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To Shareholders,

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Breaking News: Completion of A Multicenter Clinical Trial of Disposable Ultrafine Endoscope for Peritoneal Dialysis

The disposable ultrafine endoscope (hereinafter referred to as "this medical device") developed by our company was approved for support and promotion as a JSPD-supported research project at the November 2022 of the Japanese Society for Peritoneal Dialysis (JSPD) Board of Directors meeting, and in December 2023, clinical research on this medical device was approved as a JSPD Academic Committee project. A clinical practice guideline for diagnosis and other uses of this medical device was published in May 2024 ["Peritoneal Tissue and Endoscopic Finding Assessment Guideline 2024" (edited by the Academic Committee and Endoscopy Project Committee of the Japanese Society for Peritoneal Dialysis)]. To further clarify the clinical significance of this medical device, a multicenter clinical trial was initiated at six institutions, including St. Luke's International Hospital, Jikei University Hospital, Jikei University Katsushika Medical Center, Juntendo University Hospital, Juntendo University Nerima Hospital, and The University of Tokyo Hospital (disclosed on June 24, 2024). The clinical trial has now concluded, and we are pleased to announce the preliminary results.

Background and Explanation of the Clinical Trial

Peritoneal dialysis (PD) is a home-based renal replacement therapy that allows patients to maintain their independence and quality of life. However, long-term PD can cause structural and functional deterioration of the peritoneum. Furthermore, encapsulating peritoneal sclerosis (EPS)[1)] sometimes develops as a serious complication in long-term peritoneal dialysis patients. Given this background, some clinical settings have adopted a "time-based strategy" to consider discontinuing treatment based on the duration of PD. This is because objective information on the condition of the peritoneum in patients undergoing PD is difficult to obtain.

Currently, assessment of peritoneal condition primarily relies on the following tests:

- ☐ Peritoneal Equilibration Test (PET) [2)]
- ☐ Measurement of biomarkers in effluent [3)]

- ☐ Imaging tests (e.g., CT)

While these methods are useful, they do not directly observe the interior of the peritoneal cavity. Direct observation of the interior of the peritoneal cavity can be achieved through surgical procedures or laparoscopy[4], but these are invasive, require anesthesia, and make regular evaluation difficult.

This Medical Device

Peritoneal dialysis patients constantly have a tube that delivers dialysate inserted into their peritoneum. Therefore, we conceived the idea of developing an ultrafine endoscope that could be inserted through this thin tube to non-invasively observe the peritoneal cavity. This device was developed in collaboration with Tohoku University, Juntendo University, and the Jikei University School of Medicine. Based on the opinions of many physicians, this disposable fiberscope, approximately 1mm in outer diameter, meets clinical specifications. Developed based on a concept distinct from conventional gastrointestinal endoscopes, this medical device can be inserted through gastrostomy tubes, urethral balloons, tracheal tubes, and injection needles, offering a wide range of potential clinical benefits.

This ultrafine endoscope consists of a fiberscope section for visualizing the abdominal cavity and a guide catheter section for easy maneuverability. The fiberscope has received pharmaceutical approval from the Ministry of Health, Labour and Welfare. Product details are as follows:

Approval Number: 30400BZX00294000
Generic Name: Flexible Laparoscope
Brand Name: Transcatheter Laparoscope PD VIEW
Classification Code: Device 25

Manufacturing of the guide catheter has also been completed. A regulatory application for its approval is scheduled for 2026 by Hi-Lex Medical Co., Ltd., a subsidiary of Hi-Lex Corporation. Once the guide catheter is approved, Hi-Lex Medical Co., Ltd. will begin commercialization.

Clinical Trial Results

- ☐ A clinical trial was conducted on 60 outpatient peritoneal dialysis patients who had been on PD for more than three months. The clinical trial used this medical device to describe macroscopic findings of the peritoneal membrane and catheter lumen via the indwelling

PD catheter at the initial (baseline) and 12-month (follow-up) examinations.

- ☐ 60 patients underwent the initial examination, and 49 patients completed the 12-month follow-up examination. The procedure was safe in all patients, and no adverse events were observed.
- ☐ This medical device is a technology that enables noninvasive and repeated macroscopic evaluation of the peritoneal membrane and catheter lumen during ongoing peritoneal dialysis. It is possible to observe fibrin deposition, which is important for clinical guidelines, and is considered to be a practical method to complement the clinical evaluation of stable peritoneal dialysis patients.

There is currently no impact on our financial results for the fiscal year ending March 2026. However, we will make timely disclosures if any matters arise in the future.

[1)] Encapsulating Peritoneal Sclerosis (EPS)
This is the most serious complication of long-term PD. It is a condition characterized by hardening and thickening of the peritoneum, resulting in intestinal adhesions and intestinal obstruction (ileus). Symptoms include abdominal pain, vomiting, constipation, and ascites, and progression can be fatal. Early detection and transition to hemodialysis are essential for treatment.

[2)] Peritoneal Equilibration Test (PET)
A test to evaluate peritoneal function (ease of transport of substances) in PD patients.

[3)] Biomarker Measurement in Effluent
This test is being studied and implemented for the early assessment of peritoneal structural and functional deterioration and complications such as peritonitis. In particular, CA125, an indicator of peritoneal microstructure, and IL-6, an indicator of chronic inflammation, are known markers.

[4)]Laparoscopy
This is a minimally invasive procedure performed by making three or four small incisions, each measuring 5mm to 1cm, in the abdomen, inflating the abdomen with carbon dioxide gas, and inserting a camera (scope) and specialized instruments.