Suprachoroidal Triamcinolone Acetonide Suspension (CLS-TA) and Intraocular Pressure: Results from the Phase 3 PEACHTREE Clinical Trial for Uveitis

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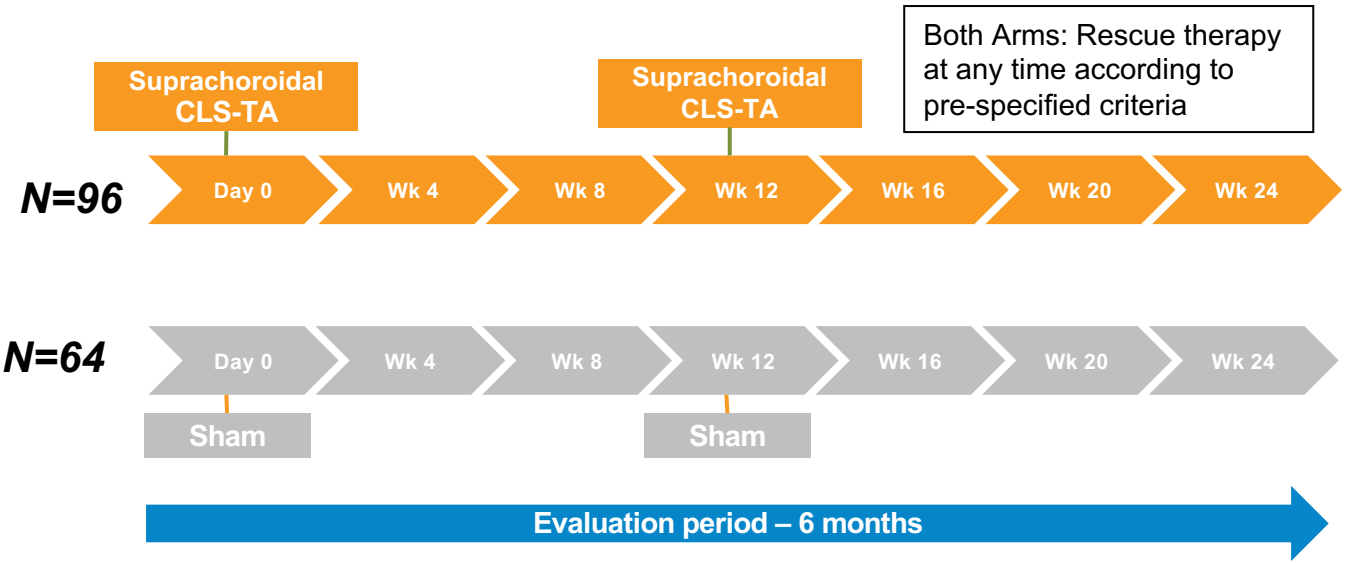
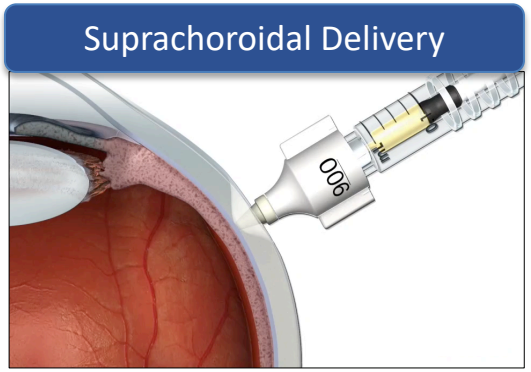
PEACHTREE: Phase 3 Randomized, Controlled Double-Masked, Multicenter Trial



