Treatment response analysis of visual acuity and central subfield retinal thickness following suprachoroidal CLS-TA

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Purpose
❖ To provide model-based evidence of a relationship between CLS-TA treatment and best corrected visual acuity (BCVA).

Methods
❖ Data from two Phase 3 trials, PEACHTREE and AZALEA, evaluating suprachoroidal CLS-TA, a proprietary triamcinolone acetonide injectable suspension for the treatment of uveitis, were used to develop model-based treatment response longitudinal models.
❖ A covariate analysis was conducted to identify clinically relevant and statistically significant intrinsic and extrinsic factors affecting changes in BCVA response to CLS-TA treatment.
❖ Covariates evaluated included race, age, sex, country, baseline BCVA, baseline central subfield retinal thickness (CST) and anatomic location of ocular inflammation.

Results
Best Corrected Visual Acuity (BCVA)
Intent-to-Treat Observed Population

Central Subfield Thickness (CST)
Intent-to-Treat Observed Population

Conclusions
❖ A model-based treatment-response longitudinal model was developed that characterized changes in both BCVA and CST following administration of CLS-TA.
❖ Result of this analysis shows that the typical patient will have a 12-letter improvement in BCVA and 157 microns decrease in CST after treatment with CLS-TA.

Results
❖ Data from 198 subjects in PEACHTREE and AZALEA were included.
❖ Results of the analysis showed that:
❖ BCVA exhibits CLS-TA treatment-dependent saturable increases over time
❖ CST exhibits CLS-TA treatment-dependent saturable reductions over time
❖ For the BCVA response model, the baseline BCVA score was significantly influenced by:
❖ Baseline CST
❖ Age
❖ Study enrollment criteria (AZALEA had less strict enrollment criteria)
❖ Maximum improvement in BCVA was influenced by the baseline BCVA (greater improvement in subjects with lower baseline BCVA)
❖ The typical subject had a baseline BCVA of 56 ETDRS letters read and a baseline CST of 463 microns.
❖ The typical improvement was 12 ETDRS letters read and 157 microns decrease in CST following suprachoroidal CLS-TA.
❖ Subjects in the control arm demonstrated an improvement in BCVA of approximately 2 letters and an improvement in CST of approximately 17 microns.