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BMS, Pfizer gets FDA nod to review Eliquis

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

The submission is supported by the ADVANCE-1, ADVANCE-2, and ADVANCE-3 clinical trials, part of the EXPANSE clinical trial program. These trials randomized nearly 12,000 patients and assessed the safety and efficacy of Eliquis compared to enoxaparin. ADVANCE-1 and ADVANCE-2 studied patients undergoing elective total knee replacement, and ADVANCE-3 studied patients undergoing elective hip replacement.

Venous thromboembolism (VTE) encompasses two serious conditions: deep vein thrombosis (DVT), a blood clot in a vein, usually in the leg, that partially or totally blocks the flow of blood; and pulmonary embolism (PE), a blood clot blocking one or more vessels in the lungs. DVT causes multiple symptoms including pain, swelling and redness and, more importantly, can progress to PE, which carries the risk of sudden death. Patients undergoing major orthopedic surgery, including total knee or total hip replacement, are at high risk for VTE.