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BMS-Pfizer stroke drug gets Japanese nod

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Singapore: Bristol-Myers Squibb and Pfizer announced that the Japanese Ministry of Health, Labor and Welfare (MHLW) has approved Eliquis (apixaban) for the prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF).

Eliquis is a novel anticoagulant that has demonstrated risk reductions versus warfarin in three important outcomes of stroke, major bleeding and all-cause death. Eliquis is an oral direct factor Xa inhibitor, part of a novel therapeutic class. This is the third approval for Eliquis for the prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, following approvals in the European Union and Canada.

"Today's approval of Eliquis is the result of our shared vision with Pfizer to introduce a differentiated treatment option to reduce the burden of stroke in patients with nonvalvular atrial fibrillation," said Mr Charles Bancroft, executive vice president, intercontinental region and Japan, and CFO, Bristol-Myers Squibb. "We are confident in the clinical profile of Eliquis and look forward to making this important medicine available to patients in Japan."

"The approval in Japan marks the third regulatory approval for Eliquis within six weeks," said Mr John Young, president and managing director, Pfizer primary care business unit. "We are excited by this momentum and confident that our combined cardiovascular leadership and expertise with BMS will lead to a successful introduction of this important medicine to patients and physicians in Japan."

The approval of Eliquis in Japan is supported by the pivotal phase III trial, Aristotle, which evaluated the safety and efficacy of Eliquis versus warfarin in 18,201 patients with NVAF, including 336 patients from Japan. Additionally, the safety and efficacy of Eliquis in Japanese patients were evaluated in a subanalysis of the Aristotle study, which demonstrated results consistent with the overall study. The application for Eliquis for the prevention of ischemic stroke and systemic embolism was submitted in Japan on December 21, 2011.