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

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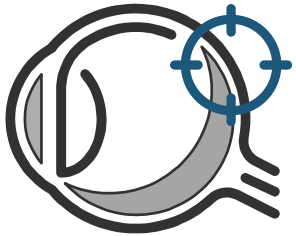
Financial Disclosures

- CH: Clearside Biomedical (C)
- TC: Clearside Biomedical (E, I)

C = Consultant; E = Employment; R = Recipient; I = Personal Financial Interest

Core Advantages of Treating Via the Suprachoroidal Space



TARGETED

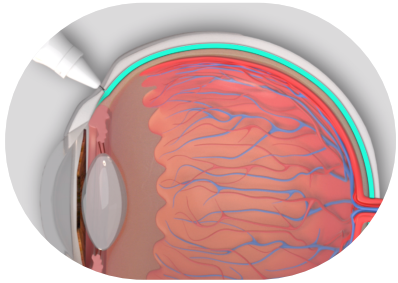
The back of the eye is the location of many irreversible and debilitating visual impairments[1]

for efficacy

COMPARTMENTALIZED

Drug is compartmentalized in the suprachoroidal space, which helps keep it away from non-diseased tissues[2]

for safety



BIOAVAILABLE

Fluid spreads circumferentially and posteriorly when injected within the suprachoroidal space, bathing the choroid and adjacent areas with drug[3]

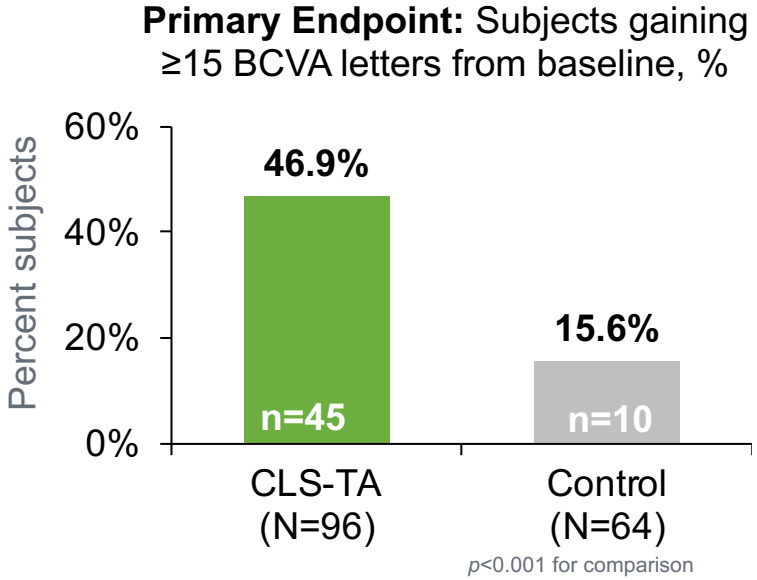
for durability

PK = pharmacokinetic

Sources 1. Rai UDJ, Young SA, Thrimawithana TR, et al. The suprachoroidal pathway: a new drug delivery route to the back of the eye. Drug Discov Today. 2015;20(4):491-495. 2. Chiang B, Jung JH, Prausnitz MR. The suprachoroidal space as a route of administration to the posterior segment of the eye. Adv Drug Deliv Rev. 2018;126:58-66. 3. Moisseiev E, Loewenstein A, Yiu G. The suprachoroidal space: from potential space to a space with potential. Clin Ophthalmol. 2016;10:173-178.

Background: Suprachoroidal Delivery of Corticosteroids

- PEACHTREE: Phase 3, Sham Controlled, Masked, Randomized trial to assess CLS-TA (investigational suspension of triamcinolone acetonide for suprachoroidal delivery) for macular edema (ME) associated with noninfectious uveitis (NIU) versus sham treatment



Safety: PEACTHREE

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

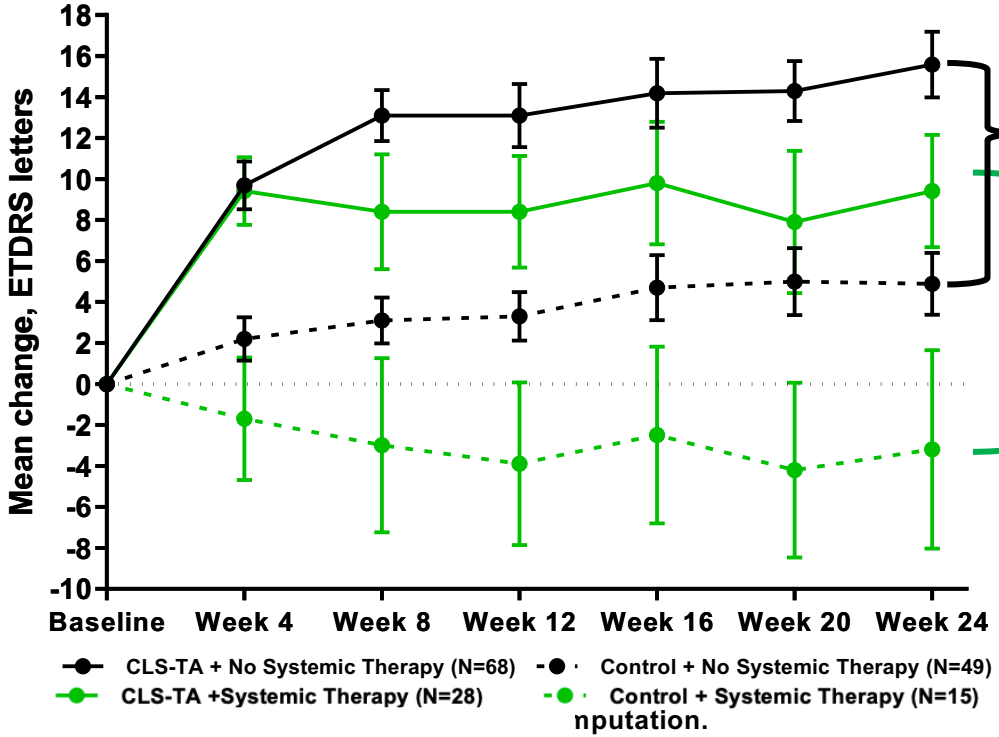
Post Hoc Analysis: Objectives and Methods

