

Suprachoroidal CLS-TA Improves Patient Outcomes in Uveitis of All Anatomic Subtypes: Results of the Phase 3 PEACHTREE Study

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PEACHTREE
CLS1001-301

- Disclosures:
 - Advisory Board: Aldeyra, Alimera, Clearside Biomedical
 - Consultant: Clearside Biomedical
 - Investigator: Adverum, Aerpio, Aldeyra, Allergan, Apellis, BIRC, Boehringer Ingelheim, Chengdu Kanghong Biotech, Clearside Biomedical, DRRCR, Mylan, NEI, Neurotech, Novartis, OHR, Opthea, Quark, Regeneron, Regenxbio, Roche, Samsung Bioepis, Santen, SciFluor, Thrombogenics, Tyrogenex,

PEACHTREE: Take Home Points

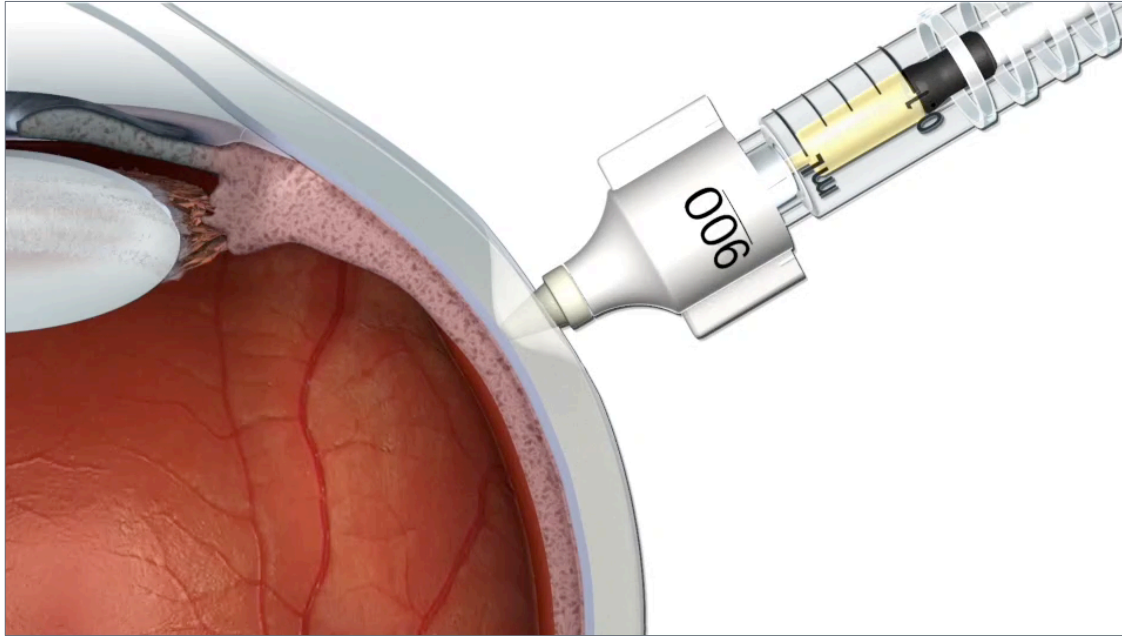
Efficacy

- Primary endpoint was met, with ~47% of patients gaining ≥ 15 ETDRS letters
- Suprachoroidally injected CLS-TA significantly improved visual acuity and macular edema in noninfectious uveitis of all anatomical subtypes

Safety

- No SAEs attributable to CLS-TA
- Low rates of elevated IOP and cataract

Suprachoroidal Injection for Posterior Segment Disease



Animal model data for suprachoroidal versus intravitreal injection of TA show:

- Higher amounts of drug in the choroid, RPE cells, and retina
- Lower exposure to the anterior segment
- A potentially useful ocular distribution of drug to target posterior segment pathologies

