Long-term safety and effectiveness of recombinant human growth hormone in Korean pediatric patients with growth disorders: 7-year interim analysis from LG Growth Study

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INTRODUCTION

LG Growth Study (LGS) aimed to evaluate the long-term safety and effectiveness of recombinant human growth hormone (rhGH) treatment in Korean pediatric patients.

OBJECTIVE

➢ To evaluate long-term safety and effectiveness of rhGH (Eutropin® Inj., Eutropin®Pen Inj., Eutropin®Plus Inj., and Eutropin®AQ Inj., LG Chem.) in pediatric patients with growth disorders including growth hormone deficiency (GHD), idiopathic short stature (ISS), Turner syndrome (TS), small for gestational age (SGA) and chronic renal failure (CRF).

METHODS

Study design

A multi-center, long-term, and prospective cohort study

Study population

Pediatric patients ≥2 years of age with GHD, ISS, TS, SGA and CRF

Written informed consent from the patients and their parents (or legal guardians) was obtained.

Statistical analysis

➢ Interim analysis has been conducted on 7-year accumulated data (from Nov. 2011 to Feb. 2019) of LGS.

➢ All adverse events (AEs) were reported for safety, and the effectiveness was assessed by height velocity (HV), height standard deviation score (HT SDS) and insulin like growth factor-1 (IGF-1).

RESULTS

Patients disposition

Enrolled: 3,144 (90%)
Excluded: 277

Safety Analysis

N=2,671 (99%)

Enrolled: 3,144 (90%)
Excluded: 277

Clinical characteristics at baseline

Table 1. Patients characteristics by indications (n/N) or mean ± SD

| Total (N=3,144) | GHD (N=1,855) | ISS (N=245) | TS (N=1,236) | SGA (N=94) | CRF (N=5)
|----------------|---------------|-------------|--------------|------------|-----------
| Gender       |               |             |              |            |           |
| Male (%)     | 1,084 (58%)   | 623 (34%)   | 221 (18%)    | 151 (16%)  | 1 (20%)   |
| Female (%)   | 760 (42%)     | 1,232 (56%) | 1,015 (82%)  | 39 (41%)   | 4 (80%)   |
| Chronological age (yr) | 7.8 ± 4.1 | 6.2 ± 4.4 | 8.5 ± 4.4 | 6.7 ± 4.5 | 8.0 ± 4.9 |
| Body age (yr) | 6.3 ± 2.4 | 7.7 ± 4.8 | 7.9 ± 4.2 | 6.2 ± 2.9 | 3.5 ± 1.6 |
| BA - CA (yr) | -1.8 ± 1.2 | -1.9 ± 1.4 | -0.9 ± 1.3 | -0.9 ± 1.5 | -1.4 ± 1.2 |
| Height SDS  | -0.7 ± 0.8   | -2.0 ± 0.8 | -0.3 ± 0.8  | 0.1 ± 0.7  | -2.5 ± 3.0 |
| BMI SDS     | -0.4 ± 1.1   | -0.7 ± 1.1 | 0.4 ± 1.2  | -0.9 ± 1.0 | -0.8 ± 0.3 |
| Tanner Stage | 615/733 (96%) | 136/200 (68%) | 128/152 (64%) | 102/125 (82%) | 2/2 (100%) |
| Treatment Duration (yr) | 3.8 (4.9) | 2.4 (1.6) | 5.2 (4.4) | 2.7 (1.7) | 4.1 (9.2) |

*Data presented as n/N or mean ± SD

RESULTS (Cont’d)

Effectiveness on Height

➢ Height velocity was 8.9 ± 1.9, 8.7±1.6, 7.3±1.8, 9.0±1.6 and 8.3±2.1 cm/year at the first year of treatment in GHD, ISS, TS, SGA and CRF, respectively.

➢ A continuous improvement of height SDS was found in most patients regardless of their disease status, in particular, with a significant increase in height SDS from baseline to 4 years in patients with GHD (from −2.9 ± 0.9 to −1.3±1.1, p<0.0001) and TS (from −3.2±0.8 to −2.2±0.8, p<0.0001).

➢ Total IGF-1 SDS was significantly increased (from −0.7±1.1 to 0.8±1.7 at 12 months, p<0.0001) and maintained within 0 to 2 SDS throughout the study period.

CONCLUSIONS

➢ In the 7-year interim results of LGS, the incidence of AEs was low, and rhGH treatment was well-tolerated.

➢ During 4 years of rhGH treatment, significant improvement in height was confirmed in Korean pediatric patients with GHD and TS.