

**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): March 13, 2019

Clearside Biomedical, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-37783
(Commission File Number)

45-2437375
(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 March 13, 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 business developments. 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.

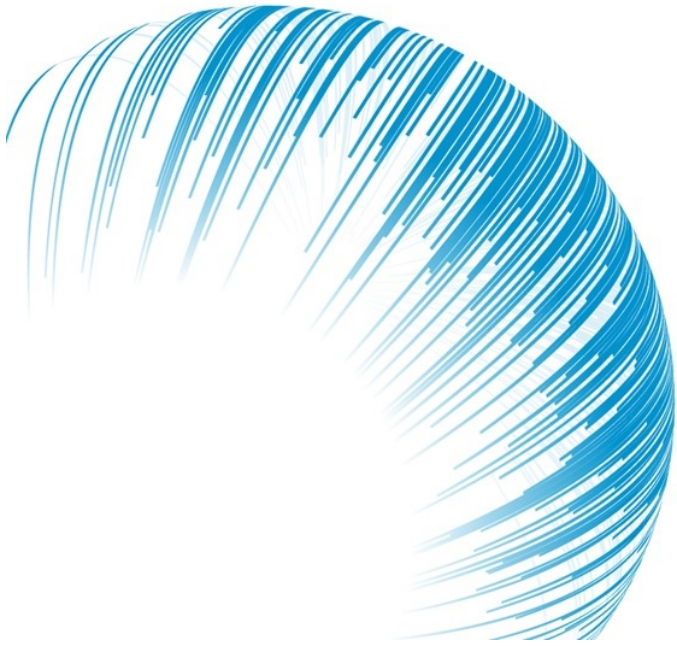
SIGNATURES

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
Charles A. Deignan
Chief Financial Officer

Date: March 13, 2019



Corporate Presentation | March 2019



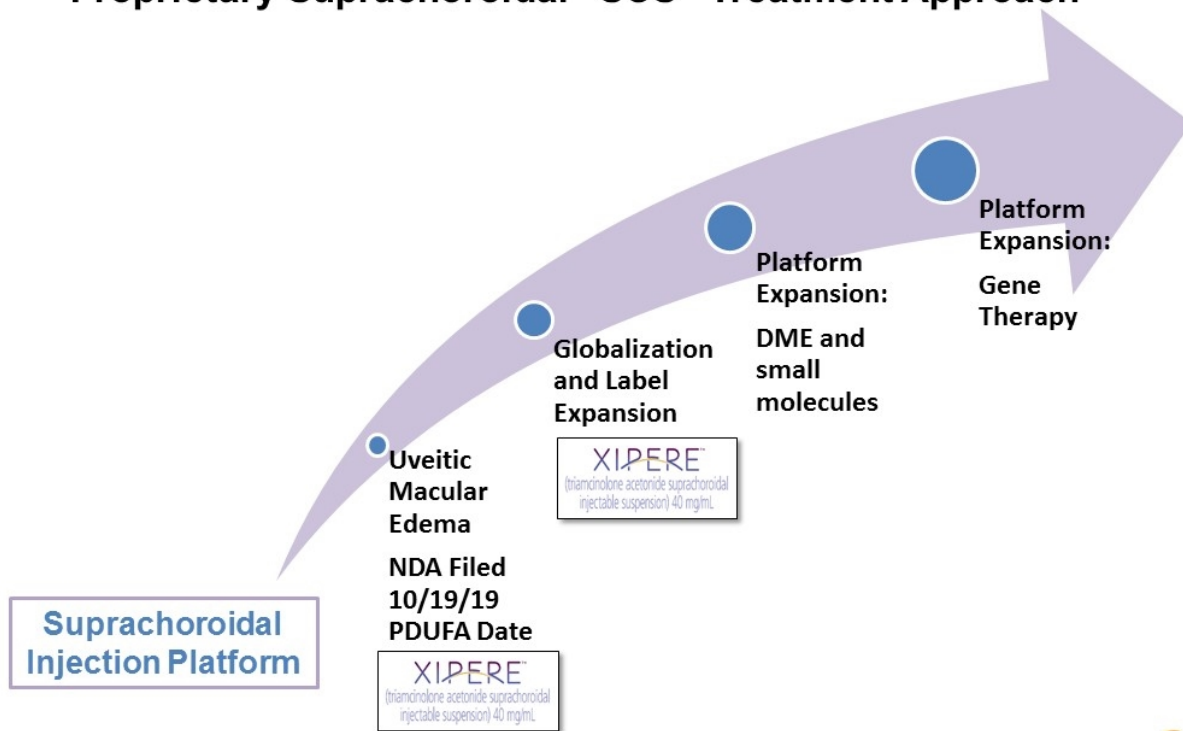
Forward-Looking Statements

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.

Proprietary Suprachoroidal "SCS" Treatment Approach



3

XIPERE (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection is an investigational product under FDA review.

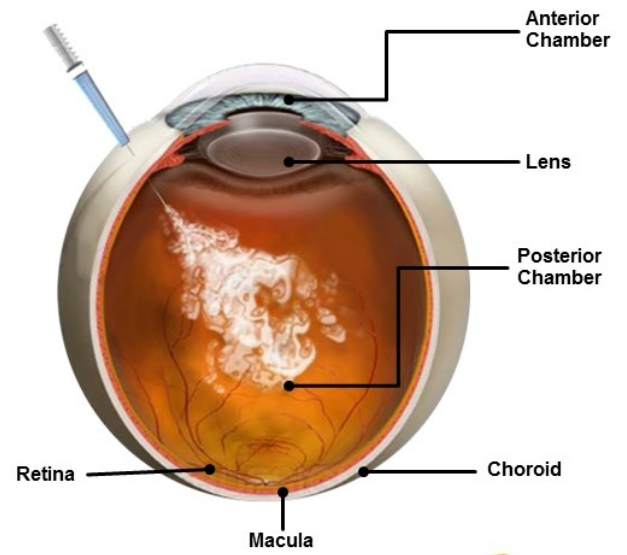
Retinal Diseases

~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

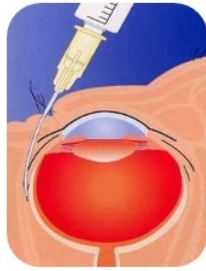


Treatment via intravitreal injection



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

Intravitreal & Periocular



VS

Suprachoroidal



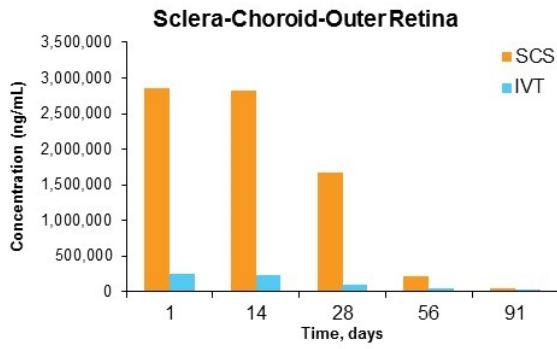
- 0.05 mL bolus at injection site
- Drug diffuses to all areas of the eye including the anterior chamber and lens