Treatment is not yet FDA approved

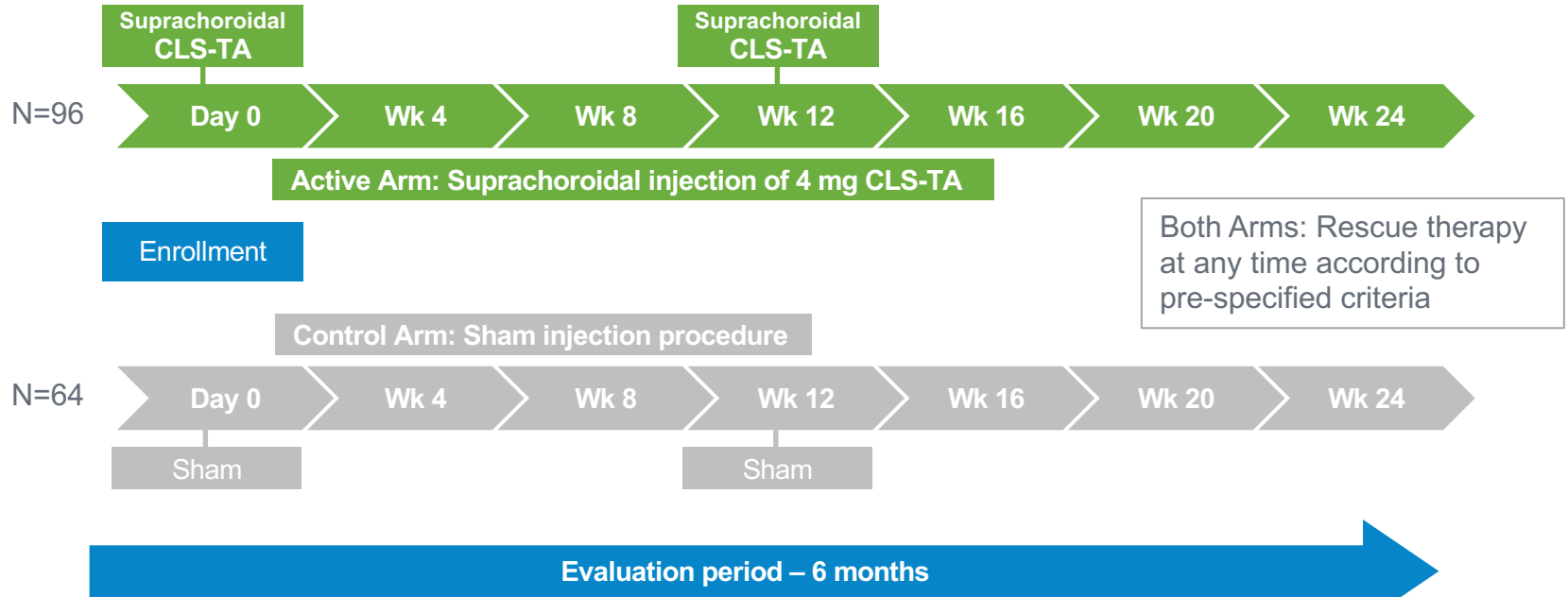
Reference:

Habot-Wilner Z, Noronha G, Wykoff C. Suprachoroidally injected pharmacological agents for the treatment of chorio-retinal diseases: a targeted approach. *Acta Ophthalmol* 2019 Jan 30. doi: 10.1111/aos.14042. [Epub ahead of print]



PEACHTREE: Phase 3, Randomized, Controlled, Double-Masked, Multicenter Trial

Primary Endpoint: Proportion of subjects with change from baseline ≥ 15 letters in BCVA at Week 24



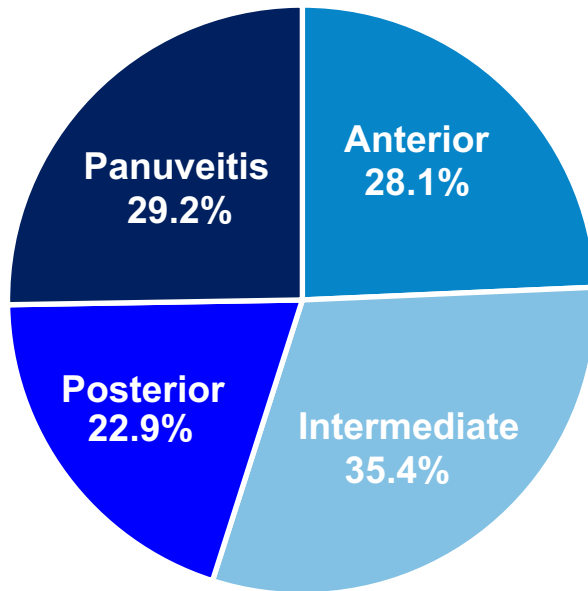
Baseline Subject Characteristics Similar Between Groups

