BACKGROUND

- Recombinant human growth hormone (rhGH) is standard treatment for children and adults with growth hormone deficiency. However, current rhGH therapy involves daily subcutaneous (sc) injections with years of treatment. The challenge of daily sc rhGH injections has proven to limit compliance, often reducing the ability to maintain height velocities or optimal clinical outcomes. Thus, long-acting rhGH should improve ease of use, compliance, and consequently efficacy.

- GX-H9 is a chimeric protein composed of rhGH fused to a hybrid Fc. The hybrid Fc (hyFc), is a novel Fc-based platform technology for generating long-acting proteins with a hybrid of IgD Fc and IgG4 Fc, which extends the half-life and the bioactivity of fused proteins.

METHODS & RESULTS – Phase 2 Adult GHD Study

- Study Design (Single Dose + Multiple Dose)

- Results – Pharmacokinetic & Pharmacodynamics

- METHODS & RESULTS – Phase 2 Pediatric GHD Study

- Study Design (Single Dose + Multiple Dose)

- Results – Pharmacokinetic & Pharmacodynamics

CONCLUSION

- GX-H9 was safe and well tolerated in healthy volunteers and patients with GHD (adult and limited injections to pediatric)
- Dose dependent PK/PD profiles were observed
- No formation of treatment-emergent ADA was found so far
- Phase 2 adult and pediatric studies showed comparable safety profile with 1st generation hGH
- Weekly and twice-monthly administration of GX-H9 showed potential for both weekly and twice-monthly treatment