Ublituximab (TG-1101) is a novel chimeric monoclonal antibody (mAb) targeting a unique epitope on the CD20 antigen, glycoengineered to enhance affinity for all variants of FcγRIIA receptors, thereby demonstrating greater antibody-dependent cellular cytotoxicity (ADCC) activity than rituximab and ofatumumab.

Ublituximab was originally developed for B-cell lymphomas in response to the need for enhanced potency to deplete malignant B-cells with reduced expression of CD20, that are able to evade depletion via standard anti-CD20 therapies.

To date, over 500 oncology patients have been treated with ublituximab either alone or in combination with other agents, and two large international Phase III trials (UNITY and GENUINE) for B-cell lymphomas are currently underway. Studies in oncology to date have demonstrated robust B-cell depletion and a well-tolerated safety profile, including in long-term follow-up, and for doses ≥ 2 years.

Evidence for the role of B-cells in the pathogenesis of Multiple Sclerosis and the success of anti-CD20s tested thus far, prompted the exploration of ublituximab in a Phase IIa proof-of-concept study in relapsing MS.

B Cell Depletion:

- **Cohort 1**: Placebo (n=2)
  - Placebo / 4h
  - Placebo / 1h

- **Cohort 2**: Placebo (n=2)
  - Placebo / 4h
  - Placebo / 1h

- **Cohort 3**: Placebo (n=2)
  - Placebo / 4h
  - Placebo / 1h

- **Cohort 4**: Ublituximab (n=2)
  - Placebo / 1h
  - Placebo / 1h

**Randomization**

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Subjects &amp; Treatment</th>
<th>Risk Day 1/infusion Time</th>
<th>Day 15/infusion Time</th>
<th>Week 24/infusion Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo (n=2)</td>
<td>Placebo / 4h</td>
<td>Placebo / 1h</td>
<td>Placebo / 1h</td>
<td></td>
</tr>
<tr>
<td>Ublituximab (n=2)</td>
<td>Placebo / 4h</td>
<td>Placebo / 1h</td>
<td>Placebo / 1h</td>
<td></td>
</tr>
</tbody>
</table>

**Results**

**Patient Population and Safety**

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Subjects and Treatment</th>
<th>Age (Years)</th>
<th>Gender (% Female)</th>
<th>Disease Duration (Years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo (n=2)</td>
<td>39±14</td>
<td>50%</td>
<td>15.5±10.3</td>
<td></td>
</tr>
<tr>
<td>Ublituximab (n=2)</td>
<td>44±10</td>
<td>0%</td>
<td>9.6±1.2</td>
<td></td>
</tr>
<tr>
<td>Placebo (n=2)</td>
<td>36±7</td>
<td>50%</td>
<td>11.3±5.7</td>
<td></td>
</tr>
<tr>
<td>Ublituximab (n=2)</td>
<td>40±11</td>
<td>67%</td>
<td>13.4±10.0</td>
<td></td>
</tr>
</tbody>
</table>

**Efficacy**

**Mean B-Cell Depletion By Cohort**

**Conclusions**

- The DSBM reviewed safety data for each cohort and approved continuation of the study at each safety review based on acceptable safety measures.
- No Adverse Events (AEs) Grade >2 have been reported, with median time on the study of 5 months.
- No infections have been reported to date.
- Most frequent AEs were infusion related reactions, all were limited to Grade ≤2 on the Common Terminology of Adverse Events (CTCAE) scale, requiring minimal intervention or delay to date.
- All scheduled doses were fully delivered to all subjects to date.