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): January 7, 2019

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.**

From January 7, 2019 to January 10, 2019, members of management of Clearside Biomedical, Inc. (the "***Company***") will hold meetings to review, among other things, the Company's product candidate pipeline and recent clinical results. A copy of the presentation that will accompany the meetings is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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	Company Presentation.

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.

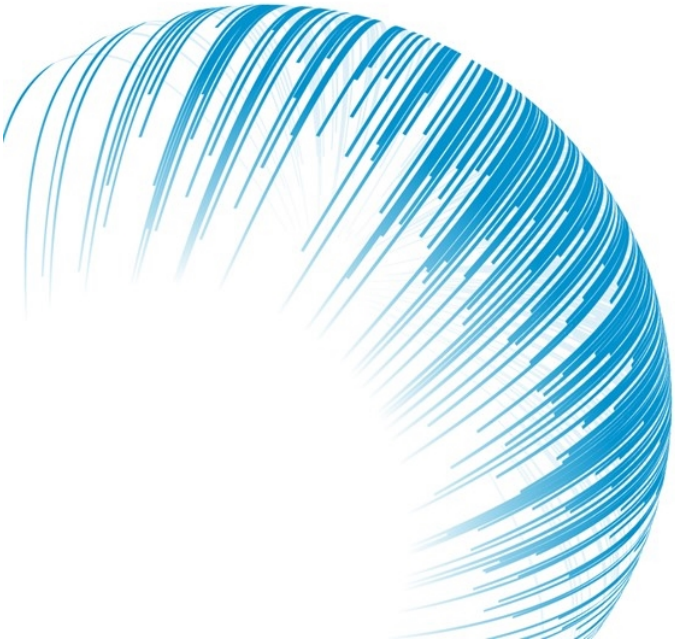
CLEARSIDE BIOMEDICAL, INC.

By:/s/ Charles A. Deignan

Date: January 7, 2019

Charles A. DeignanChief Financial Officer

Exhibit 99.1



CLEARSIDE® BIOMEDICAL

Corporate Presentation | January 2019

Forward-Looking Statements

This presentation contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Clearside Biomedical, Inc.'s views as of the date of this presentation about future events and are subject to risks, uncertainties, assumptions, and changes in circumstances that may cause Clearside's actual results, performance, or achievements to differ significantly from those expressed or implied in any forward looking statement. Although Clearside believes that the expectations reflected in the forward looking statements are reasonable, Clearside cannot guarantee future events, results, performance, or achievements. Some of the key factors that could cause actual results to differ from Clearside's expectations include its plans to develop and potentially commercialize its product candidates; Clearside's planned clinical trials and preclinical studies for its product candidates; the timing of and Clearside's ability to obtain and maintain regulatory approvals for its product candidates; the extent of clinical trials potentially required for Clearside's product candidates; the clinical utility and market acceptance of Clearside's product candidates; Clearside's commercialization, marketing and manufacturing capabilities and strategy; Clearside's intellectual property position; and Clearside's ability to identify additional product candidates with significant commercial potential that are consistent with its commercial objectives. For further information regarding these risks, uncertainties and other factors you should read the "Risk Factors" section of Clearside's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 16, 2018, Clearside's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 8, 2018, and Clearside's other Periodic Reports filed with the SEC. Clearside expressly disclaims any obligation to update or revise the information herein, including the forward-looking statements, except as required by law.

This presentation also contains estimates and other statistical data made by independent parties and by Clearside relating to market size and growth and other data about its industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of Clearside's future performance and the future performance of the markets in which Clearside operates are necessarily subject to a high degree of uncertainty and risk.

A World Without Blindness

Dedicated to developing treatments that **restore and preserve vision** for people with serious eye diseases

Proprietary suprachoroidal treatment approach offers unprecedented access to the back of the eye

XIPERE™

NDA submitted in 2018

CLEARSIDE BIOMEDICAL

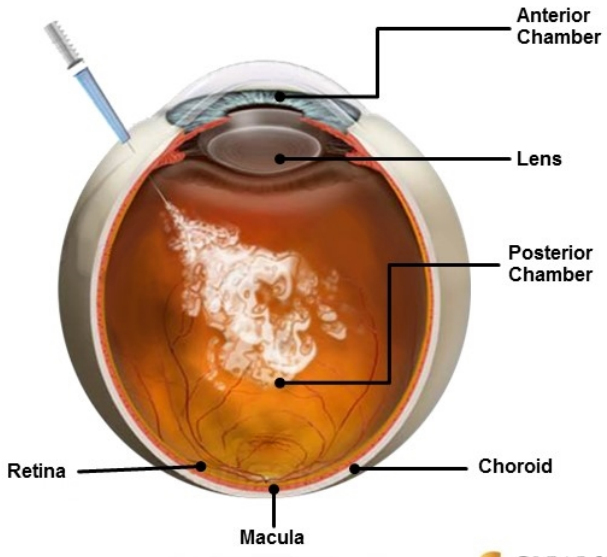
Retinal Diseases

~5 M patients in the U.S. with target indications treated by approx. **1,900 uveitis and retinal specialists**

Privileged Organ Requiring Local Therapy

Limitations of Current Therapy:

- **Corticosteroids** reach unintended tissues, causing cataracts and glaucoma
- **Gene therapies** require precise placement at diseased tissue
- **Multi-kinase inhibitors** and **complement inhibitors** require improved exposure to the choroid



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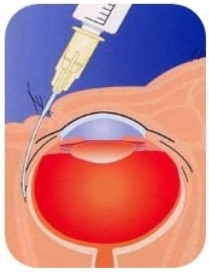
Exclusive and Proprietary Access to the Back of the Eye Through the Suprachoroidal Space ("SCS")

Intravitreal & Periocular

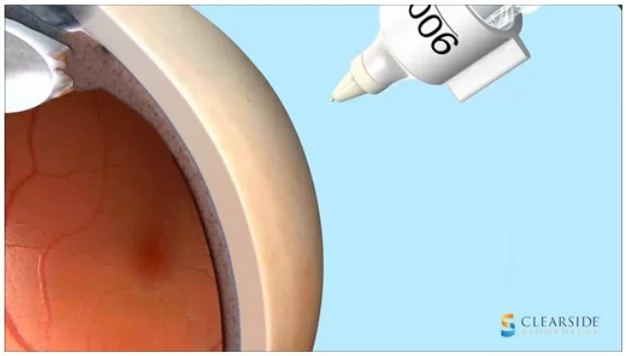


- 0.05 mL bolus at injection site
- Drug diffuses to all areas of the eye including the anterior chamber and lens

- 0.5 mL–1 mL injected into periocular space
- Highly variable drug diffusion across the sclera into the eye

VS

Suprachoroidal



- Fluid flows instantaneously and posteriorly
- Consistent suprachoroidal injection procedure
- Fluid with drug is absorbed into the choroid, retinal pigment epithelium (RPE) and retina

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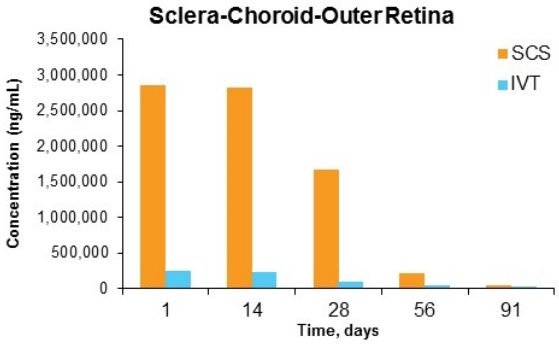
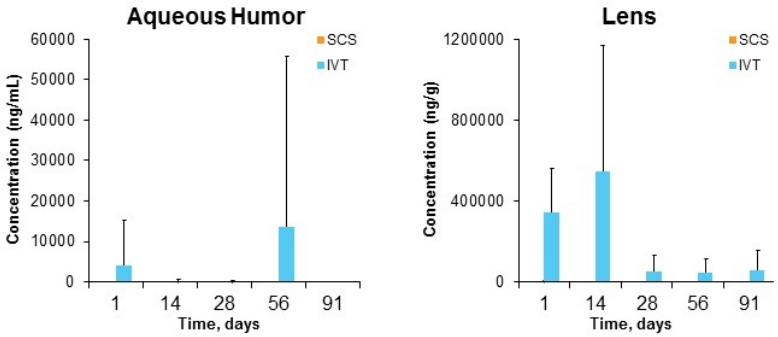
XIPERE™

Designed to Improve Ocular Distribution of Triamcinolone Acetonide (TA)



Over 10X the amount of TA remaining in the choroid and RPE following suprachoroidal administration compared to intravitreal injection