Characteristic	CLS-TA N=96	Control N=64
Gender, n (%)		
Male	42 (43.8)	30 (46.9)
Female	54 (56.3)	34 (53.1)
Age (years), mean (SD)	50.40 (14.2)	50.0 (15.1)
BCVA, study eye (ETDRS letters)		
Mean (SD)	54.7 (13.9)	53.5 (12.9)
Median (range)	57 (9 – 89)	54 (12-79)
CST, study eye (µm)		
Mean (SD)	480.9 (153.2)	525.4 (158.1)
Median (range)	453.0 (256-857)	518.5 (274-971)

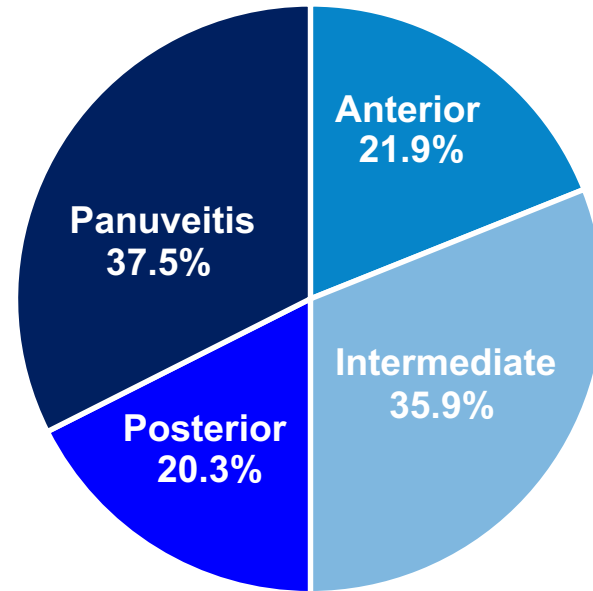
All Uveitis Anatomic Subtypes Enrolled

All Patients Had Macular Edema at Baseline (>300 microns)

CLS-TA (N=96)

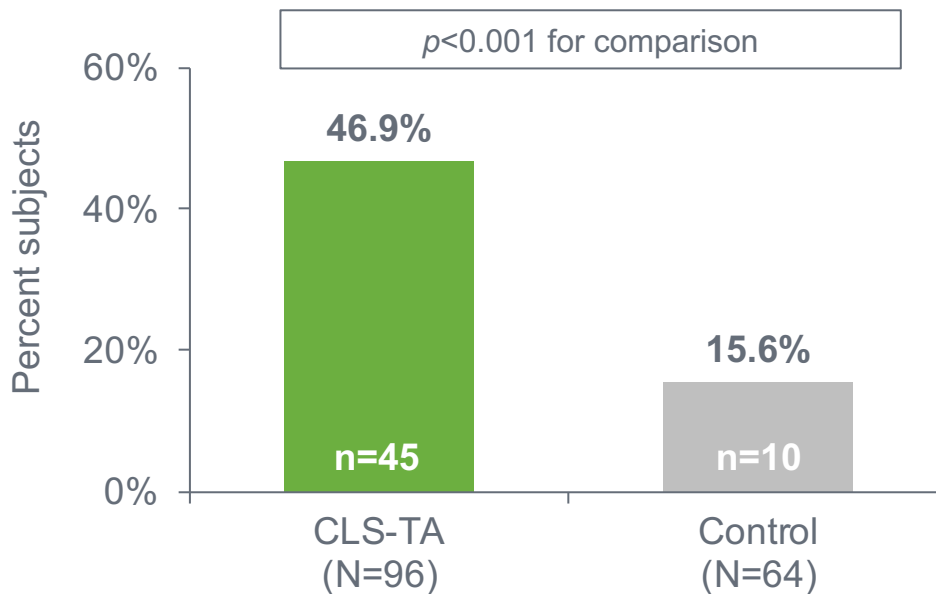


Control (N=64)



PEACHTREE: Met Primary Efficacy Endpoint

Primary Endpoint: Subjects gaining ≥ 15 BCVA letters from baseline, %



Intention-to-treat population; Last Observation Carried Forward imputation.

