Introduction

• Omnitrope® (recombinant human growth hormone (rhGH; somatropin) approved by the European Medicines Agency in 2006, with approval granted on the basis that it matches the reference medicine (Genotropin®, Pfizer) in terms of safety, efficacy and quality.
• Replacement GH therapy stimulates linear growth and increases growth rate in children with growth hormone deficiency (GH-D). 1
• GH-D is also approved for paediatric use in other indications, such as children with Turner Syndrome (TS) and Prader-Willi Syndrome (PWS), short children born small for gestational age (SGA), and children with chronic renal insufficiency (CRI). 1 GH-D therapy is also approved for the treatment of idiopathic short stature (ISS) in the United States, Canada and Brazil.

• The PATRO Children is an international, longitudinal, non-interventional observational study of the long-term safety and effectiveness of Omnitrope® in children with growth hormone deficiency (GHD). 2
• Here we present data on AH achievement as of January 2019.

Results

• As of January 2019 (approximately 13 years since the study start), 5777 patients were enrolled in the study and included in the effectiveness population (all patients with a documented height measurement at the start of Omnitrope® treatment and at least one measurement of height during Omnitrope® treatment) [Table 1].
• Overall, 4912 patients (85.0%) were rhGH-naïve at study entry and 861 (14.9%) had previously received rhGH treatment.
• To date, 1209 patients (20.9%) (male, n=625; female, n=583) have reached AH according to the opinion of their treating physician. Of these, 925 patients (76.5%) were rhGH-naïve at study entry and 283 (24.3%) were not.
• Of the patients who reached AH, 772 (63.9%) had GHD, and 309 (25.6%) were SGA. GHD patients• Among GHD patients who reached AH, 479 (62.0%) were male and 293 (38.0%) were female.
• Mean (SD) HSDS at baseline and at AH in RhGH-naïve patients
• In rhGH-naïve patients, mean (SD) baseline HSDS was –2.63 (0.88); at AH, mean (SD) HSDS was –2.08 (1.20).
• In pre-treated patients, mean (SD) baseline HSDS was –1.99 (1.11); at AH, mean (SD) HSDS was –1.66 (1.07) [Figure 1].

Conclusions

• Based on this analysis, Omnitrope® treatment improves AH of rh-GH naïve children with GHD and SGA in real-life clinical practice.
• PATRO Children is an ongoing study, and will continue to provide further long-term data on AH with Omnitrope® treatment in these and other approved indications.

References


Acknowledgements and disclosures

The PATRO Children study is funded by Sandoz/Hexal AG. SK, PB, KOS and SS have acted as advisors and/or speakers for Sandoz/Hexal AG. MG and HD are employees of Sandoz/Hexal AG. Medical writing support was provided by Tony Reid, Spirit Medical Communications Ltd, supported by Sandoz/Hexal AG. The authors thank all patients and investigators who participated in the PATRO Children study.

Figure 1. HSDS at baseline and adult height in rhGH-naive and pre-treated GHD patients

Figure 2. Difference between adult HSDS and target HSDS in SGA patients

Table 1. Patient characteristics (effectiveness population)