The **anterior segment is relatively spared** following suprachoroidal dosing when compared to intravitreal dosing

Potentially providing improved **visual outcomes**, increased **durability**, reduced **treatment burden that can lead to** improved **benefit to risk**

*Based on pre-clinical studies

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Focused Pipeline of SCS Treatments

For Multiple Blinding Eye Diseases

INDICATION	STUDY DRUG	CURRENT STATUS
Uveitis (macular edema associated with uveitis)	XIPERE (corticosteroid triamcinolone acetonide)	
DME (diabetic macular edema)	XIPERE	
WET AMD	Proprietary Compound(s)	
DME	Proprietary Compound(s)	
Usher Syndrome	Gene Therapy	

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UVEITIS

One of the World's Leading Causes of Blindness

The Opportunity

In Treating Macular Edema with Uveitis

Primary Need

1) An approved therapy that targets vision impairment due to the underlying macular edema associated with all uveitis

The Problem

1) Inflammation creates sight threatening macular edema
2) No approved treatment for macular edema associated with uveitis
3) No new local treatments for uveitis since 2009
4) Oral corticosteroids often prescribed when disease is local to the eye

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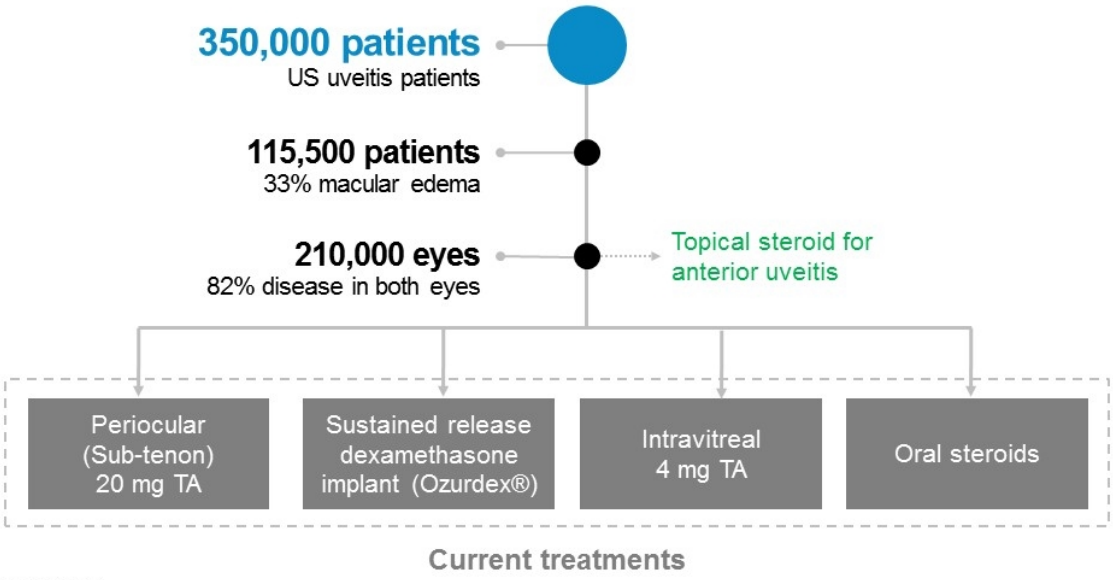
Current Treatment Paradigm for Uveitis

Corticosteroids = most common treatment
for uveitis complications



Note: TA = triamcinolone acetonide

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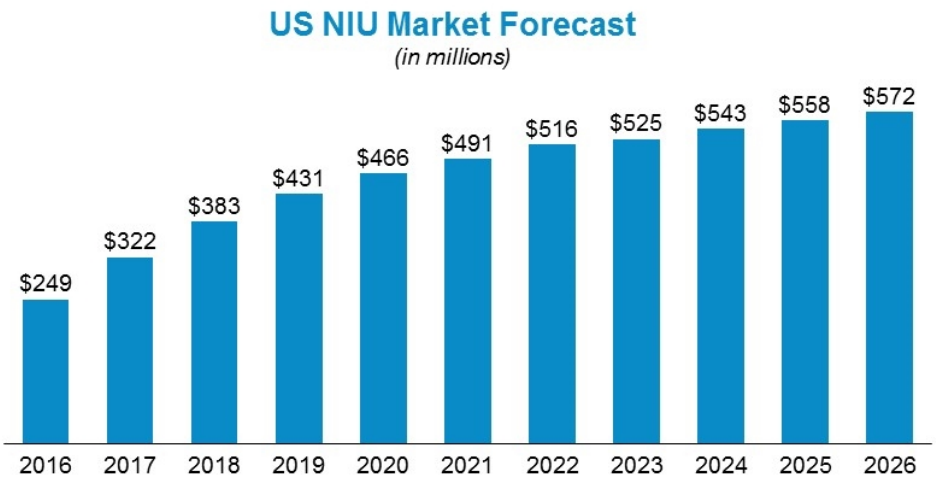
Non-Infectious Uveitis ("NIU") Market is Sizeable and Growing

Anticipated to Grow at 9% YoY



Global uveitis market expected to pass $1B by 2024[2]

Market basket Includes eye drops, ocular injections, corticosteroid implants, systemic corticosteroids, immunomodulatory therapies, and biologics

Sources: 1) Global Data Uveitis Model; Nov. 2017; 2) Variant Research; Uveitis Treatment Market Global Scenario, Market Size, Outlook, Trend and Forecast, 2015-2024.

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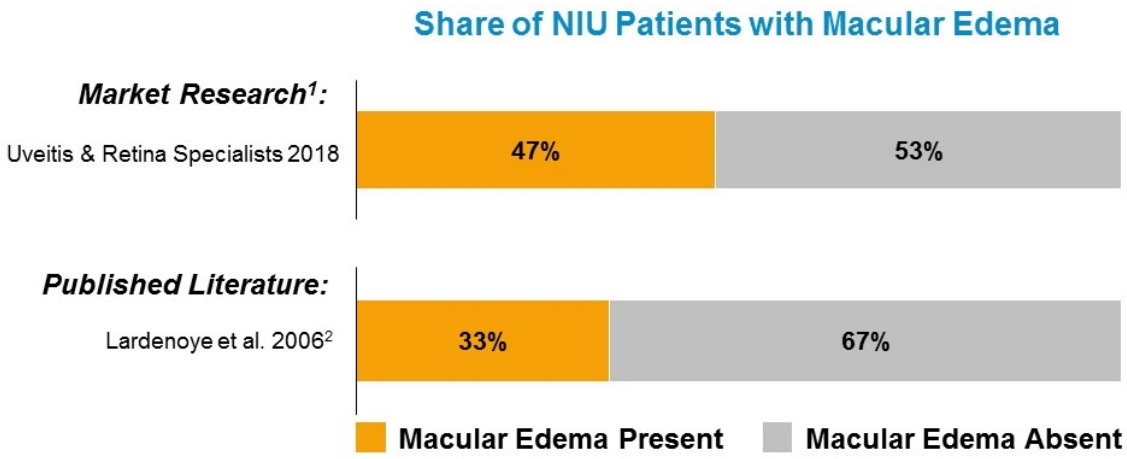
Between 1/3 to 1/2 of NIU Patients Develop Macular Edema



* Ophthalmologists with uveitis / retina fellowship who see ≥ 5 patients with macular edema secondary to NIU

Sources: 1) Target Ophthalmologist ATU, May 2018; 2) Lardenoye, C. et al. Ophthalmology 113.8 (2006): 1446-1449.

