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Eliquis approved in EU for stroke prevention

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Eliquis approved in Europe for nonvalvular atrial fibrillation

Singapore: European Commission has approved Eliquis (apixaban) for prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (NVAF) with one or more risk factors.

Eliquis, developed by Bristol-Myers Squibb and Pfizer, is the only oral anticoagulant that has demonstrated superior risk reduction versus warfarin in the three important outcomes of stroke and systemic embolism, major bleeding, and all-cause mortality.Eliquis is an oral direct factor Xa inhibitor, part of a novel therapeutic class. This is the first regulatory approval in any market for Eliquis for stroke prevention in patients with nonvalvular atrial fibrillation.

"Patients with atrial fibrillation have a five times greater risk of stroke and there remains a critical public health need for improved treatment options to reduce this risk," said Mr Lars Wallentin, director and professor, cardiology, Uppsala Clinical Research Center and University Hospital, Sweden.

"The approval of Eliquis represents an important new treatment option for health care professionals, who now have an oral anticoagulant with superior outcomes versus warfarin in the reduction of stroke, major bleeding and death in patients with nonvalvular atrial fibrillation," he added.

The marketing authorization for Eliquis is supported by the pivotal phase III trials ARISTOTLE and AVERROES, which evaluated approximately 24,000 patients with NVAF in the largest completed clinical trial program conducted to date in this patient population. The Eliquis clinical program is the only phase III clinical program among the new oral anticoagulants to evaluate the safety and efficacy of Eliquis versus aspirin in patients who were unsuitable for vitamin K antagonist (VKA) therapy.