Continued Safety and Efficacy of Weekly Longapesomatropin (TransCon hGH) for up to Two Years in Children with Growth Hormone Deficiency (GHD)

**BACKGROUND**
- TransCon hGH is an investigational pending for growth hormone deficiency (GHD) that consists of TransCon hGH (hGH) and an hGH-derived, small molecule protein that prevents it from being used for biological activities (Figure 1).

**METHODS**
- **TRIAL DESIGN**
  - Phase 2/3 safety trial
  - Subjects were treated chronically weekly with TransCon hGH for up to 2 years.
  - **Phase 3 Safety Trial**
    - Subjects received TransCon hGH for 2 years, followed by 1 year of placebo.
    - **Phase 3 Efficacy Trial**
      - Subjects received TransCon hGH for 2 years, followed by 1 year of placebo.
      - **Phase 3 Long-Term Safety and Efficacy Trial**
        - Subjects received TransCon hGH for 3 years, followed by 1 year of placebo.
      - **Phase 3 Long-Term Safety and Efficacy Trial**
        - Subjects received TransCon hGH for 3 years, followed by 1 year of placebo.

**OUTCOMES**
- **Safety**
  - Biweekly treatment was well tolerated.
  - **Efficacy**
  - TransCon hGH was associated with improvements in body composition, growth, bone density, and insulin sensitivity.

**RESULTS**
- **Safety Outcomes**
  - No serious adverse events were reported in Phase 2/3 trials.
  - **Efficacy Outcomes**
  - TransCon hGH was associated with improvements in body composition, growth, bone density, and insulin sensitivity.

**CONCLUSIONS**
- TransCon hGH is a promising investigational product for the treatment of GHD, showing both safety and efficacy in multiple clinical trials.

**REFERENCES**

**ACKNOWLEDGMENTS**
- The authors thank the patients and their families who participated in the clinical trials and the investigators who supported the studies.

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**Figure 1:** TransCon hGH Design

**Figure 2:** TransCon hGH Phase 2/3 Clinical Program

**Figure 3:** AHP Over 100 Weeks for hGH Subjects

**Figure 4:** Average IGF-1 SDS Over 100 Weeks for hGH Subjects

**Figure 5:** Continuing Improvement in Height SDS During 12 Months of hGH and RSH Subjects

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**Table 1:** Demographics and Disease Characteristics at Start of Study

**Table 2:** Efficacy Outcomes

**Table 3:** Summary of Adverse Events Across All Trials

**Table 4:** Similar Change in Bone Age Over 40 Weeks for hGH Subjects

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**Switching to the TransCon hGH Auto-Injector**
- An auto-injector is used for self-administration of TransCon hGH.
- OVERALL, fewer injection site reactions were reported with the TransCon hGH Auto-Injector (Figure 6).

**Figure 6:** Local Translatability of Subjects During the TransCon hGH Trial

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