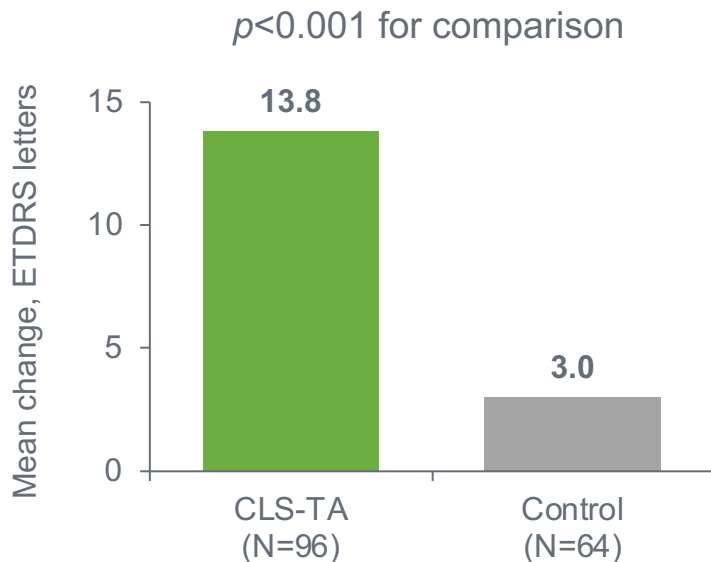
The p-value is based on a Cochran-Mantel-Haenszel test for general association between treatment and response with stratification by country.