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

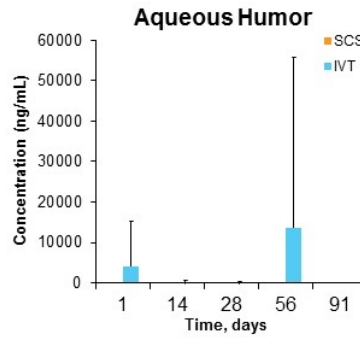
- Fluid flows instantaneously and posteriorly
- Consistent suprachoroidal injection procedure
- Fluid with drug is absorbed into the choroid, retinal pigment epithelium (RPE) and retina

XIPERE

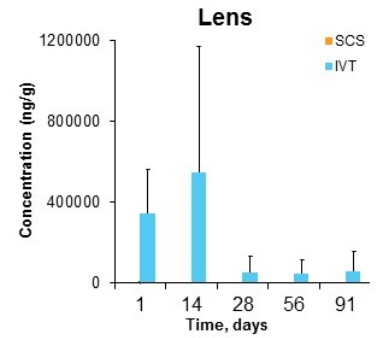
Designed to Improve Ocular Distribution of Triamcinolone Acetonide (TA)



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**

Focused Pipeline of SCS Treatments For Multiple Blinding Eye Diseases

INDICATION	STUDY DRUG	CURRENT STATUS				
Uveitis (macular edema associated with uveitis)	XIPERE (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
DME (diabetic macular edema)	XIPERE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
WetAMD	Proprietary Compound(s)	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
DME	Proprietary Compound(s)	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA
Usher Syndrome	Gene Therapy	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA



UVEITIS

One of the World's Leading Causes of Blindness



The Opportunity

First Treatment for Macular Edema Associated with Uveitis

Primary Need

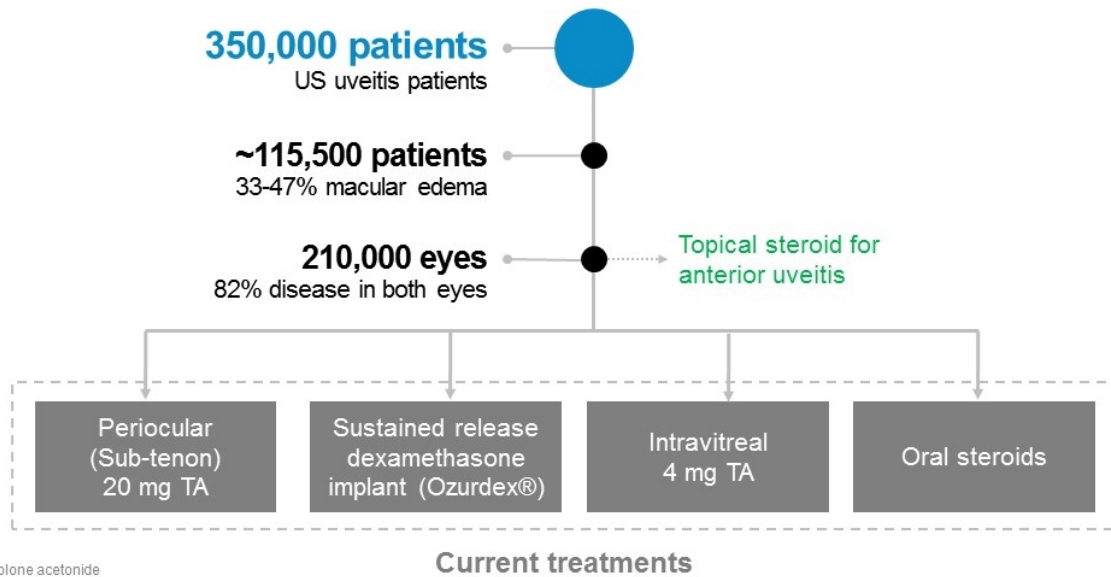
- 1) An approved therapy that targets vision impairment due to the underlying macular edema associated with all uveitis

The Problem

- 1) Inflammation creates sight threatening macular edema
- 2) No approved treatment for macular edema associated with uveitis
- 3) No approved treatments for all anatomic locations of uveitis
- 4) Oral corticosteroids often prescribed when disease is local to the eye

Current Treatment Paradigm for Uveitis

Corticosteroids = most common treatment for uveitis complications



Note: TA = triamcinolone acetonide

* 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.

Status of Current Therapy in Macular Edema Associated with Uveitis The POINT Study^{1,3}

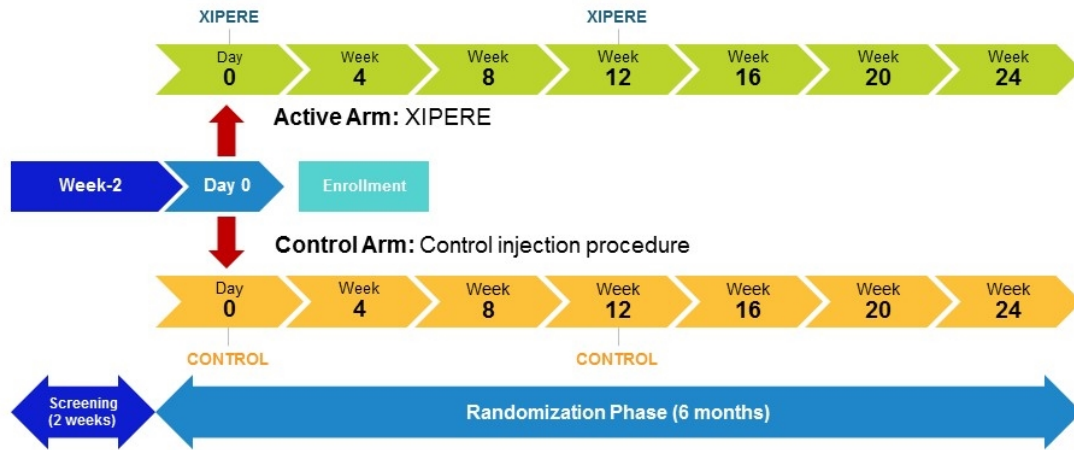
	Periocular (Sub-tenon or orbital floor) 40 mg TA (Kenalog®)	Sustained release dexamethasone implant (Ozurdex®)	Intravitreal 4 mg TA (TRIESENCE®)
Macular Edema	23%	46%	39%
Mean Visual Acuity	4.27	9.5	9.7
Rescue (2 nd steroid dose given by week 8 or 12) ^{2,4}	49%	56%	49%
IOP lowering meds initiated	24%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

