Feasibility of Subcutaneous IgPro20 Administration Via Manual Push at High Flow Rates in Patients With Primary Immunodeficiency: Findings of the HILO Study

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Poster 097

Results

Responder analysis

- The percentage of responders at 0.5-, 1.0-, and 2.0 mL/min flow rates was 100%, 100%, and 97.5%, respectively (Figure 1).
- Mean weekly duration of infusions decreased compared with Week 1 as flow rates increased (Figure 2).
- Infusion compliance was high for all flow rates, with most patients achieving >90% compliance (Table 1).
- TEAE rates were low, with mostly mild local reactions (Table 2).
- Tolerability was 100% for all flow rates.
- Only two patients had missing data for some infusions at the 0.5-mL/min rate; therefore, safety analysis set included all patients who received ≥1 dose or a partial dose of IgPro20 in the study.

Conclusions

- IgPro20 infusion via manual push at flow rates up to 3 mL/min/site were well tolerated in treatment-experienced PID patients.
- Responders exceeded the prespecified success criterion for all flow rates.
- Increasing flow rates did not impact the tolerability of IgPro20 manual push infusions.
- Manual push IgPro20 administration at flow rates of 0.5–2.0 mL/min/site allows patients to individualize SCIG therapy by reducing infusion time.

References


Disclosures

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Table 1. Infusion compliance (safety analysis set)

<table>
<thead>
<tr>
<th>Flow rate</th>
<th>Overall compliance (treatment-related)</th>
<th>Overall compliance (adverse event-related)</th>
<th>Overall compliance (treatment-related and adverse event-related)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 mL/min/site</td>
<td>100 (99.4)</td>
<td>98 (95.2)</td>
<td>97 (94.2)</td>
</tr>
<tr>
<td>1.0 mL/min/site</td>
<td>100 (99.4)</td>
<td>98 (95.2)</td>
<td>97 (94.2)</td>
</tr>
<tr>
<td>2.0 mL/min/site</td>
<td>100 (99.4)</td>
<td>98 (95.2)</td>
<td>97 (94.2)</td>
</tr>
</tbody>
</table>

Tolerability under forced upward titration conditions

- TEAE rates were low, with mostly mild local reactions.
- Tolerability was 100% for all flow rates.

Table 2. Summary of TEAEs under forced upward titration conditions (safety analysis set)

<table>
<thead>
<tr>
<th>Flow rate</th>
<th>Any TEAE</th>
<th>Treatment-related TEAE</th>
<th>Any unrelated AE</th>
<th>Treatment-related unrelated AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 mL/min/site</td>
<td>12 (7.5)</td>
<td>9 (5.6)</td>
<td>1 (0.6)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>1.0 mL/min/site</td>
<td>12 (7.5)</td>
<td>9 (5.6)</td>
<td>1 (0.6)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>2.0 mL/min/site</td>
<td>12 (7.5)</td>
<td>9 (5.6)</td>
<td>1 (0.6)</td>
<td>1 (0.6)</td>
</tr>
</tbody>
</table>

Adverse events:

- Number (%) of valid infusions
- Number of infusions before non-response
- Compliance level, n (%)
- Mean ± standard deviation values are presented.
- *Prior to start date of non-response.
- **Patient disposition and demographics
- Results

Discussion

- Treatment-emergent adverse events (TEAEs) up to a patient’s AE, treatment-related AE, as well as a protocol deviation 10% longer than the calculated infusion duration (wherever was higher). Only responders switched to the next flow rate after 4 weeks; non-responders continued at the highest tolerated rate.
- Flow rates were considered successful if the responder rate was ≥33%
- TEAE rates were low, with mostly mild local reactions (Table 2).
- Tolerability was 100% for all flow rates.
- Detailed safety and tolerability are reported in Poster 097.

Table 2. Summary of TEAEs under forced upward titration conditions (safety analysis set)