Convenience of the Once-Weekly Growth Hormone (GH) Derivative Somapacitan in Adult GH Deficiency (AGHD): Results from a 26-Week Randomized, Controlled, Phase 3 Trial

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Body

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Background: Daily subcutaneous injections of GH may be inconvenient for many patients with AGHD, leading to noncompliance, reduced efficacy and increased healthcare costs. Short-term trials have shown that somapacitan (Novo Nordisk A/S, Denmark), a once-weekly GH derivative, is well tolerated in healthy adults and in patients with AGHD. Somapacitan is a peptide produced by DNA recombinant technology, with more than 99% homology to human GH. The treatment satisfaction, tolerability and safety of once-weekly somapacitan administered in a prefilled pen device vs. once-daily GH (Norditropin® FlexPro®, Novo Nordisk A/S) were investigated in patients with AGHD in a multinational, multicenter, randomized (2:1), open-label, active-controlled trial (NCT02382939; REAL 2).
Methods: Ninety-two patients (diagnosed with AGHD, male/female, 18–79 years, previously treated with GH for ≥6 months) were randomized to once-weekly somapacitan (n=61) or once-daily Norditropin® FlexPro® (n=31). Somapacitan and Norditropin® FlexPro® doses were titrated for the first 8 weeks based on serum insulin-like growth factor-I (IGF-I) to achieve serum IGF-I standard deviation scores (SDS; within the normal range [preferably 0–2 SDS]). Doses were fixed for the remaining 18 weeks. Convenience, effectiveness and global treatment satisfaction were assessed using the Treatment Satisfaction Questionnaire for Medication-9 (TSQM-9), with an increase in scores signifying an increase in treatment satisfaction. A mixed model for repeated measurements was used to estimate treatment differences in TSQM-9 scores.

Results: Serum IGF-I levels were maintained in both treatment arms after dose titration. Mean (SD) serum IGF-I SDS scores at week 25 were 0.22 (0.89) and 0.35 (0.82) for somapacitan and Norditropin® FlexPro®, respectively. No safety issues were identified with somapacitan; the pattern and rate of adverse events (AEs) and serious AEs were similar with the two treatments. More than 1500 somapacitan injections were administered; two mild, transient injection-site reactions were observed. No anti-somapacitan or anti-GH antibodies were detected. Mean (SD) convenience score increased from 68.3 (18.3) to 83.8 (12.9) with somapacitan, and from 71.7 (17.5) at baseline to 75.8 (19.1) at end of treatment with Norditropin® FlexPro®; estimated between-treatment difference in change from

baseline to end of treatment (somapacitan–Norditropin® FlexPro®) was 8.22 (95% CI: 1.51; 14.93, P=0.0171), with somapacitan being more convenient than Norditropin® FlexPro®. Effectiveness and global satisfaction scores were not statistically significantly different between treatment arms.

Conclusions: As a once-weekly GH treatment for AGHD, somapacitan was well tolerated with no detected safety issues and may be more convenient for patients than once-daily treatment.

Disclosure: GJ: Consultant, Viropharma, Speaker, Novo Nordisk, Speaker, Merck Serono, Speaker, Pfizer, Inc., Speaker, Ipsen, Consultant, Astra Zeneca, Consultant, Shire, Speaker, Novartis Pharmaceuticals, Speaker, Otsuka. UF: Consultant, Pfizer, Inc., Consultant, Novo Nordisk. IHH: Employee, Novo Nordisk. PR: Speaker, Merck Serono, Speaker, HRA Pharma. AT: Speaker, Pfizer, Inc., Principal Investigator, Novo Nordisk. MHR: Employee, Novo Nordisk. Nothing to Disclose: HB, ST

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