UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 25, 2018

Clearside Biomedical, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-37783**	**45-2437375**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

900 North Point Parkway, Suite 200
Alpharetta, GA 30005
(Address of principal executive offices, including zip code)

(678) 270-3631
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial account standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 Regulation FD Disclosure.

On July 25, 2018, Dr. Steven Yeh presented a presentation titled "Suprachoroidally Injected CLS-TA Improves Visual Acuity and Macular Edema in Noninfectious Uveitis: Results of the Phase 3 PEACHTHREE Study" at the 2018 American Society of Retina Specialists Annual Meeting containing the final clinical data from Clearside Biomedical Inc.'s (the "***Company***") PEACHTREE trial, a pivotal Phase 3 trial of suprachoroidal CLS-TA in patients with macular edema associated with non-infectious uveitis. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is available on the Company's website.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Presentation titled "Suprachoroidally Injected CLS-TA Improves Visual Acuity and Macular Edema in Noninfectious Uveitis: Results of the Phase 3 PEACHTHREE Study"

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CLEARSIDE BIOMEDICAL, INC.

Date: July 25, 2018

By:/s/ Charles A. Deignan
Charles A. Deignan
Chief Financial Officer

Exhibit 99.1

Suprachoroidally Injected CLS-TA Improves Visual Acuity and Macular Edema in Noninfectious Uveitis: Results of the Phase 3 PEACHTREE Study

Steven Yeh, MD
M. Louise Simpson Associate Professor of Ophthalmology
Faculty Fellow, Emory Global Health Institute
Emory Eye Center

American Society of Retina Specialists Annual Meeting
Vancouver, B.C.
July 25, 2018

Financial Disclosures

- Clearside Biomedical, Inc. (Consultant)
- Santen (Consultant)
- AGTC (Consultant)
- Research to Prevent Blindness (Grant)
- Marcus Foundation Combating Childhood Illness Seed Funding (Grant)

Thank You to the PEACHTREE Investigators!

Macular Edema Due to Noninfectious Uveitis

Uveitis and Macular Edema

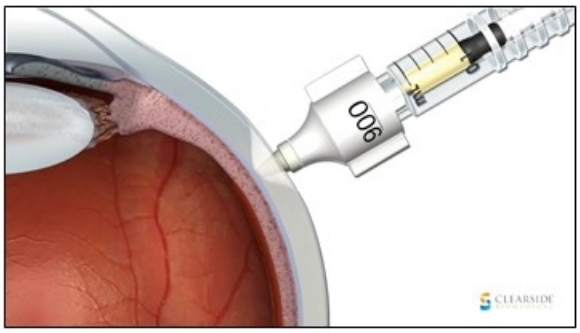
- Macular edema (ME) is the leading cause of vision impairment and vision loss in uveitis
- ME is common
  - 40% to 60% of intermediate, posterior and panuveitis
  - 20% anterior

Therapeutic options for ME

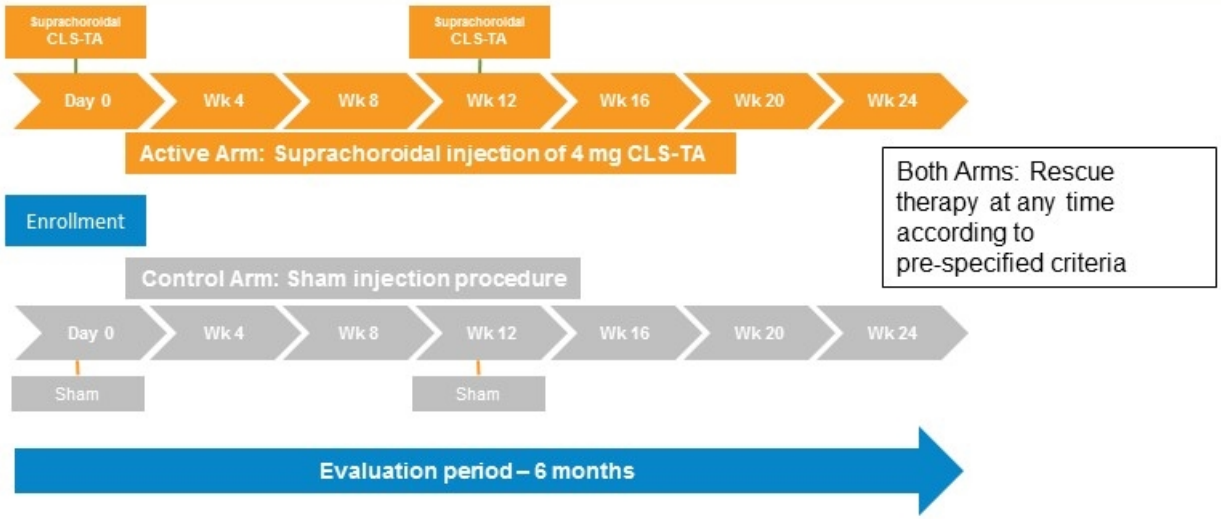
- Local periocular and intravitreal corticosteroids
- Systemic corticosteroids and steroid-sparing medications

