Non-interventional post-marketing safety study on the long-term safety of HyQvia (global)

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Background: We describe the design of a non-interventional, prospective, uncontrolled, multicenter, open-label, post-marketing surveillance study to be conducted in the US and other countries where recombinant human hyaluronidase (rHuPH20)-facilitated subcutaneous infusion of immunoglobulin G (fSCIG; HyQvia) is licensed.

Objective: To obtain additional safety and tolerability data in patients with primary immunodeficiency diseases.

Methods: A target of 250 adults who were prescribed/initiated fSCIG will be recruited over 3-years. Treatment regimens/schedules will be at physician discretion. All patients will enroll in period 1 (~1-year duration). Patients who test positive for rHuPH20 antibodies (titer ≥ 1:160) during period 1 or were positive pre-enrollment will continue to period 2 (2-year duration). Overall study duration will be ~6 years. There will be no required predefined visits, medical/laboratory tests, and procedures beyond the treatment centers’ standard clinical practice, except rHuPH20 antibody assessment. All assessments will be performed during routine clinical visits.

Results: Documented data will include safety (including binding/neutralizing rHuPH20 antibody titers), health-related quality of life, and health resource use.

Conclusions: Additional data on fSCIG long-term safety will be acquired and prescribed treatment regimens and administration in routine clinical practice assessed.

Keywords: Post-marketing safety; Recombinant human hyaluronidase-facilitated subcutaneous infusion of IgG; HyQvia