Hyqvia® (immune globulin infusion 10% [human] with recombinant human hyaluronidase) – Expanded Indication

- On April 11, 2023, Takeda announced the FDA approval of Hyqvia (immune globulin infusion 10% [human] with recombinant human hyaluronidase), for the treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
    - Previously, Hyqvia was only approved for this indication in adults.
    - The safety and efficacy of chronic use of Recombinant Human Hyaluronidase in Hyqvia have not been established in conditions other than PI.
- The approval of Hyqvia's expanded indication was based on an open-label, non-controlled study in 44 PI patients between the age of 2 to 16. The primary endpoint was the rate of acute serious bacterial infections (aSBI), per subject per year.
    - During the 12-month trial period, the mean aSBI rate per year was 0.04 (with an upper 1-sided 99% confidence interval of 0.21, $p < 0.001$), which met the predefined success rate of less than one aSBI per subject per year.
    - The mean rate of all infections per subject-year was 3.20, with an upper limit of the 95% CI of 4.05.
- Hyqvia carries a boxed warning for thrombosis.
- Hyqvia is administered subcutaneously via an infusion pump, with weight-based dosing. For complete dosing and administration recommendations, refer to the Hyqvia drug label.