

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



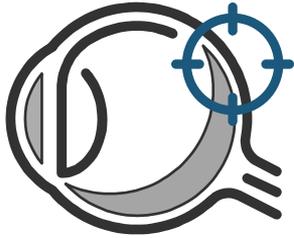
ASRS 2020 Virtual Program
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Financial Disclosures

- AR: Clearside Biomedical (Ad board), Alimera (Ad board)
- TC: Clearside Biomedical (E, I)

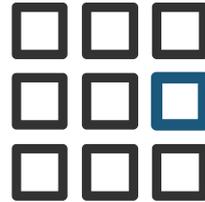
Core Advantages of Treating Via the Suprachoroidal Space



TARGETED

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

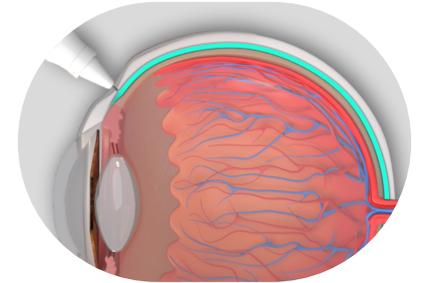
for efficacy



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

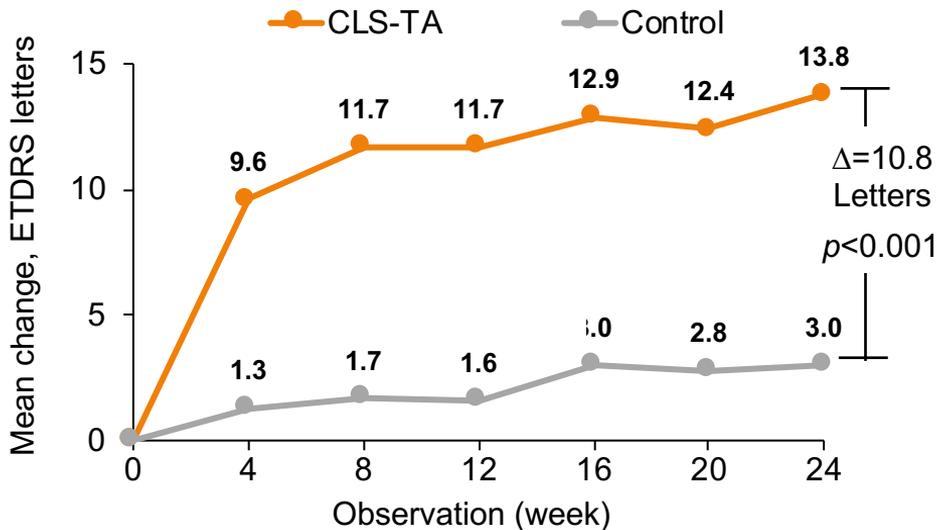
PK = pharmacokinetic

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

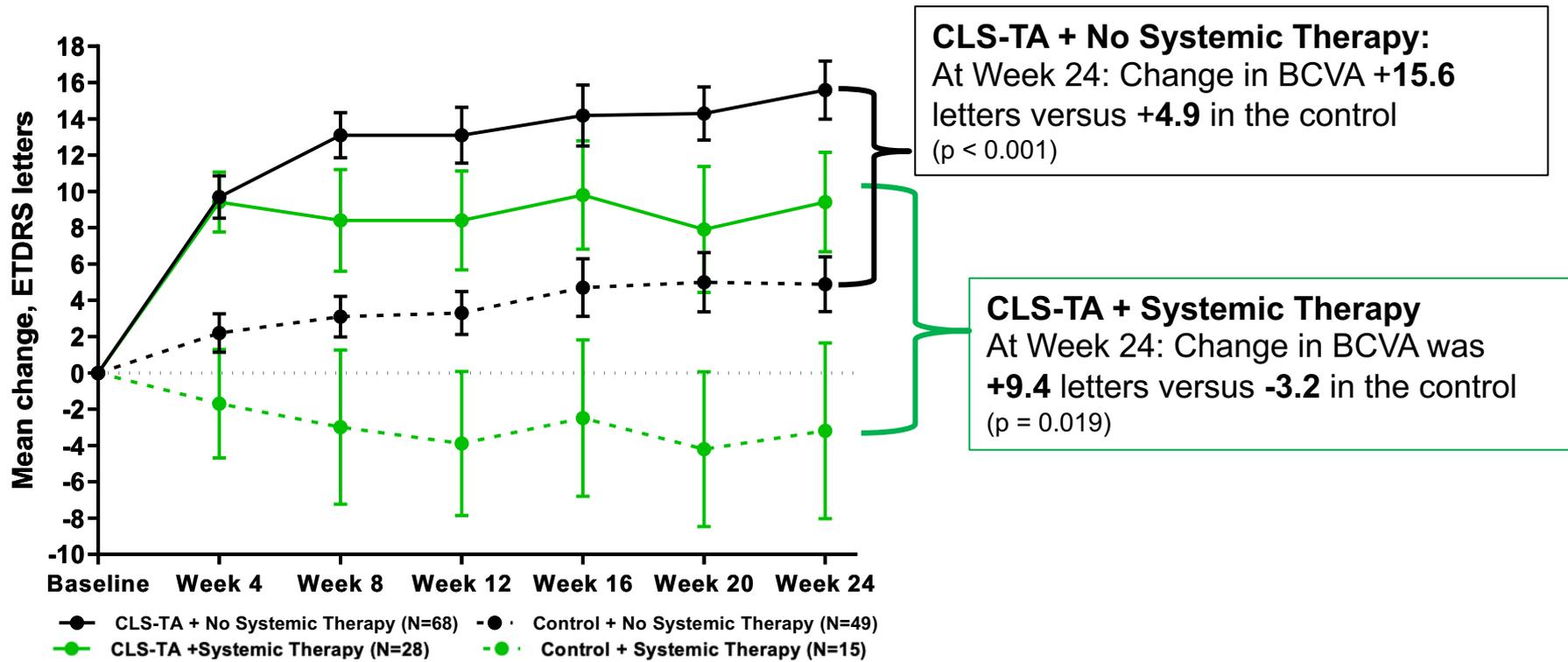
Post Hoc Analysis: Objectives and Methods

