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To whom it may concern:

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# Notice regarding Marketing Approval for Radiation Proctitis Wound Healing Material

3-D Matrix, Ltd. is pleased to announce that the 510(k) premarket notification ("510(k)")[*1] that its US subsidiary 3-D Matrix, Inc. submitted to the United States Food and Drug Administration (FDA) for the Company's wound healing material for radiation proctitis as a medical device (class II) has been approved.

The Company had already received FDA clearance in October 2021 for the 510(k) premarket notification submitted ahead of this application for its oral mucositis wound healing material.

This product was developed by the Group using the self-assembling peptide technology licensed from the Massachusetts Institute of Technology (MIT) in the US. Applied to mucosal tissue injured by radiation proctitis and other forms of rectal mucositis, it forms a protective film on the tissue with the aim of providing a moist environment optimal for wound healing in addition to preventing secondary inflammation and reducing pain.

Radiation proctitis is a side effect of radiation therapy used to treat prostate and uterine cancers which frequently causes inflammation of the rectal mucosa. About 20% of patients suffer from late effects involving chronic melena, frequent bowel movements, severe abdominal pain, and rectal stenosis, but no effective treatment method has been established with symptomatic therapy being the mainstay at present. There are significant unmet needs, particularly in terms of patient quality of life.

As patients eagerly await an effective treatment for radiation proctitis, doctors have reported that the Company's hemostatic material "PuraStat," which has been used in gastrointestinal endoscopies in Europe for the treatment of symptoms, not only stops bleeding but also has groundbreaking healing effects such as promoting the recovery of tissue to normal. There is strong demand in healthcare settings for the product to be commercialized as a wound healing material for radiation proctitis.

The Company is further aiming to develop a wound healing material targeting inflammatory bowel disease, a disease that similarly causes inflammation in the mucosa of the gastrointestinal tract, as its next step following

the development of wound healing materials for radiation proctitis. Inflammatory bowel disease is a collective term for ulcerative colitis and Crohn's disease, which affect about 1.3% of the US population (approximately 3 million people). While extremely common, their causes are still not clearly understood, and effective treatment methods that contribute to improved quality of life for patients are being eagerly awaited to accompany the medical treatments and surgeries presently available.

The Company has begun sales of the anti-adhesion and hemostatic material "PuraSinus" in the US and received marketing approval for its hemostatic material for the prevention of postoperative bleeding "PuraStat" for the gastrointestinal endoscopy specialty in June 2021, with sales set to start imminently. In addition to these products, the Company plans to further expand its product lineup from the next fiscal year by rapidly commercializing healing materials for oral mucositis, radiation proctitis, as well as inflammatory bowel disease.

Through this approval, the Company aims to provide an array of value including hemostasis, prevention of postoperative bleeding, and wound healing, particularly in the gastrointestinal endoscopy specialty, and in doing so contribute to improved patient quality of life as well as improved safety in advanced treatments.

This announcement has no impact on the financial result forecasts for the current full fiscal year that have been announced. The Company is currently examining the impact on its medium to long-term business performance and will promptly announce if any impact is found.

1. One of the review systems for medical devices in the U.S. In general, reviews are completed in 90 to 180 days. The Company plans to promptly start sales upon receiving clearance.