Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) – New orphan drug approval

- On June 20, 2023, Argenx announced the FDA approval of Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc), for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.
- Vyvgart Hytrulo is a subcutaneous (SC) formulation of efgartigimod. Efgartigimod alfa is also available as an intravenous (IV) formulation under the brand name Vyvgart.
- The efficacy of Vyvgart Hytrulo was established based on a study conducted with the IV formulation of efgartigimod alfa. Additionally, in a separate study, Vyvgart Hytrulo demonstrated a comparable pharmacodynamic effect on AChR antibody reduction as compared to the efgartigimod alfa IV formulation.
- Warnings and precautions for Vyvgart Hytrulo include infections and hypersensitivity reactions.
- The most common adverse reactions (≥ 10%) with efgartigimod alfa use were respiratory tract infections, headache, and urinary tract infection.
- The recommended dosage of Vyvgart Hytrulo is 1,008 mg/11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered SC over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks.
    - Subsequent treatment cycles should be administered according to clinical evaluation. The safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.
    - Vyvgart Hytrulo is to be administered by a healthcare professional only.
- Argenx's launch plans for Vyvgart Hytrulo are pending. Vyvgart Hytrulo will be available as a 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6 mL (180 mg/2,000 units per mL) single-dose vial.