JASDAQ

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Surgical Hemostat (TDM-621): IDE Submission to FDA

The company hereby announces that our US subsidiary, 3-D Matrix, Inc. has completed the IDE (Investigational Device Exemption; corresponds to submission of clinical protocol in Japan) submission to the US Food and Drug Administration (FDA) on February 1, 2013 regarding surgical device, hemostat (U.S. development code: TDM-621-US01). The hemostat is made from RADA16, which is the first product based on self-assembling peptide technique exclusively licensed to 3DM by Massachusetts Institute of Technology.

Note: This is the same product that is currently under review by Pharmaceuticals and Medical Devices Agency, Japan (PMDA) for manufacturing and marketing approval, application submitted to PMDA in May 2011.

TDM-621 is a clear liquid made from a peptide that consists of three kinds of amino acid that constitute the human body. When it comes into contact with blood, it self-assembles into a hydrogel that physically coats the surface of blood vessels, and can be applied to general surgical operations. As the peptide is manufactured through chemical synthesis without using any animal derived materials, it has no risk of infection with hepatitis C virus or interfusion of unknown elements.

Furthermore, TDM-621 has characteristics that are clearly differentiated from existing products based on adhesion. It comes in a prefilled syringe (solution filled into syringe) and is easy to use, it can be rinsed off after use, material that is left in the body dissolves into amino acids and is ejected out of the body quickly, and is transparent and does not hinder visibility during surgery. It is expected to be adopted in circumstances where existing hemostats are difficult to use, and to reduce risk of medical professionals and patients.

In the current surgical hemostat market, widely used products are either based on fibrin derived from humans, or on collagen from cattle, with an estimated market size of ¥100 billion in the U.S. By leveraging the safety features and unique qualities of our product, we aim to replace existing products,

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develop new applications such as use in endoscopic surgery or laparoscopic surgery, and through these actions establish a strong position in the surgical hemostat market. To drive this, in parallel with the clinical study, we will focus our efforts to seek sales partners in the U.S.

This IDE submission does not influence the earning forecast of the company at this moment.

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