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China approves Bayer's Xarelto

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Singapore: Bayer's anticoagulant drug, Xarelto (rivaroxaban), has been approved by the China Food and Drug Administration (CFDA) for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors.

Additionally, the CFDA has approved Xarelto for the treatment of deep vein thrombosis (DVT) and for the reduction of the risk of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults. Since 2009, Xarelto has been available in China for the prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.

"This approval is the result of many years of research and a robust development program," said Dr Joerg Moeller, member, Bayer HealthCare Executive Committee and Head of Global Development. "We are delighted to bring the benefits of Xarelto to patients and physicians in China in need of an effective and convenient therapy against blood clots to prevent strokes and treat DVT."

The approval of rivaroxaban for the prevention of stroke in patients with atrial fibrillation by the China Food and Drug Administration is based on the clinical benefits demonstrated in ROCKET, a double-blind global Phase III study that compared once-daily rivaroxaban with warfarin in more than 14,000 patients.