Imaavy™ (nipocalimab-aahu) – New orphan drug approval

- On April 30, 2025, Johnson & Johnson announced the FDA approval of Imaavy (nipocalimab-aahu), for the **treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive**.

- MG is an autoantibody disease in which the immune system mistakenly makes antibodies (eg, AChR) which target proteins at the neuromuscular junction and can block or disrupt normal signaling from nerves to muscles. Initial disease manifestations are usually eye-related but approximately 85% of MG patients experience additional disease progression (gMG). This is characterized by severe muscle weakness and difficulties in speech and swallowing

    — Approximately 100,000 individuals in the U.S. are living with gMG.

- Imaavy is a neonatal Fc receptor blocker.

    — **There are other drugs approved for gMG including two other drugs in the same class – Vyvgart® (efgartigimod alfa-fcab) and Rystiggo® (rozanolixizumab-noli).**

- The efficacy of Imaavy was established in a randomized, double-blind, placebo-controlled study in patients with gMG. Patients were randomized to Imaavy or placebo. The primary efficacy analysis population included 153 patients. The primary endpoint was the comparison of the mean change from baseline to weeks 22, 23, and 24 between treatment groups in the Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score. The MG-ADL total score ranges from 0 to 24, with the higher scores indicating more impairment.

    — The change in MG-ADL total score was -4.7 and -3.3 with Imaavy and placebo, respectively (difference 1.5, 95% CI: -2.4, -0.5; p = 0.002).

- Warnings and precautions for Imaavy include infections, hypersensitivity reactions, and infusion-related reactions.

- The most common adverse reactions (≥ 10%) with Imaavy use were respiratory tract infections, peripheral edema, and muscle spasms.

- The recommended initial dosage of Imaavy is 30 mg/kg administered once via intravenous infusion over at least 30 minutes. Two weeks after the initial dosage, a maintenance dosage of 15 mg/kg should be administered via intravenous infusion over at least 15 minutes. The maintenance dosage should be continued every two weeks thereafter.

- Johnson & Johnson's launch plans for Imaavy are pending. Imaavy will be available as 300 mg/1.62 mL and 1,200/6.5 mL single-dose vials.