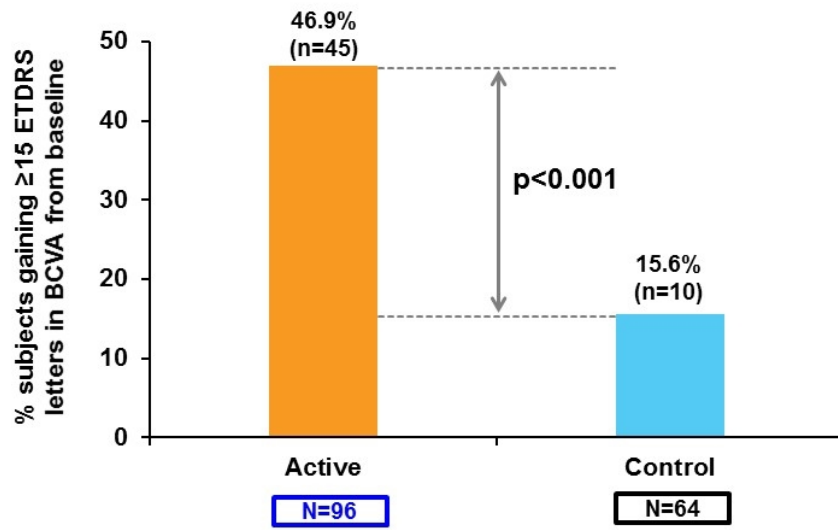
3:2 randomization of XIPERE vs. sham injection; 160 subjects total

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

PEACHTREE Met Its Primary Endpoint

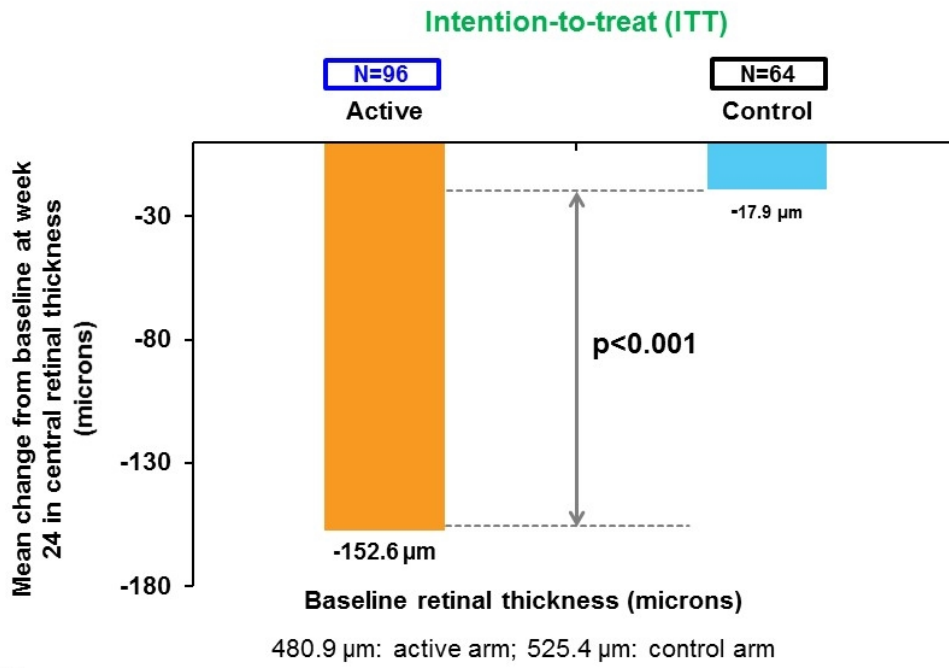
ETDRS BCVA

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



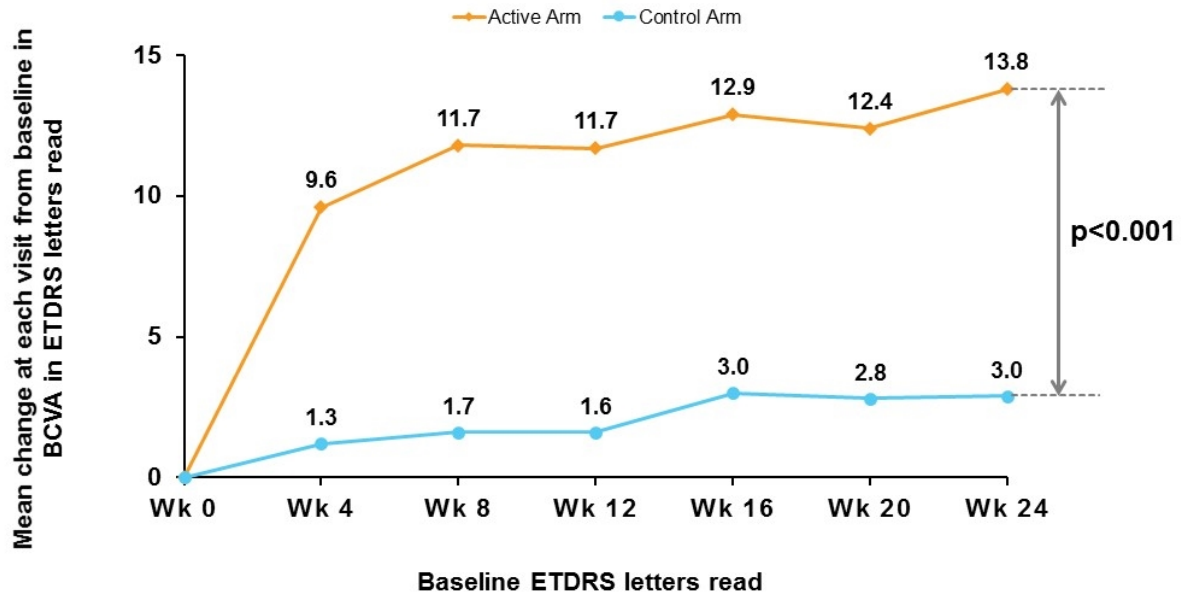
PEACHTREE Met Its Secondary Endpoint

Mean Change from Baseline in CST at Week 24 in Microns



Vision Gained Rapidly and Sustained Through Week 24

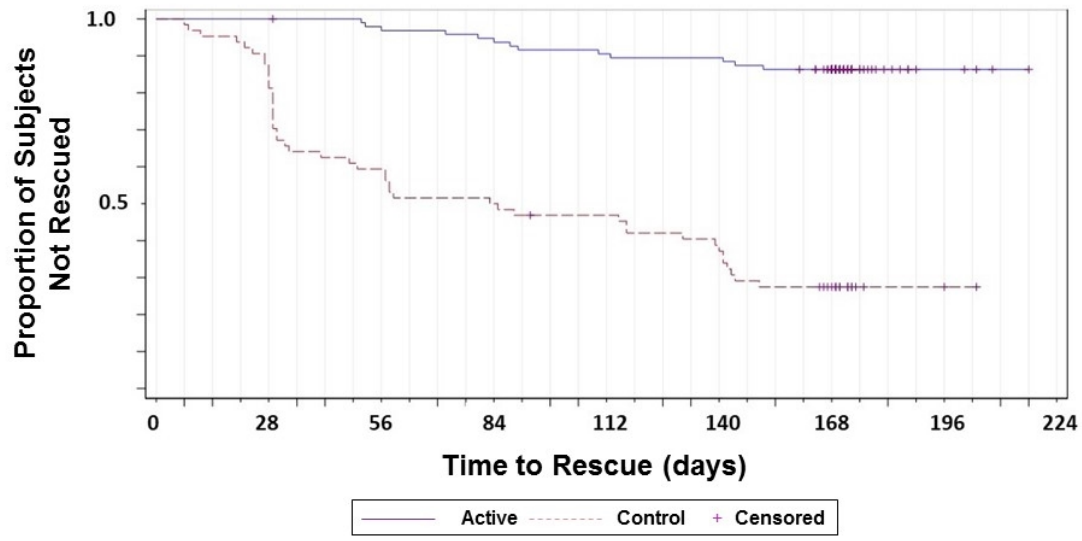
Mean Change in BCVA in ETDRS Letters by Visit



