Vyepti™ (eptinezumab-jjmr) – New drug approval

- On February 21, 2020, Lundbeck announced the FDA approval of Vyepti (eptinezumab-jjmr), for the preventive treatment of migraine in adults.

- Vyepti is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.

    — Vyepti is the first FDA-approved intravenous (IV) treatment for migraine prevention.

- The efficacy of Vyepti was established as a preventive treatment of episodic and chronic migraine in two randomized, placebo-controlled studies, both with 6-month double-blind periods: one study in patients with episodic migraine (study 1; N = 665) and one study in patients with chronic migraine (study 2; N = 1,072). In both studies, patients were randomized to receive placebo, Vyepti 100 mg, or Vyepti 300 mg. The primary endpoint was the change from baseline in mean monthly migraine days (MMD) over months 1 to 3.

    — In study 1, the change from baseline in mean MMDs over months 1 to 3 was -3.9, -4.3, and -3.2 for Vyepti 100 mg ($p = 0.018$ vs. placebo), Vyepti 300 mg ($p < 0.001$ vs. placebo), and placebo, respectively.
    — In study 2, the change from baseline in mean MMDs over months 1 to 3 was -7.7, -8.2, and -5.6 for Vyepti 100 mg ($p < 0.001$ vs. placebo), Vyepti 300 mg ($p < 0.001$ vs. placebo), and placebo, respectively.

- A warning and precaution for Vyepti includes hypersensitivity reactions.

- The most common adverse reactions (≥ 2% and 2% or greater than placebo) with Vyepti use were nasopharyngitis and hypersensitivity.

- The recommended dose of Vyepti is 100 mg administered by IV infusion every 3 months. Some patients may benefit from a dosage of 300 mg administered by IV infusion every 3 months.

- Lundbeck plans to launch Vyepti in April 2020. Vyepti will be available as a 100 mg/mL solution in a single-dose vial.