Zypitamag™ (pitavastatin) – New drug approval

- On July 14, 2017, the FDA approved Zydus Pharmaceuticals’ Zypitamaq (pitavastatin) for patients with primary hyperlipidemia or mixed dyslipidemia as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C).
  - Doses > 4 mg once daily were associated with an increased risk for severe myopathy in premarking clinical studies. Daily doses should not exceed 4 mg.
  - The effect of Zypitamag on cardiovascular morbidity and mortality has not been determined.
  - Zypitamag has not been studied in Fredrickson Type I, III, and V dyslipidemias.

- Pitavastatin is also available as Livalo®.
  - Livalo carries the same indication as Zypitamag.
  - Similar to Livalo, Zypitamag will be available as 1 mg, 2 mg, and 4 mg tablets.

- The efficacy of Zypitamag was based on the clinical trials conducted for Livalo.
  - Pitavastatin, given as a single daily dose for 12 weeks, significantly reduced plasma LDL-C, TC, TG, and Apo-B vs. placebo and was associated with variable increases in HDL-C across the dose range.
  - For the percent change from baseline to endpoint in LDL-C, pitavastatin was non-inferior to atorvastatin and simvastatin for comparable doses.
  - Pitavastatin significantly reduced LDL-C vs. pravastatin at comparable doses.

- Zypitamag is contraindicated in patients with active liver disease which may include unexplained persistent elevations of hepatic transaminase levels, coadministration with cyclosporine, during pregnancy, during lactation, and in patients with a known hypersensitivity to any component of pitavastatin.

- Warnings and precautions of Zypitamag include skeletal muscle effects, liver enzyme abnormalities, and endocrine function.

- The most common adverse reactions (≥ 2% in at least one marketed dose) with Zypitamag use were myalgia, back pain, diarrhea, constipation, and pain in extremity.

- The recommended starting dosage of Zypitamag is 2 mg orally once daily.
  - The dose range of Zypitamag is 1 mg to 4 mg orally once daily.
  - The starting dose and maintenance doses of Zypitamag should be individualized according to patient characteristics, such as goal of therapy and response.
  - After initiation or upon titration of Zypitamag, lipid levels should be analyzed after 4 weeks and the dosage adjusted accordingly.

- Zydus Pharmaceuticals’ launch plans for Zypitamag are pending.