Suprachoroidal Injection for Posterior Segment Disease

- **Novel technique for suprachoroidal injection**
  - 30G needle approx. 1000 microns in length
  - Proprietary microinjector syringe
- **Laboratory data: Suprachoroidal vs. intravitreal injection**
  - Higher bioavailability in the choroid, RPE, and retina
  - Lower exposure to the anterior segment
  - Potential for improved efficacy and safety



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



- **Primary endpoint:** Proportion of subjects in each arm gaining ≥15 ETDRS letters in BCVA from baseline at week 24
- 3:2 randomization of suprachoroidally injected CLS-TA (N=96) vs. sham procedure (N=64)

Key Inclusion and Exclusion Criteria

Inclusion

- Non-infectious uveitis of any associated diagnosis/ etiology
- Any anatomic location: anterior, intermediate, posterior and panuveitis
- Diagnosis of macular edema with central subfield thickness >300 microns
- Visual acuity: ≥5 and ≤70 ETDRS letters; 20/40 to 20/800
- Patients could have active or controlled disease at enrollment

Exclusion

- Any active ocular disease or infection in the study eye other than uveitis
- Intraocular pressure >22 mmHg or uncontrolled glaucoma; subjects could be on up to 2 IOP-lowering medications

ETDRS: Early treatment of diabetic retinopathy study
IOP: intraocular pressure

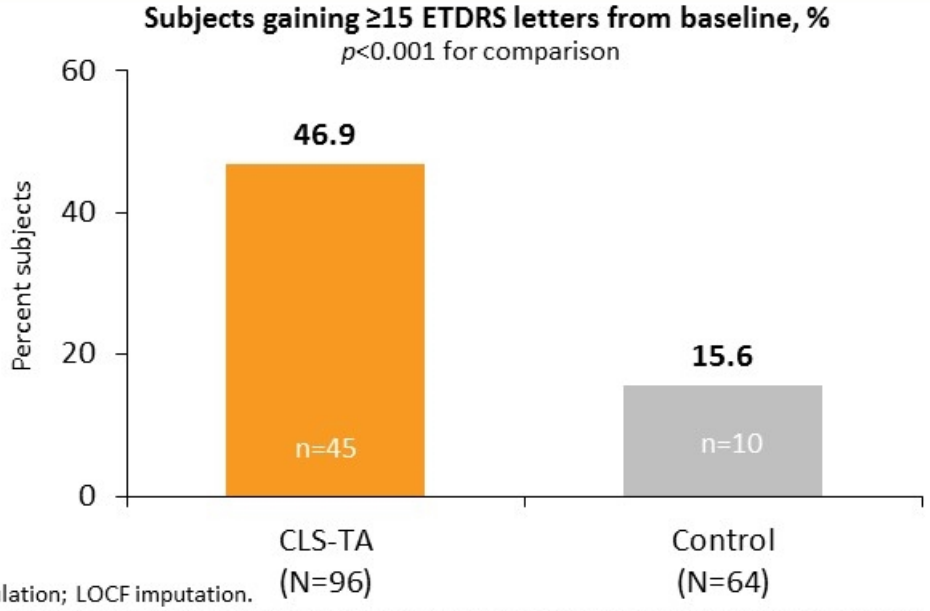
Baseline Demographic Characteristics Were Similar Between Treatment Groups

Characteristic	CLS-TA N=96	Control N=64	Overall N=160
Gender, n (%)			
Male	42 (43.8)	30 (46.9)	72 (45.0)
Female	54 (56.3)	34 (53.1)	88 (55.0)
Age (years), mean (SD)	50.4 (14.2)	50.0 (15.1)	50.2 (14.5)

