

Astellas Pharma Inc.: Withdraws Application for Marketing Approval of Darexaban (YM150), an Oral Direct Factor Xa Inhibitor, in Japan

Tokyo, February 15, 2011 - [Astellas Pharma Inc.](#) (“Astellas”; headquarters: Tokyo; President and CEO: Masafumi Nogimori) announced that it withdrew a market authorization application for darexaban maleate (“darexaban”; generic name; development code name: YM150), an oral Factor Xa direct inhibitor, which was submitted to the Ministry of Health, Labour and Welfare (“MHLW”) in Japan. The application is for the indication of the prevention of venous thromboembolism (“VTE”) in patients at risk, such as those undertaking orthopedic surgical procedures in the lower limbs.

On September 29, 2010, Astellas submitted the application to MHLW. Subsequently, Pharmaceuticals and Medical Devices Agency (“PMDA”) provided their view that Astellas should conduct additional clinical studies to supplement the current application package in order to achieve approval. Following that discussion with PMDA, Astellas decided to withdraw the application today.

Astellas is considering the appointment of a partner for the development and commercialization of darexaban for the indications of the prevention of VTE in the U.S. and Europe, and stroke prevention in atrial fibrillation globally. Astellas expects to decide future plan, including the indication of VTE in Japan, based on the outcome of the partnership discussion above.

The impact of the application withdrawal on Astellas’ current fiscal year (from April 1, 2010 to March 31, 2011) financial forecast will be immaterial.

* VTE is a condition consisting of both Pulmonary Embolism (“PE”) and Deep-Vein Thrombosis (“DVT”) causing PE. DVT is the disease condition caused by the formation of blood clot in the deep vein. PE is the disease condition caused by a blockage of the pulmonary artery by a blood clot which is formed mainly in the deep vein and reaches the lungs through the blood stream, resulting in the disturbance in the pulmonary circulation. It is extremely important to prevent DVT, which frequently occurs after orthopedic surgical procedures in the lower limbs and the abdominal area, because the mortality of PE is high.

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