Purpose

- Suprachoroidal injection (SCI) via SCS Microjector® is an investigational ocular injection developed to provide high, compartmentalized drug concentrations to chorioretinal layers via the suprachoroidal space (SCS).
- This post hoc study evaluated safety of SCIs across multiple clinical trials involving an investigational proprietary suspension of triamcinolone acetonide (CLS-TA), focusing on serious adverse events (SAEs) and events occurring on the day of the injection procedure.

Methods

- Datasets were assessed from 8 clinical trials involving three separate disease states:
  - Noninfectious uveitis (NIU)
  - Diabetic macular edema (DME)
  - Retinal vein occlusion (RVO)
- Patients who received one or more SCI were included, either as monotherapy or in conjunction with an intravitreal (IVT) anti-VEGF.
- Disposition, exposure, demographics and baseline characteristics were summarized by disease state and study treatment.
- Rare but SAEs known to occur with intraocular injections, including lens injury, suprachoroidal hemorrhage, retinal tear, retinal detachment, endophthalmitis and reduced visual acuity were assessed.
- Treatment emergent adverse events (TEAEs) assessed included eye pain on the day of the procedure.
- Outcomes were compared to control eyes randomized to receive IVT anti-VEGF monotherapy in conjunction with a sham SCI.

Results

- 626 patients received one or more SCI, either as monotherapy (N=166) or in conjunction with IVT anti-VEGF (N=460) with the majority (>66%) receiving 2 or more study treatments.
- Three of 626 patients experienced 3 SAEs of interest, all occurring in patients receiving multiple SCI injections.
- One NIU monotherapy patient experienced retinal detachment, and 2 RVO patients receiving combination therapy experienced reduced vision; each were deemed not related to treatment by a masked Investigator.
- There were no SAEs involving lens injury, suprachoroidal hemorrhage, endophthalmitis, or retinal tear in patients receiving SCIs, either alone or in conjunction with anti-VEGF.
- In the control, 449 patients received IVT anti-VEGF in conjunction with a sham SCI. Three RVO patients experienced 3 SAEs of interest, including retinal detachment, vitreous hemorrhage and endophthalmitis. Each was deemed not related to treatment by a masked Investigator.
- 18 of 156 (11.5%) NIU patients, 0 of 56 DME patients and 25 of 414 (6.0%) RVO patients experienced a TEAE related to eye pain on the day of the procedure.

Conclusions

- Overall, across 8 clinical trials involving NIU, DME and RVO, the safety profile of SCI, either as monotherapy or in conjunction with IVT anti-VEGF injections, is comparable to IVT anti-VEGF injections alone for events occurring during or after the procedures.
- Overall incidence of eye pain (6.9%) observed in SCIs with CLS-TA is comparable to labeled incidences with IVF aflibercept in wet AMD (9%), DME (9%), and RVO (10.4%).

References