Eliquis® (apixaban) – New indication, new formulation

- On April 17, 2025, the FDA approved Bristol Myers Squibb's Eliquis (apixaban), for the **treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric patients from birth and older after at least 5 days of initial anticoagulant treatment**.

- Eliquis is also approved:

    - To reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation
    - 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
    - For the treatment of adults with DVT
    - For the treatment of adults with PE
    - To reduce the risk of recurrent DVT and PE in adult patients following initial therapy.

- In addition to the new indication, Eliquis was also approved as a 0.5 mg tablet for oral suspension and a 0.15 mg capsule for oral suspension.

- The approval of Eliquis for the new indication was based on Study CV185325, a randomized, active-controlled, open-label study in 229 pediatric patients from birth to less than 18 years with confirmed VTE. Patients were randomized to receive either an age-appropriate formulation and body weight-adjusted dose of Eliquis or standard of care.

    - The percentage of patients with symptomatic and asymptomatic recurrent VTE and VTE related mortality was 2.6% (95% CI: 0.7, 6.5) with Eliquis vs. 2.7% (95% CI: 0.3, 9.4) with standard of care.

- Eliquis carries a boxed warning for premature discontinuation increases the risk of thrombotic events and spinal/epidural hematoma.

- The most common adverse reactions (≥ 10%) with Eliquis use in pediatric patients were headache, vomiting, and excessive menstrual bleeding.

- Refer to the Eliquis drug label for completing dosing and administration recommendations in both adult and pediatric patients.

- Bristol Myers Squibb's launch plans for the tablet for oral suspension and capsule for oral suspension are pending.