Hyqvia® (immune globulin infusion 10% [human] with recombinant human hyaluronidase) – New orphan indication

- On January 16, 2024, Takeda announced the FDA approval of Hyqvia (immune globulin infusion 10% [human] with recombinant human hyaluronidase), for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults.

- Hyqvia is also approved for the treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age and older.

- The approval of Hyqvia for the new indication was based on a randomized, placebo-controlled study (Study 1) and a single-arm, open-label, extension study (Study 2). In Study 1, 122 patients underwent efficacy evaluation of Hyqvia as a maintenance therapy to prevent relapse. Patients were randomized to Hyqvia or placebo. The primary endpoint was the proportion of patients who experienced a relapse.

    — The analysis of the primary endpoint demonstrated a statistically significant difference between the relapse rates in the Hyqvia group (14.0%) compared to the placebo group (32.3%) ($p = 0.0314$). The treatment difference of -18.3% (95% CI: -32.1, -3.1) indicated that Hyqvia demonstrated superiority over placebo in preventing relapse of CIDP.

- Study 2 was open to patients who completed Study 1 without CIDP worsening or relapse. An interim analysis was performed, and the data included 79 patients with a range of follow-ups from 0 to 5.1 years and a total follow-up of 169 patient-years. The proportion of patients who developed CIDP relapse was 8.8% during the interim study period. The 6-month relapse rate was 1.6%.

- Hyqvia carries a boxed warning for thrombosis.

- The most common adverse reactions (> 5%) with Hyqvia use for CIDP were local reactions, headache, pyrexia, nausea, fatigue, erythema, pruritus, increased lipase, abdominal pain, back pain, and pain in extremity.

- The recommended rHuPH20 dose is 80 U/g immune globulin (IgG), which corresponds to 0.5 mL rHuPH20 solution per 10 mL immune globulin infusion 10% (human) solution for both indications.

- For patients switching from immune globulin intravenous (human) (IGIV) treatment for CIDP, the starting dose and dosing frequency of Hyqvia is the same as the patient's previous IGIV treatment. The typical dosing interval range in the clinical trial for Hyqvia was 4 weeks. For patients with less frequent IGIV dosing (greater than 4 weeks), the dosing interval can be converted to 3 or 4 weeks while maintaining the same monthly equivalent IgG dose.

    — Hyqvia should be administered by a healthcare professional, caregiver or self-administered by the patient after appropriate training.
    — Refer to the Hyqvia drug label for complete dosing and administration recommendations.