Local adverse reaction rates decreased over time during treatment with recombinant human hyaluronidase-facilitated subcutaneous infusion of immunoglobulin G (fSCIG) in patients with primary immunodeficiency diseases in the fSCIG phase 3 studies

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Background: fSCIG can be administered at similar doses/volumes and dosing intervals as intravenous immunoglobulin G (IgG) (IVIG) but, similar to conventional subcutaneous IgG, is associated with a lower risk of systemic and higher risk of local adverse reactions (ARs).

Objective: We report local AR rates over time in patients with PID aged ≥ 16 years treated with fSCIG for up to ~3.5 years in the fSCIG pivotal phase 3 study and its extension.

Methods: Following a 3-month IVIG treatment period, patients initiated fSCIG on a dose ramp-up schedule and thereafter received fSCIG every 3 (Q3W) or 4 weeks (Q4W) for ~18 months, followed by up to an additional 21 months. Local AR (temporally associated and/or causally related adverse events) rates were evaluated over time.

Results: Of the 63 enrolled patients aged ≥ 16 (16-78) years, 61 received fSCIG for up to ~3.5 years at the established dose. Overall, the local AR rate per infusion was 0.191; discomfort/pain was the most commonly reported local AR. Rates of ARs per infusion decreased over time: 0.28 (months 1-12), 0.15 (months 13-24), and 0.08 (months 25-33.6). The percentage of patients experiencing ≥ 1 local AR per infusion was highest during the dose

ramp-up period (33.3-41.7 % [Q3W] and 29.2-37.5 % [QW4]), and rapidly declined over time.
Conclusions: In adults treated with fSCIG for up to ~3.5 years, rates of local ARs per infusion and the percentage of patients experiencing ≥ 1 local AR markedly declined over time.

Keywords: Recombinant human hyaluronidase-facilitated subcutaneous infusion of immunoglobulin G; Primary immunodeficiency diseases