March 13, 2015

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Withdrawal of Application for the Approval of the Hemostat (TDM-621)

We hereby announce that we have decided to withdraw the application for the manufacturing and marketing approval of the hemostat (development code: TDM-621) in Japan which has been developed with our self-assembling peptide technology as a medical device, and to proceed with the preparation for a subsequent clinical trial and the reapplication for the approval, as of March 13, 2015.

The company has conducted the initial clinical trial in three indications: gastrointestinal surgery, cardiovascular surgery, and gastrointestinal endoscopy, and has submitted the application for the manufacturing and marketing approval to Pharmaceuticals and Medical Devices Agency, Japan (PMDA) on May 31, 2011. Since the precise validation of the efficacy of the hemostat was deemed necessary to obtain the approval through consultations between PMDA and the company, we have decided to conduct the subsequent clinical trial and reapply for the approval.

The subsequent clinical trial has already begun to be studied and is planned to start in FY2015. The specific amount of research and development cost for the study recognized in year after FY2014 is difficult to be estimated at present. The company will make its best efforts to submit the reapplication early after the completion of the trial; however, the specific schedule is still under review.

For the influence to the earning forecast of the company, please refer to our announcements “Revision of forecast of financial results for FY2014 and Reduction of Board Members’ Compensation” and “Revision of mid-term business plan (FY2014-FY2016)” made public as of March 13, 2015.