Vyvgart Hytrulo® (efgartigimod alfa/hyaluronidase-qvfc) – New dosage form approval

- On April 10, 2025, argenx announced the FDA approval of **self-injectable prefilled syringe version of Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc)**, for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive and chronic inflammatory demyelinating polyneuropathy (CIDP).
- The new dosage form contains 1,000 mg efgartigimod alfa and 10,000 units hyaluronidase per 5 mL (200 mg/2,000 units per mL) in a single-dose prefilled syringe.
- **Vyvgart Hytrulo was previously approved as a single-dose vial** containing 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6 mL (180 mg/2,000 units per mL).
    - The vial required administration by a healthcare professional.
- The recommended dose of Vyvgart Hytrulo prefilled syringe for gMG is 1,000 mg / 10,000 units administered subcutaneously over approximately 20 to 30 seconds in cycles of once weekly injections for 4 weeks.
- The recommended dose of Vyvgart Hytrulo prefilled syringe for CIDP is 1,000 mg / 10,000 units administered subcutaneously over approximately 20 to 30 seconds as once weekly injections.
- Refer to the Vyvgart Hytrulo drug label for dosing for the single-dose vial.
- Argenx's launch plans for Vyvgart Hytrulo prefilled syringe are pending.