Xarelto® (rivaroxaban) – Expanded indication

- On October 30, 2017, Janssen Pharmaceuticals announced the FDA approval of Xarelto (rivaroxaban) 10 mg for the reduction in the risk of recurrence of deep vein thrombosis (DVT) and/or pulmonary embolism (PE) in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months.

- Xarelto is also indicated:

    - To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
    - For the treatment of DVT
    - For the treatment of PE
    - For the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

- The expanded indication for Xarelto was based on the EINSTEIN CHOICE study. Patients who had completed 6 - 12 months of anticoagulant treatment for DVT and/or PE received Xarelto 10 or 20 mg once daily or 100 mg aspirin once daily. Because the benefit-risk assessment favored the 10 mg dose vs. aspirin compared to the 20 mg dose vs. aspirin, only the data for 10 mg dose is reported.

    - Xarelto 10 mg was superior vs. aspirin 100 mg for the primary composite endpoint of time to first occurrence of recurrent DVT or nonfatal or fatal PE (1.2% vs. 4.4%, respectively; Hazard ratio = 0.26; 95% CI: 0.14, 0.47; $p < 0.0001$).

- Xarelto carries a boxed warning stating that premature discontinuation of Xarelto increases the risk of thrombotic events and spinal/epidural hematoma.

- The recommended dosage of Xarelto for the expanded indication is 10 mg orally once daily with or without food, after at least 6 months of standard anticoagulant treatment.

- Consult Xarelto's drug label for recommended dosing for all other indications.