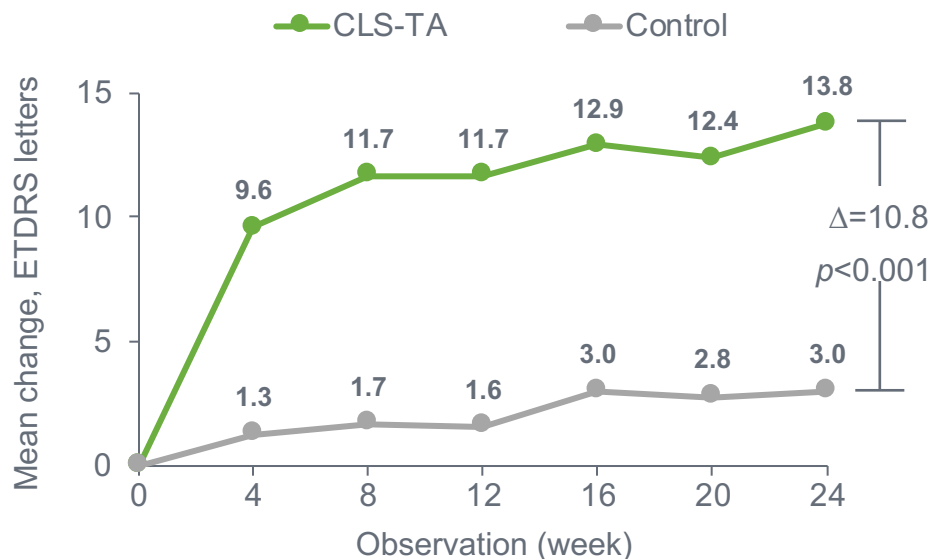
Mean Change in BCVA

Improvement Observed as Early as Week 4 Through Week 24 in the CLS-TA Arm

Mean change from baseline in BCVA at Week 24



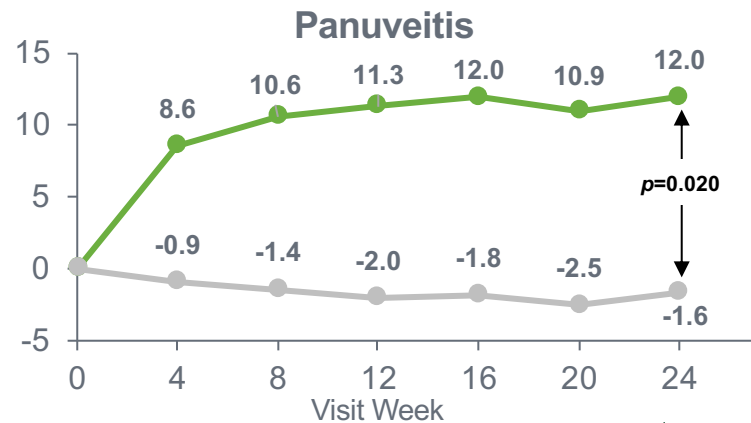
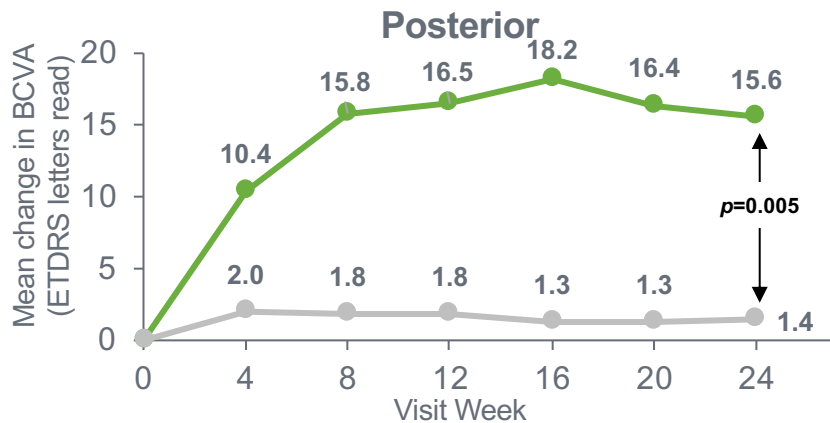
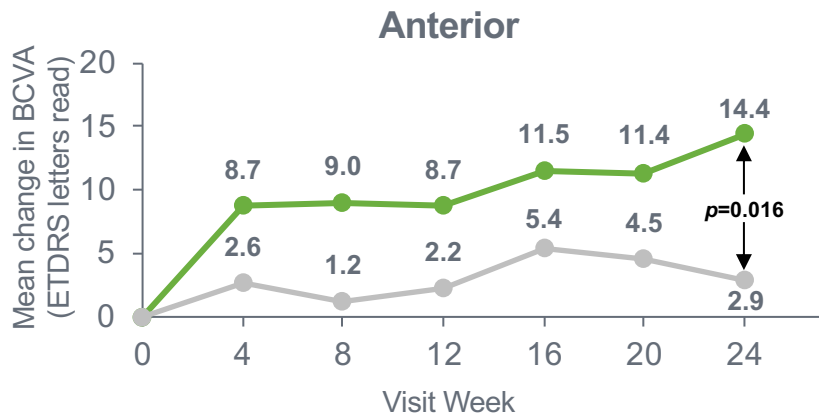
Mean change from baseline in BCVA by visit



Intention-to-treat population; last observation carried forward imputation.
t-test. Differences between the CLS-TA and control arms were significant at each visit.
BCVA, best corrected visual acuity.



Mean Change From Baseline in BCVA by Anatomic Location



● CLS-TA ● Control

Intention-to-treat population, last observation carried forward.

