Rapid and Robust B cell Depletion in Preliminary Results of Phase 2 Multicenter Study of Ublituximab, a Novel Glycoengineered Anti-CD20 Monoclonal Antibody, in Patients with Relapsing Forms of Multiple Sclerosis.

Edward Fox, MD, PhD
Disclosures

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

- TG1101 RMS201 (clinicaltrials.gov NCT02738775) is a randomized, placebo controlled, multi-center study to test the safety and efficacy of ublituximab, at doses markedly less than used in ongoing Phase 3 oncology studies, and at a range of infusion times, with a goal of rapid infusions.

- Primary endpoint is the Responders Rate, defined as percent of subjects with ≥95% reduction in peripheral CD19+ B-cells within 2 weeks after the second infusion (day 15).

- The TG1101 RMS201 study is ongoing and will incorporate additional clinical and MRI measures (see Study Design). We report preliminary results of B cell depletion after the second infusion.
Study Design

Placebo Phase

Clinical Assessment

Lab

Radiological assessment

TG1101 Administration

Weeks
Three additional cohorts have been added to further reduce infusion times to 1 hr.

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Subjects and treatment</th>
<th>Day 1/ infusion time</th>
<th>Day 15/ infusion time</th>
<th>Week 24/ infusion time</th>
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<tbody>
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<td>Placebo / 4h</td>
<td>Placebo / 3h</td>
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<td>450 mg / 1.5h</td>
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<td>450 mg / 1h</td>
<td>600 mg / 1h</td>
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</tbody>
</table>
B Cell Analysis

*No statistical difference (ANOVA) between cohorts at each time point. Error bars are mean±SEM.

All patients received the same total dose of 600 mg, only infusion times differed.
In patients with relapsing MS, treatment with ublituximab resulted in 99% depletion of B-cells after two infusions.

This is comparable to previous reports for ocrelizumab\textsuperscript{3,4}

Most commonly reported AEs were infusion related reactions (Grade 1 or 2)

A decrease in infusion time, as low as one hour for the second infusion, was well tolerated and produced similar levels of B cell depletion

This one year study of ublituximab in RMS patients is ongoing and clinical and MRI measures will be reported at future congresses.
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