A Hybrid Fc-Fused Human Growth Hormone, GX-H9, Shows a Potential for Twice-Monthly Administration in Both Adult and Pediatric Growth Hormone Deficiencies

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Body

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GX-H9 is a hybrid Fc-based long-acting recombinant human growth hormone (rhGH) and targets both weekly and twice-monthly treatment options for growth hormone deficiency (GHD) patients. The safety, tolerability, and efficacy along with PK/PD of GX-H9 were assessed in Phase 2 studies in patients with adult (AGHD) and pediatric growth hormone deficiencies (PGHD) and compared to those of a daily recombinant hGH. A multinational, randomized, active-controlled, open-label, sequential cohort, dose-escalation Phase 2 study of GX-H9 (0.1 mg/kg/weekly, 0.2 and 0.3 mg/kg/twice-monthly) was completed in patients with AGHD (n=45). The results in AGHD trial have indicated that administration of GX-H9 for 12 weeks were safe and efficacious. The weekly treatment of 0.1mg/kg in AGHD patients demonstrated the mean increase in IGF-1 to be comparable with those receiving 6 μg/kg of Genotropin® daily for 12 weeks (101.3±31.2 ng/mL vs 109.1±45.0 ng/mL, respectively). The administration of 0.2mg/kg and 0.3mg/kg showed dose-dependent increase in mean $AUEC_{14d}$, 1337.14±529.61 ng·day/mL and 1776.06±714.43 ng·day/mL, respectively, when compared to the mean $AUEC_{7d}$ value (809.48±193.58 ng·day/mL) induced by the administration of 0.1mg/kg. Additionally, a randomized, active-controlled, open-label, parallel group, dose finding Phase 2 study of GX-H9 with weekly and twice-monthly administrations is being conducted in patients with PGHD (n=48). The interim analysis after single dosing of GX-H9 demonstrated dose-dependent PK profile in pediatric patients. The $AUEC_{28d}$ of IGF-1 SDS increased in a dose-dependent manner without having the average Emax of IGF-1 level exceeding 2 SDS in all cohorts. The administration of higher doses of GX-H9 showed a potential for twice-monthly treatment of both AGHD and PGHD with safety, tolerability and efficacy comparable to those of daily rhGH. No drug-related SAEs, no lipoatrophy and no treatment-emergent formation of anti-drug antibodies were observed in both studies thus far. The interim height velocity data of Phase 2 study in PGHD with weekly and twice-monthly treatment of GX-H9 for 3 months will be presented.

Disclosure: JWW: , Genexine, Inc.. HMK: , Genexine, Inc., , Genexine, Inc., , Genexine, Inc.. Nothing to Disclose: MA, EB, NZ, EJL, JS, TKK, HYR, WIJ, YCS

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Sessions

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Saturday, Apr 01 1:00 PM
OCCC - West Hall B (EXPO Hall)
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