Latest results from the PATRO Adults study of Omnitrope® for the treatment of adult patients with growth hormone deficiency

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Introduction

• Growth hormone deficiency (GHD) is a well-recognised condition across all ages. All adults with severe GHD are eligible for GH replacement treatment, the main goals of which are to reverse the metabolic, functional, and psychological abnormalities associated with adult GHD.

• Treatment of GHD in adults with GH replacement therapy has proved to be effective for improving body composition, exercise capacity, skeletal integrity, blood lipid profile and overall quality of life.

• The assessment of clinical practice guidelines is that the risks associated with GH therapy are low. However, extended clinical studies are required to confirm the long-term safety of GH therapy in routine clinical practice, particularly with regard to the diabeticogenic risk.

• Omnitrope® (somatropin) is a recombinant human GH (r-HGH) approved by the European Medicines Agency in 2006, with approval granted on the basis of comparable quality, safety and efficacy to the reference product, Genotropin® (Ferring).

• PATRO Adults is an ongoing observational, multicentre, open, longitudinal study of Omnitrope®, conducted in hospitals and specialised endocrinology clinics across Europe. The primary objective is to assess the safety and efficacy of Omnitrope® in adults treated in routine clinical practice.

• Here we present status and safety data from an interim analysis.

Methods

• Eligible patients are male or female adults who are receiving treatment with Omnitrope® and who have provided informed consent.

• Patients who have received treatment with another r-HGH product before starting Omnitrope® therapy are also eligible for inclusion.

• Efficacy assessments are based on analysis of:
  - Insulin-like growth factor (IGF) 1 levels within age and gender-adjusted normal ranges
  - Anthropometric measures such as weight, waist circumference, total fat mass, lean body mass, total body water
  - Bone mineral density
  - Lipids
  - Cardiovascular risk factors (glucose metabolism, blood pressure, inflammatory markers)
  - Quality of life.

• All adverse events (AEs) are monitored and recorded.

• Particular emphasis is placed on: long-term safety; the recording of malignancies; the occurrence and clinical impact of antirecombinant IGF antibodies; the incidence, severity and duration of hyperglycaemia; and the development of glucose intolerance or diabetes.

• Data is collected at each routine visit during treatment with Omnitrope®.

• For all patients included in the study, all available data (visits, laboratory findings, etc.) are recorded in a CRF.

Results

As of March 2016, 1043 patients were enrolled in the study (Table 1). Among these, 562 (53.9%) had previously been treated with r-HGH.

• Characteristics of enrolled patients are shown in Table 2.

• A total of 2052 AEs have been reported to date in 597 patients (Table 3); 317 of these (in 187 patients) were regarded as serious. Most AEs (1872/2052 [92.0%]) were mild to moderate in intensity, with few (227/2052 [11.2%]) resulting in any changes to Omnitrope® treatment.

• Table 4 shows treatment-related AEs that occurred with an incidence of >1%. The MedDRA preferred term and intensity-safety population (N=1443) are provided.

Conclusions

• Based on the interim analysis, Omnitrope® treatment in adults with GHD is well tolerated in a real-life clinical practice setting, both in r-HGH-naive and previously treated patients.

• The ongoing PATRO Adults study will provide important data on the diabeticogenic potential and overall safety of long-term GH replacement therapy in this population.

• In addition, this large, postmarketing surveillance study will extend the safety database for Omnitrope®, as well as contributing to the safety profile for all r-HGH products.

References


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