- In Peachtree, enrollment criteria allowed for:
  - low dose corticosteroid or
  - stable dose of immunomodulatory therapy throughout study if no increase anticipated during study
- Post-hoc analyses were performed to evaluate improvement in BCVA and CST in subjects receiving systemic corticosteroids and/or steroid-sparing therapy at baseline versus subjects receiving no systemic therapies
  - Dosage reduction / stoppage during study after baseline not accounted for in analysis

Results

Any Systemic Steroid or Steroid-Sparing Therapy at Baseline	**CLS-TA** n=96	**Control** n=64
NO Systemic Therapy	68/96 (70.8%)	49/64 (76.6%)
YES Systemic Therapy (steroid or steroid-sparing)	28/96 (29.1%)	15/64 (23.4%)

Mean change in BCVA significantly greater than control in both CLS-TA groups

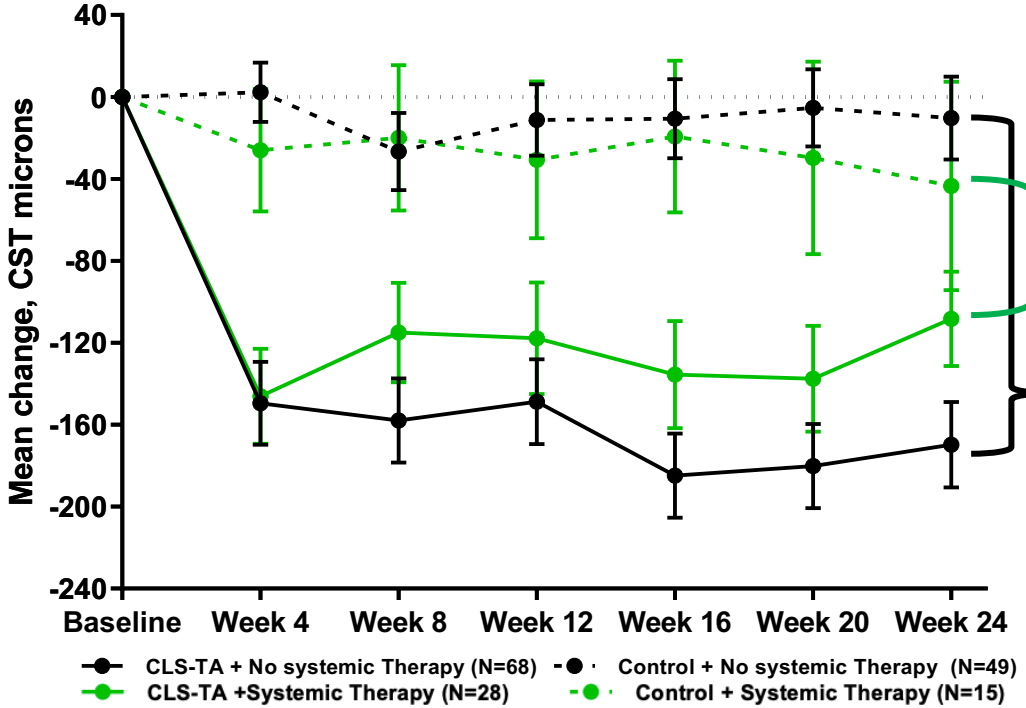


Intention-to-treat population; LOCF imputation.

CLS-TA + No Systemic Therapy:
At Week 24: Change in BCVA +**15.6** letters versus +**4.9** in the control
($p < 0.001$)

CLS-TA + Systemic Therapy
At Week 24: Change in BCVA was **+9.4** letters versus **-3.2** in the control
($p = 0.019$)

Mean change in CST significantly greater than control in No Systemic Therapy group



CLS-TA + Systemic Therapy
At Week 24: Reduction in CST was **108.3 µm** versus **43.5 µm** in the control
(p =.190)

CLS-TA + No Systemic Therapy
At Week 24: Reduction in CST was **169.8 µm** vs. **10.3 µm** in the control
(p < 0.001)

Intention-to-treat population; LOCF imputation.

Conclusion

- These results corroborate the prespecified study analyses in PEACHTREE

- The benefit of CLS-TA over the control in treating ME associated with NIU was noted regardless of administration of systemic therapy at baseline.