Safety of the Suprachoroidal Injection Procedure Utilizing SCS Microinjector® across Three Retinal Disorders

Shree Kurup, MD, FACP
Director, Division of Vitreoretinal Diseases, Surgery and Ocular Immunology and Uveitis, University Hospitals

Co-Authors:
Colette Hall, MD¹
Barry Kapik, MS¹
Thomas Ciulla, MD, MBA¹

The 44th Virtual Annual MACULA SOCIETY MEETING
February 6-7, 2021
Financial Disclosures

• SK: Allergan C, Clearside (this talk) none other, Alimera C, Regeneron G, I CROWD C
• CH: Clearside Biomedical, Employment & Shareholder
• BK: Clearside Biomedical, Employment & Shareholder
• TC: Clearside Biomedical, Employment & Shareholder
Suprachoroidal Injection (SCI) with the SCS Microinjector®
Core Advantages of Treating Via the Suprachoroidal Space

**TARGETED**
The back of the eye is the location of many irreversible and debilitating visual impairments¹

**COMPARTMENTALIZED**
Drug is compartmentalized in the suprachoroidal space, which helps keep it away from non-diseased tissues²

**BIOAVAILABLE**
Fluid spreads circumferentially and posteriorly when injected within the suprachoroidal space, bathing the choroid and adjacent areas with drug³

---

Methods

- Safety data collected from datasets from 8 clinical trials and 3 disease states
  - SCI Group: Subjects who received 1+ SCI (4.0 mg CLS-TA) as monotherapy (n=161) or w/ IVT anti-VEGF (n=460)
  - Control: Subjects who received an IVT + sham SCI (n=449)
- Treatment emergent adverse events (TEAES) occurring on the day of SCI were considered temporally related, regardless of whether Investigators reported them as such.

<table>
<thead>
<tr>
<th>Noninfectious Uveitis</th>
<th>Diabetic Macular Edema</th>
<th>Retinal Vein Occlusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOGWOOD PEACHTREE AZALEA</td>
<td>HULK TYBEE</td>
<td>TANZANITE SAPPHIRE TOPAZ</td>
</tr>
</tbody>
</table>
Results: Serious Adverse Events (SAEs)

SCI Group
- No SAEs involving lens injury, suprachoroidal hemorrhage, endophthalmitis, retinal tears in any patient receiving 1 or more SCI
- 3 SAEs of interest, all deemed “not related” by masked investigator
  - NIU: Retinal detachment (n=1)
    - Occurred 8 weeks post-injection in different quadrant than SCI
  - RVO: reduced vision (n=2)

Control (IVT + sham SCI)
- In control group: 3 SAEs of interest, all deemed “not related” by masked investigator
  - RVO: retinal detachment, vitreous hemorrhage, endophthalmitis
Results: Treatment Emergent Adverse Events

Both groups: No serious TEAEs involving the study eye and no cases of lens injury, suprachoroidal hemorrhage, endophthalmitis, retinal tear, or retinal detachment were reported on the day of injection.

SCI Group: Incidence of Eye Pain or Discomfort, by Disease State

<table>
<thead>
<tr>
<th></th>
<th>NIU (n=17)</th>
<th>DME (n=0)</th>
<th>RVO (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11.3%</td>
<td>0%</td>
<td>6.0%</td>
</tr>
</tbody>
</table>

Control (IVT + sham SCI, RVO and DME)
- 1.6% of subjects experienced a TEAE associated with eye pain or discomfort

SCI = suprachoroidal injection;
Conclusion

The safety profile of SCIs is comparable to IVT injections alone for events occurring at or after the procedures.

- Across 8 clinical trials involving NIU, DME and RVO, either as monotherapy or in conjunction with IVT injection.