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Tolerability of Human Immunoglobulin 10% Administered Subcutaneously Following Administration of Recombinant Human Hyaluronidase (rHuPH20) in Primary Immunodeficiency Disease (PID) Patients

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Abstract:

Rationale: Intravenous (IV) and subcutaneous (SC) routes of immunoglobulin (IG) administration have both advantages and disadvantages. One disadvantage of IGSC therapy is the small volumes that can be administered subcutaneously, requiring multiple infusion sites and frequent administrations. rHuPH20 is a permeation enhancer that increases systemic absorption of SC infused fluids. This Phase 3 study evaluated the tolerability of rHuPH20-enabled 10% IGSC infusions at rates and frequencies equivalent to IGIV administration in PID patients.

Methods: PID patients were injected SC with 75 U of rHuPH20/g IgG, followed at the same site by IGSC doses equivalent to their previous IGIV dose and administration schedule. Subsequent IGSC dosing was adjusted based on IgG trough levels. An interim analysis of tolerability data was performed on a subset of 30 subjects.

Results: A total of 486 10% IGSC infusions, with or without rHuPH20, were all administered without interruption. Mean infusion volume every 4 weeks was 302 mL (30.2 g). The mean maximum infusion rate for a single site was 227 mL/h, and the mean time to infuse was 2.4hrs. Of the 30 patients analyzed, 29 reached their previous IV dosing interval, with the vast majority using a single site. Local adverse events (AEs) occurred in 16% of infusions. Most treatment-related AEs were mild and localized to the infusion site. The rate of all treatment-related systemic AEs was 8% of the infusions.

Conclusion: The subcutaneous administration of 10% IGSC facilitated by rHuPH20 was well tolerated, at infusion intervals and rates comparable to the patient's previous IGIV administration.

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