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Status of Current Therapy in Macular Edema Associated with Uveitis

The POINT Study[1,3]

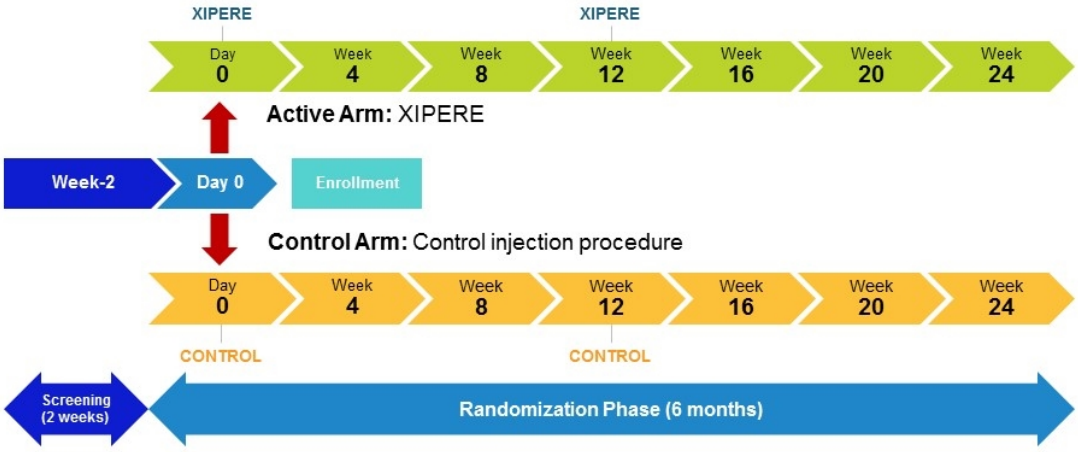
	Periocular (Sub-tenon or orbital floor) 40 mg TA (Kenalog®)	Sustained release dexamethasone implant (Ozurdex®)	Intravitreal 4 mg TA (TRIESENCE®)
Macular Edema	23%	46%	39%
Mean Visual Acuity	4.27	9.5	9.7
Rescue (2nd steroid dose given by week 8 or 12)[2,4]	49%	56%	49%
IOP lowering meds initiated	24%	33%	31%

POINT Study Conclusion: Intravitreal TA and intravitreal dexamethasone implant were superior to Periocular TA in visual acuity improvements in uveitic macular edema subjects

1. Thorne, 2018; study was conducted and funded by the NEI
2. 2nd injections were based on macular edema criteria, either because of not improving or worsening edema
3. Clearside does not make any comparative claims regarding any products included in the POINT study
4. Protocol allowed week 8 for intravitreal and subtenon TA but suggested week 12 in the case of intravitreal Ozurdex

PEACHTREE

Pivotal Phase 3 Clinical Trial Testing XIPERE in CME Involved Uveitis



Two-arm, randomized, controlled, double-masked, multi-center trial at ~60 clinical sites

3:2 randomization of XIPERE vs. sham injection; 160 subjects total

Primary endpoint at 6 months; superiority of best corrected visual acuity outcome from treatment

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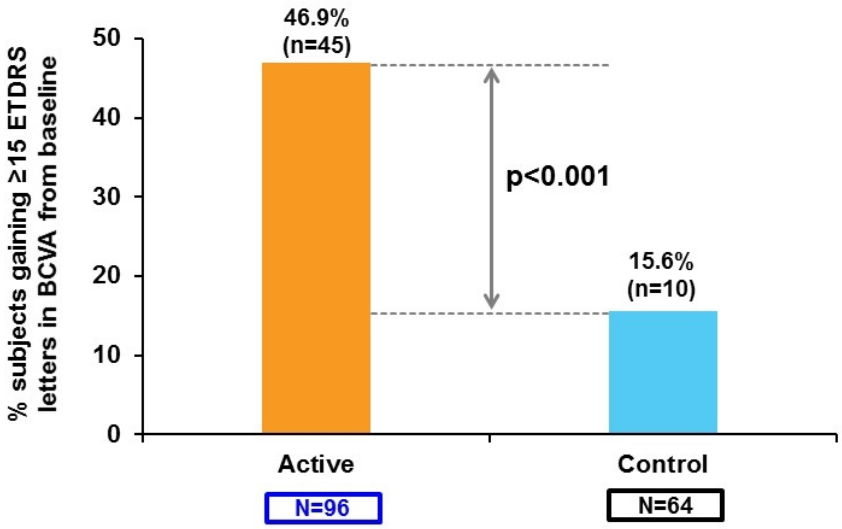
PEACHTREE Met Its Primary Endpoint

ETDRS BCVA

Proportion of subjects in each arm gaining ≥ 15 ETDRS letters in BCVA from baseline at Week 24



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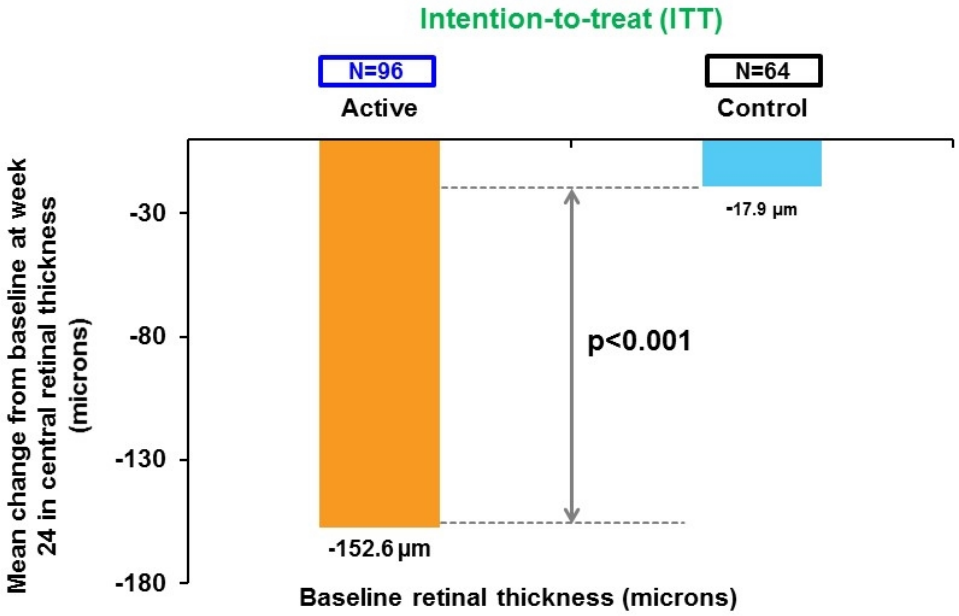
PEACHTREE Met Its Secondary Endpoint

Mean Change from Baseline in CST at Week 24 in Microns



480.9 µm: active arm; 525.4 µm: control arm

Source: Tables 14.2.5.1; 14.2.6.1.1

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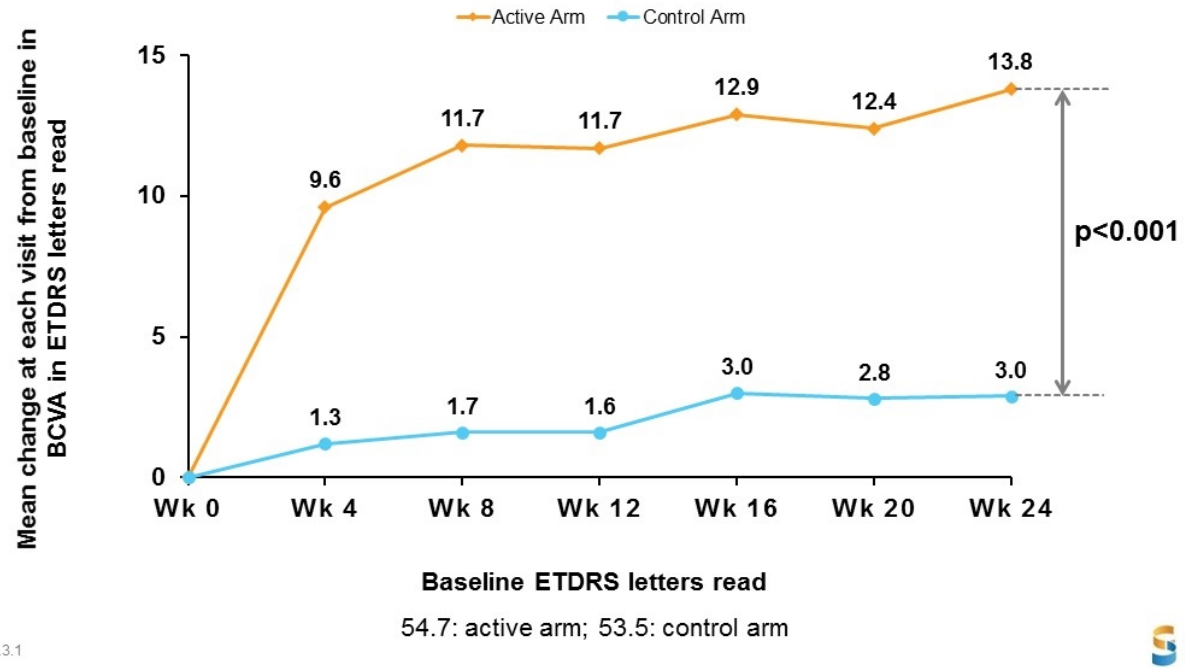
Vision Gained Rapidly and Sustained Through Week 24

