

April 9, 2025

To Shareholders,

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(Code: 4889 TSE Growth)
For inquiries, please contact Administration Dept.

Notification of achievement of target number of registered cases in clinical performance test for regulatory approval of programmed medical device using artificial intelligence (AI) to support maintenance hemodialysis

We are developing a programmed medical device using artificial intelligence (AI) to support safe and secure maintenance hemodialysis. In order to evaluate the performance (prediction accuracy) of this programmed medical device, we are conducting clinical performance test¹⁾ for regulatory approval at eight medical institutions in Japan, including Tohoku University, a national university corporation, and St. Luke's International Hospital (the clinical performance test coordinating physician is Professor Tetsuhiro Tanaka, Department of Nephrology, Graduate School of Medicine, Tohoku University). We are pleased to announce that the number of registered patients has reached the target number of cases (150 cases). We will analyze the results and compile them into a clinical trial summary report.

This project was selected for the Japan Agency for Medical Research and Development (AMED)'s "Medical Device Development Promotion Research Project" in fiscal year 2023 (the principal research institution is Tohoku University), and an evaluation test of the performance of the developed program medical device to predict the optimal dialysis conditions (such as the amount of water removed) for maintenance hemodialysis patients has been conducted since October 2024.

Approximately 350,000 patients with end-stage renal failure in Japan undergo hemodialysis three times a week to remove water and waste products in place of their abolished kidneys. In hemodialysis treatment, the most important medical issue is "appropriate water removal," and setting the optimal amount of water removal is the issue that doctors struggle with the most. Insufficient water removal impairs cardiopulmonary function, and excessive water removal causes low blood pressure during dialysis, leading to adverse events such as feeling unwell and loss of consciousness. In dialysis hospitals, many patients are treated by one doctor and a small staff of several nurses and clinical engineers, and when adverse events occur, the burden on the staff increases.

This program medical device was developed in collaboration with Tohoku University, NEC

Corporation (NEC), and NEC Solution Innovators, Ltd. (NES). It learns by imitating the target amount of water removal set by dialysis specialists, and presents the target amount of water removal to non-specialists and other less experienced doctors with the same accuracy as specialists. Experienced dialysis doctors set the amount of water removal based on their experience (tacit knowledge), taking into consideration 1) the weight gain since the end of the previous dialysis, 2) the difference between the set dry weight²⁾ and the weight before dialysis, and 3) the patient's condition (swelling of the face and lower limbs, bowel movement status, sleep, food intake status, etc). However, while there are 12,000 specialists required for dialysis treatment, there are only about 4,000 actual specialists, and non-specialists (other than dialysis specialists or dialysis instructors) are forced to engage in dialysis treatment. In the Ministry of Health, Labor and Welfare document (Ministry of Health, Labor and Welfare document surveyed in 2007), only 54.1 % of respondents said that "dialysis doctors are always in charge." For example, in rural areas such as Iwate and Fukushima, 50 % of doctors are non-specialists, and it is known that there is a tendency for specialists to be in short supply in rural areas. For this reason, in many dialysis facilities, non-specialists, experienced nurses, and clinical engineers assist in setting the amount of water removed under the direction of specialists. To solve this medical issue, we are developing a programmed medical device that uses AI to support safe and secure maintenance hemodialysis.

This programmed medical device imitates the treatment of dialysis specialists by having AI learn dialysis treatment information from approximately 3,000 cases (approximately 1 % of dialysis patients in Japan), and provides non-specialists with predictions equivalent to those of dialysis specialists. By using this programmed medical device, non-specialists can supplement the knowledge and experience of non-specialists and are expected to contribute to the implementation of appropriate maintenance hemodialysis treatment for dialysis patients. In addition, dialysis with appropriate water removal settings is expected to suppress the occurrence of adverse events such as blood pressure drops, which is expected to reduce the burden on patients themselves and contribute to improving their quality of life.

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

Please note that this matter does not have any particular impact on our performance at this time.

¹⁾ Clinical performance test

In order to make the program medical device under development available for use in medical settings,

it is necessary to verify whether the program medical device performs as expected in clinical settings using actual human clinical data. A clinical performance test is a clinical study conducted for this verification. Based on the performance confirmed in the clinical performance test, an application (regulatory application) will be submitted to the Ministry of Health, Labor and Welfare to manufacture and sell it as a program medical device. This clinical study has a similar nature to the verification test (Phase III test) for pharmaceuticals.

2) Dry weight

This refers to the target weight of dialysis patients, and is the weight after excess water has been removed from the body. Dry weight varies from patient to patient and is determined taking into account their physical condition, blood pressure, edema, etc. Maintaining an adequate dry weight can help reduce the drop in blood pressure and strain on the cardiovascular system during dialysis.