A follow-up Study up to adult height of the patients included in the phase III clinical trial with the Biosimilar human recombinant Growth Hormone (Omnitrope®) on the treatment of Spanish children with Growth Hormone Deficit

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Introduction
- Recombinant human growth hormone (rhGH) has been used for several years in the treatment of growth disorders in children and adolescents with Growth Hormone Deficiency (GHD)1.
- rhGH therapy improves growth with almost full normalization of height, pubertal development, bone mass, and quality of life2.
- Omnitrope® is a rhGH approved by EMA (European Medicines Agency) in 2006. It was the first drug ever to be approved via the biosimilar regulatory pathway3.
- The results of the phase III clinical trial that evaluated the efficacy and safety of Omnitrope® on the treatment of Spanish children with GHD were published in 20114.
- At the end of the trial those patients that were still growing remained on treatment within the usual clinical practice.

Objectives
- To know the values of adult height of the children who participated in the Spanish phase III clinical trial.
- To ascertain the long term safety of treatment with Omnitrope®.

Methods
- Multicentre, observational, retrospective follow-up study of the patients that participated in the Spanish phase III clinical trial.
- Auxologic data were calculated from the measured height and using known data of the Spanish population (Spanish growth study 2008).
- Adverse events were also recorded.

Conclusions
The adult height reached is considered within the normal values for the adult Spanish population5. This follow-up study up shows that long term treatment with Omnitrope® in pediatric patients with GHD is both safe and effective.

Results
- Data from 39 patients: 27 men and 12 women were gathered. The mean age of the patients was 18.5±2.7 years (men 18.5±2.8; women 18.5±2.6).

Efficacy
- Auxological data of the patients at the end of the Phase III Spanish clinical trial and at adult height are shown in the next table:

<table>
<thead>
<tr>
<th></th>
<th>Mean ± s.d.</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height at the end of the phase III clinical trial (cm) (n=39, 27 y 12)</td>
<td>144.8±13.9</td>
<td>145.1±14.3</td>
<td>144.1±13.3</td>
</tr>
<tr>
<td>SDS at the end of the phase III clinical trial (n=39, 27 y 12)</td>
<td>-1.16±0.63</td>
<td>-1.11±0.69</td>
<td>-1.26±0.50</td>
</tr>
<tr>
<td>Adult height (cm) (n=36, 25 y 11)</td>
<td>163.1±7.6</td>
<td>165.5±7.8</td>
<td>157.6±3.2</td>
</tr>
<tr>
<td>Height SDS (n=36, 25 y 11)</td>
<td>-1.01±0.59</td>
<td>-1.07±0.52</td>
<td>-0.86±0.72</td>
</tr>
<tr>
<td>Difference between adult height and height at the end of the phase III clinical trial (cm)</td>
<td>16.7±12.2</td>
<td>18.9±11.8</td>
<td>11.6±12.0</td>
</tr>
</tbody>
</table>

- The height evolution in each year of the follow-up period is represented in the next figure:

Two patients have not yet reached adult height and remain in treatment. In one patient adult height could not be measured.

Safety
- No adverse events were reported.

1. Bell J. et al 2010
2. Baroncelli et al 2009; Balencia et al 2013
4. López Siguero et al 2011
5. Sánchez-González et al 2011

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