Mean Change in BCVA in ETDRS Letters by Visit



54.7: active arm; 53.5: control arm

Source: Table 14.2.3.1

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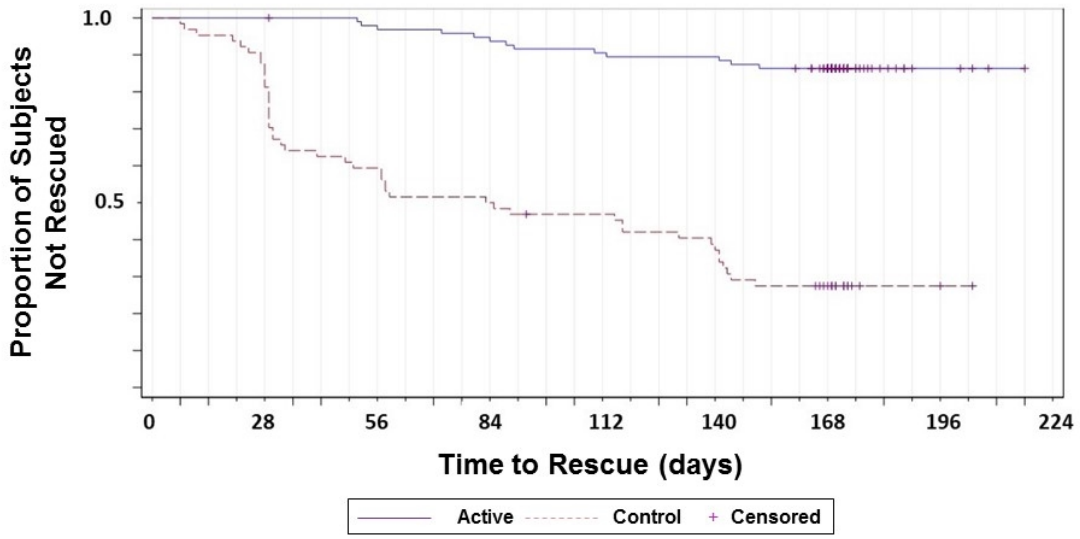
Subject Rescue: Kaplan-Meier

Over **85% of subjects in the Active arm** did not require rescue therapy, **compared to 28% of subjects in the Control arm**



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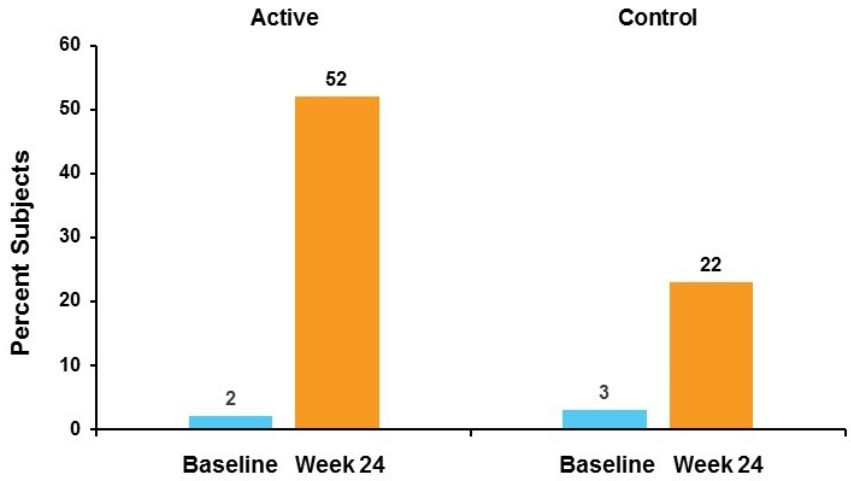
% Subjects Reading 20/40 or Better

Legal Driving Vision in Most States



- Starting at week 8, approx. 50% of the Active subjects could read 70 or more ETDRS letters (20/40)
- This improvement was sustained through the 24 weeks of the trial

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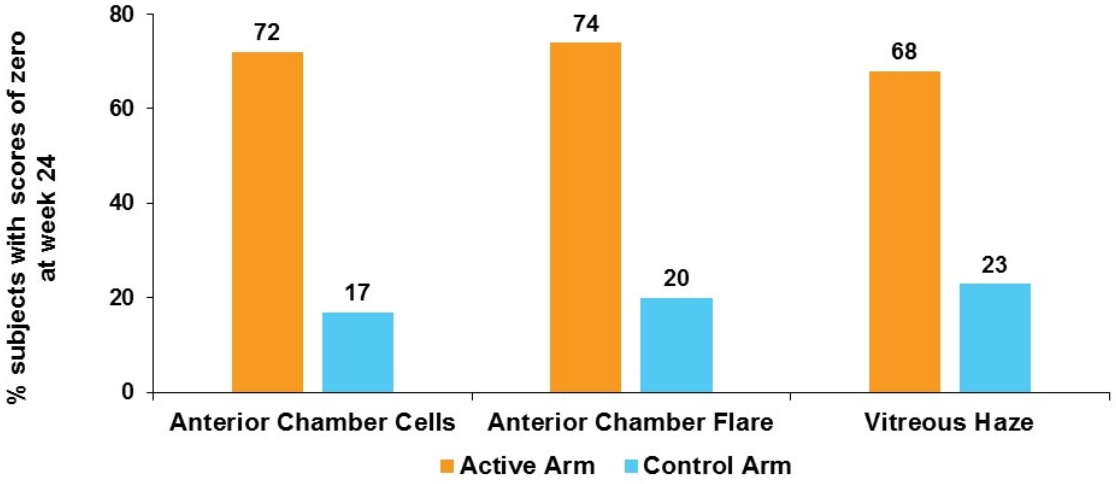
XIPERE

Resolves Inflammation in 2 of 3 Subjects in PEACHTREE



- Resolution of each of these three signs of inflammation on the SUN* scales is clinically and statistically significant
- In subjects with scores of 2 or greater in vitreous haze, 40.9% experienced resolution in the active arm, compared to 0% of subjects in the control arm

*Standardization of Uveitis Nomenclature

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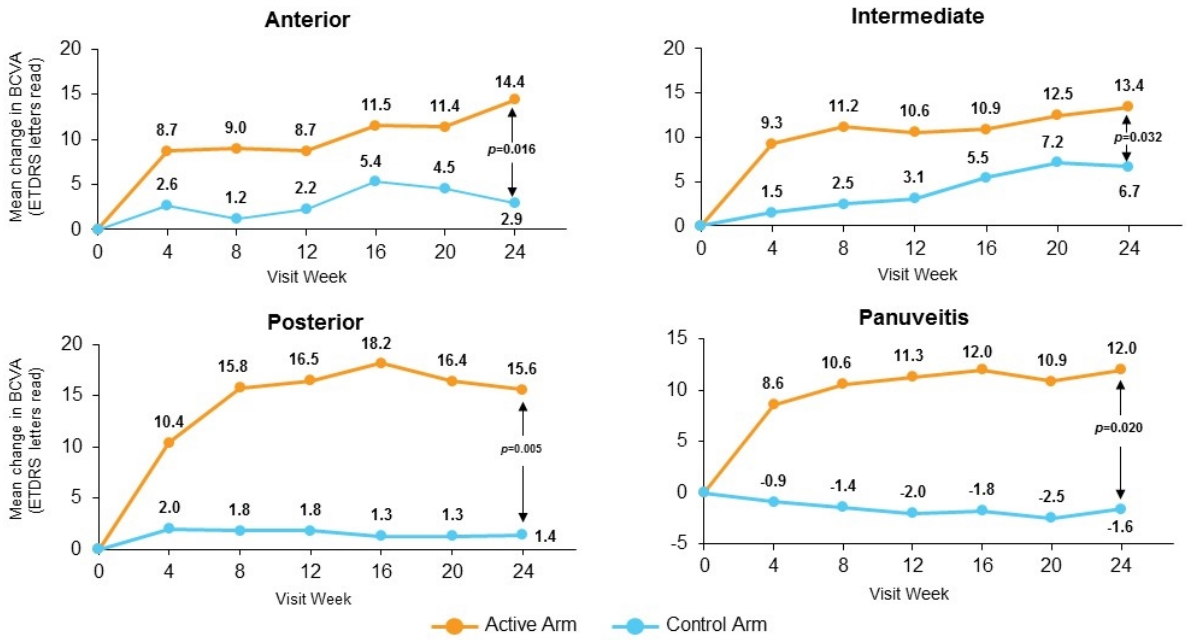
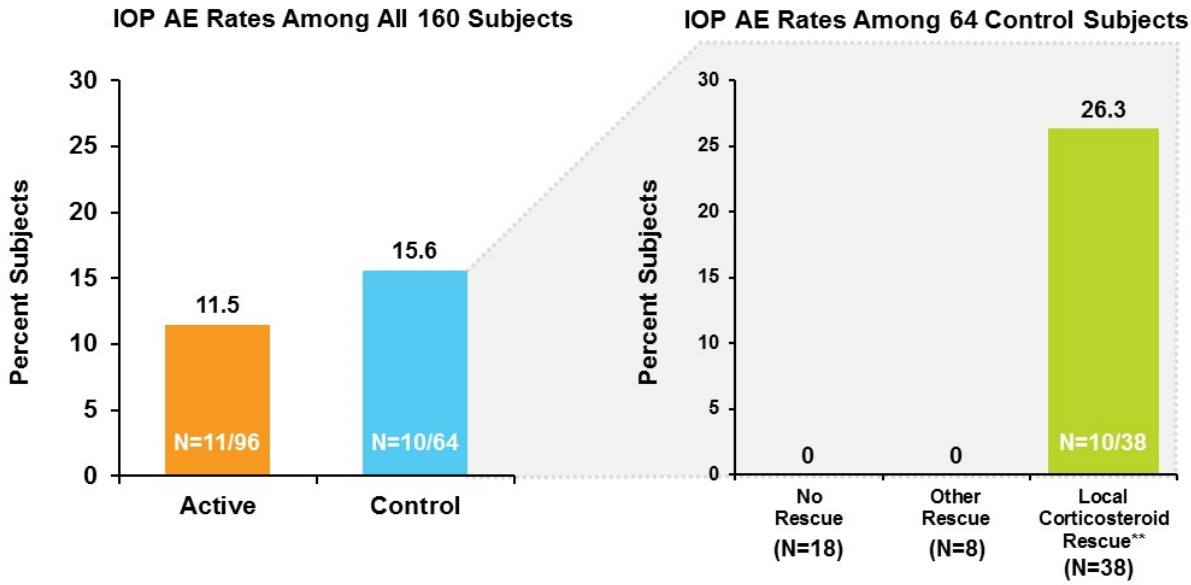
Subjects From Each of the Four Anatomic Subtypes of Uveitis Treated with XIPERE Achieved Significant Visual Improvement