Baseline Ocular Characteristics Were Similar Between Treatment Groups

Characteristic	CLS-TA N=96	Control N=64	Overall N=160
BCVA, study eye (ETDRS letters)			
Mean (SD)	54.7 (13.9)	53.5 (12.9)	54.2 (13.5)
Median (range)	57 (9-89)	54 (12-79)	56 (9-89)
CRT, study eye (µm)			
Mean (SD)	479.8 (149.7)	518.0 (150.0)	495 (150.5)
Median (range)	456 (256-857)	517 (274-861)	481 (256-861)
Uveitis anatomic location, n (%)			
Anterior	27 (28.1)	14 (21.9)	41 (25.6)
Intermediate	34 (35.4)	23 (35.9)	57 (35.6)
Posterior	22 (22.9)	13 (20.3)	35 (21.9)
Panuveitis	28 (29.2)	24 (37.5)	52 (32.5)

PEACHTREE Met Its Primary Efficacy Endpoint: Visual Acuity Gain ≥15 ETDRS Letters from Baseline



Intention-to-treat population; LOCF imputation.

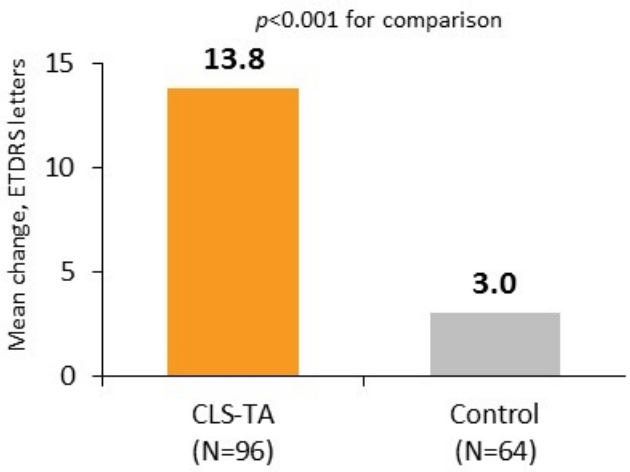
The *p*-value is based on a CMH Cochran-Mantel-Haenszel test for general association between treatment and response with stratification by country.