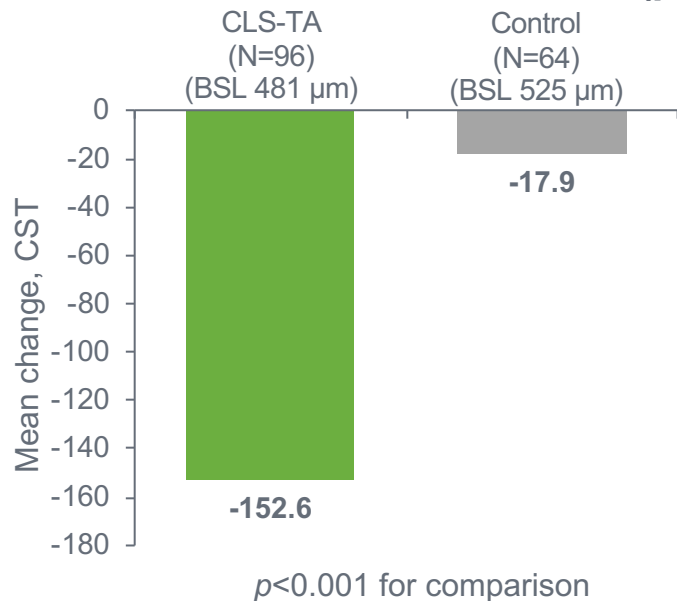


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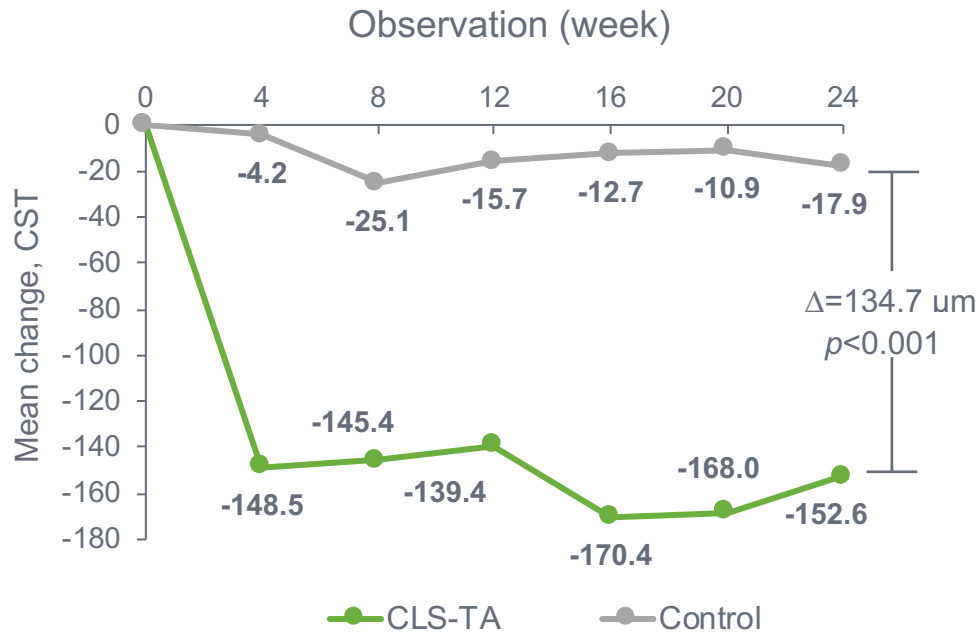
Mean Change in Central Subfield Thickness

Improvement Observed as Early as Week 4 through Week 24 in CLS-TA Arm

Mean change from baseline at week 24 in central subfield thickness (μm)



