Methods & Study Design (cont’d)

To qualify for the study, subjects needed to have a diagnosis of relapsing MS, by 2010 McDonald Criteria, and have either one confirmed MS relapse in the past year, 2 relapses in the past two years, or at least one active gadolinium T1 lesion at the screening MRI. Other inclusion/exclusion criteria were detailed in the study protocol.

Primary endpoint is the Responders Rate, defined as percent of subjects with ≥50% reduction in peripheral CD8+ T cells within 2 weeks after the second infusion (day 10).

Additional clinical and radiological measures of efficacy are being evaluated. Herein, we report the preliminary safety and efficacy of 24 weeks of the 48 week study, in the first three patient cohorts.

MRI Acquisitions

- Acquisition of the MR images were performed at the individual sites using existing MRI equipment operating at 3 and 3.0 Tesla, using commercially available (multi-channel) head coils.
- MRI acquisitions were obtained at baseline, Week 24 and Week 48.
- All MRI analyses were performed at the School of Medicine of New York University.

RESULTS

T1 Gd Enhancing Lesions Baseline vs. 24 Weeks

- There was a decrease of 3.1% (p=0.001) in T1 lesion volume at Week 24 compared to baseline (N=20).
- The mean number of New/bulging T2 lesions from baseline to Week 24 was 3.4 (IQR 0–8).

Safety

- Ultrasound was well tolerated and no drug-related discontinuation from study due to adverse events.
- A total of 160 subjects received treatment in Cohort 1, 51 subjects in Cohort 2, and 30 subjects in Cohort 3.
- 120 subjects received at least one infusion and 34 subjects received at least two infusions.
- No subject withdrew from the study due to pregnancy after having received 2 ulbituximab infusions, but continued to be followed with ultrasound monitoring for adverse events.

Baseline Characteristics

<table>
<thead>
<tr>
<th>Number of Gd Enhancing Lesions</th>
<th>Number of Subjects in (%)</th>
<th>% Subjects presented with ADCC activity in baseline</th>
<th>Mean Gd-enhancing lesion volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>12 (60)</td>
<td>0</td>
<td>18.7 ± 24.3 mm³</td>
</tr>
<tr>
<td>1</td>
<td>0 (0%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 (1%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1 (1%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>0 (0%)</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

CONCLUSIONS

- No T1 Gd-enhancing lesions detected in any subjects at 24 weeks (p=0.001).
- T1 Gd-enhancing lesions were not different between baseline and 24 weeks, suggesting a decrease in burden of disease.
- 6.2% reduction in T1 hypointense lesion volume at Week 24 from baseline (p=0.001).
- A 0% rate of adverse events in most patients within 26 hours of receiving the first dose of ulbituximab, with 95% depletion by all patients at Week 4. Detailed immunological results are provided in Poster #1156 (27 October 2017).
- 50% improvement from baseline of 0.5% with 70% of subjects improving or stable (N=20). Detailed clinical results are provided in Poster #100 (26 October 2017).
- Ulbituximab was well-tolerated, most frequent AE were infusion-related reactions (IRRs), of Grade 2 or less.
- A rapid infusion time, as low as one hour, was well tolerated, and produced similar levels of cell depletion, with no identified changes in MRI or safety profile.

These data present results from an ongoing multicenter Phase 3 program evaluating ulbituximab (ublituximab) for the treatment of relapsing forms of multiple sclerosis (RMS). The Phase 3 trials, entitled UNITY I and II, are being conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) and are led by Lawrence Steinman, MD, of Stanford University.

Methods & Study Design

Study Cohorts: Doses and Infusion Times

<table>
<thead>
<tr>
<th>Dose (mg)</th>
<th>Infusion Time (h)</th>
<th>Subjects</th>
<th>Time of Study</th>
<th>Treatment Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>3h</td>
<td>2</td>
<td>Baseline</td>
<td>Placebo / 3h</td>
</tr>
<tr>
<td>Placebo</td>
<td>3h</td>
<td>2</td>
<td>Week 24</td>
<td>Placebo / 3h</td>
</tr>
<tr>
<td>Ublitximab</td>
<td>150 mg</td>
<td>4</td>
<td>Baseline</td>
<td>Placebo / 3h</td>
</tr>
<tr>
<td>Ublitximab</td>
<td>450 mg</td>
<td>4</td>
<td>Week 24</td>
<td>Placebo / 3h</td>
</tr>
<tr>
<td>Ublitximab</td>
<td>600 mg</td>
<td>4</td>
<td>Baseline</td>
<td>Placebo / 3h</td>
</tr>
<tr>
<td>Ublitximab</td>
<td>600 mg</td>
<td>4</td>
<td>Week 24</td>
<td>Placebo / 3h</td>
</tr>
</tbody>
</table>

Subject T1-MRI at Baseline and Week24

- T1 hypointense lesion volume was decreased by 6.6% (p=0.03) at Week 24 compared to baseline (N=20).
- No T1 Gd-enhancing lesions detected in any subjects at 24 weeks (p=0.001).
- T1 Gd-enhancing lesions were not different between baseline and 24 weeks, suggesting a decrease in burden of disease.
- 6.2% reduction in T1 hypointense lesion volume at Week 24 from baseline (p=0.001).
- A 0% rate of adverse events in most patients within 26 hours of receiving the first dose of ulbituximab, with 95% depletion by all patients at Week 4. Detailed immunological results are provided in Poster #1156 (27 October 2017).
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