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 life[2].
- 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 pathway[3].
- 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 2011[4].
- 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 population[5]. This follow-up study up shows that long term treatment with Omnitrope® in pediatric patients with GHD is both safe and effective.

Results

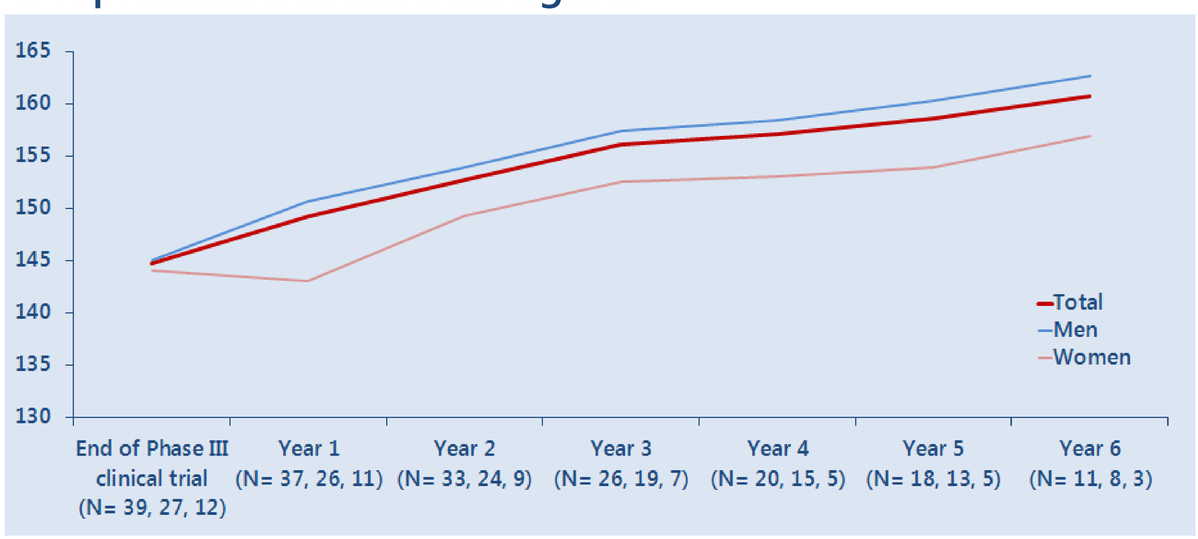
- Data from 39 patients: 27 men and 12 women were gathered. The mean age of the patients was 18.5±2.7 years (men 18.5±2,8; women 18.5±2.6).

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:

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

- 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. el al 2010
2. Baroncelli et al 2005; Balercia et al 2013
3. European Medicines Agency 2008. Omnitrope® European Public Assessment Report 2008
4.Lopez Siguero el al 2011
5. Sánchez-González et al 2011

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