Intention-to-treat population, last observation carried forward.

Safety: Elevated IOP



- IOP lowering medications were initiated in 7.3% and 9.4% subjects in the XIPERE and control arms respectively

"Elevated IOP" includes (a) increased IOP, (b) ocular hypertension, and (c) glaucoma
AE = adverse event; IOP, intraocular pressure.
** intravitreal OZURDEX® (dexamethasone intravitreal implant) and subtenon and intravitreal triamcinolone acetonide

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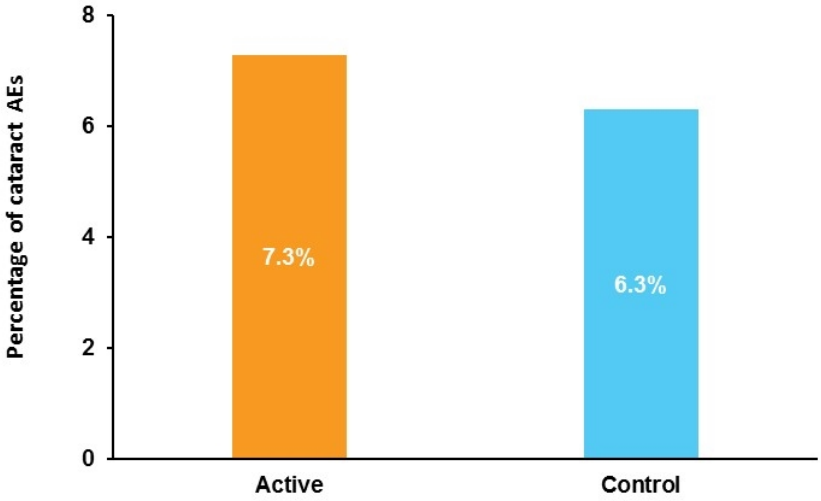
Safety: Cataracts in XIPERE and Control Arms

% Cataract AEs in Each Arm



No cataract surgeries in this trial

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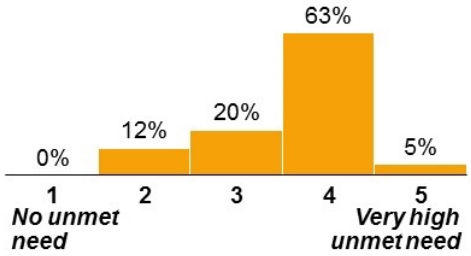
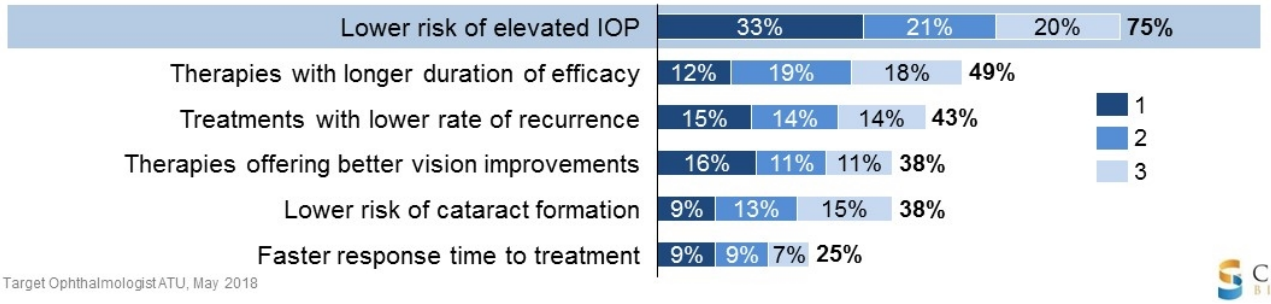
Specialists Perceive High Unmet Need Among Current Therapies, with Greatest Concern Over Elevated IOP

Perceived Unmet Need for treating ME Secondary to NIU



Top Unmet Needs in Treating ME Secondary to NIU



Source: Target Ophthalmologist ATU, May 2018

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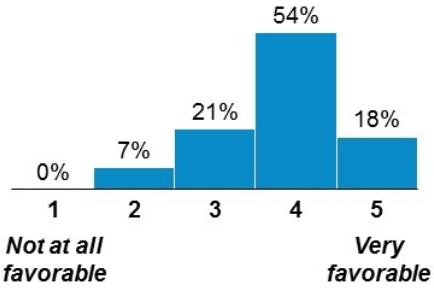
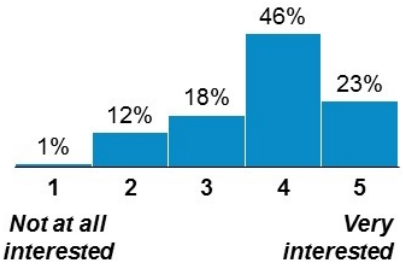
When Introduced to CLS-TA Profile, ~70% of Specialists React Favorably and Are Interested in Using

Overall Reaction to CLS-TA



Interest in Using CLS-TA



"When you've got a drug that is that same you've been using all along but you can deliver more efficiently and comfortably – that's a winner"

-Academic uveitis specialist

Source: Target Ophthalmologist ATU, May 2018

DME

Potential Path Forward for XIPERE as a Monotherapy

The Opportunity
In Treating DME

Primary Need

1) Improved resolution of edema and lower burden of care for diabetic patients

The Problem

1) DME course and response to anti-VEGF injection is largely variable
2) 40% and 55% of patients have continued macular edema in years 2 and 3, respectively, even after monthly intravitreal anti-VEGF injections
3) Need for ongoing monthly intravitreal anti-VEGF therapy results in high burden for DME patients leading to poor compliance

