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Switch Data From the Open-Label Extension of the Pivotal Phase 3 Study of Once Weekly Somatrogon Compared to Daily Somatropin in Pediatric Patients With Growth Hormone Deficiency (pGHD)

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OBJECTIVES: Somatrogon (hGH-CTP) is a long acting recombinant human growth hormone, consisting of the amino acid sequence of hGH and three copies of the carboxy-terminal peptide (CTP) of human chorionic gonadotropin (hCG) being developed as a once weekly treatment for children with pGHD. This report summarizes data from the first year of the optional open-label extension (OLE) of the pivotal phase 3 global trial (ClinicalTrials.gov: NCT02968004), comparing the efficacy and safety of children switched from Genotropin (rhGH; somatropin) to somatrogon (Geno/Soma) and children maintained on somatrogon (Soma/Soma).
METHODS: During the main study, 224 children were randomized to receive either once weekly somatrogon (0.66 mg/kg, n=109) or once daily Genotropin (0.24 mg/kg/wk, n=115) for 12 months. Of these, 222 completed the 12-month main study, and 212 chose to enter the OLE study. By Sept 30, 2020, 161 children (including 76 Geno/Soma) had complete auxological data at month 12 of the OLE.
RESULTS: At the end of the main study, mean height velocity and gain in height SDS for the somatrogon cohort were 10.10 cm/year and 0.92; for the Genotropin cohort these were 9.78 cm/year and 0.87. Baseline values for the OLE (Soma/Soma group and Geno/Soma group, respectively): height SDS was -1.95 and -1.84, BMI was 17.03 and 15.48 kg/m^2 while bone age was 6.54 and 6.40 years. At month 12 (of the OLE), the mean height velocity and the change in height SDS was 8.04 cm/year and 0.41 (Soma/Soma group) and 8.21 cm/year and 0.47 (Geno/Soma group); BMI was 18.07 and 17.49 kg/m^2 and bone age was 8.48 and 8.41 years. IGF-1 SDS values were 1.15, and 1.28, while the IGFBP-3 SDS were 0.29 and 0.42, respectively. Dose reductions were required in 16.3% and 20.4% of patients due to IGF-1 SDS >2. Pubertal status changed from Tanner 1 (at OLE baseline) for 13.6% of Soma/Soma patients and 14.6% of Geno/Soma patients. Mean glucose, HbA1c, thyroid function (free T4 and TSH) and cholesterol (total, LDL and HDL) values remained similar to baseline in both groups across the 12 months OLE. The majority of adverse events in both cohorts were mild to moderate (Soma/Soma 94.2%, Geno/Soma 93.5%) and there were no clinically concerning safety observations. During the first 12 months of the OLE six patients discontinued in the Geno/Soma group due to AEs vs zero in the Soma/Soma group.
CONCLUSIONS: Height velocities and change in height SDS in the OLE were similar between the Geno/Soma and Soma/Soma cohorts. The main phase of the global pivotal phase 3 trial demonstrated that somatrogon (hGH-CTP) given once weekly is non-inferior to Genotropin (hGH) while the OLE demonstrated that catch-up growth continued into the second year of treatment, with 'switch' from Genotropin to somatrogon non-inferior to somatrogon given for two years. Metabolic (glycemic, lipid and thyroid) parameters were similar between groups and not meaningfully different from the main study.

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Author Disclosure Information:

M. Wajnrajch: Employee; Self; Pfizer, Inc.. Stock Owner; Self; Pfizer, Inc. **B.S. Miller:** Advisory Board Member; Self; Pfizer, Inc.. Consulting Fee; Self; Pfizer, Inc.. Research Investigator; Self; OPKO Health. **J. Steelman:** None. **L.A. Silverman:** Advisory Board Member; Self; Pfizer, Inc.. Consulting Fee; Self; OPKO Health. **M. Phillip:** Grant Recipient; Self; OPKO Health. **E. Vlachopapadopoulou:** None. **R. Stawerska:** Research Investigator; Self; OPKO Health, Ascendis. **H. Kim:** None. **O. Malievskiy:** None. **C. Ko:** None. **S.R. Valluri:** Employee; Self; Pfizer, Inc.. Stock Owner; Self; Pfizer, Inc. **C. Turich Taylor:** Employee; Self; Pfizer, Inc.. Stock Owner; Self; Pfizer, Inc. **C.L. Roland:** Employee; Self; Pfizer, Inc.. Stock Owner; Self; Pfizer, Inc. **J. Choe:** Employee; Self; OPKO Health. **A. Pastrak:** Owner/Co-Owner; Self; OPKO Health. Stock Owner; Self; OPKO Health. **C.L. Deal:** Advisory Board Member; Self; Pfizer, Inc.. Consulting Fee; Self; Pfizer, Inc., OPKO Health. Research Investigator; Self; Pfizer, Inc., OPKO Health. Speaker; Self; Pfizer, Inc., OPKO Health.

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