Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) – New indication

- On June 21, 2024, argenx announced the FDA approval of Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc), for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

- Vyvgart Hytrulo is also approved for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

- The approval of Vyvgart Hytrulo for the new indication was based on a two-stage study that included an open-label period to identify Vyvgart Hytrulo responders (stage A), who then entered a randomized, double-blind, placebo-controlled, withdrawal period (stage B). In stage B, a total of 221 patients were randomized to receive Vyvgart Hytrulo or placebo. The primary endpoint was the time to clinical deterioration defined as a 1-point increase in adjusted Inflammatory Neuropathy Cause and Treatment (aINCAT) at two consecutive visits or a > 1-point increase in aINCAT at one visit.

    — Patients who received Vyvgart Hytrulo experienced a longer time to clinical deterioration compared to patients who received placebo (hazard ratio 0.394, 95% CI: 0.253, 0.614; $p < 0.0001$).

- The recommended dosage of Vyvgart Hytrulo is 1,008 mg/11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered subcutaneously over approximately 30 to 90 seconds as once weekly injections. If a scheduled injection is missed, Vyvgart Hytrulo may be administered up to 3 days after the scheduled time point. Thereafter, resume the original dosing schedule.

    — Vyvgart Hytrulo is to be administered by a healthcare professional only.
    — Refer to the Vyvgart Hytrulo drug label for dosing for gMG.