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

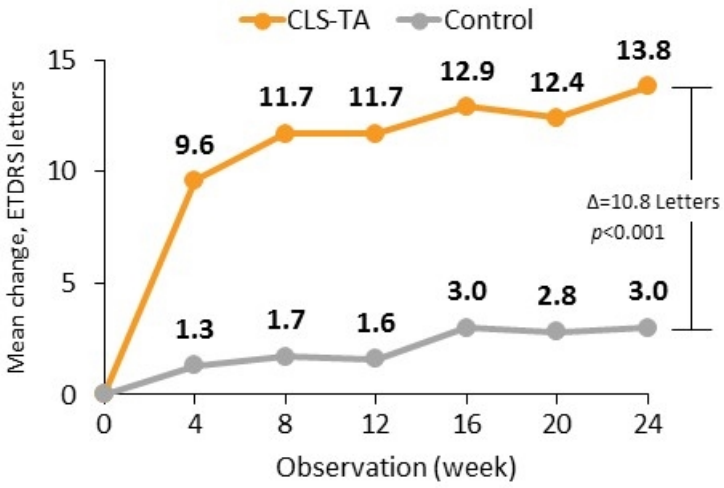
Mean Change in BCVA

Improvement From as Early as Week 4 Through Week 24 in the CLS-TA Arm

Mean change at week 24 from baseline in BCVA in ETDRS letters read

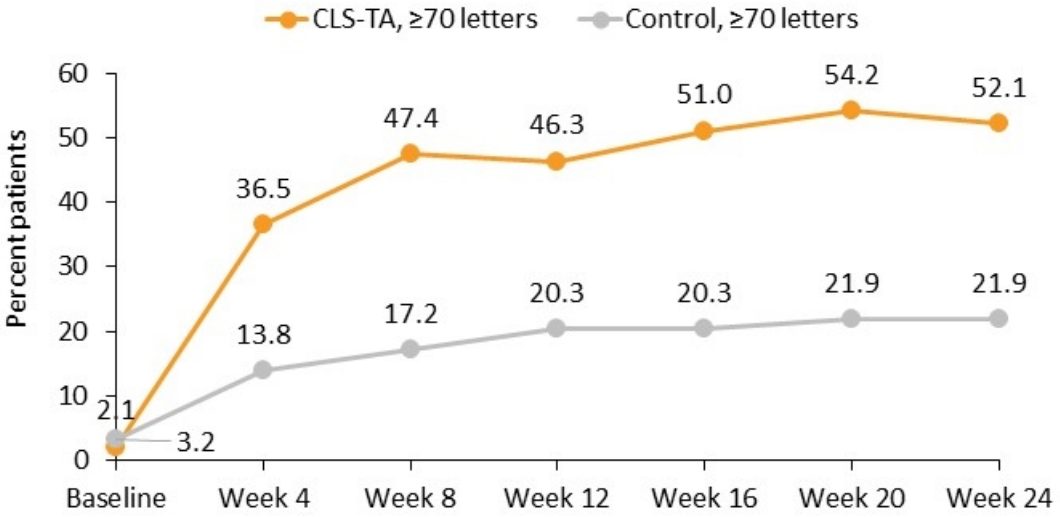


Mean change at each visit from baseline in BCVA in ETDRS letters read



Intention-to-treat population; LOCF imputation.
t-test. Differences between the CLS-TA and control arms were significant at each visit.
BCVA, best corrected visual acuity.

% Subjects Reading ≥70 ETDRS Letters (20/40 or Better) by Treatment Arm

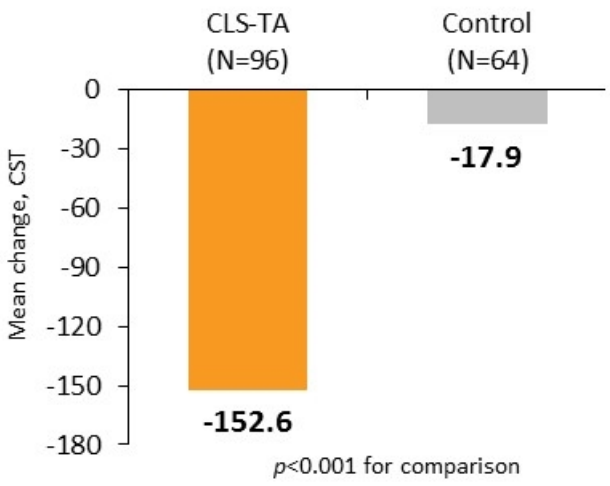


Intention-to-treat population; LOCF imputation.

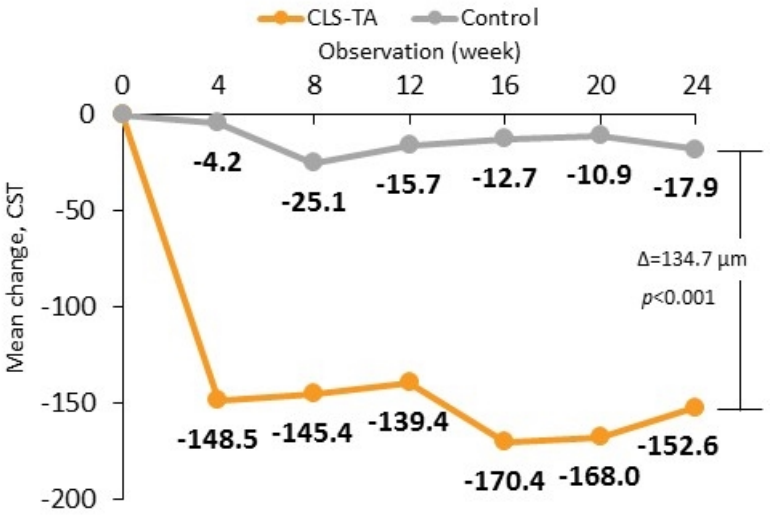
Mean Change in Central Subfield Thickness

Improvement From as Early as Week 4 through Week 24 in CLS-TA Arm

Mean change from baseline at week 24 in central subfield thickness (µm)