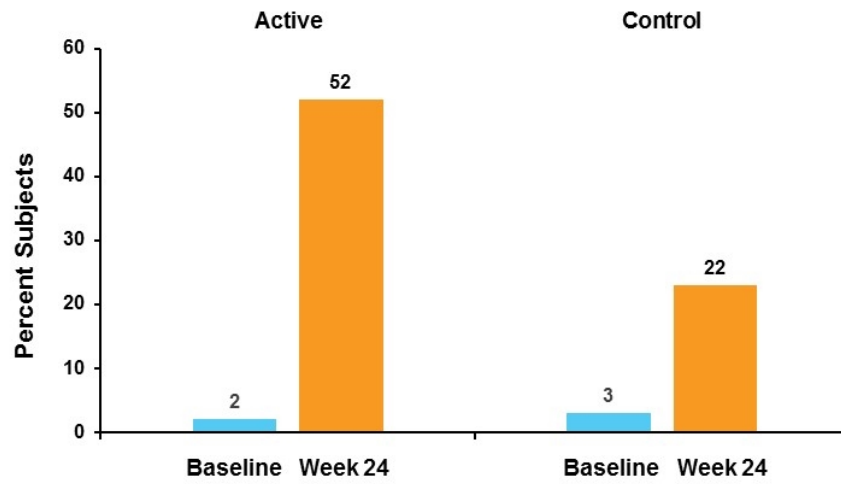
Baseline ETDRS letters read
54.7: active arm; 53.5: control arm

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**



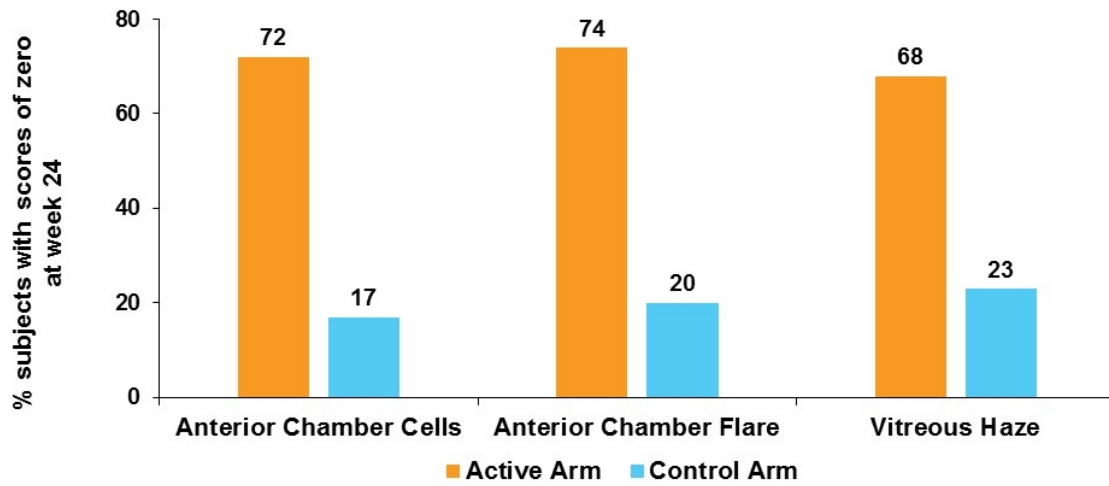
% Subjects Reading 20/40 or Better Legal Driving Vision in Most States