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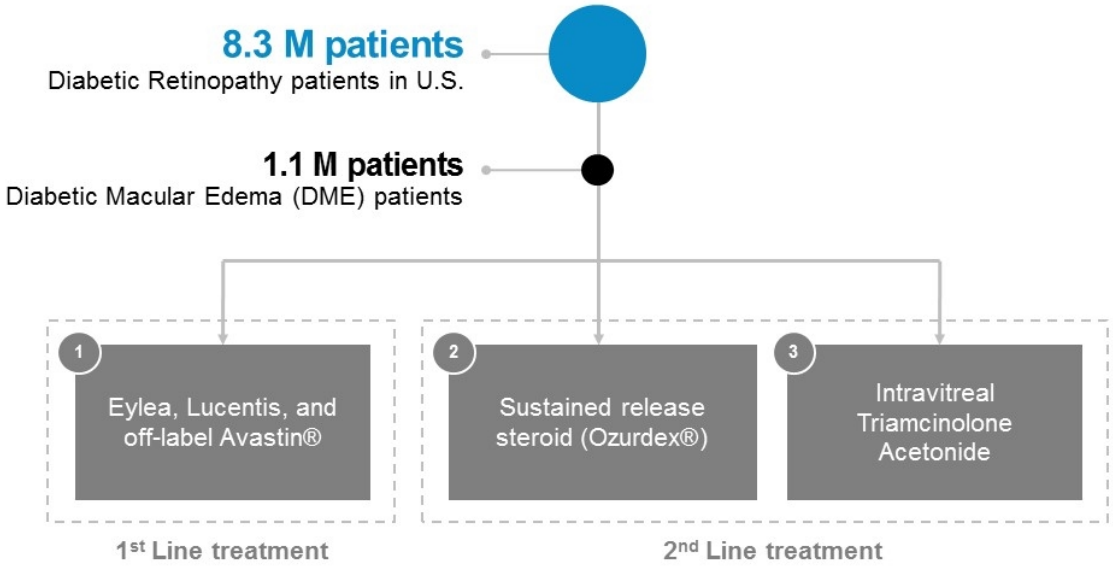
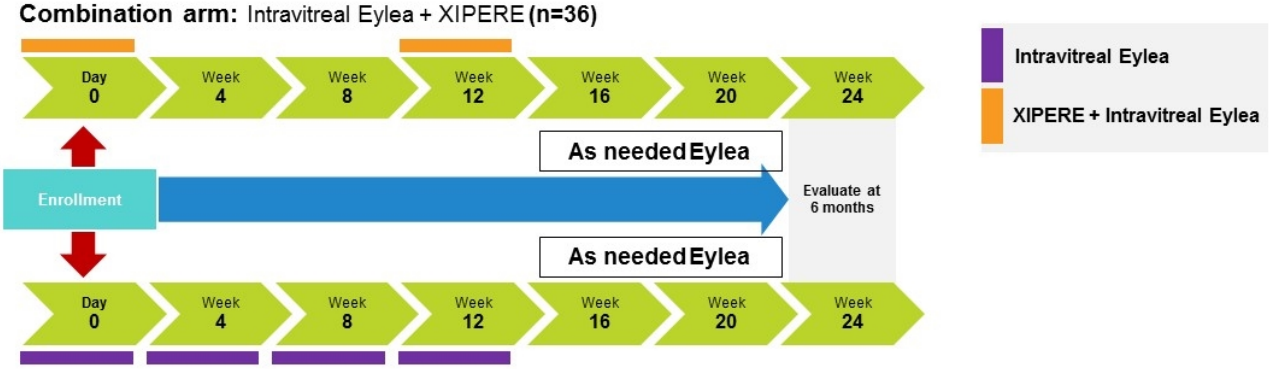
Current Treatment Paradigm for DME



TYBEE

Design for Phase 2 DME Clinical Trial

Combination arm: Intravitreal Eylea + XIPERE **(n=36)**



Control arm: Intravitreal Eylea only **(n=35)**

Any additional treatment based on **as needed** criteria at Week 16 and Week 20 will be intravitreal Eylea

- Controlled, masked, randomized study of combination XIPERE + intravitreal Eylea vs. intravitreal Eylea alone
- Evaluation at Month 6; treatment is based on PRN criteria from Month 3
- Primary outcome measure is comparison of mean change from baseline in BCVA at 24 weeks between the combination arm and the control arm. The study was powered and designed to show that the mean change in BCVA is not different between the two arms.

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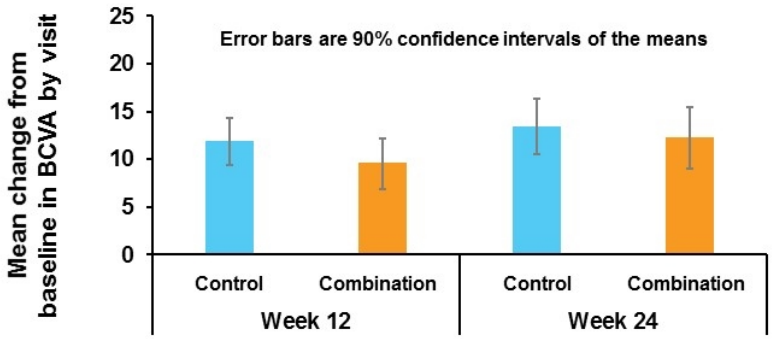
Quarterly Treatments with XIPERE and Anti-VEGF Showed Similar Outcomes to Anti-VEGF Given Monthly



Baseline BCVA in ETDRS letters:
58: control arm; 57: active arm

- XIPERE appears to be able to extend visual gains: data from XIPERE and anti-VEGF at week 12 and week 24 show similar outcomes compared to anti-VEGF alone given monthly

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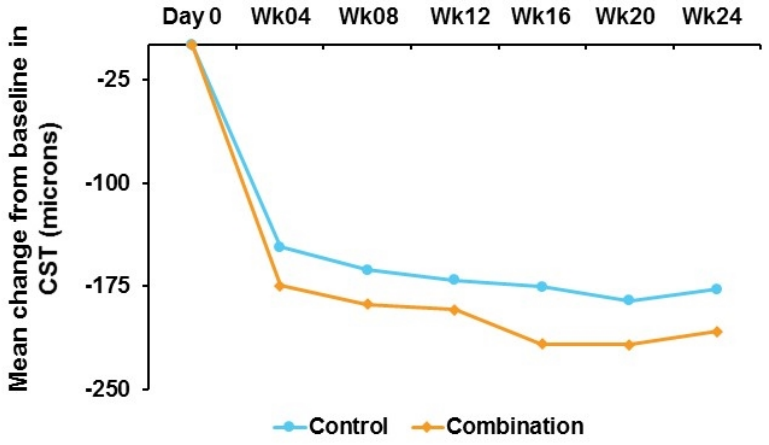
Lesson 1: Central Subfield Thickness (CST) Persisted Through Week 24

Mean Change from Baseline in CST by Visit

Each arm shows a **statistically significant improvement in CST** from baseline at week 24 (*p<0.001)



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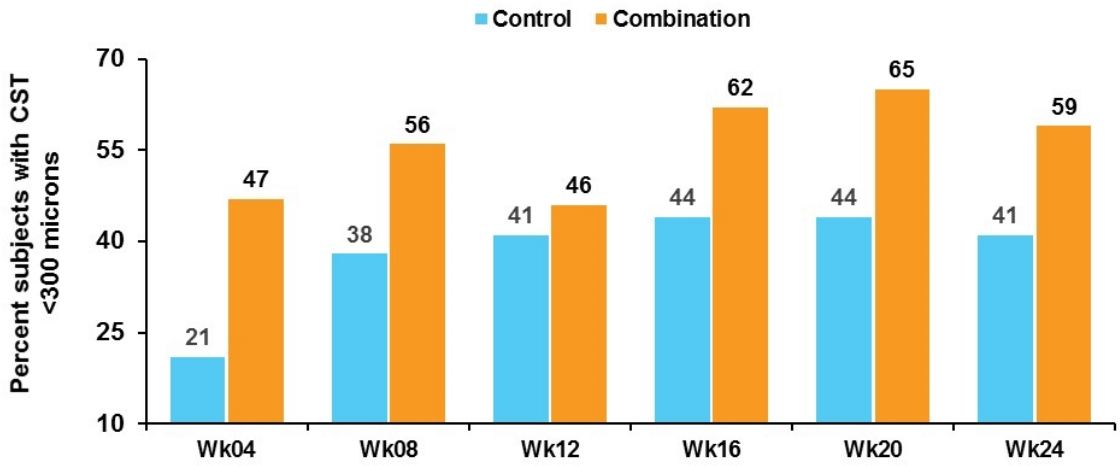
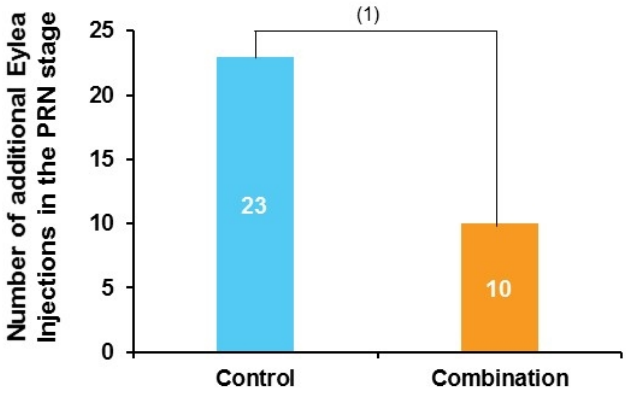
Lesson 2: Resolution* of CST By Visit



