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To whom it may concern:

3-2-4 Kojimachi, Chiyoda-ku, Tokyo, JAPAN
Company Name: 3-D Matrix, Ltd.
Name of Representative: Representative Director and President Jun Okada
(Code Number: 7777)
Contact Information: Director Tomoyuki Arai
Telephone Number: +81 3 (3511) 3440

Notice Regarding the Marketing Clearance in the US of PuraStat-OM, a Hydrogel Material for treatment of Oral Mucosa Wounds

This is to announce the clearance of the 510(k) submitted to the Food and Drug Administration (FDA) by 3-D Matrix, Inc., our U.S. subsidiary, for the pre-marketing clearance of PuraStat-OM, an oral hydrogel wound dressing product.

We developed PuraStat-OM using self-assembling peptides under license from the Massachusetts Institute of Technology (MIT) in the US. PuraStat-OM is intended to adhere to oral tissue and form a protective barrier over the wound to prevent further irritation and contamination, and to provide a moist wound environment for optimal wound healing. It is intended to manage the pain in all types of oral wounds, mouth sores, injuries, and ulcers of the oral mucosa (e.g., oral mucositis and stomatitis).

Oral mucositis is said to occur in over 40% of cases of solid cancers (e.g., head and neck cancers) and hematopoietic malignancies as a side effect of chemotherapy and radiation. It is an inflammation of the oral mucosa that causes pain and secondary infection and has a significant impact on the patient's quality of life. Current standard of care is limited to treatment of symptoms, and include administering medications to relieve pain, and use of materials to protect the mucosal tissue as well as steroids.

Although the site of occurrence for oral mucositis is the oral cavity, the inflammatory symptoms are understood to be similar to those of radiation proctitis. Additionally, following our product development strategies for the US market, we expect the clearance of PuraStat-OM to contribute to the development of a wound dressing material for radiation proctitis in the US.

Radiation Proctitis occurs as a side effect of radiation treatments for abdominal cancers such as prostate and uterine cancers, and frequently develops inflammation of the mucosa in the large intestines. While current standard of care is limited to treatment of symptoms, about 20% of patients suffer from chronic bleeding, frequent defecation, severe stomachache, and late disabilities including esophageal strictures, and unmet needs relating to patient QOL is significant.

In the European market, 3-D Matrix's hemostatic device, PuraStat, approved for clinical use under the CE mark, has been applied endoscopically for treatment of radiation proctitis patients, where in addition to its intended hemostatic effect, doctors have reported effects of inflammatory tissue healing to normal tissue.

Following development of a wound dressing material for radiation proctitis, we aspire to develop a product to improve QOL of inflammatory bowel disease (IBD) patients, as the inflammatory conditions of the GI-tract mucosa are considered to be comparable. IBD, which encompasses patients diagnosed with both ulcerative colitis and Crohn's disease, had an estimated patient population of 3M, or 1.3% of US adults in 2015. Despite the large number of patients, the exact cause of IBD has not yet been fully understood, and there is a strong need for better treatments to improve patient QOL.

In the US we have started commercialization of PuraSinus, an ENT adhesion-prevention/hemostatic/wound healing product, and have recently received 510(k) clearance for PuraStat-GI, our hemostatic product for the gastrointestinal endoscopy specialty, planned for market introduction this fiscal year . Over the coming months, we aim to move forward in development of products addressing the oral mucosa and radiation proctitis, to further expand our product portfolio.

This clearance does not impact our forecasted financial results for the current fiscal year. The impact to the current Mid-Term Business plan is under evaluation, and prompt announcement will be made in the event we determine that this approval or other related matters affect our projected performance.

(*1) A marketing pathway for medical devices in the US. Generally, the evaluation is completed in 90 to 180 days.