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Announcement of submission of a premarket notification 510 (k) for approval of wound healing material (TDM-511) in the U.S.

We announce that, on October 22, 2014, 3-D Matrix Inc., our subsidiary in the U.S., made a submission of a premarket notification 510 (k) to the Food and Drug Administration (FDA) for approval of the wound healing material (development code: TDM-511) whose development our group promoted, aiming to introduce it as a medical device to the U.S. market.

Our group has promoted development of wound healing materials using the self-assembling peptide technology. This product under the 510 (k) application quickly stops bleeding by covering injured skin (epidermis, epidermis/dermis) with gel formed by nanofibers produced by self-assembly. The advantage of this product is that peptide gel provides the regenerating environment for injured skin tissues, which results in acceleration of wound healing and assurance of aesthetic effect on the regenerated part (minimization of scar).

The premarket notification is made under the 510 (k) process for medical device review in the U.S. Unlike the review process of premarket approval (PMA) required for new medical devices without any substantially equivalent products, 510 (k) requires companies to submit the application documents to the FDA at least 90 days before the scheduled date of release of the product under the 510 (k) application. Once the applicant submits a 510 (k) application, the FDA checks within 90 days the contents of the application for substantial equivalence to previously approved medical devices in the U.S. After approval by the FDA, the applicant receives the marketing authorization.

With this product under the 510 (k) application, our group starts to make a full-scale entry into the field of skin regeneration. We started by applying for approval of this indications for treatment of mild to moderate skin injuries (burn, pressure ulcer, etc.), and then plan to gradually expand the indications to the field of cosmetic surgery (applications to hyaluronic acid injection etc.). The product under the 510 (k) application is expected to improve conventional treatments because the mixture of this product and antibiotic/anti-inflammatory drugs may control infection or inflammation at the site of skin injury. Local administration of drugs tends to reduce their toxic effects. Therefore, we examine the possibility of application of the mixture of this product and anticancer drugs to treatment of skin cancer.

The influence of market introduction of this product has not been considered in our financial results forecasts for the full year and the business revenues stated in the current Mid-Term Business Plan. If there is any influence on our business in the course of acquisition of the approval, we will soon announce our latest situation.