval, and will be conducted at eight medical institutions in Japan, including St. Luke's International Hospital (the principal researcher is Professor Tetsuhiro Tanaka, Department of Nephrology, Connective Tissue Diseases and Endocrinology, Tohoku University Graduate School of Medicine).

This project, with Tohoku University as the representative institution, has been selected for the FY2023 "Medical Device Development Promotion Research Project" by the Japan Agency for Medical Research and Development (AMED).

In hemodialysis treatment, approximately 350,000 hemodialysis patients in Japan remove fluid and waste products in place of their failed kidneys. Insufficient fluid removal can impair cardiopulmonary function, while excessive fluid removal can cause low blood pressure during dialysis, leading to adverse events such as feeling unwell and losing consciousness. However, dialysis hospitals treat many patients with a small staff of just one doctor, several nurses and clinical engineers, and the occurrence of adverse events places a heavy burden on the staff.

If this project can predict an individual patient's blood pressure drop during dialysis in real time and determine an appropriate and safe amount of water to be removed, it will reduce the burden on medical professionals involved in dialysis care with limited human resources, enable safe and secure dialysis treatment, and solve an important medical issue of improving the quality of life and prognosis of dialysis patients.

We have been developing a maintenance hemodialysis medical support AI in collaboration with Tohoku University, NEC Corporation (NEC), and NEC Solution Innovators, Ltd. (NES). This AI is a programmed medical device that mimics the target water removal volume set by dialysis specialists and presents the target water removal volume to non-specialists and other doctors with little experience with the same accuracy as specialists. The core technology of AI is an AI engine (DCCN (Dual-Channel Combiner Network)) that can analyze medical data, which is heterogeneous time data, as a single data group, which we developed in collaboration with NEC. DCCN can predict the target water removal volume set by dialysis specialists with an error of about 130 ml. In order to make the developed AI usable in the medical field, it is necessary to confirm whether it performs as expected in the clinical field using actual human clinical data, and for that purpose, we will conduct this clinical performance test. Based on the performance confirmed in the clinical performance test, we will submit an application (pharmaceutical application) to the Ministry of Health, Labor and Welfare to manufacture and sell it as a programmed medical device.

In addition, in order to utilize this program medical device in clinical settings, we signed a joint development agreement with Nipro Corporation in March 2024 toward commercialization.

This AI predicts the target water removal volume for dialysis patients with the same accuracy as a dialysis specialist. If it can be put into practical use, it will be of help to the shortage of dialysis specialists, and even in dialysis clinics operated with limited resources, it is expected to be possible to prevent the occurrence of sudden drops in blood pressure caused by excessive water removal, and to avoid the concentration of resources due to the occurrence of blood pressure drops.

There is no change in the earnings forecast for the fiscal year ending March 2025 due to this matter.

*1 Clinical performance testing

In order for a software as a medical device (SaMD) under development to be usable in the medical field, it is necessary to verify whether the software as a medical device will perform as expected in the clinical field using actual human clinical data. Clinical performance testing is a clinical study conducted for this verification. Based on the performance confirmed in the clinical performance testing, an application (pharmaceutical application) is submitted to the Ministry of Health, Labor and Welfare to manufacture and sell the device as a software as a medical device. This clinical study has a similar nature to verification testing (phase 3 testing) for pharmaceuticals.