

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

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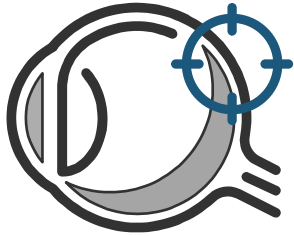
Financial Disclosures

- PTM:
 - Study funding: Clearside, Gilead, Santen, NEI
 - Consulting: Santen, Eyepoint, Alimera
- TAC:
 - Employment & Financial Interest: Clearside Biomedical

Key Takeaways

- The benefit of suprachoroidally injected CLS-TA versus the control in treating macular edema associated with non-infectious uveitis was noted regardless of administration of systemic therapy at baseline
- These results corroborate the prespecified study analyses in PEACHTREE

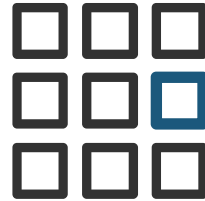
Core Advantages of Treating Via the Suprachoroidal Space



TARGETED

The back of the eye is the location of many irreversible and debilitating visual impairments¹

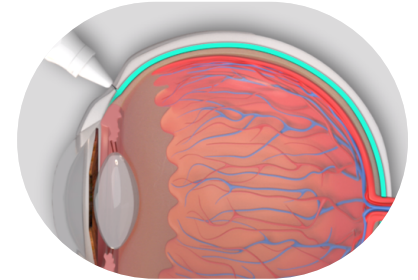
for efficacy



COMPARTMENTALIZED

Drug is compartmentalized in the suprachoroidal space, which helps keep it away from non-diseased tissues²

for safety



BIOAVAILABLE

Fluid spreads circumferentially and posteriorly when injected within the suprachoroidal space, bathing the choroid and adjacent areas with drug³

for durability

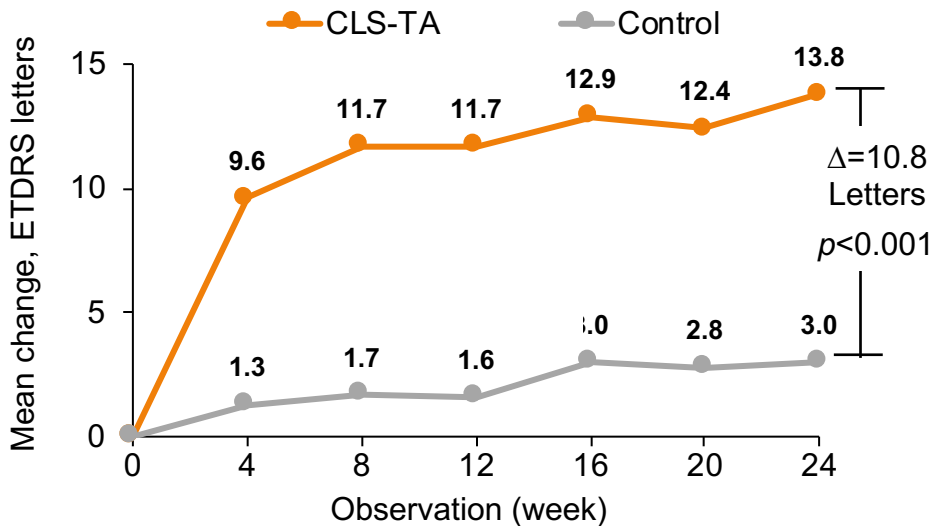
PK = pharmacokinetic

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, Pransnitz 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: Macular Edema in NIU met Primary Endpoint
 - **46.9% of subjects gained ≥ 15 BCVA letters** from baseline vs. 15.6% in the control

Mean change from baseline in BCVA by visit



- Treatment of uveitis often requires a combination of systemic and local therapies
- This analysis explores the efficacy in patients receiving and not receiving other systemic therapies at baseline.

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

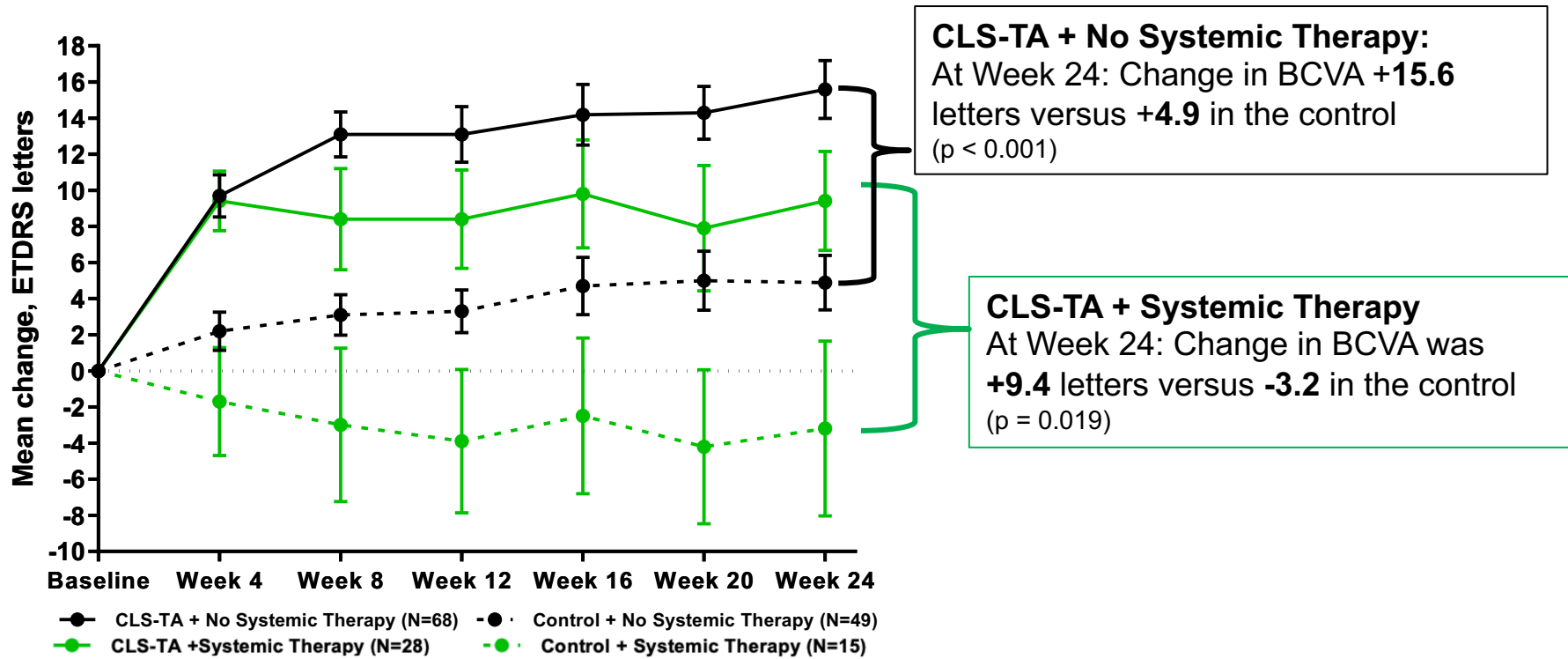
Post Hoc Analysis: Objectives and Methods

