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Notification of completion of the recruitment for the clinical trials of absorbable hemostat (TDM-621)

Regarding our absorbable hemostat (hereinafter referred to as "TDM-621"), wherein self-assembling peptide technology is utilized, we hereby notify that we have completed the recruitment of patients at the trial sites in Japan.

Regarding TDM-621 as a medical device, we submitted a notification of clinical trial protocol dated April 11, 2017 to the Pharmaceuticals and Medical Devices Agency, Japan (hereinafter referred to as the "PMDA") and then have been conducting the clinical trial.

We have been conducting the clinical trial, which is a randomized, comparative study to verify the efficacy and safety of TDM-621 in the field of gastrointestinal endoscopy, at multiple medical institutions including academic medical centers. As the number of recruitment have reached the target that we considered necessary to assess efficacy and safety, we will complete the clinical trials in cases scheduled for endoscopic treatment on July 24, 2019. From now onward, we will conduct data analysis after completion of the subject observation period and file an application for manufacturing and marketing approval with the PMDA in the second quarter of FYE 04/2020.

In Japan, we have entered into a domestic exclusive distributorship agreement regarding TDM-621 with Fuso Pharmaceutical Industries, Ltd. (head office: Osaka). In Europe, the indication to use for post-bleeding prevention have been added, and FUJIFILM Europe BV has signed an exclusive distributorship agreement in the gastrointestinal endoscopy field, and we place this field as our main target in Europe.

It is estimated that the number of the gastrointestinal endoscopic treatments in Japan is more than 800,000 cases a year and the market size of Japan could be larger than that of Europe. We are planning to spread TDM-621 quickly into the Japanese market, making the most of our sales experience in Europe.

The subject matter will have no impacts on our full-year business performance for FYE 04/2020. At this

point, we predict that the subject matter will have no impacts on our midterm business plan published on June 14, 2019, either. Should there arise any impact, however, we will review the details of the impact and then promptly make an announcement of it.

END

[Characteristics of the hemostat TDM-621]

TDM-621 is a transparent liquid made of a peptide consisting of three types of amino acids found within the human body. It forms a hydrogel instantaneously after coming into contact with blood (is self-assembling), and thus is intended to utilize this characteristic to physically cover a bleeding surface and thereby arrest hemorrhage.

Whereas conventional surgical hemostatic agent (material) products are made of human-derived fibrin and a group of products made of bovine-derived collagen, TDM-621 is completely free of animal-derived substances and eliminates the risk of becoming infected with the hepatitis C virus, etc. because the raw material, i.e., peptide, is manufactured by chemical synthesis. Moreover, TDM-621 has numerous characteristics including the following, whereby it is differentiated from the adhesive force-based conventional products: it is easy to use because it is supplied as a pre-filled syringe product (syringe filled with aqueous solution); it can be washed off after use; the residual in the body, if any, is decomposed into amino acids and promptly eliminated from the body; and its transparency provides good visibility of the operative site. TDM-621 is therefore expected to be applicable to a wider range of procedures, including those for which the use of the conventional hemostatic materials has been difficult, and reduce the risks to and burdens of medical professionals and patients.

[Endoscopic Submucosal Dissection (ESD)]

This is a procedure to peel off the lesion at the submucosal layer level using an endoscopically usable high-frequency surgical knife. It is mainly used to treat gastrointestinal tract tumors. This procedure has the following features: 1. cutting of the circumferential mucosa; 2. peeling-off operation performed in the submucosal layer. Addition of the above allows to determine resection area as intended (accurately cut out the target area), and to eliminate any limits on the size of the resectable area, enabling to resect lesions that are associated with ulcers and adhered to the muscularis propria.