Repatha™ (evolocumab) – New Drug Approval

- On August 27, 2015, the FDA announced the approval of Amgen’s Repatha (evolocumab) as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C); and as an adjunct to diet and other LDL-lowering therapies for the treatment of patients with homozygous familial hypercholesterolemia (HoFH), who require additional lowering of LDL-C.

  — The effect of Repatha on cardiovascular morbidity and mortality has not been determined.

- HeFH and HoFH are inherited conditions associated with high levels of LDL-C. A high level of LDL-C in the blood is linked to cardiovascular or heart disease.

  — Heart disease is the number one cause of death for Americans, both men and women. According to the Centers for Disease Control and Prevention, about 610,000 people die of heart disease in the United States every year.

- Repatha is the second drug approved in the new class of drugs known as proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors. PCSK9 is a protein that reduces the number of receptors on the liver that remove LDL-C from the blood. By blocking PCSK9’s ability to work, more receptors are available to get rid of LDL-C from the blood and, as a result, lower LDL-C levels.

  — Praluent® (alirocumab) was the first PCSK9 inhibitor approved in July 2015. Aside from HoFH, Praluent has the same indications as Repatha.

- The efficacy and safety of Repatha were based on one 52-week and eight 12-week placebo-controlled trials in subjects with primary hyperlipidemia, including two that specifically enrolled patients with HeFH and one that enrolled patients with HoFH. Adding Repatha to background lipid-lowering therapy (including statins) resulted in LDL-C reductions.

  — In patients with clinical ASCVD or HeFH, Repatha reduced LDL-C by approximately 54% to 77% compared with placebo. In patients with HoFH, Repatha reduced LDL-C by approximately 30% compared with placebo.

  — Moreover, one trial demonstrated that 90% of clinical ASCVD patients who received Repatha in addition to maximum doses of statins achieved a LDL-C level < 70 mg/dL.

- A trial evaluating the effect of adding Repatha to statins for reducing cardiovascular risk is ongoing. Results are expected no later than 2017.

- Repatha is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha. Hypersensitivity reactions (e.g. rash, urticaria) have been reported in patients treated with Repatha, including some that led to discontinuation of therapy.

- The most common adverse reactions (> 5% and more common than placebo) with Repatha use were nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection-site reactions.
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- For adults with HeFH or ASCVD, the recommended dose of Repatha is 140 mg subcutaneously every 2 weeks or 420 mg subcutaneously once a month.
  - For adults with HoFH, the recommended dose is 420 mg subcutaneously once a month.

- The Wholesale Acquisition Cost (WAC) price of Repatha is $542.31 for one 140 mg single-use prefilled autoinjector or prefilled syringe, or $14,100 annually for the every 2 weeks administration.

- Amgen’s RepathaReady™ program is a comprehensive suite of services to help patients and providers. Services include one or more months of free Repatha while insurance coverage is pending. Other services include a Repatha $5 co-pay card for eligible commercial patients, insurance coverage support, and injection training.

- Amgen plans to launch Repatha next week. Repatha will be available as single-use 140 mg prefilled SureClick™ autoinjectors or prefilled syringes for self-administration. A once monthly 420 mg injection is expected to be available next year.