Evkeeza® (evinacumab-dgnb) – Expanded indication

- On March 22, 2023, Regeneron Pharmaceuticals announced the FDA approval of Evkeeza (evinacumab-dgnb), as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with homozygous familial hypercholesterolemia (HoFH).
    - Evkeeza was previously approved for this indication in patients aged 12 years and older.
    - The safety and effectiveness of Evkeeza have not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH).
    - The effects of Evkeeza on cardiovascular morbidity and mortality have not been determined.
- The approval of Evkeeza for the expanded indication was based on a three-part, single-arm, open-label study in 14 pediatric patients aged 5 to 11 years with HoFH. Part B of this trial evaluated the efficacy of Evkeeza every 4 weeks as an adjunct to other lipid-lowering therapies (eg, statins, ezetimibe, lomitapide, and lipoprotein apheresis) for 24 weeks. The primary endpoint was percent change in calculated LDL-C from baseline to week 24.
    - At week 24, the mean percent change in calculated LDL-C from baseline was -48% (95% CI: -69% to -28%).
- The recommended dosage of Evkeeza is 15 mg/kg administered by intravenous infusion over 60 minutes once monthly (every 4 weeks).

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