- 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

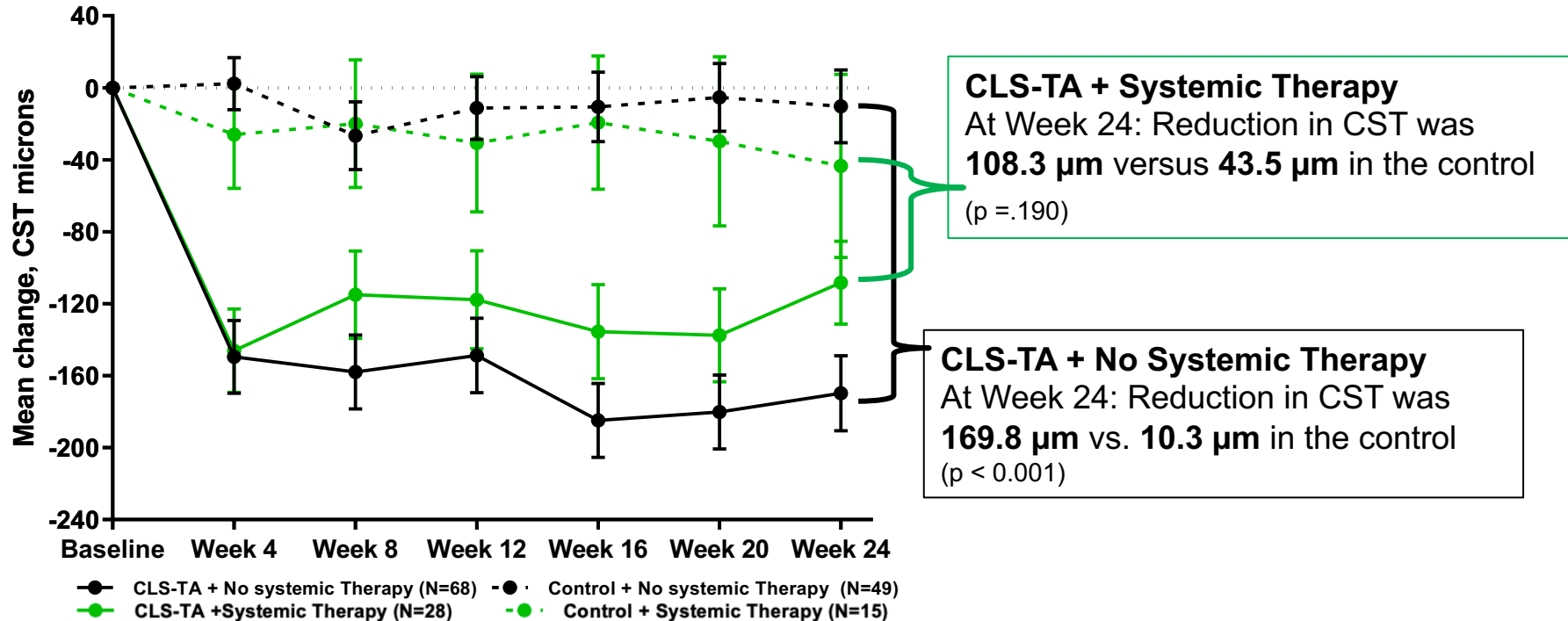
Any Systemic Steroid or Steroid-Sparing Therapy at Baseline	CLS-TA n=96	Control n=64
NO Systemic Therapy	68/96 (70.8%)	49/64 (76.6%)
YES Systemic Therapy (steroid and/or steroid-sparing)	28/96 (29.2%)	15/64 (23.4%)

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



Intention-to-treat population; LOCF imputation.

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



Intention-to-treat population; LOCF imputation.

Conclusion

- The benefit of suprachoroidally injected CLS-TA versus the control in treating macular edema associated with non-infectious uveitis was noted regardless of administration of systemic therapy at baseline
- These results corroborate the prespecified study analyses in PEACHTREE