

2020 Annual Meeting of the American Academy of Ophthalmology

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

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for the PEACHTREE Investigators

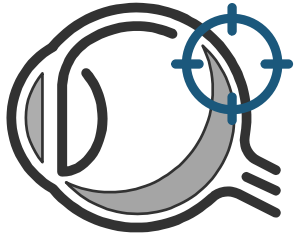


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Financial Disclosures

- **QDN**
 - Dr. Nguyen has served as advisor for Bayer, Clearside, Genentech/Roche, Regeneron, and Santen among others
 - Stanford University, the employer of Dr Nguyen, has received research funding from Genentech, Regeneron, and Santen, among others
- **TAC**
 - Employment & Financial Interest: Clearside Biomedical

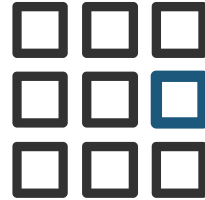
Core Advantages of Treating Via the Suprachoroidal Space



TARGETED

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

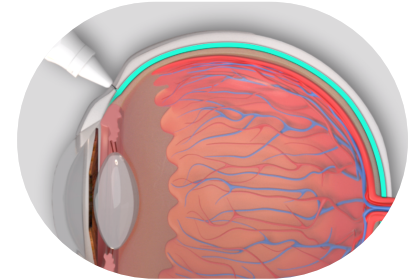
for Efficacy



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

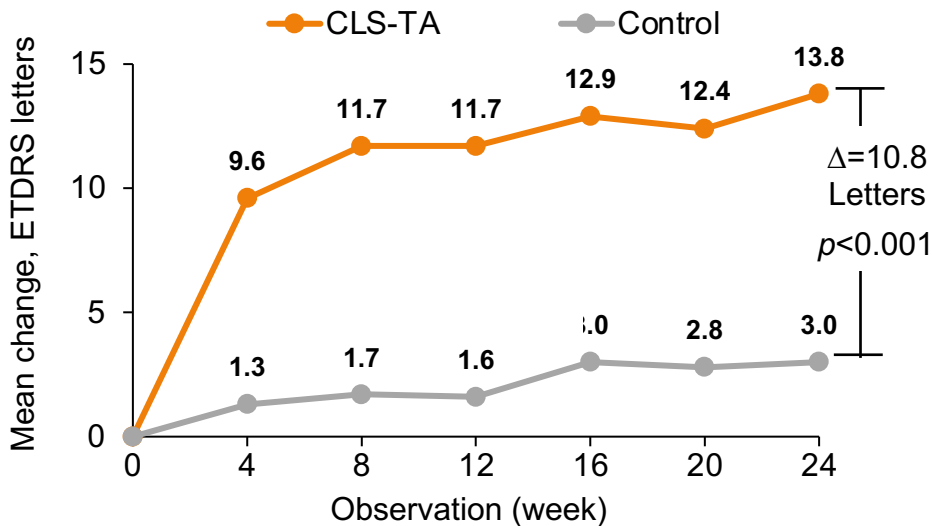
PK = pharmacokinetic

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
- **The index analysis explores the efficacy in patients receiving and not receiving other systemic therapies at baseline**