- 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

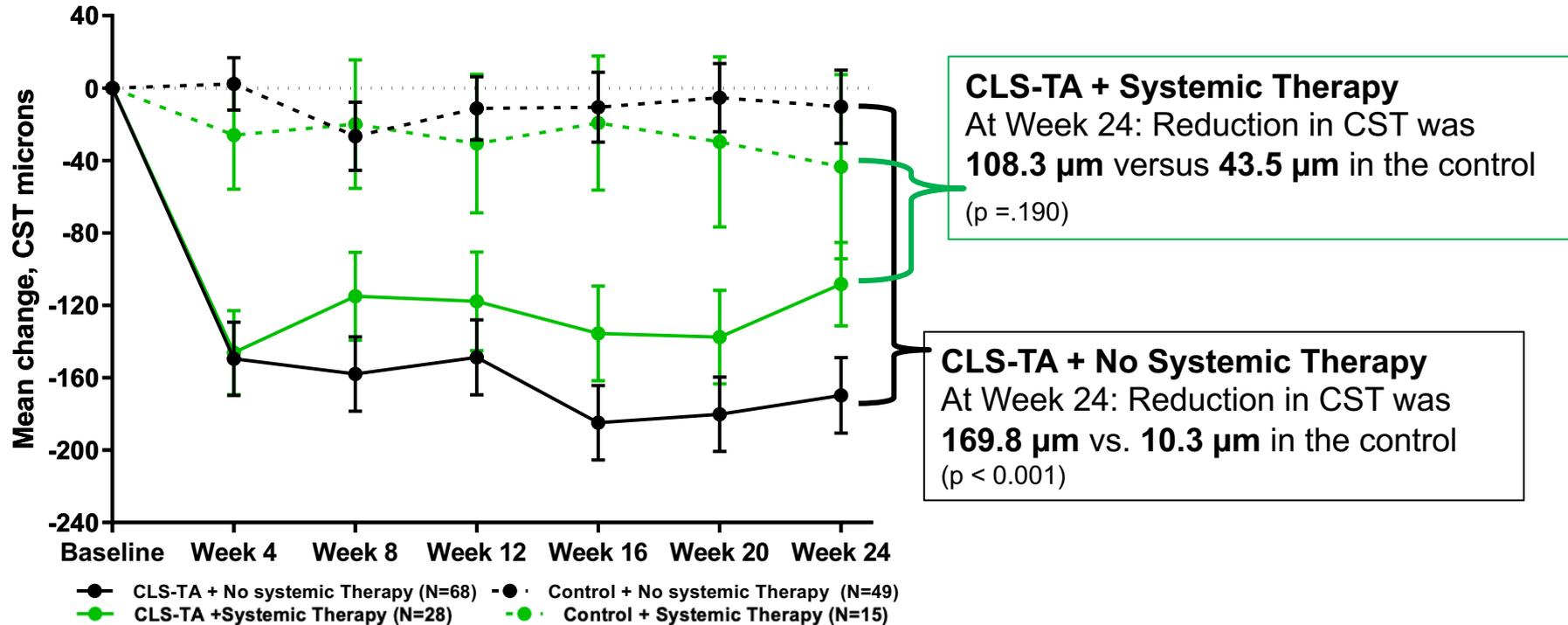
Any Systemic Steroid or Steroid-Sparing Therapy at Baseline	CLS-TA n=96	Control n=64
NO Systemic Therapy	68/96 (70.8%)	49/64 (76.6%)
YES Systemic Therapy (steroid and/or steroid-sparing)	28/96 (29.2%)	15/64 (23.4%)

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

- 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.