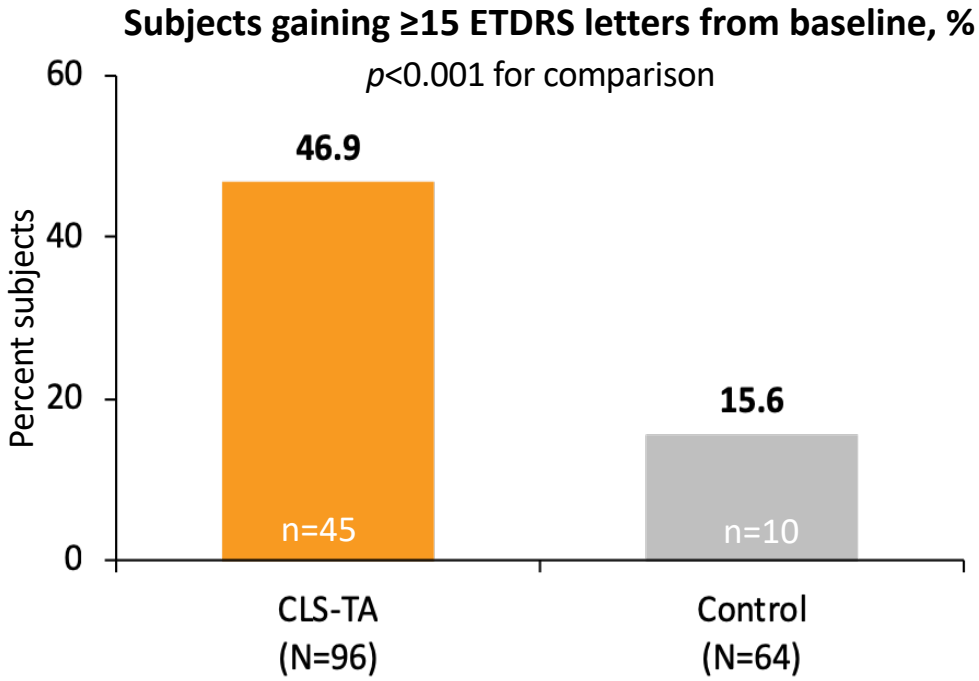


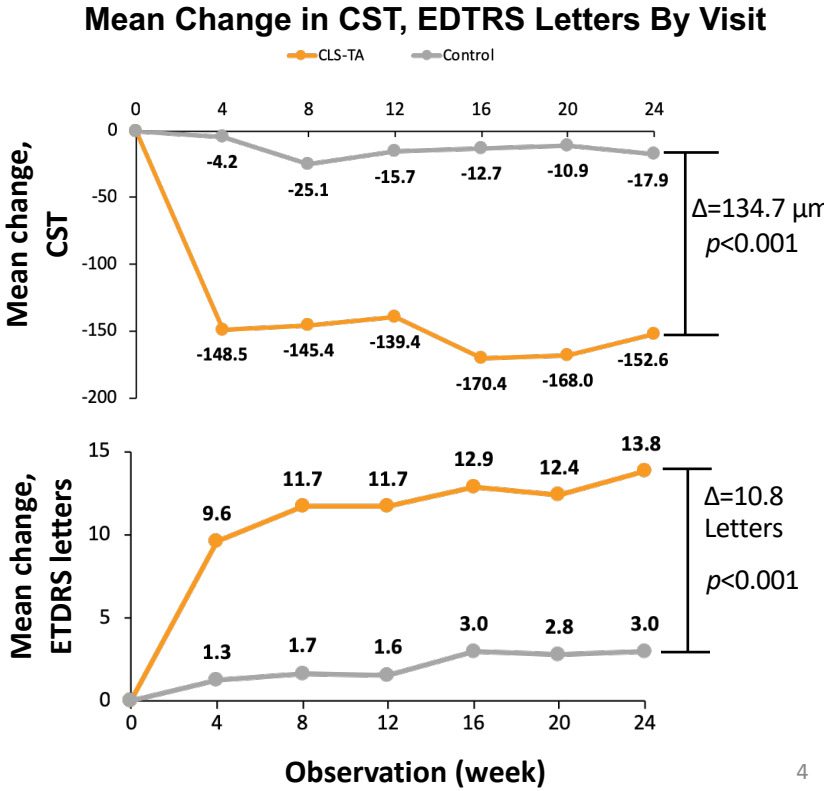
Favorable drug concentrations:

- Retina, RPE, choroid >> Anterior segment
- Potential for uveitic macular edema with fewer side effects

- **Primary endpoint:** Proportion of subjects gaining ≥15 ETDRS letters in BCVA at week 24
- 3:2 randomization of suprachoroidal CLS-TA vs. sham procedure

PEACHTREE Met Its Primary Efficacy Endpoint





Intention-to-treat population; LOCF imputation.