- 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

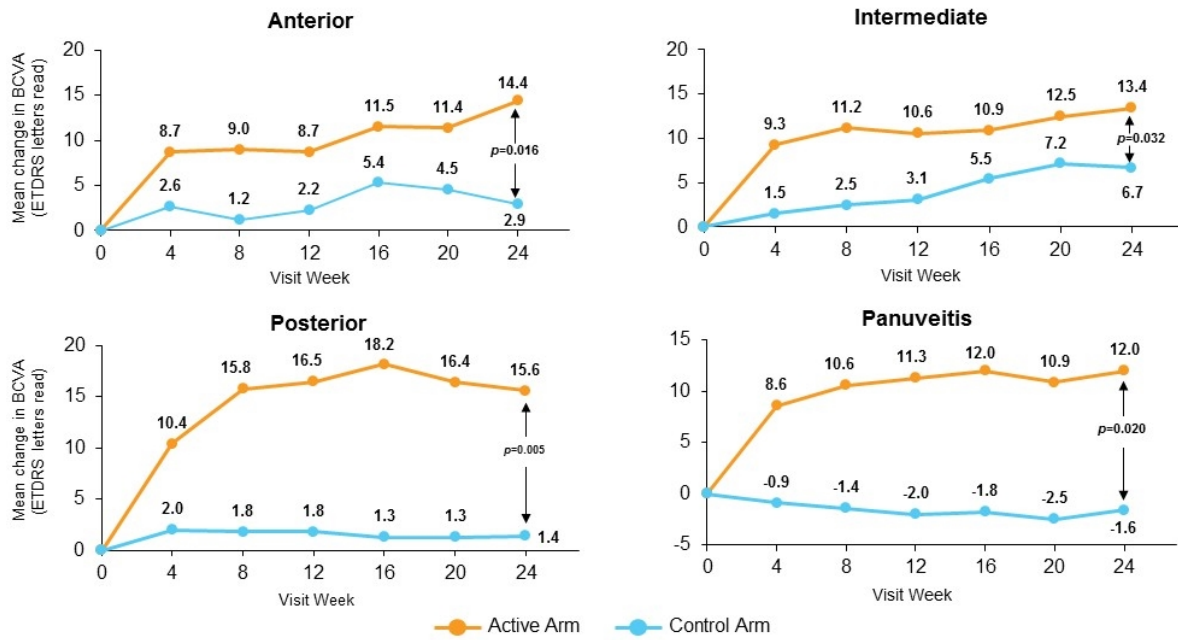
XIPERE

Resolved Inflammation in 2 of 3 Subjects in PEACHTREE

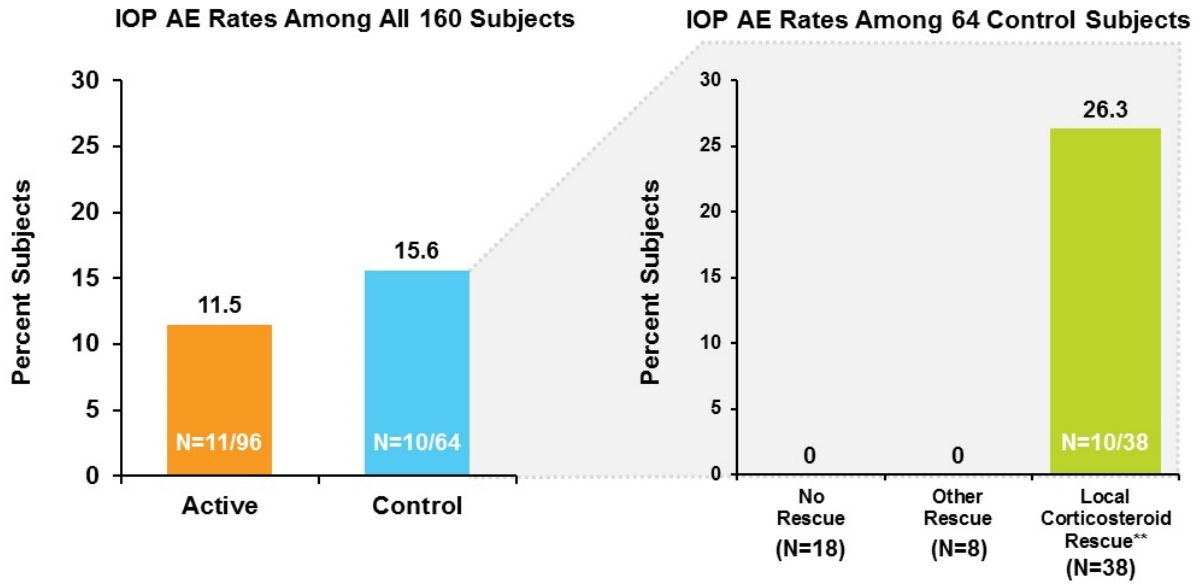


- Resolution of each of these three signs of inflammation on the SUN* scales is clinically and statistically significant
- In subjects with scores of 2 or greater in vitreous haze, 40.9% experienced resolution in the active arm, compared to 0% of subjects in the control arm

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



Safety: Elevated IOP

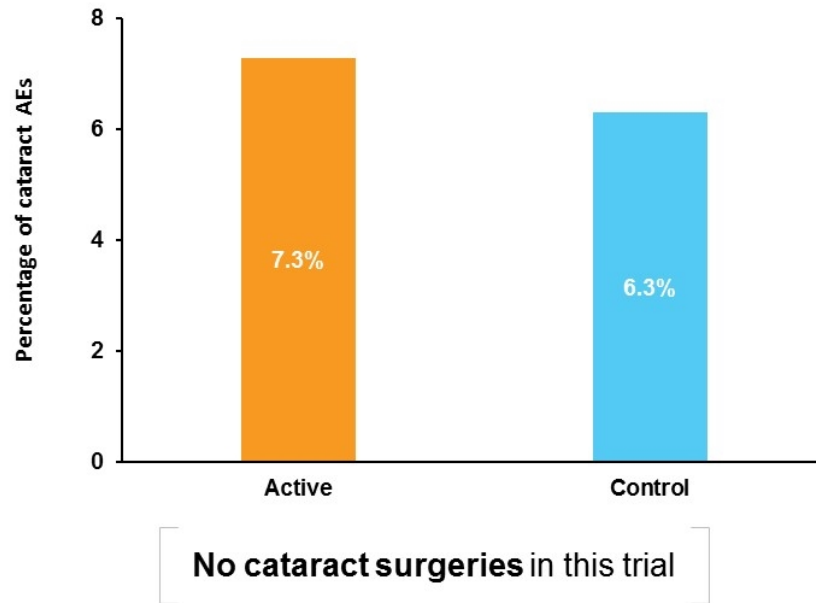


- IOP lowering medications were initiated in 7.3% and 9.4% subjects in the XIPERE and control arms respectively

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

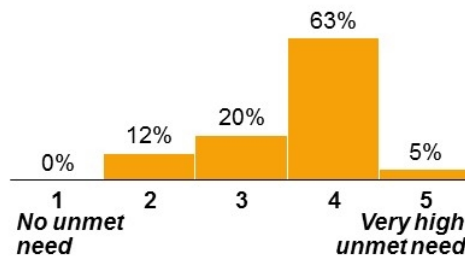
Safety: Cataracts in XIPERE and Control Arms

% Cataract AEs in Each Arm

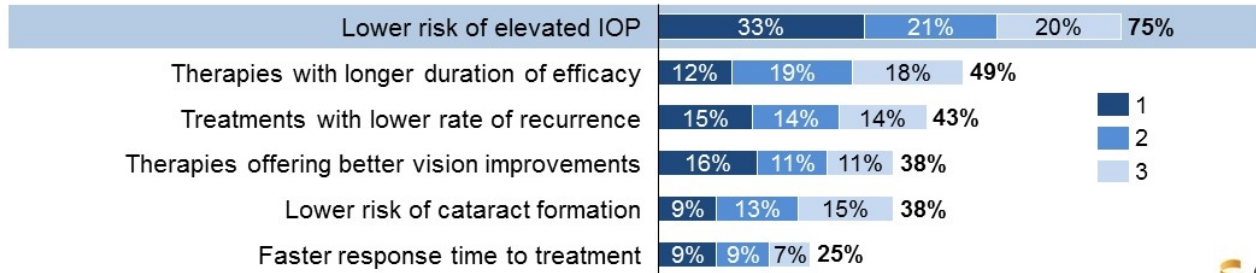


Specialists Perceive High Unmet Need Among Current Therapies, with Greatest Concern Over Elevated IOP

Perceived Unmet Need for treating ME Secondary to NIU

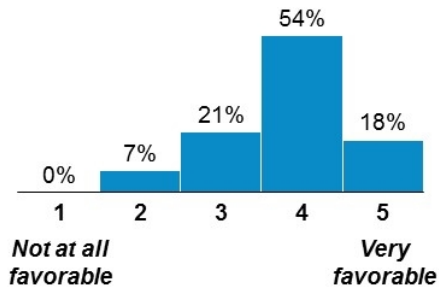


Top Unmet Needs in Treating ME Secondary to NIU

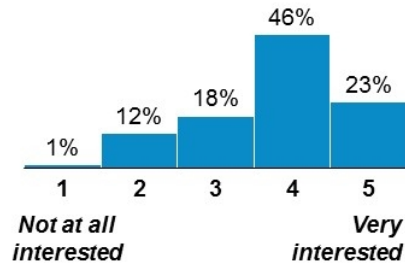


When Introduced to XIPERE Profile, ~70% of Specialists React Favorably and Are Interested in Using

