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To Shareholders,

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(Code: 4889 TSE Growth)
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Prompt announcement of the result of the clinical performance test for the artificial intelligence (AI) predicting optimal insulin dosage for hospitalized diabetic patients

We are pleased to announce the result of a clinical performance test[*1] for the pharmaceutical approval of the 'the artificial intelligence (AI) predicting optimal insulin dosage for hospitalized diabetic patients', conducted at six hospitals in Japan.

In Japan, among the approximately 10 million diabetic patients, 1 million patients control their blood sugar with insulin treatment. Insulin injection treatment is necessary to strictly control blood sugar level and prevent diabetic complications, but the safe dosage range of insulin is narrow, and excessive administration can cause adverse events such as hypoglycemia. Diabetes specialists set the dosage taking into account tacit knowledge based on experience, but the reality is that it is difficult for non-specialists to do so. Unfortunately, specialists make up less than 2% of all doctors and are unevenly distributed geographically, so currently, diabetic patients do not necessarily have a diabetic specialist as their doctor, and rather often visit a non-specialist. The shortage and uneven distribution of diabetic specialists has the following effects on treatment.

(1) For non-diabetic specialists, the hurdle of insulin treatment to control blood sugar is high, and there are cases where hospitalization is not performed and patients' poor blood sugar control continues, or even if hospitalization is performed, appropriate insulin treatment is not performed.

(2) Even if the main purpose of hospitalization is not blood sugar control, blood sugar control during hospitalization is important. Inappropriate insulin treatment during hospitalization increases the number of deaths during hospitalization, prolonged ICU stays, new onset of infections and acute renal failure, and new onset of respiratory failure requiring ventilator management.

We have developed a 'software as a medical device (SaMD) that relies on artificial intelligence (AI) to predict optimal insulin dose' to be used as an assistant for non-diabetic specialists (users) to provide appropriate insulin treatment to hospitalized diabetic patients (target patients). This SaMD was

developed with the support of the "Medical Engineering Collaboration Innovation Promotion Project" of the Japan Agency for Medical Device Development (AMED), a national funding agency.

Clinical performance test (prompt announcement)

From August 2024, a clinical performance test for pharmaceutical approval of this SaMD was conducted as a multi-center, clinical performance test at Tohoku University Hospital, Yamaguchi University Hospital, Sendai City Hospital, Osaki Municipal Hospital, Miyagi Prefecture South Core Hospital, and Tohoku Rosai Hospital (the coordinating physician for the clinical study was Professor Hideki Katagiri, Department of Diabetes and Metabolic Medicine, Tohoku University Graduate School of Medicine).

• A multi-center, clinical performance test was conducted for 116 clinical data cases of hospitalized patients with type 2 diabetes who received insulin treatment from a diabetes specialist for the purpose of blood sugar control, comparing the results actually prescribed by the specialist (insulin units) with the results predicted by this AI (insulin units), to prove the non-inferiority (equivalence) of the AI prediction to the specialist.

• In consultation with the Pharmaceuticals and Medical Devices Agency (PMDA), the primary efficacy endpoint was set to the correct rate when the difference between the prescription unit by this AI and that by the specialist was within the acceptable range. The tolerance range was calculated from the inter-dosage error of insulin units (dosage) prescribed by 10 specialists in a preliminary exploratory study.

• As a result of the clinical performance test, the average accuracy rate was 85.46%, which is expected to exceed the initial target accuracy rate of 80% for the primary endpoint by 5%, proving the non-inferiority (equivalent) of AI predictions to specialists.

• This AI predicts insulin dosage with the same accuracy as specialists, and is a SaMD that reduces the burden on non-specialists and contributes to improving patients' QOL through appropriate blood sugar control.

• We will compile the results of this clinical performance test in a summary report and proceed with preparations for practical application.

There is currently no impact on the financial results for the fiscal year ending March 2024, but we will

disclose any matters that need to be disclosed in the future in a timely manner.

[*1] Clinical Performance Test

In order for a software as a medical device (SaMD) under development to be used 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. A clinical performance test is a clinical study conducted for this verification. Based on the performance confirmed in the clinical performance test, an application (pharmaceutical application) is submitted to the Ministry of Health, Labor and Welfare to manufacture and sell the software as a medical device. This clinical study has a similar nature to a verification test (phase 3 trial) for pharmaceuticals.