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

ETDRS, Early treatment diabetic retinopathy study; LOCF, last observation carried forward.

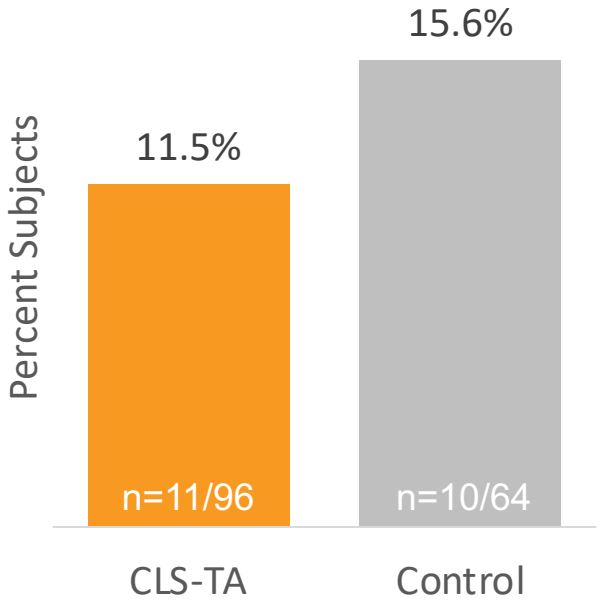
Safety

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

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

Safety population; includes subjects in the control group who received rescue medication
*Based on elevated intraocular pressure adverse reactions

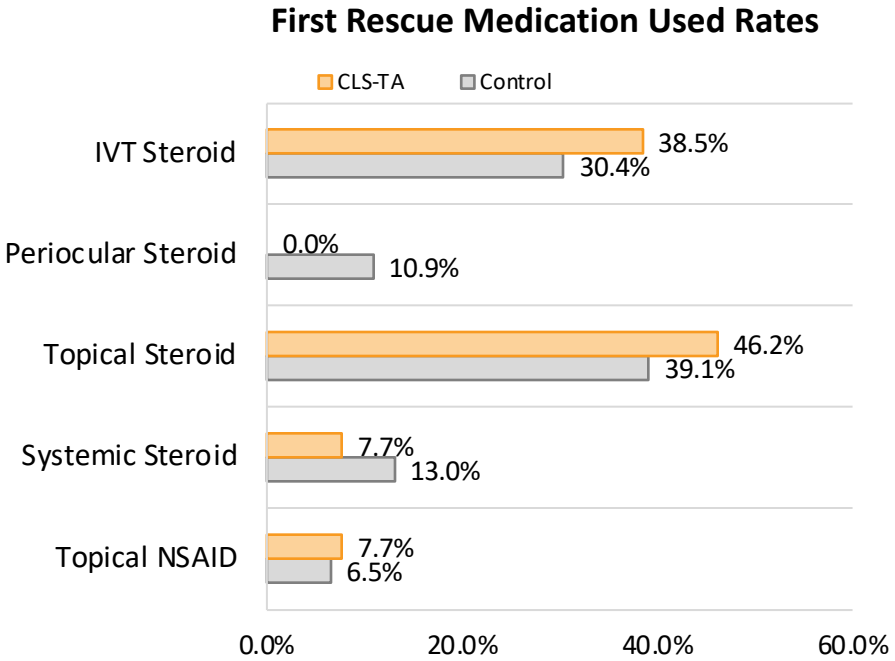
Elevated IOP Adverse Events in PEACHTREE

