**INTRODUCTION**

- Somatostatin analogues (SSA) are the current standard of medical management in acromegaly; the first-generation SSA, octreotide, reliably decreases growth hormone (GH) before and after oral prandial testing and cross-trial equipoise bind to somatostatin receptor subtype 2 (ssSR2).
- Pasireotide is a non-peptide SSA which binds to 4 of the 5 somatostatin receptor subtypes and has greater binding affinity for ssSR1, ssSR2, and ssSR5 compared to octreotide or lanreotide.
- Pasireotide long-acting repeatable (LAR) was recently approved for the treatment of acromegaly by both the FDA and EMA.
- Patients aged ≥18 years who had inadequately controlled acromegaly (growth hormone [GH] levels >2.5 μg/L and insulin-like growth factor-1 [IGF-1] >1.3 times the age- and sex-adjusted upper limit of normal despite receiving octreotide long-acting repeatable 30 mg or lanreotide Autogel 120 mg monthly).
- Biochemical control was defined as GH levels <2.5 μg/L and normalized IGF-1.
- At the end of the core phase (week 24), a significantly greater proportion of patients achieved biochemical control with pasireotide LAR 40 mg and 60 mg than with active control (13.4% vs. 6.0% and 20.6% vs. 6.0%, respectively).
- Patients who completed the core study (except active control patients who were biochemically controlled at the end of the core phase) were eligible for the extension phase.

**METHODS**

**Figure 1. Study Design**

**Endpoints and Analysis – Data Cut-off at June 3, 2013**

- Patients who had reached 28 weeks of treatment in the extension phase or discontinued before week 28 of the extension were included in this analysis.
- Key efficacy endpoints included:
  - Proportion of patients at extension week 28 at the time of data cut-off with (a) biochemical control; (b) GH levels <2.5 μg/L; and (c) normal IGF-1 levels.
  - Overall changes in GH and IGF-1 levels from core baseline.
  - Safety and tolerability was assessed and analysed for all the treatment groups.

**RESULTS**

**Table 1. Patient Disposition and Analysis Groups**

<table>
<thead>
<tr>
<th>PASL LAR 40 mg</th>
<th>PASL LAR 60 mg</th>
<th>Crossover</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled in core phase</td>
<td>69</td>
<td>65</td>
<td>134</td>
</tr>
<tr>
<td>Completed core phase</td>
<td>59</td>
<td>57</td>
<td>116</td>
</tr>
<tr>
<td>Enrolled in extension</td>
<td>57</td>
<td>54</td>
<td>111</td>
</tr>
<tr>
<td>Not reached week 28 at the time of the data cut-off (excluding current analysis)</td>
<td>8</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Included in analysis</td>
<td>49</td>
<td>45</td>
<td>94</td>
</tr>
<tr>
<td>GH levels &gt;2.5 μg/L</td>
<td>10</td>
<td>12</td>
<td>22</td>
</tr>
<tr>
<td>GH levels &gt;2.5 μg/L and IGF-1 &gt;1.3 times the age- and sex-adjusted upper limit of normal</td>
<td>10</td>
<td>12</td>
<td>22</td>
</tr>
</tbody>
</table>

**DISCUSSION**

- Adoption of GH levels >2.5 μg/L and IGF-1 >1.3 times the age- and sex-adjusted upper limit of normal as a co-primary efficacy measure in large studies is recommended.

**REFERENCES**


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**Available Models**

- No models are available for this poster.