- A significantly greater percentage of subjects in the Combination arm showed resolution* in their CST at the week 4 visit ($p<0.01$) compared to those in the Control arm
- The greater resolution in CST appeared to be sustained through each visit through week 24 in the trial

*Defined as CST <300 microns | CST: central subfield thickness

Lesson 3: Combination Arm Achieved Equivalent Vision with Fewer Treatments



- ~50% fewer treatments through week 12
- ~57% fewer treatments in the PRN period (p=0.03)

(1) p=0.03

Path Forward in DME

Treatment burden and patient compliance are significant barriers to optimal treatment in DME

Real world data demonstrates patients missing out on visual gains

- DME subjects receive 3-7 anti-VEGF injections and gain ~5 letters in vision
- Phase 3 trials demonstrate that compliant subjects have the potential to gain ~10 to 12 letters*

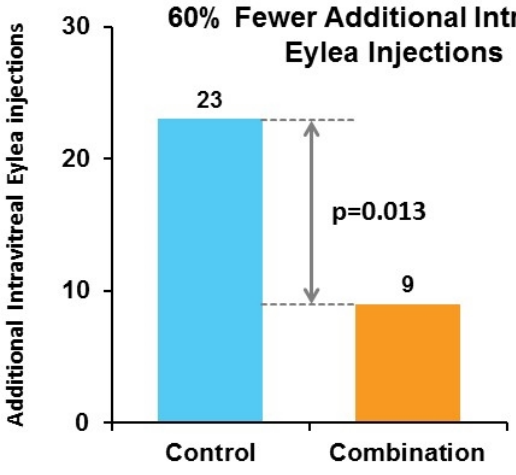
Current anti-VEGFs require retreatment every 4 to 8 weeks

- Subjects gained approximately 10 letters and were maintained for 12 weeks with XIPERE + intravitreal Eylea in TYBEE
- XIPERE has the potential to maintain visual gains on a quarterly dosing regimen and could address treatment burden in DME patients

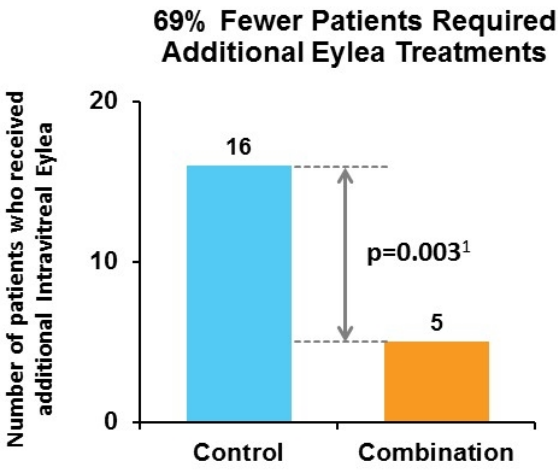
* Lucentis PI, 2018; Eylea PI, 2018
Holekamp AJO July 2018
Ciulla AAO 2018 https://doi.org/10.1016/j.oret.2018.06.004

RVO

TANZANITE Phase 2 Trial: XIPERE with Intravitreal Eylea for Macular Edema Associated with RVO



Intent-to-treat (ITT) population:
N = 46 (23:23)



Intent-to-treat (ITT) population:
N = 46 (23:23)

[1] Based on post-hoc analysis

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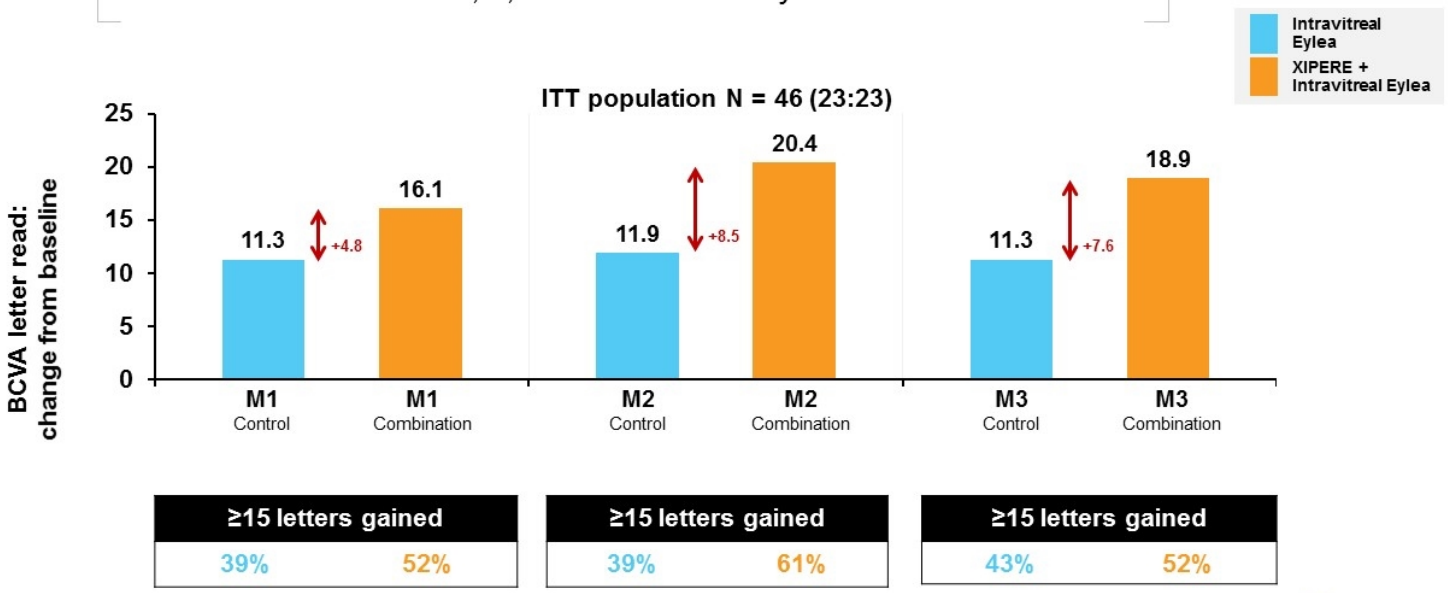
TANZANITE: Improved Visual Acuity Over Time

XIPERE + Intravitreal Eylea resulted in more improved visual acuity at months 1, 2, 3 vs. intravitreal Eylea alone



≥15 letters gained		≥15 letters gained		≥15 letters gained	
39%	52%	39%	61%	43%	52%

M1 = month 1; M2 = month 2; M3 = month 3

TANZANITE

Safety Summary

- All subjects completed the TANZANITE trial
- There were no serious adverse events
- AEs ≥5% in any arm were: conjunctival haemorrhage (8.7%; 4.3%); IOP increased (0%; 8.7%); eye pain (8.7%; 30.4%), ocular hypertension (0%; 8.7%);
- XIPERE and intravitreal Eylea used together in the combination arm was generally well tolerated and there were no unique safety events

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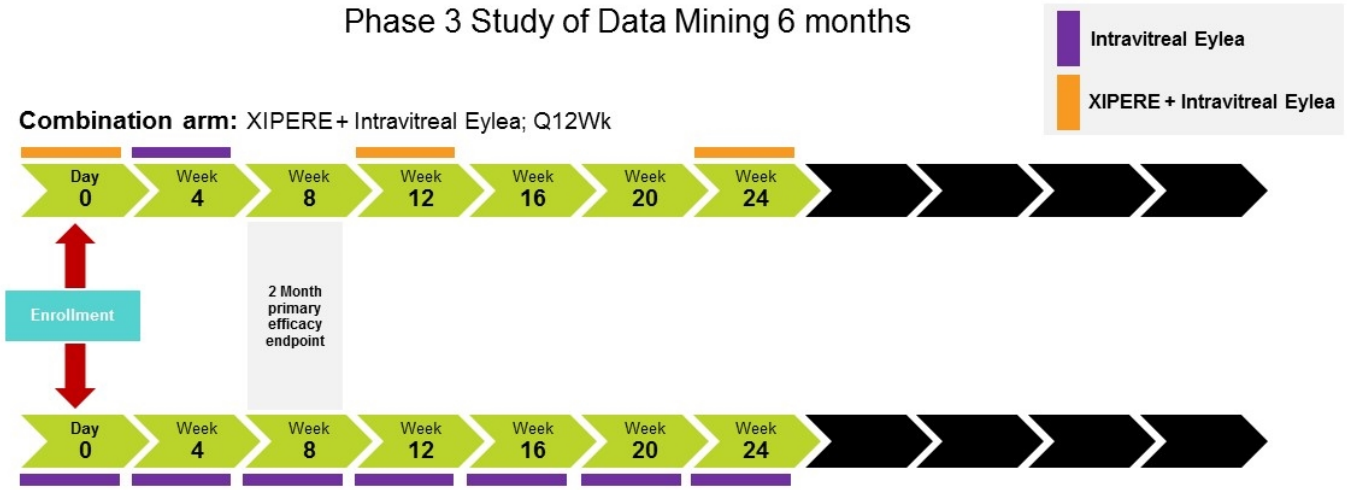
SAPPHIRE