Overall Reaction to XIPERE



Interest in Using XIPERE



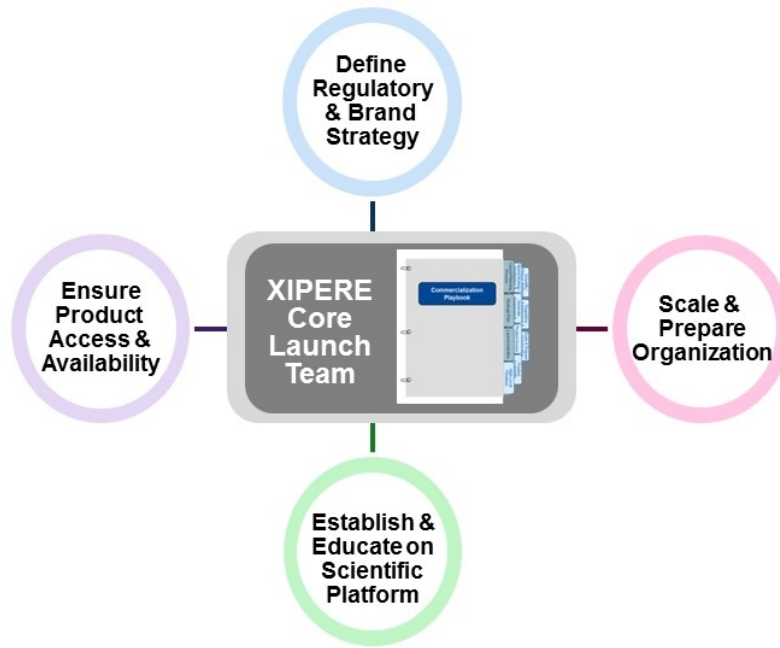
“When you’ve got a drug that is that same you’ve been using all along but you can deliver more efficiently and comfortably – that’s a winner”

-Academic uveitis specialist

Preparing for Launch

Key Focus Areas:

- Physician and patient education
- Injection training for the physicians
- Reimbursement support



A photograph of a male doctor in blue scrubs with a stethoscope around his neck, leaning over a female patient. He is examining her eye with a small instrument. The patient is lying down, looking up at the doctor. The scene is brightly lit, suggesting a clinical setting.

DME

Potential Path Forward for
XIPERE as a Monotherapy



The Opportunity In Treating DME

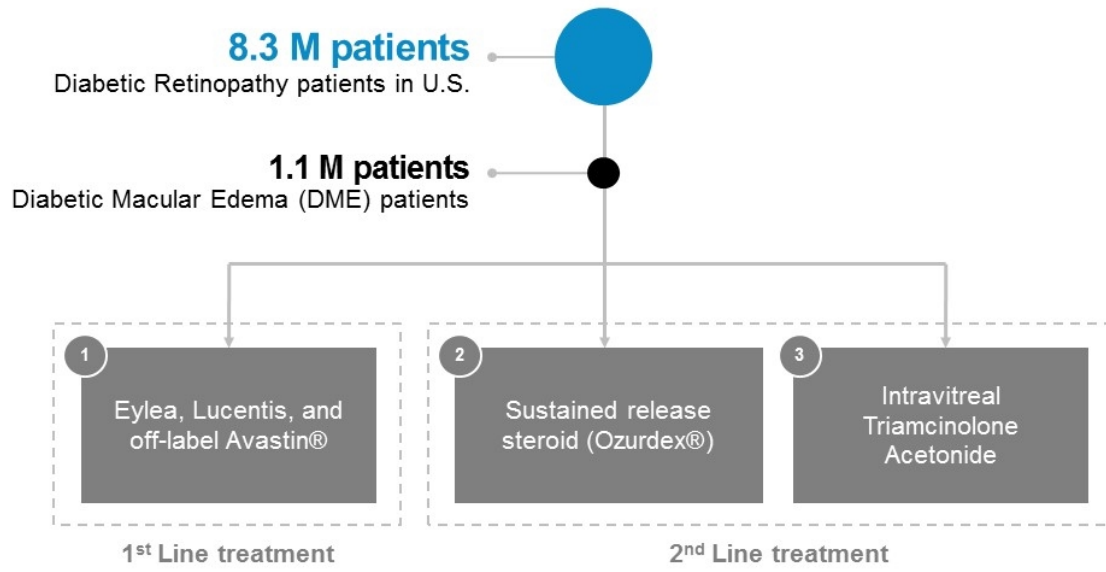
Primary Need

- 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) High burden for DME patients leading to poor compliance

Current Treatment Paradigm for DME



TYBEE

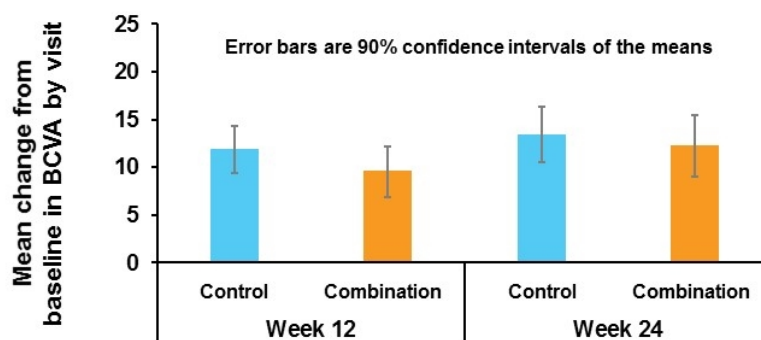
Design for Phase 2 DME Clinical Trial



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.

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



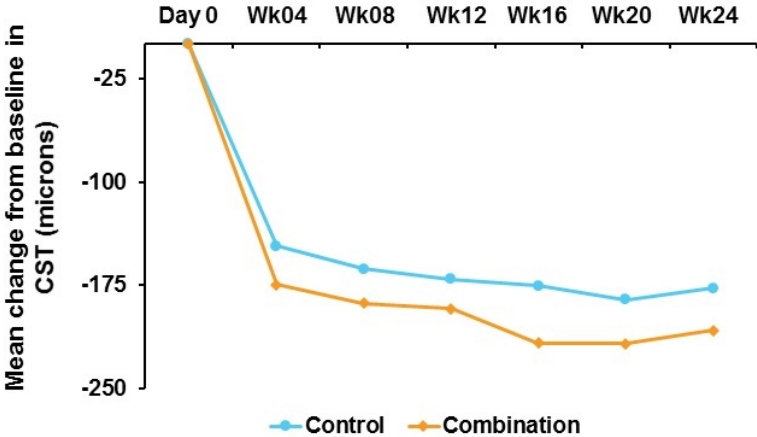
Baseline BCVA in ETDRS letters:

58: control arm; 57: active arm

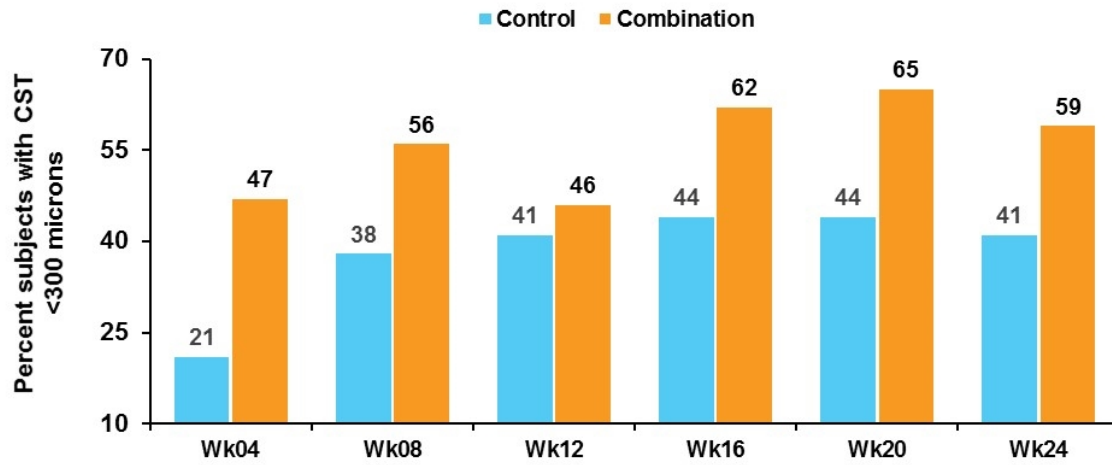
- XIPERE appears to be able to extend visual gains: data from XIPERE and anti-VEGF at week 12 and week 24 show similar outcomes compared to anti-VEGF alone given monthly