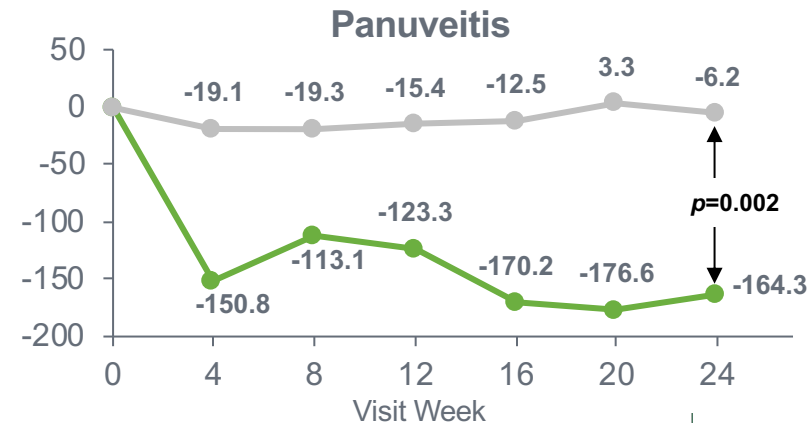
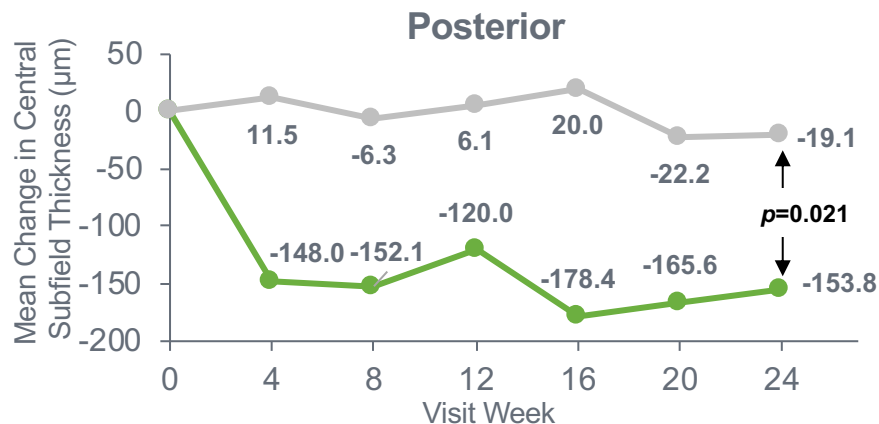
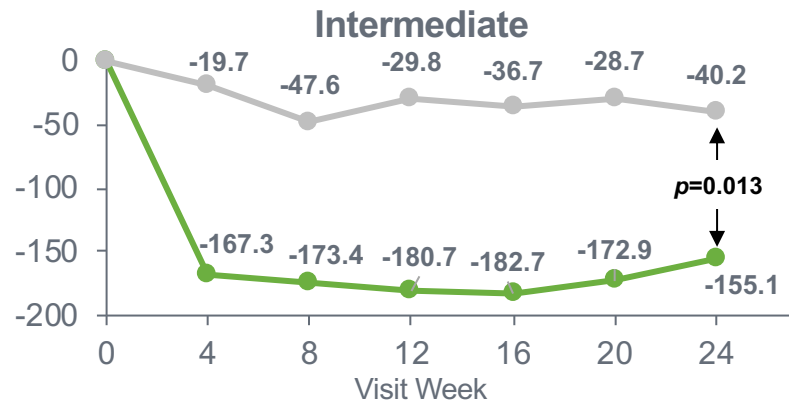
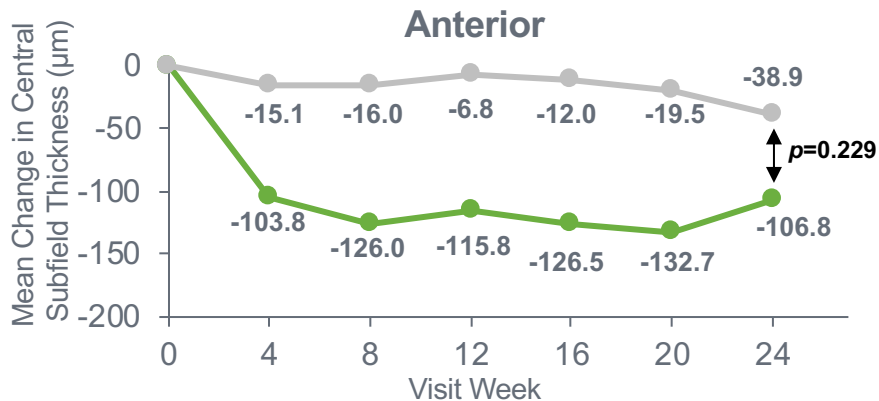
Mean change at each visit from baseline in central subfield thickness (μm)



Intention-to-treat population; last observation carried forward imputation.
BSL, baseline mean value; CST, central subfield retinal thickness.



Mean Change From Baseline in CST by Anatomic Location



● CLS-TA ● Control

Intention-to-treat population, last observation carried forward.



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Safety

IOP-Related Events	CLS-TA 4.0 mg N = 96	Control N = 64
Elevated IOP adverse events	11 (11.5%)	10 (15.6%)
IOP elevation ≥ 10 mmHg change from baseline at any visit*	9 (9.4%)	7 (10.9%)
IOP elevation ≥ 30 mmHg absolute reading at any post baseline visit*	5 (5.2%)	4 (6.3%)
Given any additional IOP-lowering medication	7 (7.3%)	6 (9.4%)
Any surgical intervention for an elevated IOP Adverse Event	0	0

- Cataract: 7.3% (7/96) in the CLS-TA arm vs. 6.3% (4/64) in the sham arm
- One serious ocular AE
 - Retinal detachment 8 weeks after CLS-TA
 - Determined to be unrelated to study drug by the Investigator

Safety population; includes subjects in the control group who received rescue medication

*Based on elevated intraocular pressure adverse reactions

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Thank You PEACHTREE Investigators!

USA



India



Israel



Thank You

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Thank You

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