Safety: PEACHTREE Study

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

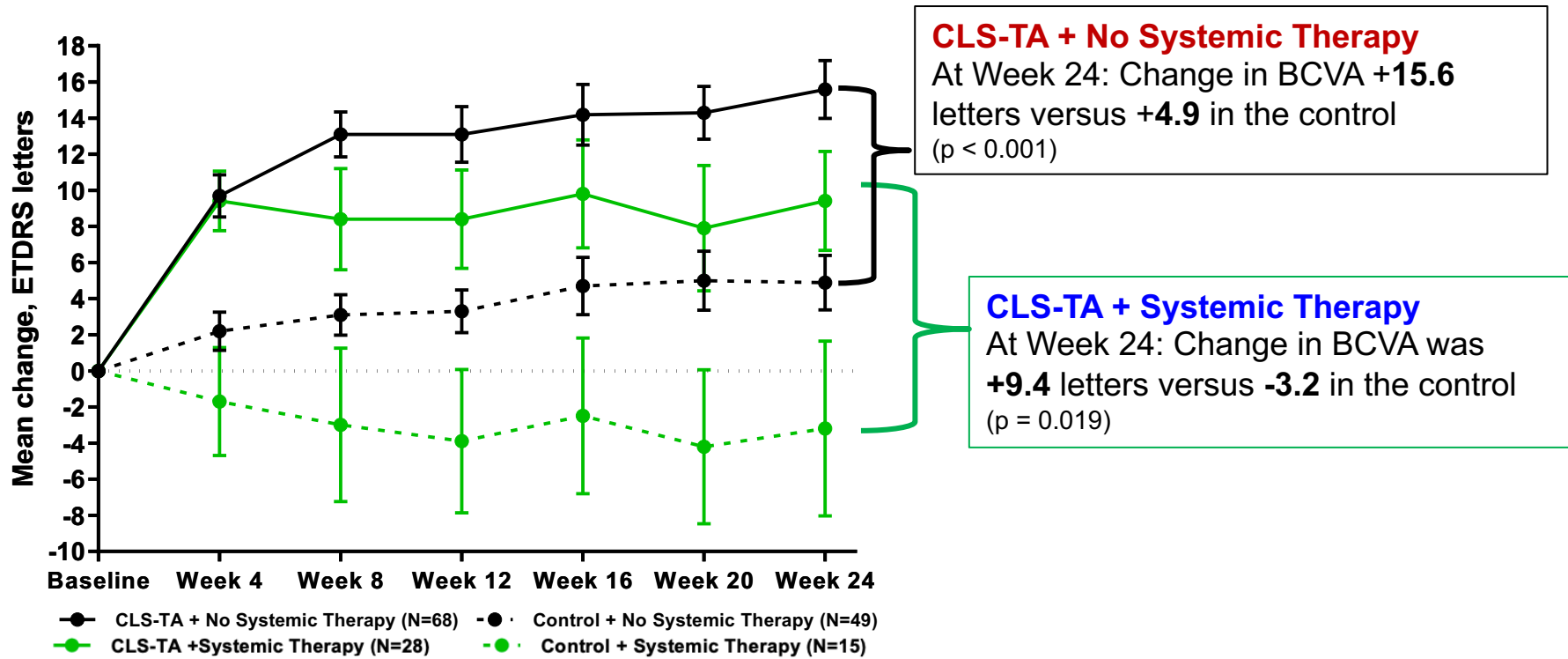
- Cataract: 7.3% (7/96) in the CLS-TA arm vs. 6.3% (4/64) in the sham arm
- One serious ocular AE
 - Retinal detachment 8 weeks after CLS-TA
 - Determined to be unrelated to study drug by the Investigator

