Results from the Phase 3 PEACHTREE Clinical Trial: Systemic Therapy and the Efficacy of CLS-TA, a Post-Hoc Analysis

ASRS 2020 Virtual Program
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Financial Disclosures

- AR: Clearside Biomedical (Ad board), Alimera (Ad board)
- TC: Clearside Biomedical (E, I)

C = Consultant; E = Employment; R = Recipient; I = Personal Financial Interest
Core Advantages of Treating Via the Suprachoroidal Space

**TARGETED**
The back of the eye is the location of many irreversible and debilitating visual impairments\(^1\)

**COMPARTMENTALIZED**
Drug is compartmentalized in the suprachoroidal space, which helps keep it away from non-diseased tissues\(^2\)

**BIOAVAILABLE**
Fluid spreads circumferentially and posteriorly when injected within the suprachoroidal space, bathing the choroid and adjacent areas with drug\(^3\)

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\(^{1}\) PK = pharmacokinetic

Background: Suprachoroidal Delivery of Corticosteroids

• PEACHTREE: Macular Edema in NIU met Primary Endpoint
  - 46.9% of subjects gained ≥15 BCVA letters from baseline vs. 15.6% in the control

Mean change from baseline in BCVA by visit

• Treatment of uveitis often requires a combination of systemic and local therapies

• This analysis explores the efficacy in patients receiving and not receiving other systemic therapies at baseline.
Safety: PEACTHREE

<table>
<thead>
<tr>
<th>IOP-Related Events</th>
<th>CLS-TA 4.0 mg N = 96</th>
<th>Control N = 64</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>

- 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
Post Hoc Analysis: Objectives and Methods

• In PEACHTREE, enrollment criteria allowed for:
  – low dose corticosteroid or
  – stable dose of immunomodulatory therapy throughout study if no increase anticipated during study

• Post-hoc analyses were performed to evaluate improvement in BCVA and CST in subjects receiving systemic corticosteroids and/or steroid-sparing therapy at baseline versus subjects receiving no systemic therapies
  – Dosage reduction / stoppage during study after baseline not accounted for in analysis
## Results

<table>
<thead>
<tr>
<th>Any Systemic Steroid or Steroid-Sparing Therapy at Baseline</th>
<th>CLS-TA n=96</th>
<th>Control n=64</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO Systemic Therapy</td>
<td>68/96 (70.8%)</td>
<td>49/64 (76.6%)</td>
</tr>
<tr>
<td>YES Systemic Therapy (steroid and/or steroid-sparing)</td>
<td>28/96 (29.2%)</td>
<td>15/64 (23.4%)</td>
</tr>
</tbody>
</table>
Mean change in BCVA significantly greater than control in both CLS-TA groups

**CLS-TA + No Systemic Therapy:**
At Week 24: Change in BCVA +15.6 letters versus +4.9 in the control 
(p < 0.001)

**CLS-TA + Systemic Therapy**
At Week 24: Change in BCVA was +9.4 letters versus -3.2 in the control 
(p = 0.019)

Intention-to-treat population; LOCF imputation.
Mean change in CST significantly greater than control in No Systemic Therapy group

CLS-TA + Systemic Therapy
At Week 24: Reduction in CST was 108.3 µm versus 43.5 µm in the control (p = 0.190)

CLS-TA + No Systemic Therapy
At Week 24: Reduction in CST was 169.8 µm vs. 10.3 µm in the control (p < 0.001)

Intention-to-treat population; LOCF imputation.
Conclusion

• These results corroborate the prespecified study analyses in PEACHTREE
• The benefit of CLS-TA over the control in treating ME associated with NIU was noted regardless of administration of systemic therapy at baseline.