

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

Tokyo, September 29, 2010 - Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Masafumi Nogimori) announced that it submitted a market authorization application for darexaban maleate (“darexaban”; generic name; development code name: YM150) to the Ministry of Health, Labour and Welfare today in Japan. Astellas is seeking an approval 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.

Darexaban is an oral Factor Xa inhibitor discovered and developed by Astellas. Darexaban directly and selectively inhibits activated Factor X in the cascade of blood coagulation and, thus, is expected to prevent VTE by suppressing the thrombin production. The two Phase-II/III studies, which enrolled patients after having elective total knee or hip replacement surgeries in Japan and other Asian countries proved superior efficacy of darexaban over placebo in VTE prevention. The development program also supported safety of darexaban.

Currently YM150 is under global development for indications of prevention of VTE, stroke prevention in atrial fibrillation (“AF”) patients and the prevention of ischemic vascular events in subjects with recent acute coronary syndromes (“ACS”). The North American Phase-II study for VTE prevention in patients after elective primary knee arthroplasty demonstrated dose dependent efficacy of darexaban in VTE prevention. The international Phase-IIa study, which was conducted in Japan and other Asian countries, etc., identified optimal dose range for further development of darexaban for stroke prevention in AF patients.

Astellas expects to provide an additional therapeutic option, and further contribute to VTE prevention by introducing darexaban, an oral anticoagulant with a new mechanism of action, into the Japanese market.

\* 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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