A subgroup analysis of subjects diagnosed with anterior uveitis from the Phase 3 PEACHTREE clinical trial

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Financial Disclosures

- Abbvie (S)
- Santen (C)
- Clearside (C)
Macular Edema Due to Noninfectious Uveitis

• Macular edema (ME) is the leading cause of vision impairment and vision loss in uveitis¹

• ME is common, occurring in 34-66% of intermediate, posterior, and panuveitis and 11% of anterior uveitis²

• May persist in spite of adequate control of uveitis itself³

Suprachoroidal Injection

Animal model data for suprachoroidal vs. intravitreal injection of TA show:

• Higher amounts of drug in the choroid, RPE cells, and retina
• Lower exposure to the anterior segment

A potentially useful ocular distribution of drug for the treatment of uveitic macular edema
PEACHTREE: Phase 3, Randomized, Controlled, Double-Masked, Multicenter Trial

**Primary Endpoint:** Proportion of subjects with change from baseline ≥15 letters in BCVA at Week 24

**Suprachoroidal CLS-TA**

- **Active Arm:** Suprachoroidal injection of 4 mg CLS-TA
- **Control Arm:** Sham injection procedure

- **Enrollment**
  - N=96
  - Day 0
  - Wk 4
  - Wk 8
  - Wk 12
  - Wk 16
  - Wk 20
  - Wk 24

- **Evaluation period – 6 months**

- **Both Arms:** Rescue therapy at any time according to pre-specified criteria
Anterior Uveitis accounted for 28% of CLS-TA group (n=27) and 22% of the Control (n=14).
# Baseline Subject Characteristics Similar Between Groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CLS-TA All Uveitis N=96</th>
<th>Control All Uveitis N=64</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>42 (43.8)</td>
<td>30 (46.9)</td>
</tr>
<tr>
<td>Female</td>
<td>54 (56.3)</td>
<td>34 (53.1)</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>50.4 (14.18)</td>
<td>50.0 (15.08)</td>
</tr>
<tr>
<td>BCVA, study eye (ETDRS letters)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>54.7 (13.92)</td>
<td>53.5 (12.91)</td>
</tr>
<tr>
<td>Median (min, max)</td>
<td>57 (9, 89)</td>
<td>54 (12, 79)</td>
</tr>
<tr>
<td>CST, study eye (μm)</td>
<td></td>
<td></td>
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<tr>
<td>Mean (SD)</td>
<td>480.9 (153.24)</td>
<td>525.4 (158.14)</td>
</tr>
<tr>
<td>Median (min, max)</td>
<td>453.0 (256, 857)</td>
<td>518.5 (274, 971)</td>
</tr>
</tbody>
</table>

CST: central subfield thickness; ETDRS: Early Treatment Diabetic Retinopathy Study
Intention-to-treat population; Last Observation Carried Forward imputation. The p-value is based on a Cochran-Mantel-Haenszel test for general association between treatment and response with stratification by country.
Mean Change in BCVA

Improvement Observed as Early as Week 4 Through Week 24 in the CLS-TA Arm

Mean change from baseline in BCVA at Week 24

Intention-to-treat population; last observation carried forward imputation.
t-test. Differences between the CLS-TA and control arms were significant at each visit.
BCVA, best corrected visual acuity.
Mean Change in Central Subfield Thickness

Improvement Observed as Early as Week 4 through Week 24 in CLS-TA Arm

Mean change from baseline at week 24 in central subfield thickness (µm)

- CLS-TA (N=96) (BSL 481 µm)
- Control (N=64) (BSL 525 µm)

Mean change at each visit from baseline in central subfield thickness (µm)

Observation (week)

CLS-TA: -152.6
Control: -17.9

$p < 0.001$ for comparison

Intention-to-treat population; last observation carried forward imputation.
BSL, baseline mean value; CST, central subfield retinal thickness.
Sub Analysis: Patients with Anterior Uveitis
## Baseline Subject Characteristics Similar Between Groups

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<td>56.7 (12.02)</td>
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CST: central subfield thickness; ETDRS: Early Treatment Diabetic Retinopathy Study
Anterior Uveitis: Mean Change in BVCA from Baseline at Week 24

Intention-to-treat population; last observation carried forward imputation. BCVA, best corrected visual acuity.
Anterior Uveitis: Mean Change From Baseline in BCVA by visit

Intention-to-treat population; last observation carried forward imputation. BCVA, best corrected visual acuity.
Anterior Uveitis: Mean Change From Baseline in CST by visit

Intention-to-treat population; last observation carried forward imputation.

CST, Central Subfield thickness
Anterior Uveitis: Anterior Chamber Cell Resolution

In patients with any signs of inflammation at baseline

- CLS-TA, Anterior Uveitis: 73.70% (N=14/19)
- Control, Anterior Uveitis: 16.70% (N=1/6)
Anterior Uveitis: Resolution at Week 24 in Patients with $\geq 2+$ AC Cells at Baseline

- **CLS-TA, Anterior Uveitis**: N=4/4 (100.0%)
- **Control, Anterior Uveitis**: 0.0% (N=0/1)
Anterior Uveitis: Rescue Therapy through Week 24

<table>
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<th>Percentage</th>
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<th>Control, Anterior Uveitis</th>
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<tr>
<td>3.7%</td>
<td>N=1/27</td>
<td>N=11/14</td>
</tr>
<tr>
<td>78.6%</td>
<td></td>
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Safety

- Cataract: 7.3% (7/96) in the CLS-TA arm vs. 6.3% (4/64) in the sham arm

- One serious ocular AE
  - Retinal detachment 8 weeks after CLS-TA
  - Determined to be unrelated to study drug by the Investigator

### IOP-Related Events

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<th>CLS-TA 4.0 mg N = 96</th>
<th>Control N = 64</th>
</tr>
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<tr>
<td>Elevated IOP adverse events</td>
<td>11 (11.5%)</td>
<td>10 (15.6%)</td>
</tr>
<tr>
<td>IOP elevation ≥10 mmHg change from baseline at any visit*</td>
<td>9 (9.4%)</td>
<td>7 (10.9%)</td>
</tr>
<tr>
<td>IOP elevation ≥30 mmHg absolute reading at any post baseline visit*</td>
<td>5 (5.2%)</td>
<td>4 (6.3%)</td>
</tr>
<tr>
<td>Given any additional IOP-lowering medication</td>
<td>7 (7.3%)</td>
<td>6 (9.4%)</td>
</tr>
<tr>
<td>Any surgical intervention for an elevated IOP Adverse Event</td>
<td>0</td>
<td>0</td>
</tr>
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</table>

Safety population; includes subjects in the control group who received rescue medication

*Based on elevated intraocular pressure adverse reactions
PEACHTREE Take Home Points

EFFICACY

• Primary Endpoint was met, with ~47% of patients gaining ≥15 EDTRS letters
• Suprachoroidally injected CLS-TA significantly improved visual acuity in non-infectious uveitis of the anterior segment

SAFETY

• No SAEs attributable to CLS-TA
• Low rate of elevated IOP and cataract