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FDA approves SNDA for BMS-Pfizer DVT prevention drug

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Singapore: U.S. Food and Drug Administration (FDA) has approved a Supplemental New Drug Application (sNDA), co-developed by Bristol-Myers Squibb and Pfizer, for Eliquis (apixaban) for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.

"FDA approval of Eliquis for DVT prophylaxis in patients who have undergone hip or knee replacement is a significant milestone for this important medicine, which is also approved to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation," said Dr. Brian Daniels, senior vice president, global development and medical affairs, Bristol-Myers Squibb. "This approval reflects the continued commitment of the alliance to deliver new treatment options for patients and physicians."

"As the number of hip and knee replacement surgeries performed in the U.S. continues to increase, the risk of DVT following these surgeries remains a concern for physicians," said Dr. Steven J. Romano, senior vice president and Medicines Development Group Head, Global Innovative Pharmaceuticals Business. "Eliquis provides patients and physicians with a new treatment option that offers twice daily oral dosing and no routine coagulation testing, and is broadly accessible through hospitals and managed health care formularies."