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Japan approves first and only facilitated subcutaneous immunoglobulin for Agammaglobulinemia and Hypogammaglobulinemia

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HYQVIA is the first plasma-derived therapy for subcutaneous injection in Japan

Takeda has announced that the Japanese Ministry of Health, Labour and Welfare has approved the use of HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] in patients with agammaglobulinemia or hypogammaglobulinemia, disorders characterised by very low or absent levels of antibodies and an increased risk of serious recurring infection caused by primary immunodeficiency (PID) or secondary immunodeficiency (SID).

The approval marks availability of the first and only facilitated subcutaneous immunoglobulin (fSCIG) therapy as a treatment option for appropriate patients in Japan.

HYQVIA is the first plasma-derived therapy for subcutaneous injection in Japan that consists of a combination of one vial of Immunoglobulin 10% and one vial of Recombinant Human Hyaluronidase PH20 (rHuPH20). The administration of rHuPH20 increases the dispersion and absorption of immunoglobulin (IG) in the subcutaneous tissue, allowing larger volumes to be infused in the infusion site. This allows for less frequent dosing compared to other subcutaneous IG products, while avoiding the need for venous access.

The ability to infuse a larger infusion volume is expected to increase administration flexibility for patients with agammaglobulinemia or hypogammaglobulinemia by decreasing the dosing frequency to once every 3 or 4 weeks, as compared to weekly or bi-weekly with conventional SCIG treatments.

With this approval, Takeda is now able to offer a range of SCIG therapies to patients based on their individual administrative needs, reflecting the company’s commitment to offer patients in Japan a broader choice of treatment options. It also follows the announcement of a significant investment to build a new manufacturing facility for plasma-derived therapies (PDTs) in Osaka, Japan. HYQVIA is also currently under review in Japan for additional indications.