The HILO Study: High Volumes and Flow Rates of Subcutaneous IgPro20
Pump-assisted Infusions in Patients With Primary Immunodeficiency

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Introduction
IgPro20 (CSL Behring, King of Prussia, PA, USA) is a ready-to-use formulation of polyvalent subcutaneous immunoglobulin (pIg), purified (≥98% purity) immunoglobulin G (IgG) content, approved for the treatment of primary immunodeficiency (PID) in patients ≥2 years of age. The safety and tolerability of pump-assisted IgG20 infusion volumes of ≥25 mL/injection site and flow rates of ≥15 mL/h/injection site have not been systematically evaluated. The HILO study evaluated the safety and tolerability of pump-assisted infusions at infusion volumes of 25-50 mL and flow rates of 25-100 mL/h/injection site administered by pump in patients with PID.

Methods
HILO (NCT03033745) was the first multicenter, open-label, parallel-arm, non-randomized study of IgPro20 using a forced upward titration conditions (safety analysis set). The safety and tolerability of pump-assisted IgPro20 infusions at a constant dose were also evaluated.

**Flow Rate Cohort**: the overall TEAE rate per infusion was 0.216 (0.158); the most common TEAEs were injection site pain, injection site erythema, and injection site swelling. No deaths or serious adverse events were reported in either cohort.

**Overall safety and tolerability are reported in Poster 097**

Results
**Patient disposition and demographics**

- **Volume Cohort**: 15 patients were included, of whom 14 completed the study; 1 patient discontinued because of a TEAE at the 25-mL/h level.
- **Flow Rate Cohort**: 18 patients were included, of whom 17 completed the study; 1 patient was withdrawn at the 25-mL/h level.

**Number (%) of valid infusions**

<table>
<thead>
<tr>
<th>Flow Rate Cohort</th>
<th>Volume Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients with ≥1 infusiona</td>
<td>11/18</td>
</tr>
<tr>
<td>Number of valid infusions</td>
<td>77.8% at the 25-mL/h level</td>
</tr>
<tr>
<td>Patient disposition and demographics</td>
<td></td>
</tr>
</tbody>
</table>

**Infusion compliance rates** were ≥90% for all patients in the Volume Cohort and for 83.3% of patients in the Flow Rate Cohort.

**Tolerability of high infusion parameters**

- **Volume Cohort**: 100% of patients in Volume Cohort had ≥90% compliance, as the sum of all individual durations of single pump-assisted infusions given in the respective week, even if the infusions were overlapping.
- **Flow Rate Cohort**: 100% of patients in Flow Rate Cohort had ≥90% compliance, as the sum of all individual durations of single pump-assisted infusions given in the respective week, even if the infusions were overlapping.

**Serum IgG trough levels**

- **Flow Rate Cohort**: the overall TEAE rate per infusion was 0.216 (0.158); the most common TEAEs were injection site pain, injection site erythema, and injection site swelling.
- **Overall safety and tolerability are reported in Poster 097**

Conclusions

- **Serum IgG trough levels** were similar between Day 1 and the end of the study in both the Volume Cohort and Flow Rate Cohort.
- **Increasing the infusion parameters did not negatively impact the tolerability of IgPro20**

Acknowledgments
This study was supported by CSL Behring.

References
2. CSL Behring. HIZENTRA®, Immune Globulin Subcutaneous (Human), 20% Liquid. US Prescribing Information [Internet]. [Accessed 2020 Mar 13].

Disclosures
 None.

Funding
None.

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Responders, %

<table>
<thead>
<tr>
<th>Flow Rate Cohort</th>
<th>Volume Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responders at 25 mL/h/site</td>
<td>50</td>
</tr>
<tr>
<td>Responders at 40 mL/site</td>
<td>40</td>
</tr>
<tr>
<td>Responders at 50 mL/site</td>
<td>33</td>
</tr>
<tr>
<td>Responders at 75 mL/h/site</td>
<td>25</td>
</tr>
</tbody>
</table>

**Overall safety and tolerability are reported in Poster 097**

*Poster 097: Safety and Tolerability of Pump-assisted Infusions at Volumes of 25-50 mL and Flow Rates of 25-100 mL/h in Patients With Primary Immunodeficiency*