BACKGROUND

- Daily growth hormones (GH) have been used to treat growth disorders in children since 1980s in Korea.
- A weekly sustained-release GH was approved for growth hormone deficiency (GHD) in 2009 in Korea. The weekly GH is supposed to improve patient adherence and convenience to GH treatment.
- LGS has been conducted to evaluate the safety and effectiveness of daily or weekly GH treatment among patients in Korea and the third interim analysis results are presented here.

OBJECTIVE

- To evaluate the safety and effectiveness of daily (Eutropin inj.) and weekly (EutropinPlus inj.) GH in Korean pediatric patients

RESULTS

METHODS

Study design
- A multi-center, prospective and retrospective cohort study

Study population
- Pediatric patients aged >2 years with GHD
- Written informed consent from the patients, their parents or legal guardians

Endpoints
- Effectiveness endpoints
  - Change in height velocity between baseline and each year
  - Change in height SDS between baseline and each year
- Safety endpoints
  - Adverse events, laboratory tests

Statistical analysis
- The difference between groups was tested using the two sample t-test or Wilcoxon’s rank sum test.
- Categorical data were tested using the Chi-square test or Fisher’s exact test.

RESULTS (Cont’d)

Effectiveness

- Height SDS and height velocity were not statistically different between daily and weekly GH.
- The pattern of change in IGF-I SDS was comparable and consistent in both groups.

Safety

Table 2. Adverse events occurred during GH treatment

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Daily GH (N=537)</th>
<th>Weekly GH (N=221)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse events (AE)</td>
<td>79 (14.7%)</td>
<td>21 (9.5%)</td>
<td>NSa</td>
</tr>
<tr>
<td>Adverse drug reactions (ADR)</td>
<td>17 (3.2%)</td>
<td>6 (2.7%)</td>
<td>NSa</td>
</tr>
<tr>
<td>Serious adverse events (SAE)</td>
<td>9 (1.7%)</td>
<td>2 (0.9%)</td>
<td>NSb</td>
</tr>
<tr>
<td>Serious adverse drug reaction (SADR)</td>
<td>1 (0.2%)</td>
<td>0 (0.0%)</td>
<td>NSb</td>
</tr>
</tbody>
</table>

Table 3. The 5 most commonly reported Adverse events

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Daily GH (N=537)</th>
<th>Weekly GH (N=221)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence of AE (%)</td>
<td>16 (3.0%)</td>
<td>23 (10.4%)</td>
<td>5</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>6 (1.1%)</td>
<td>6 (2.7%)</td>
<td>1</td>
</tr>
<tr>
<td>Headache</td>
<td>6 (0.9%)</td>
<td>2 (0.9%)</td>
<td>2</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>6 (0.9%)</td>
<td>4 (1.8%)</td>
<td>1</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4 (0.7%)</td>
<td>4 (1.8%)</td>
<td>1</td>
</tr>
</tbody>
</table>

- Most of reported AEs were mild to moderate.

CONCLUSION

- Both daily and weekly GH were comparable in terms of safety and effectiveness.
- The weekly GH can be considered an alternative to improve patient adherence to GH treatment.