Arixtra® (fondaparinux) – New indication

- On December 23, 2024, the FDA approved Mylan's Arixtra (fondaparinux), for the treatment of venous thromboembolism (VTE) in **pediatric patients aged 1 year or older weighing at least 10 kg**.
- Arixtra is also approved in adults for prophylaxis of deep vein thrombosis (DVT), treatment of acute DVT, and treatment of acute pulmonary embolism.
- The approval of Arixtra for the new indication was based on an open-label, single-arm retrospective clinical study in 366 pediatric patients aged 0.3 years to 17 years with VTE. The efficacy of Arixtra was based on measuring the proportion of patients with complete clot resolution up to 3 months (± 15 days).
    - Among the 325 pediatric patients in the efficacy analysis set, **44.9%** (95% CI: 39.6, 50.4) experienced complete resolution of at least one clot, while **44%** (95% CI: 38.7, 49.4) had complete resolution of all clots.
- Arixtra carries a boxed warning for spinal/epidural hematomas.
- The recommended initial dose of Arixtra for pediatric patients is 0.1 mg/kg subcutaneously once daily.
    - Refer to the Arixtra drug label for complete dosing and administration recommendations for pediatric and adult patients.