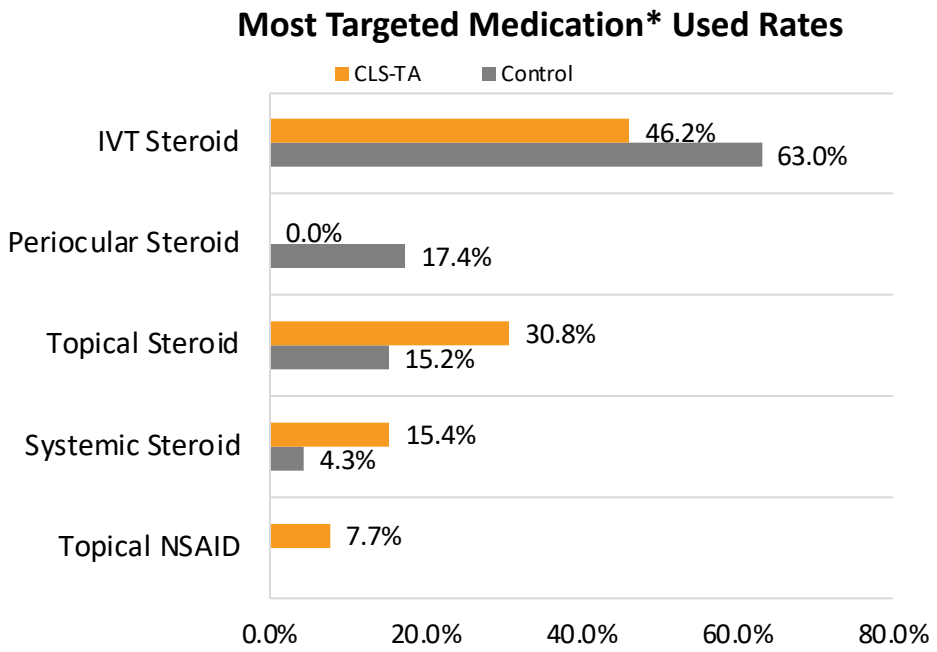


- Why are IOP AEs higher in the control group?
  - 46/64 (72%) control patients received rescue therapy
  - All 10 patients with IOP AEs received intravitreal steroids as rescue therapy

"Elevated IOP" includes (a) increased IOP, (b) ocular hypertension, and (c) glaucoma.
AE, adverse event; IOP, intraocular pressure.

Post-Hoc IOP Sub-Analysis:
Rescue Therapies in PEACHTREE





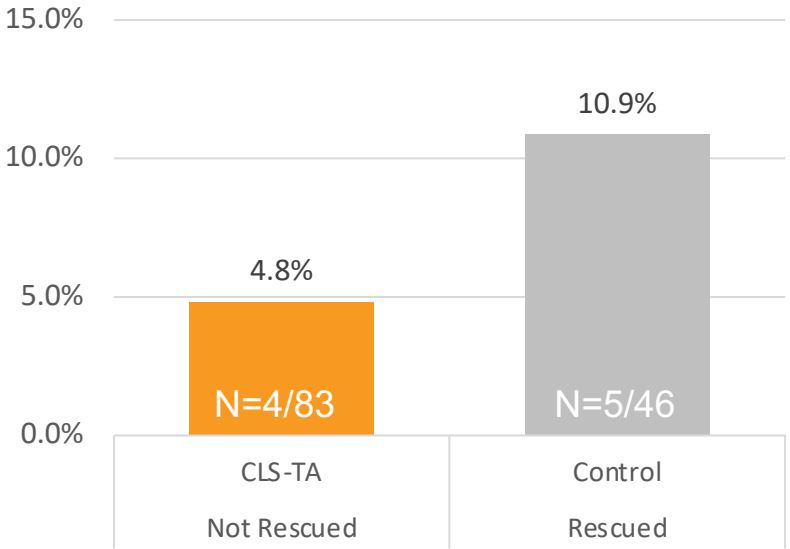
*Rescue medications classified by most targeted type of therapy used during study, were:

Intravitreal Corticosteroid > Periocular corticosteroid > Topical Corticosteroid > Systemic Corticosteroid > Topical NSAID

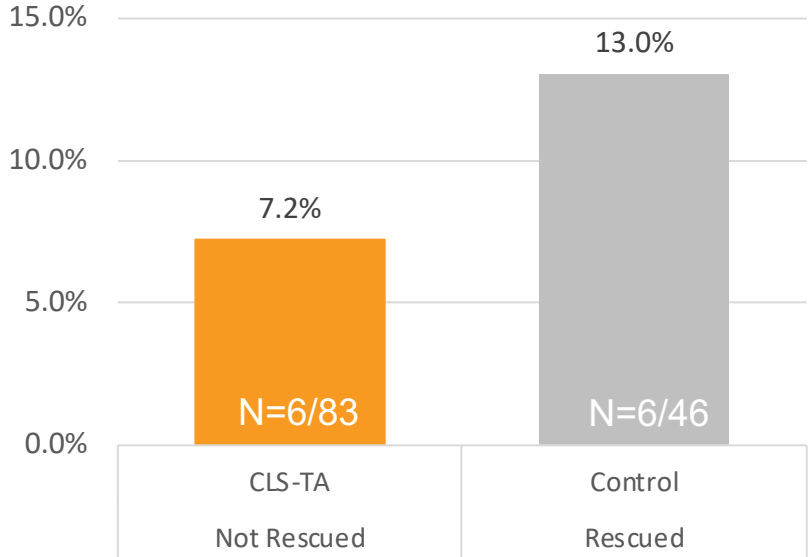
Rescue medication used per investigator discretion.