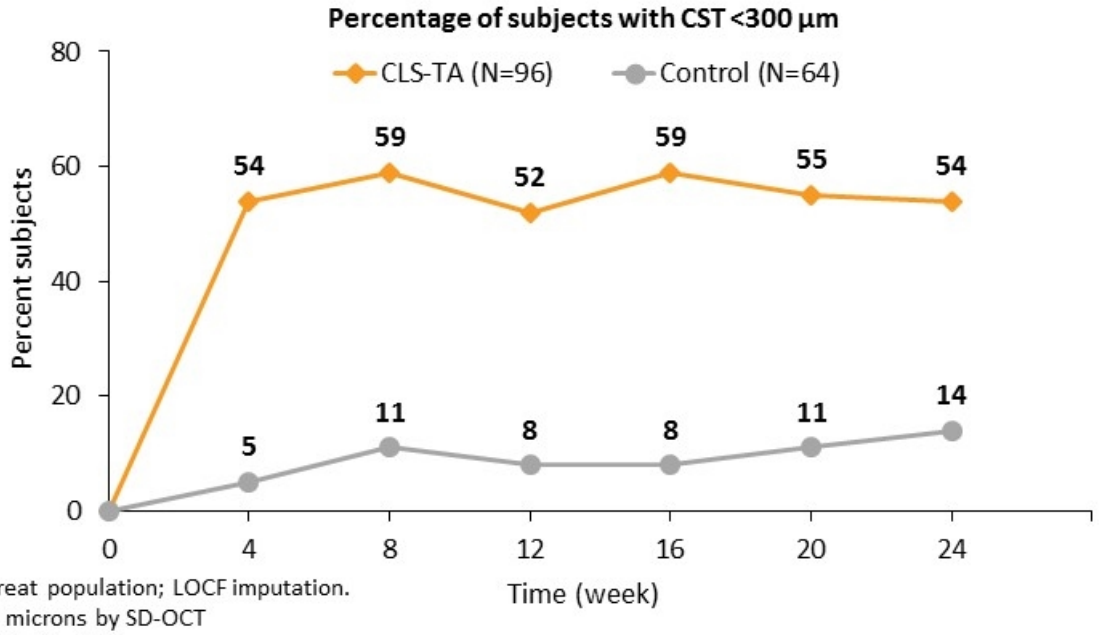
Mean change at each visit from baseline in central subfield thickness (µm)



Intention-to-treat population; LOCF imputation.
CST, central subfield retinal thickness.

Resolution of Macular Edema, CST <300 µm

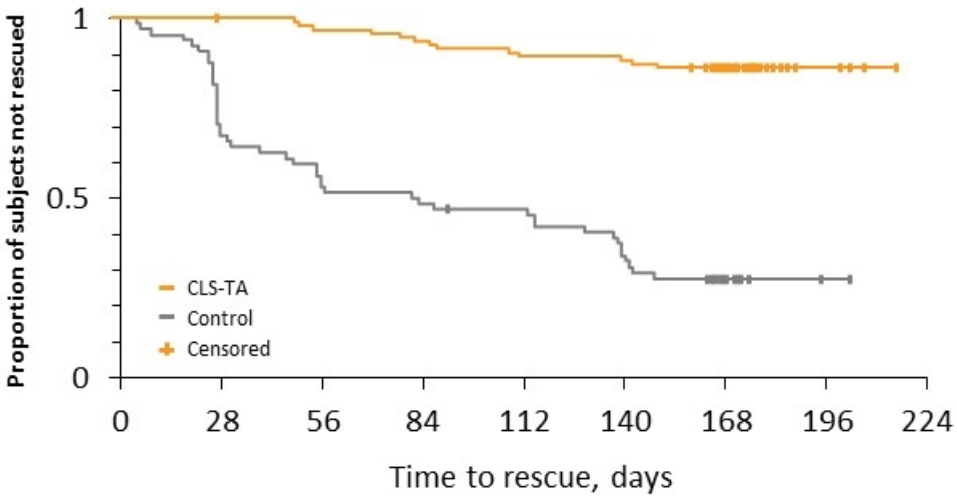
Improvement in CLS-TA group at Week 4, Maintained through Week 24



Intention-to-treat population; LOCF imputation.
Less than 300 microns by SD-OCT

CST, central subfield retinal thickness

Kaplan–Meier Analysis: Time to Rescue



Over 85% of the patients in the CLS-TA arm did not require rescue therapy

Safety

Patient Retention

- 97% of patients completed the study

Serious Adverse Events

- There were no deaths in the study
- Three serious adverse events none considered to be treatment-related; none led to study discontinuation

