YoungHoon (Nicholas) Cho
Director, Business Development
nicholas.cho@genexine.com
+82-10-9953-3235

Genexine
(주) 제 넥 신

KDDF-201502-11 / KDDF-201509-12

GX-H9 Long-Acting rhGH

· Hybrid Fc (hyFc) technology based long-acting recombinant human Growth Hormone (rhGH-hyFc).

hyFc technology

· hyFc technology enables weekly & semi-monthly dosing of rhGH to address unmet needs for less frequent injections.

Phase II in AGHD (EU/KR)

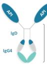
· Phase II in Adult Growth Hormone Deficiency (AGHD) in EU/KR to be completed in 2H 2016

Phase II in PGHD (EU/KR)

· First top-line data of Phase II in Pediatric Growth Hormone Deficiency (PGHD) to be available in 2H 2016

hyFc technology

hyFc (Hybrid Fc), Genexine's proprietary platform technology consists of IgD & IgG4 and generates a Fc fusion protein which is long-acting and safe.



Broad range of drug moiety
API : Active Pharmaceutical Ingredient

- Wide & flexible hinge
- No Fc-binding site for phagocytes (no ADCC[1])
- No binding site for complement C1q (no CDC[2])
- Long acting via FcRn[3]-mediated recycling

1. ADCC : Antibody Dependent Cell-mediated Cytotoxicity
2. CDC : Complement Dependent Cytotoxicity
3. FcRn : Neonatal Fc Receptor

Human Ig Isotypes	IgG1	IgG4	IgD
Hinge flexibility	++	+	++++
Binding of FcγR of phagocytes (ADCC)	++++	++	-
Activation of C1q(CDC)	++	-	-
Binding of FcRn	++++	++++	-
In vivo serum half-life (days)	21	21	3

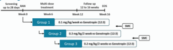
Interim PK/PD data for Phase II of GX-H9 in AGHD

Subjects with AGHD (Adult Growth Hormone Deficiency) received 0.1 mg/kg GX-H9 weekly (Group1) or 0.3 mg/kg GX-H9 semi-monthly (Group 2) for 12 weeks subcutaneously. The PK/PD (Pharmacokinetics/Pharmacodynamics) results suggest a potential for both weekly and semi-monthly dosing of GX-H9. No SAE (Serious Adverse Effects), lipoatrophy and ADA (Anti-Drug Antibodies) have been reported to date. Phase II study in PGHD (Pediatric Growth Hormone Deficiency) is also on-going to investigate safety, efficacy and PK/PD of GX-H9.

Objective

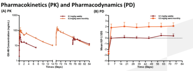
1) To evaluate the change in insulin-like growth factor-1 (IGF-1) levels in relation to time and dose strength
2) To assess the PK and PD profiles of GX-H9 in the treatment of AGHD
3) To evaluate the safety and tolerability of GX-H9 in the treatment of AGHD

Study Design



After week 6 of last patients in each group, available safety and tolerability data have been reviewed by SMC

Pharmacokinetics (PK) and Pharmacodynamics (PD)



PK and PD of GX-H9 in AGHD. Subjects received 0.1 mg/kg GX-H9 weekly or 0.3 mg/kg GX-H9 semi-monthly for 12 weeks subcutaneously. (A) Serum GX-H9 Concentration-Time profiles following GX-H9 administration.
(B) Mean change from baseline in IGF-1 SDS for GX-H9 dosing groups. Each point indicates C_{max} value of IGF-1 SDS measured at 3 days of post-injection. Baseline was defined as the Day 1 pre-dose value.

KDDF
Korea Drug Development Fund