Ezallor™ (rosuvastatin) – New drug approval

- On December 18, 2018, the FDA approved Sun Pharmaceutical's Ezallor (rosuvastatin) capsules, as adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia or primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia); and as adjunctive therapy to other lipid-lowering treatments (eg, low-density lipoprotein [LDL] apheresis) or alone if such treatments are unavailable to reduce LDL-cholesterol, total cholesterol, and apolipoprotein B in adult patients with homozygous familial hypercholesterolemia.
    - Ezallor has not been studied in Fredrickson Type I and V dyslipidemias.
- Rosuvastatin is also available generically as a tablet and approved for the same indications as Ezallor.
- The approval of Ezallor was based upon efficacy studies conducted for rosuvastatin tablets.
- Ezallor is contraindicated in patients with active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels; pregnancy; and lactation.
- Warnings and precautions of Ezallor include skeletal muscle effects, liver enzyme abnormalities, concomitant coumarin anticoagulants, proteinuria and hematuria, and endocrine effects.
- The most common adverse reactions (> 2%) with Ezallor use were headache, myalgia, abdominal pain, asthenia, and nausea.
- The recommended dose of Ezallor in adults is 5 mg to 40 mg orally once daily, with or without food. The usual starting dose is 10 mg to 20 mg once daily.
    - The maximum Ezallor dose of 40 mg should be used only for those patients who have not achieved their LDL-C goal utilizing the 20 mg dose.
- Sun Pharmaceuticals' launch plans for Ezallor are pending. Ezallor will be available as 5 mg, 10 mg, 20 mg, and 40 mg capsules.