Ocular Adverse Events: Study Eye

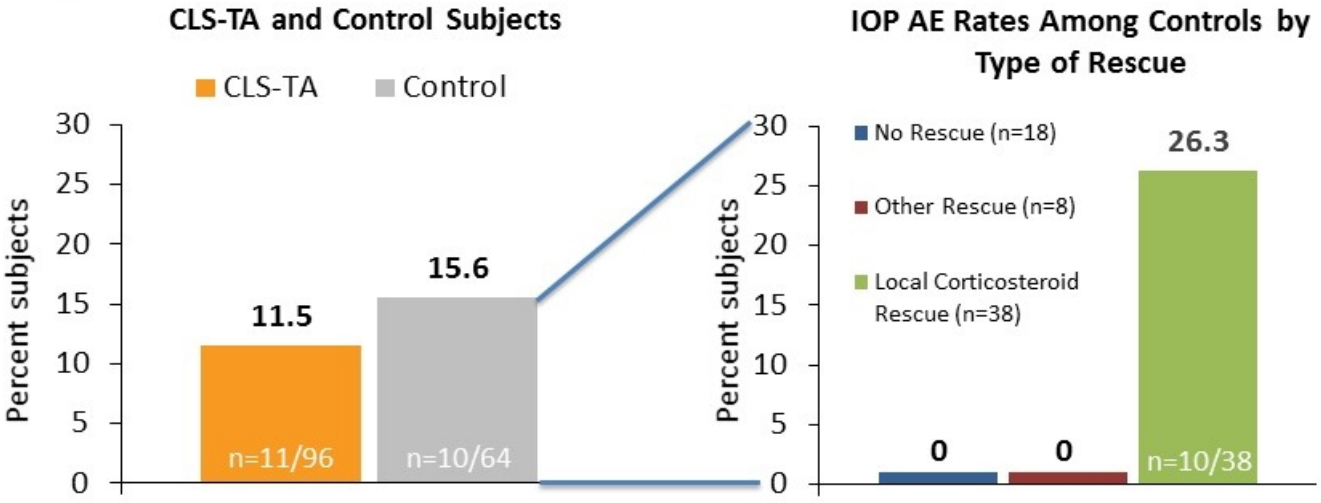
Adverse Events, n (%)	CLS-TA 4.0 mg N=96	Control N=64
Total number of ocular adverse events	122	54
Number of subjects with ≥1 ocular AEs	49 (51.0)	37 (57.8)
Treatment-related ocular AEs	29 (30.2)	8 (12.5)
Serious ocular AEs	1 (1.0)	0
Treatment-related serious AEs	0	0
Number of subjects with ≥1 eye disorder	41 (42.7)	34 (53.1)

Ocular Adverse Events in ≥5% of Subjects

Adverse Events, n (%)	CLS-TA 4.0 mg N=96	Control N=64
Cataract	7 (7.3)	4 (6.3)
Cystoid macular edema	0	11 (17.2)
Eye pain: time of procedure	12 (12.5)	3 (4.7)
Eye pain: any time post procedure	6 (6.3)	0
Elevated IOP: time of procedure	8 (8.3)	0
Elevated IOP: corticosteroid-related	11 (11.5)	(10) 15.6*
Uveitis	2 (2.1)	7 (10.9)
Vitreous detachment	5 (5.2)	1 (1.6)

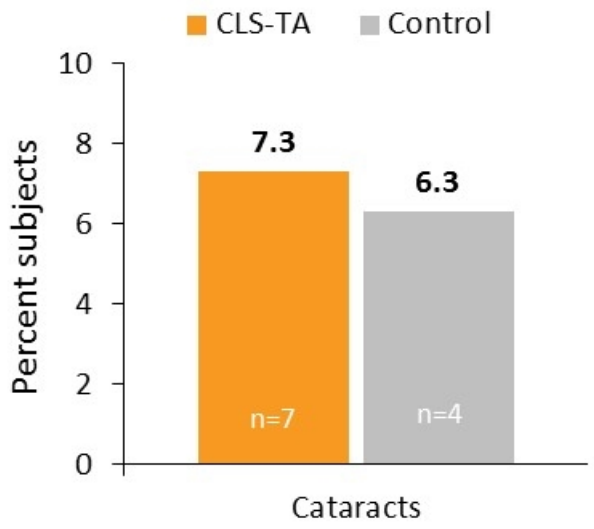
*All IOP-related events in the control group occurred after rescue local corticosteroid administration.

Elevated IOP Adverse Events



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

Cataract Adverse Events



- New or worsening cataracts occurred with similar frequency in the CLS-TA and control groups
- No AE of cataract-related surgeries in this trial

"Cataract" includes (a) cataract, (b) cataract subcapsular, and (c) cataract nuclear.

PEACHTREE Study: Take Home Points

Efficacy

- Suprachoroidal CLS-TA met the primary study endpoint, with a significantly greater proportion of subjects vs. control with ≥15 ETDRS BCVA gain at 6 months
- CLS-TA improved macular edema in uveitis patients by OCT criteria
- Vast majority of patients in CLS-TA arm did not require rescue therapy during study

Safety

- Favorable safety profile overall with no SAEs attributable to suprachoroidal CLS-TA
- Low rates of elevated IOP and cataract

THANK YOU