Lesson 1: Improved Central Subfield Thickness (CST)

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

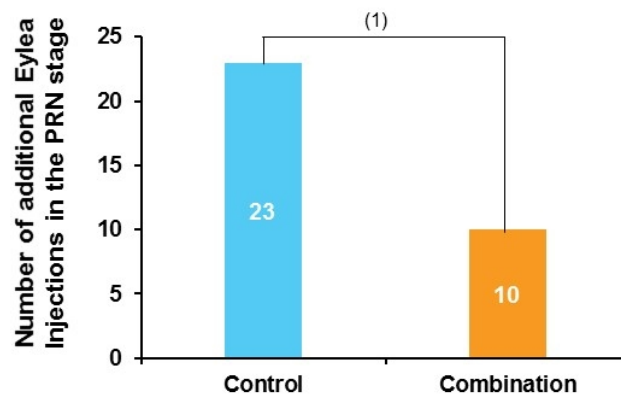


Lesson 2: Resolution* of CST By Visit



- 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

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)

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

Plan to advance clinical development of XIPERE monotherapy into the therapeutic rotation with anti-VEGF for DME

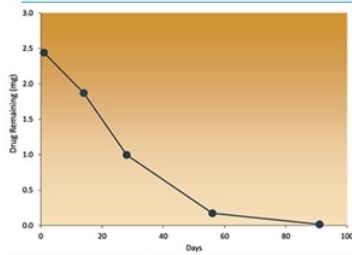
The SCS Platform

Nonclinical

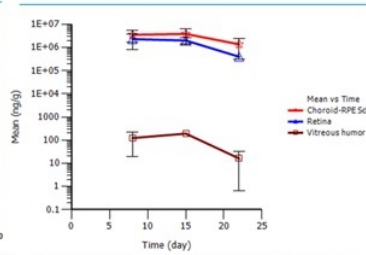
Like TA, Small Molecules offer Unique Distribution and Durability

Small molecule compounds evaluated exhibiting lower solubility result in favorable pharmacokinetic and ocular distribution profiles.

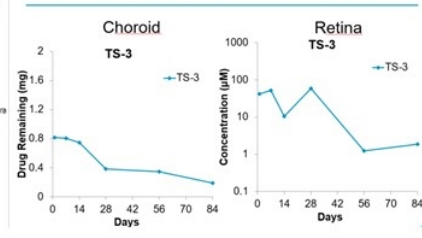
Compound A: Drug Remaining RPE/Sclera/Choroid



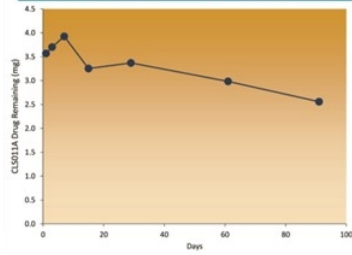
Compound C: Tissue Concentration Profile



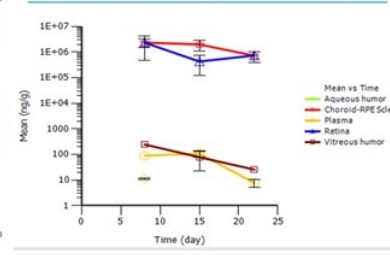
Compound E Tissue Concentration



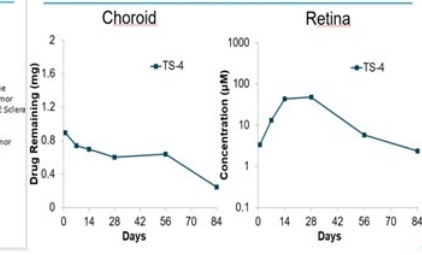
Compound B: Drug Remaining RPE/Sclera/Choroid



Compound D: Tissue Concentration Profile



Compound F Tissue Concentration

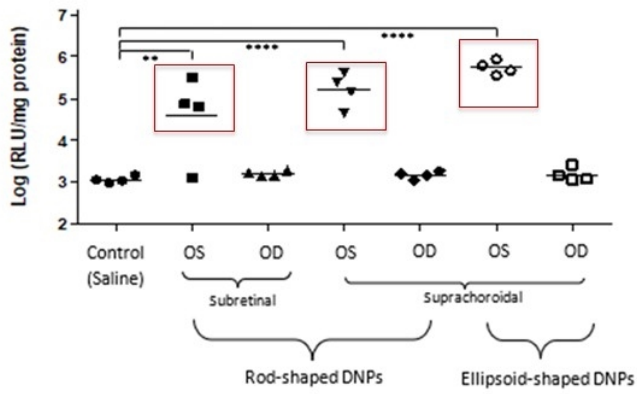


Suprachoroidal (SC) Injection Offers Potential for Safe, Targeted, and Efficient Ocular Gene Therapy

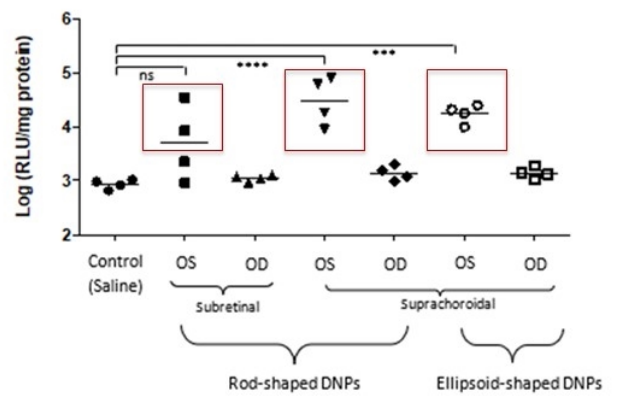
- Targeted treatment of posterior tissues possible via SC injection
 - Spread of injectate flows circumferentially and posteriorly
- Safety
 - Avoids the risks of sub-retinal surgery
 - Does not require detachment of the photoreceptors from the RPEs, without associated risk of iatrogenic injection to already compromised disordered retina
 - SC injection procedure training is minimal
- Access to care
 - Does not require specialized gene therapy surgery treatment centers
 - In-office SC injection procedure is less expensive than surgical procedures
 - Procedure time is significantly less than standard sub-retinal procedure