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

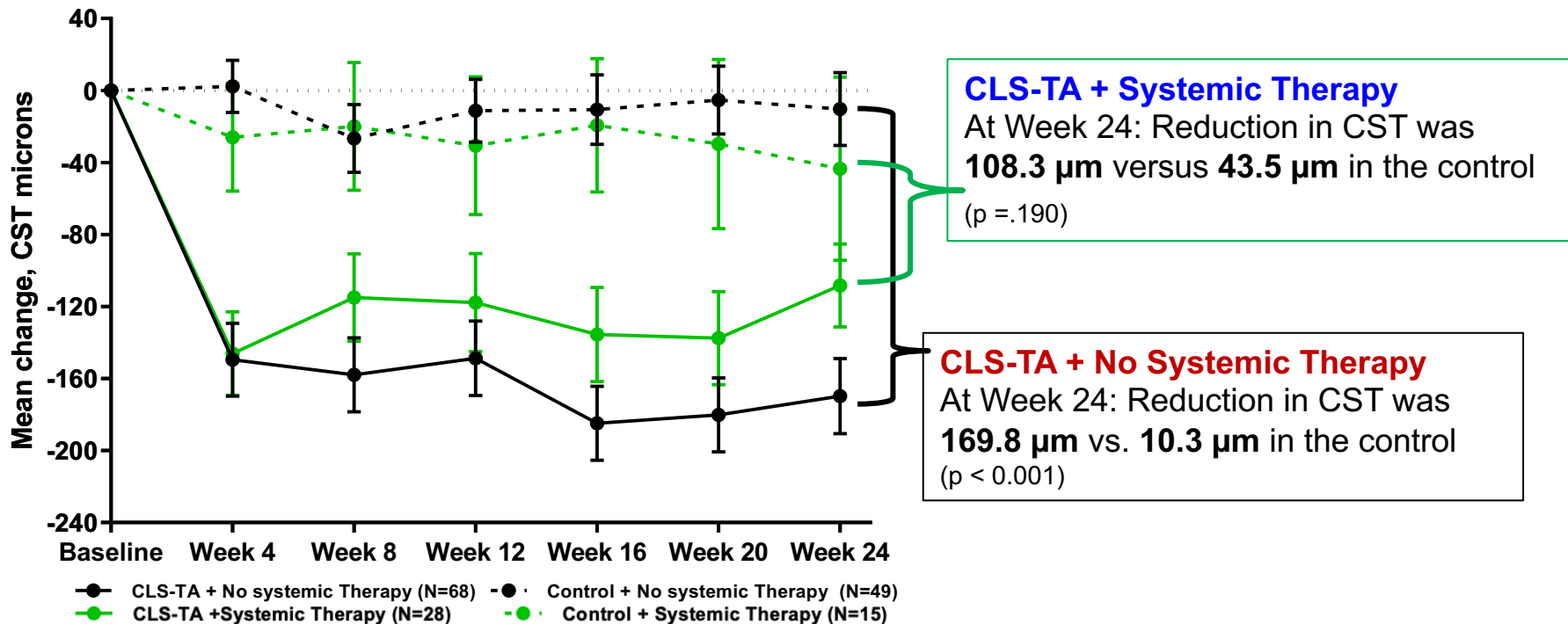
Any Systemic Steroid or Steroid-Sparing Therapy at Baseline	CLS-TA n=96	Control n=64
NO Systemic Therapy	68/96 (70.8%)	49/64 (76.6%)
YES Systemic Therapy	28/96 (29.2%)	15/64 (23.4%)

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



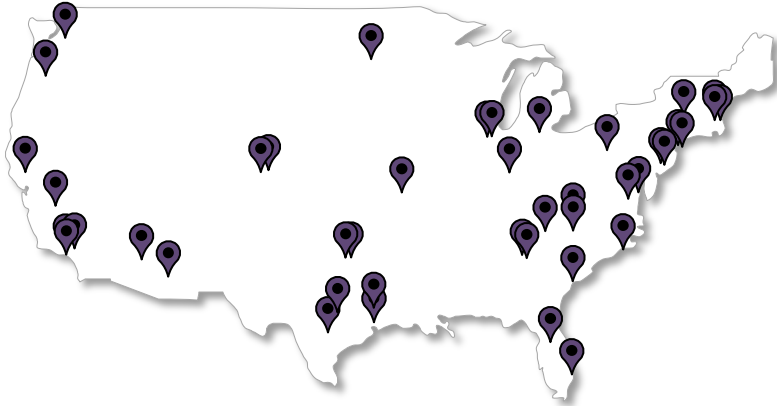
Intention-to-treat population; LOCF imputation.

Conclusion

- The benefit of suprachoroidally injected CLS-TA versus the control in treating macular edema associated with NIU was noted **regardless of administration of systemic therapy** at baseline
 - Significant improvement in visual acuity and reduction in retinal thickness
- These results corroborate the prespecified study analyses in the PEACHTREE Study

Sincere Appreciation to the PEACHTREE Subjects, Investigators, and Study Staff

USA



India



Israel

