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ASIA EDITION

# FDA Approves New Dosing for XARELTO (rivaroxaban) to Reduce the Continued Risk of Venous Thromboembolism (VTE)

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**XARELTO is the only Factor Xa inhibitor to demonstrate superior efficacy in reducing the continued risk ofrecurrent VTE after initial treatment and with major bleeding rates similar to aspirin.**

**Singapore -** Janssen Pharmaceuticals, announced the U.S. Food and Drug Administration (FDA) approved the 10 mg once-daily dose of XARELTO (rivaroxaban) for reducing the continued risk for recurrent venous thromboembolism (VTE) after completing at least six months of initial anticoagulation therapy. This approval follows a FDA Priority Review and is based on data from EINSTEIN CHOICE, the only clinical study to find that a Factor Xa inhibitor, specifically XARELTO, demonstrates superior efficacy in reducing the continued risk of recurrent VTE and with major bleeding rates similar to aspirin.

VTE includes deep vein thrombosis (DVT), a blood clot in a deep vein (often the legs), and pulmonary embolism (PE), a clot that travels to the lung. It is the third most common cause of cardiovascular death worldwide, after heart attack and stroke.

"We believe the availability of the 10 mg XARELTO® dose will change clinical practice and the management of VTE recurrence," said Paul Burton, MD, PhD, FACC, Vice President, Medical Affairs, Janssen. "The landmark EINSTEIN program results yet again demonstrate XARELTO® is a safe and highly effective option, not only for the initial treatment of a VTE, but also for the continued prevention of a recurrent event."

With this approval, the XARELTO prescribing information provides instructions for physicians to begin treatment with XARELTO 15 mg, dosed twice daily, for the first 21 days after a VTE occurrence. On day 22 through at least day 180, the daily dose decreases to XARELTO 20 mg once daily. After at least 180 days (6 months), physicians can prescribe XARELTO 10 mg once daily in patients at continued risk for DVT and/or PE.