Phase 3 Study of Data Mining 6 months



- Two-arm, randomized, controlled, double-masked, multi-center trial
- 1:1 randomization of XIPERE + intravitreal Eylea vs. intravitreal Eylea alone
- Randomization across similar populations of branch retinal vein occlusion (BRVO) and central retinal vein occlusion (CRVO)

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SAPPHIRE

8-Week Topline Results

- Primary endpoint was to determine proportion of subjects in each arm gaining ≥ 15 ETDRS letters from baseline at eight weeks
- In SAPPHIRE, control and combination were similar and did not meet its primary endpoint
  - ~50% of subjects gained 15 ETDRS letters from baseline in both arms
  - There was not a statistically significant difference between arms
- There was no additional benefit for subjects receiving a corticosteroid together with an intravitreal anti-VEGF agent

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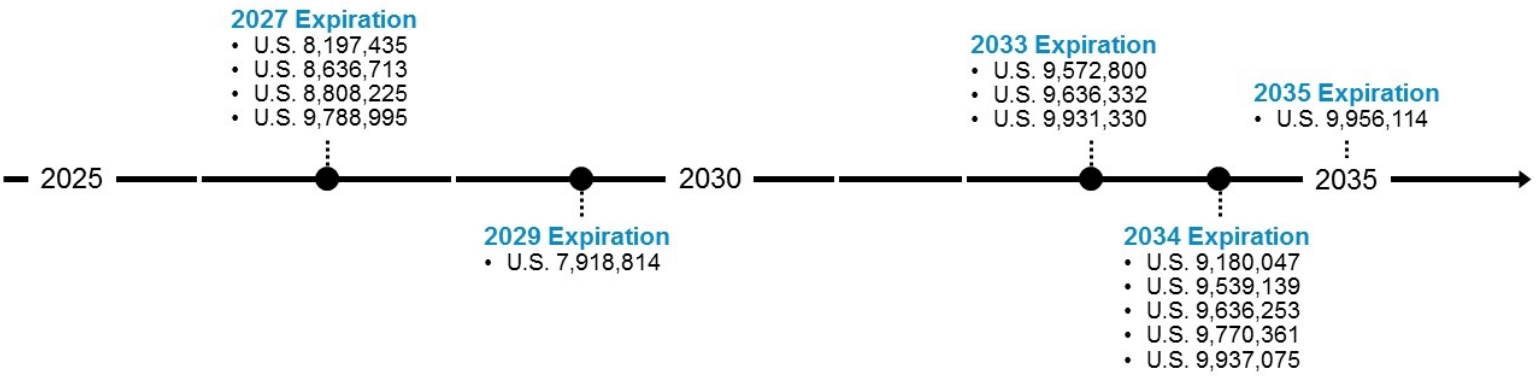
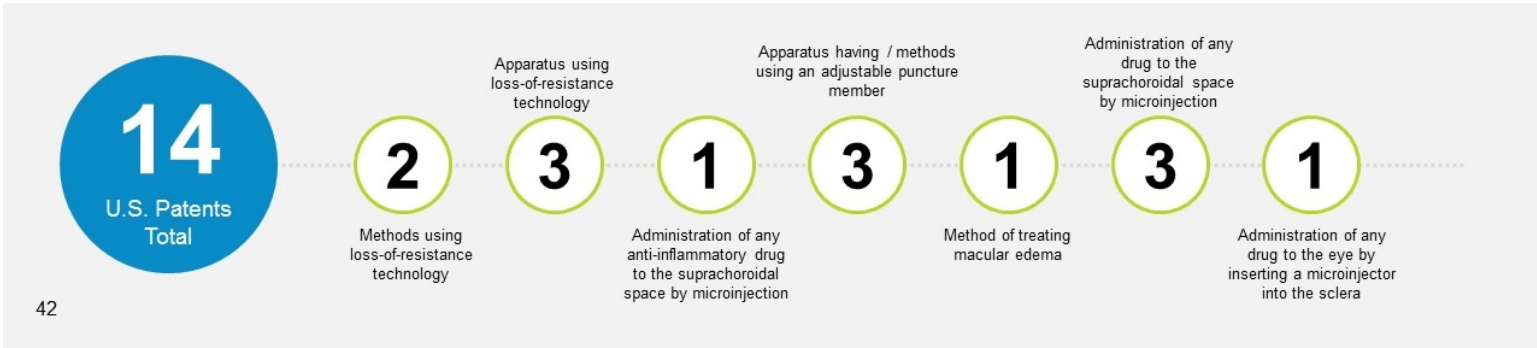
A WORLD WITHOUT BLINDNESS

In Summary

Opportunity is Well Protected





Accomplished Leadership Team With Deep Ophthalmic Experience

	Experience	Years
Daniel White President, CEO and Director	GSK, Stiefel, CIBA Vision, Alimera	25
Thomas Ciulla, M.D., MBA Chief Medical Officer	Spark Therapeutics, Indiana University School of Medicine	27
Charles Deignan Chief Financial Officer	AtheroGenics, AAIPharma, Schering-Plough	27
Brion Raymond Chief Commercial Officer	Genentech, Carl Zeiss Meditec, Xoma	14
Leslie Zacks General Counsel and Chief Compliance Officer	Arbor, Shionogi	24
Rafael Andino VP, Engineering & Manufacturing	CR Bard, CIBA Vision, Dupont, GE, IBM	26
Carol Hoang, Pharm.D. VP, Medical Affairs	DigiSight, Novartis, Genentech, BMS	17
Viral Kansara, Ph.D. VP, Discovery	Novartis, Merck, Alcon	12
Jennifer Kissner, Ph.D. VP, Clinical Development	Alcon, Acucela	17
Rick McElheny VP, Business Development	Sanofi, MEDA, Vidara	18
Lester Rodríguez VP, Quality	Pharma Tech, Ciba Vision, Novartis, Shionogi	30

Ophthalmic Experience

Alcon
ALIMERA SCIENCES
CIBA VISION
Genentech
MERCK
NOVARTIS
SHIONOGI
Spark THERAPEUTICS

Multiple Potential Value Inflection Points

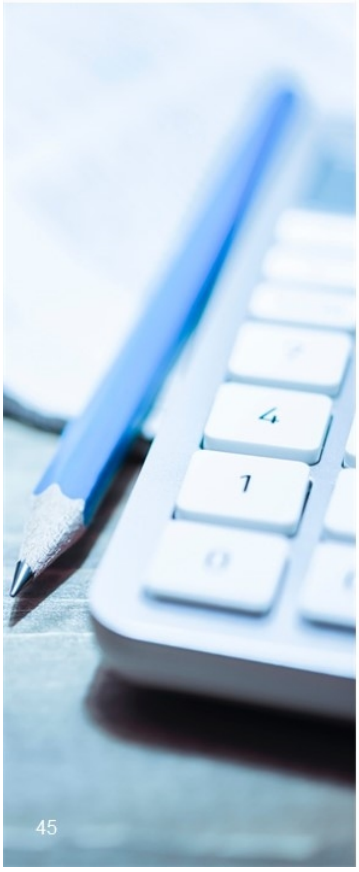
Upcoming Milestones 2019 & 2020

Uveitis

- FDA acceptance of NDA
- PDUFA response
- U.S. Launch
- EMA application

Other Pipeline

- Additional data from 6 month Sapphire results
- DME program update
- Additional non clinical results from 2 preclinical gene therapy programs
- Additional preclinical data on two small molecule programs



Investment Summary

- Lead product candidate, XIPERE, for the treatment of macular edema associated with uveitis
  - Pivotal Phase 3 PEACHTREE trial success
  - NDA submitted in Q4-2018
  - If approved, XIPERE would be the first therapy with this indication
  - Building commercial readiness for potential U.S. launch in 2019
- Exclusive and proprietary access to the back of the eye through the SCS®
- Suprachoroidal platform includes late-stage and nonclinical product candidates targeting multiple blinding eye diseases
- Large and growing retinal market opportunity; ~5 million patients in U.S. treated by approx. 1,900 uveitis and retina specialists

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THANK YOU!

CLEARSIDE® BIOMEDICAL

We see a world without blindness; relentlessly pursuing transformative, elegant, precise solutions to restore and preserve vision.