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Absorbable Hemostat「PuraStat®」 Product Registration Obtained in Indonesia

The 3-D Matrix group is working towards commercialization of absorbable hemostat「PuraStat® (*Development code: TDM-621)」globally. The company hereby announces that its subsidiary in Singapore, 3-D Matrix Asia Pte. Ltd.'s sales and marketing partner for Indonesia, PT. Teguhsindo Lestaritama (head office located at Jl. H Miran No. 32, Jakarta, Indonesia), has received notification from the Ministry of Health on April 16, 2015 that the medical device product registration approval in Indonesia has been granted.

The group has obtained CE marking for the absorbable hemostat「PuraStat®」on January 14, 2014. This CE marking can be leveraged by using it as a reference regulatory agency approval in various countries in Asia-Pacific and Latin America. The product can be commercially marketed once approval is obtained in each country.

The application for product registration in Indonesia which PT. Teguhsindo Lestaritama submitted on July 18, 2014, had utilized the CE marking approval in the evaluation. With this medical device product registration approval from the Ministry of Health, our commercialization activities in Indonesia can start. Therefore, PT. Teguhsindo Lestaritama expects commercial sales to take place in next fiscal year in Indonesia.

Based on the previously signed partnership agreement with PT. Teguhsindo Lestaritama, 3-D Matrix Asia Pte. Ltd. will receive milestone payment of approximately 50,000,000 Japanese Yen. This amount will be recognized as revenue. We are currently assessing the impact from this change on our earning forecast and will make appropriate announcement as soon as assessment is completed.

*TDM-621 is the development code of the company's absorbable hemostat. PuraStat® is the product name of the absorbable hemostat, which CE marking was granted on January 14, 2014 allowing sales in countries who are members of the European Union.