Xarelto® (rivaroxaban) – New indication

- On October 11, 2018, the FDA announced the approval of Xarelto (rivaroxaban), in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular [CV] death, myocardial infarction [MI] and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

- Xarelto is also indicated for the following:

    - To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
    - For the treatment of deep vein thrombosis (DVT)
    - For the treatment of pulmonary embolism (PE)
    - For the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months
    - For the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

- The efficacy and safety of Xarelto for the reduction in the risk of stroke, MI, or CV death in patients with CAD or PAD was demonstrated in the COMPASS study enrolling 27,395 patients. The mean duration of follow-up was 23 months. The primary composite outcome was the reduction in the rate of stroke, MI, or CV death.

    - The event rate of stroke, MI or CV death was 2.2% per year for the Xarelto + aspirin treated patients vs. 2.9% per year for the aspirin treated patients (HR = 0.76 [95% CI: 0.66, 0.86]).

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

- The recommended dose of Xarelto for the new indication is 2.5 mg orally twice daily, plus aspirin (75 - 100 mg) once daily.

- Refer to the Xarelto drug label for dosing recommendations for all other indications.