Post-Hoc IOP Sub-Analysis:
Clinically Relevant IOP Endpoints, CLS-TA Not Rescued vs. Control Rescued

≥ 30 mmHg at any visit through Week 24



≥ 1 IOP lowering medication



	Not Rescued	Rescued
CLS-TA	n=83/96 (86.5%)	n=13/96 (13.5%)
Control	n=18/64 (28.1%)	n=46/64 (71.8%)

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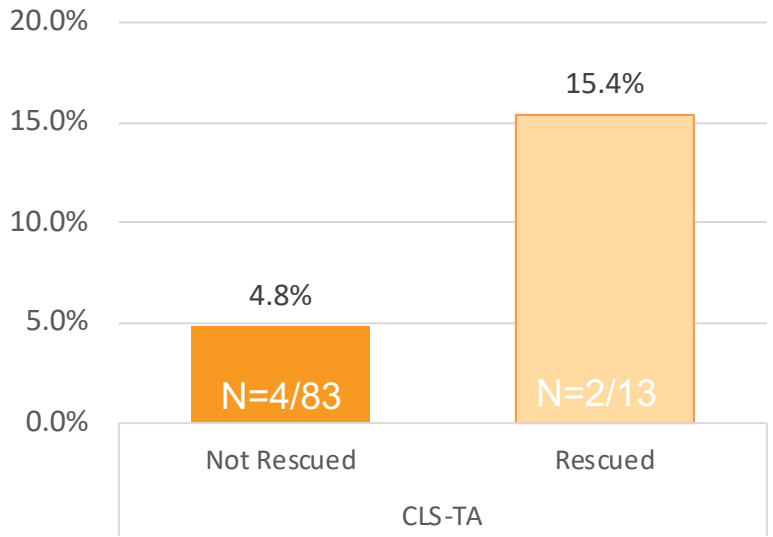

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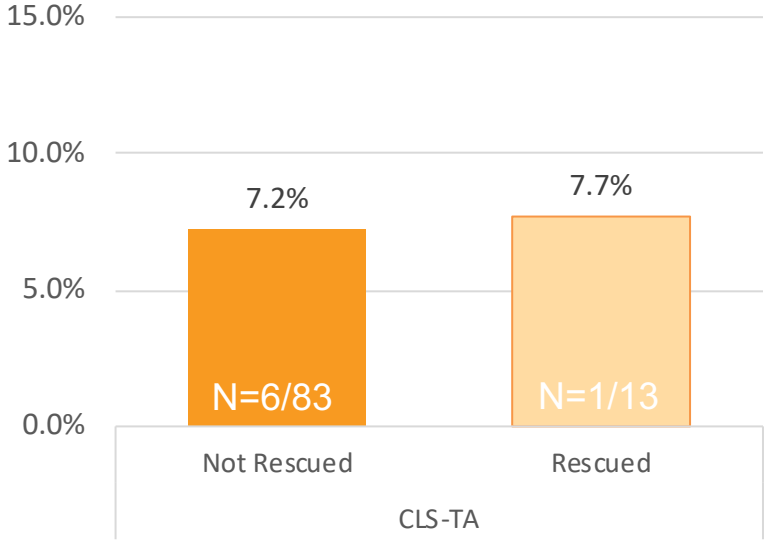

PEACHTREE: Take Home Points

EFFICACY

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

SAFETY

- No SAEs attributable to CLS-TA
- Low rates of elevated IOP and cataract
- Cataract rate was similar to control arm