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

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Purpose:
The purpose of this post hoc analysis was to explore the effect of systemic corticosteroid or steroid-sparing immunotherapy (systemic therapies) on the efficacy of CLS-TA administered by suprachoroidal (SC) injection, a proprietary suspension of triamcinolone acetonide, in patients in the Phase 3 PEACHTREE trial.

Methods:
In PEACHTREE, 160 patients were randomized 3:2 to receive CLS-TA or sham at baseline and week 12. Patients were allowed to be included in PEACHTREE if on a low dose corticosteroid or stable dose of immunomodulatory therapy. The primary endpoint was the percentage of patients with an increase of ≥ 15 letters in EDTRS best corrected visual acuity (BCVA). Secondary endpoints included mean change from baseline in BCVA and central subfield macular thickness (CST). Post-hoc analyses were performed to evaluate the improvement in BCVA and CST in patients receiving systemic corticosteroid and/or steroid-sparing therapy at baseline, and in patients receiving no systemic therapies. Comparisons between treatment groups were based on an analysis of variance model with treatment group as a fixed effect.

Results:
There were 68 patients in the CLS-TA and 49 in the control arm that were not receiving additional systemic therapies at baseline. At week 24, the increase in BCVA among these patients was 15.6 letters in the CLS-TA arm versus 4.9 letters in the control arm (p<0.001) and reduction in CST was 169.8 µm versus 10.3 µm in the control (p<0.001). There were 28 patients in the CLS-TA and 15 in the control arm receiving systemic therapy at baseline. At week 24, the change in BCVA was +9.4 letters in the CLS-TA arm versus -3.2 letters in the control arm (p=0.002) and reduction in CST in the active arm was 108.3 µm versus 43.5 µm in the control (p<0.001).

Conclusions:
These post hoc results corroborate the prespecified study analyses in the PEACHTREE trial. With respect to BCVA and CST, a clinically meaningful relative benefit of CLS-TA over control was noted, with and without systemic corticosteroid or steroid-sparing therapy.