Human Phase 1 clinical data of ALT-P1 (hGH-NexP™) by Healthy Korean males
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BACKGROUND

NexP™ Carrier
NexP™ is a long-acting fusion carrier developed by Alteogen, Inc.

- A further engineered human alpha-1 antitrypsin, which is abundant in human blood and its safety has been already proven.
- Increase of in vivo half life and reduced inherent protease inhibitor activity by genetic engineering

NexP™ Fusion Therapeutic Proteins

- Can be fused to both C-terminus or N-terminus of therapeutic proteins by recombinant technology
- Prolonged in-vivo half life of therapeutic proteins
- Maintained in-vivo bioactivity of therapeutic proteins
- Reduced immunogenicity
- High productivity

OBJECTIVES

Currently available Growth Hormone (GH) is developed as daily injections, which cause inconvenience and poor compliance for patients. ALT-P1 was developed for once weekly administration in growth hormone deficient (GHD) adults and children. 1) Safety and tolerability, 2) pharmacokinetics and pharmacodynamics of once-weekly subcutaneous (SC) administration of ALT-P1 were evaluated in a Phase 1 study of Korean healthy male volunteers.

METHODS

This Phase 1, single-blinded, placebo-controlled, single-dosed, dose-escalated, randomized study was conducted by Yonsei University in Korea. A total of forty subjects were enrolled and randomized to one of the five dose cohorts: 0.03 mg/kg, 0.06 mg/kg, 0.12 mg/kg, 0.24 mg/kg, and 0.35 mg/kg. In each dose cohort, six subjects were randomized into the test cohort and two to the placebo group. The mean age was 25.7 ± 5.1 and the BMI was 22.0 ± 1.7 kg/m².

PRE-CLINICAL STUDIES

ALT-P1 in-vivo half life is much longer than 1st generation hGH
Higher IGF-1 concentration due to ALT-P1 injection than 1st generation hGH
In case of every other day dose of ALT-P1, it showed linear growth and treatment-related growth

RESULTS

ALT-P1 Pharmacokinetics

- No severe adverse events
- Only 11.1% as drug related adverse effects that are typically reported adverse effects of hGH
- Mild tenderness and pain in some subjects around injection sites
- Anti-drug antibody formation was not observed

ALT-P1 Pharmacodynamics

- No ADA (anti-drug antibody) was detected in human blood by injection of ALT-P1.
- The results of the current study warrant further developments and clinical studies of ALT-P1 in adult and pediatric GHD patients.
- The human clinical study proved that ALT-P1 was safe and suitable for at least one injection per week in the tested dose range of 0.12 mg/kg and 0.35 mg/kg.
- Acknowledgement: This work was conducted jointly with CJ Healthcare Corp

CONCLUSIONS

- ALT-P1 is a long-acting recombinant hGH fused to NexP™ protein carrier.
- In animal studies, ALT-P1 showed its safety and pharmacological characteristics that indicates the potential in clinical use.
- In Phase 1 clinical trials by use of healthy male volunteers, ALT-P1 showed the increase of in vivo half life from 19 hrs (0.12mg/kg) to 40 hrs (0.35mg/kg) along with increase of IGF-1 levels.

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- The human clinical study proved that ALT-P1 was safe and suitable for at least one injection per week in the tested dose range of 0.12 mg/kg and 0.35 mg/kg.
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