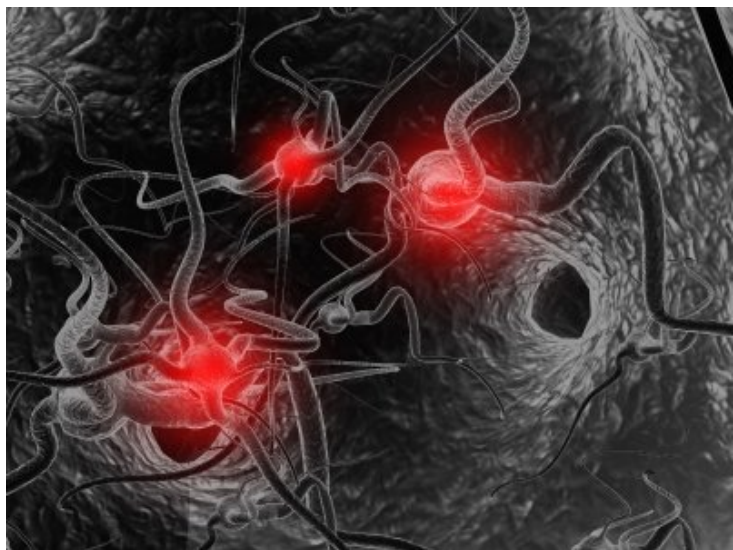


Bayer's thrombosis drug approved in Japan

September 28, 2015 | News | By BioSpectrum Bureau

Bayer's thrombosis drug approved in Japan



Tokyo: Bayer HealthCare has announced that the company has received approval in Japan for its oral Factor Xa inhibitor Xarelto (rivaroxaban) for the treatment and secondary prevention of pulmonary thromboembolism and deep vein thrombosis by the Japanese Ministry of Health, Labor and Welfare (MHLW).

Deep vein thrombosis (DVT) is a condition in which blood clots form in one of the large, deep veins, usually in the legs. Pulmonary embolism (PE) is a condition that most commonly occurs when part or all of a DVT dislodges and travels to the lung, via the heart, where it can partially or completely block a branch of a pulmonary artery.

When PE occurs with large clots, multiple clots, or when the patient has pre-existing heart or lung disease, the event may be fatal. Bayer has statistically noted that on an average every 37 seconds someone in the Western World dies from a venous blood clot, making PE and DVT (known collectively as Venous Thromboembolism, VTE) the third most common cardiovascular condition.

Bayer's MHLW approval of Xarelto is based on data from the global EINSTEIN Clinical Trial Program and is supported by the J-EINSTEIN studies (J-EINSTEIN DVT and J-EINSTEIN PE), which were run entirely in Japan. The EINSTEIN Clinical Trial Program demonstrated the efficacy and safety profile of rivaroxaban in the treatment of patients with acute symptomatic PE or DVT and the prevention of recurrent PE and DVT in these patients.

"Xarelto provides fast and effective treatment for patients suffering from PE and DVT. While the overall rates of major bleeding and clinically relevant non-major bleeding as the primary endpoint were comparable, Xarelto nearly halved the risk of major bleeding compared with the conventional dual-drug treatment approach," said Dr Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "With the approval of Xarelto for the treatment and secondary prevention of pulmonary thromboembolism and deep vein thrombosis, we can now provide physicians and patients in Japan with the first oral treatment without the need for injections."

Ã?Â