Visual Function and Anatomic Outcomes Stratified by Baseline Visual Acuity in Patients Undergoing Suprachoroidal Injections for Macular Edema Associated with Noninfectious Uveitis

Christopher Henry, MD1 sponsored by Rosa Kim, MD1 | Barry Kapik, MS2 | Thomas A. Ciulla, MD, MBA2

BACKGROUND
Uveitic Macular Edema
Macular edema associated with noninfectious uveitis, also known as uveitic macular edema (UME), is the leading cause of vision loss and blindness in patients diagnosed with uveitis and can occur from the disease affecting any anatomic location—anterior, intermediate, posterior or panuveitis1.

Suprachoroidal Injection via Microinjector
Suprachoroidal injection (SCI) via a microinjector is an in-office ocular injection procedure designed to deliver therapeutic suspensions to tissues in the back of the eye, compartmentalized away from non-diseased anterior segment tissues2. SCIs are currently under investigation for therapies in uveitis, neovascular age-related macular degeneration, diabetic retinopathy, and choroidal melanoma3.

PEACHTREE & AZALEA Clinical Trials
The PEACHTREE (NCT02595338) and AZALEA (NCT03097315) clinical trials were phase 3 trials evaluating the efficacy and safety of CLS-TA (triamcinolone acetonide for suprachoroidal injection) for NIU. Patients receiving CLS-TA received a suprachoroidal injection via Microinjector at baseline and week 12, and were followed for 24 weeks.

METHODS
This post hoc analysis included data from the PEACHTREE and AZALEA in patients that received CLS-TA. BCVA and central subfield thickness (CST) outcomes were evaluated in eyes that received CLS-TA, stratified by baseline vision:

- ≥20/40,
- <20/40 to 20/80,
- <20/80 to 20/200, and
- ≤20/200

Demographics and baseline disease characteristics were summarized. Mean and mean change from baseline (ΔX) values were calculated for BCVA and CST values for the intent-to-treat (ITT) population. Values for missing data or post rescue were imputed using the last observation carried forward method.

RESULTS
An inverse relationship between BCVA improvement and baseline vision was observed in CLS-TA patients. Lower baseline visual acuity corresponded to greater improvements in BCVA over 12 and 24 weeks:

Macular thickness was improved to approximately 300 microns regardless of baseline vision in CLS-TA patients:

Overall, 17 out of 134 (12.7%) CLS-TA patients required rescue. The type of rescue administered was at the discretion of the investigator.

DISCUSSION
• Patients with macular edema associated with noninfectious uveitis treated with CLS-TA experienced visual and anatomic benefits at 24 weeks regardless of baseline visual acuity status.
• For this post hoc analysis, patients with worse vision at baseline gained more letters over the 24 weeks of the studies than those with better vision at baseline; a ceiling effect was observed in better baseline groups.
• Patients with worse vision at baseline experienced a greater reduction in CST; a floor effect was observed in retinal thickness values as the retina approached normal thickness.
• NOTE: Patients in the AZALEA trial were not required to have ME. Patients in PEACHTREE had to have a retinal thickness of ≥300 μm as measured by SO-OCT at baseline.

CONCLUSION
Patients in the CLS-TA study arm of both PEACHTREE and AZALEA Phase 3 clinical trials experienced a clinically significant improvement in vision relative to the sham procedure, regardless of visual acuity at baseline, demonstrating the efficacy of suprachoroidal injection of CLS-TA for the treatment of ME in noninfectious uveitis.

SOURCES

Financial Disclosures
CH: Clearside Biomedical (C). BK, TC: Clearside Biomedical, Inc. (E, S)
C = Consultant, E = Employee, S = Shareholder