DNA Nanoparticles Transfect the Retina and Choroid

Non Viral-Luciferase, Rabbit
CHOROID



Non Viral-Luciferase, Rabbit
RETINA



OS: Dosed OD: Undosed	Bonferroni's multiple comparison test: ** p<0.01, *** p<0.001, **** p<0.0001 ns, non-significant
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OS: Dosed OD: Undosed	Bonferroni's multiple comparison test: *** p<0.001, **** p<0.0001 ns, non-significant
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DNA Nanoparticles Offer Potential for Safe, Efficacious, and Repeat Dosing Ocular Gene Therapy

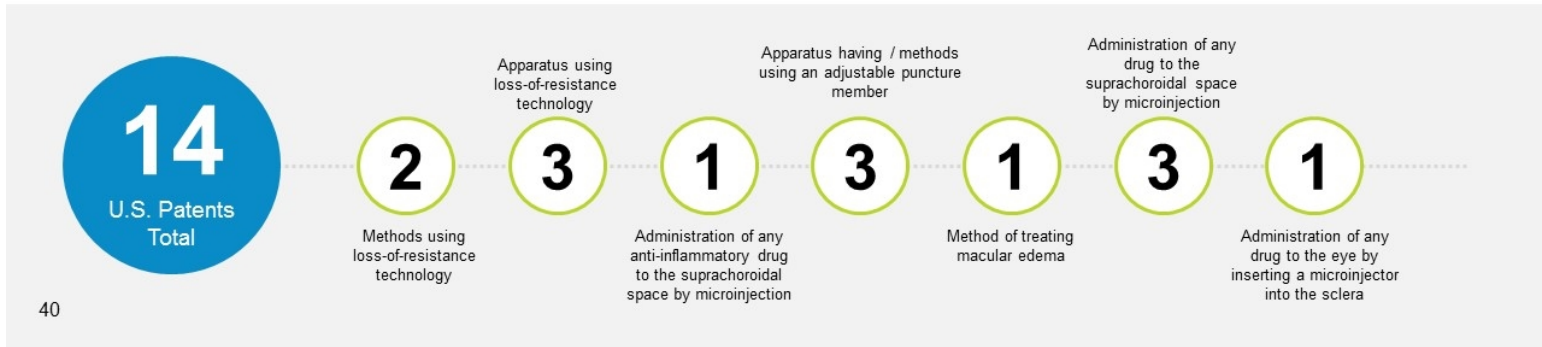
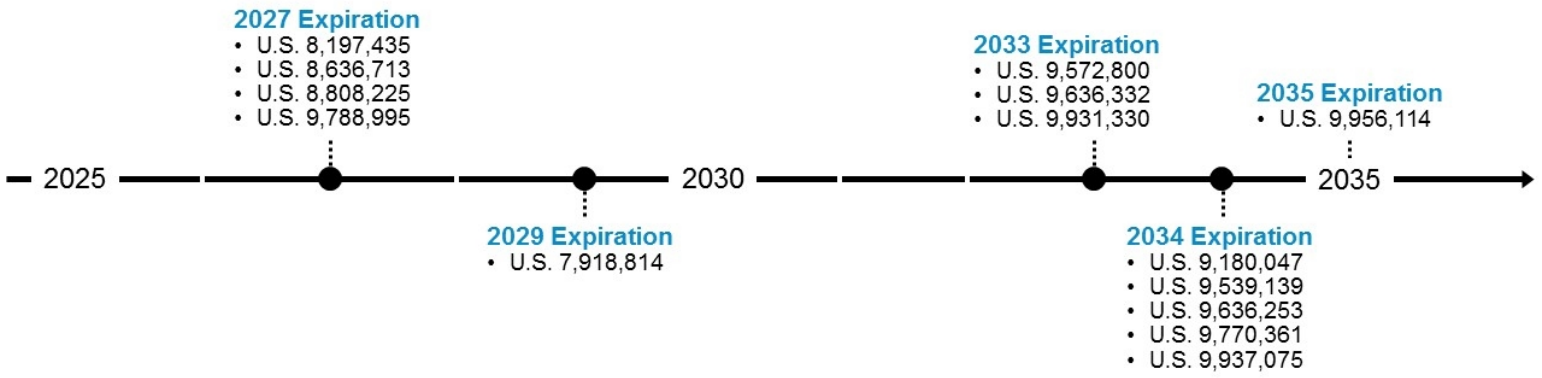
- Potential advantages: DNA nanoparticles versus viral vector-mediated gene therapy
 - Unlike AAV (payload capacity of 5 kb), can transfer large genes (up to ~20 kb)
 - Safety: non-immunogenic, without viral capsid proteins or pre-existing immunity
 - Potential for repeat and greater dosing
 - Efficacy in numerous ocular animal models
 - Higher doses may be used to enhance transfection
 - Manufacturing: simpler than viral-based gene therapy
- Potential disadvantages: DNA nanoparticles versus viral vector-mediated gene therapy
 - Durability: may not represent one time therapy



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 Rodriguez VP, Quality	Pharma Tech, Ciba Vision, Novartis, Shionogi	30

Ophthalmic Experience










Multiple Upcoming Milestones

2019 & 2020

Uveitis

- FDA acceptance of NDA
- PDUFA date – Oct. 19, 2019
- U.S. Launch – Q1 2020
- EMA application

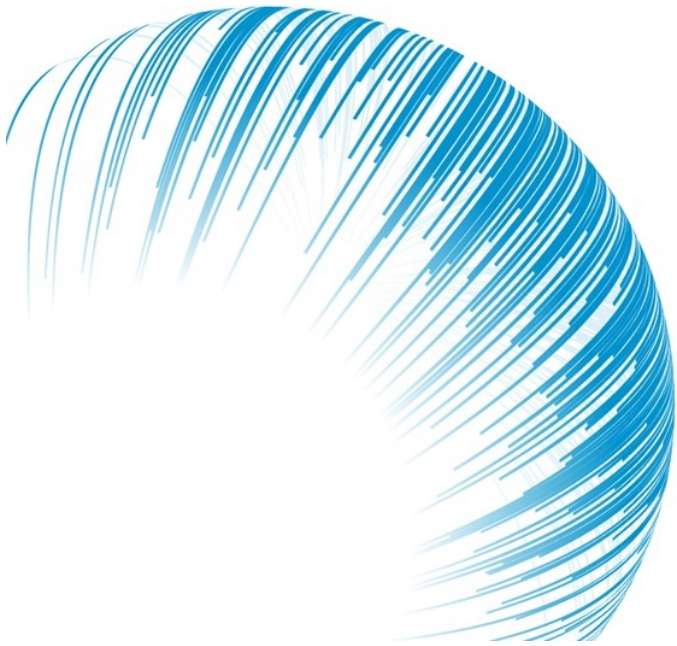
Other Pipeline

- Presentation of data on suprachoroidal platform at medical meetings
- DME program next steps
- Additional nonclinical results from preclinical gene therapy programs
- Additional preclinical data on 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 with October 19, 2019 PDUFA
 - If approved, XIPERE would be the first therapy with this indication
 - If approved, formal launch for XIPERE anticipated in Q1 2020
- Exclusive and proprietary access to the back of the eye through the SCS
 - Technology and approach well protected with 14 patents
- 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



THANK YOU!



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



