UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): **October 4, 2023**

OCULAR THERAPEUTIX, INC.
(Exact Name of Company as Specified in Charter)

Delaware	**001-36554**	**20-5560161**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

24 Crosby Drive
Bedford, MA 01730
(Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: **(781) 357-4000**

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	**OCUL**	**The Nasdaq Global Market**

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 accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On October 4, 2023, Antony Mattessich, Chief Executive Officer of Ocular Therapeutix, Inc. (the "Company") will make a presentation at the EURETINA Innovation Spotlight (EIS) regarding the Company's clinical development program in wet age-related macular degeneration, OTX-TKI. The slides to be used during the presentation are included as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, shall be deemed to be "furnished" and not "filed" under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference in applicable filings 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

99.1	Ocular Therapeutix, Inc. slide presentation, dated October 4, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

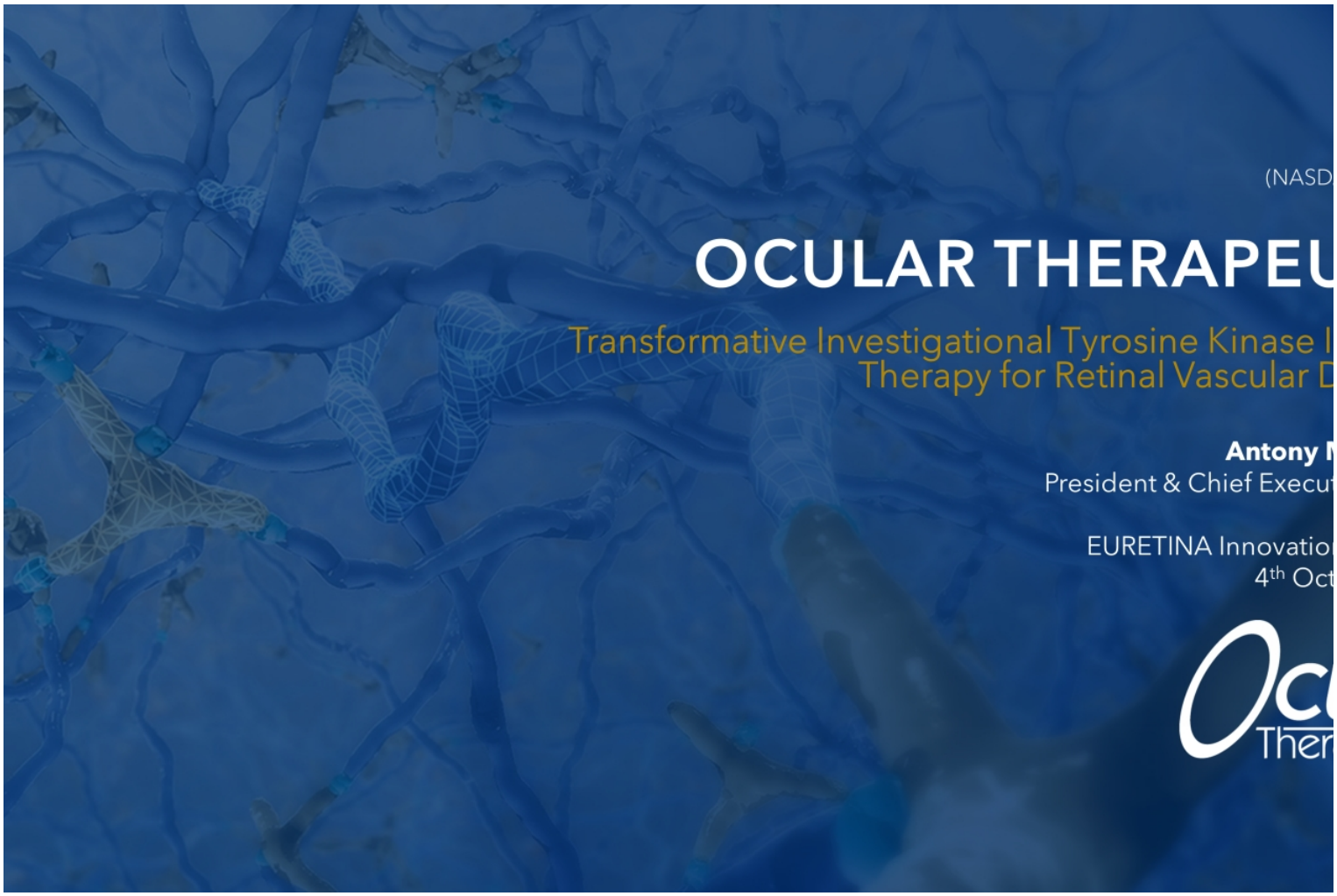
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OCULAR THERAPEUTIX, INC.

Date: October 4, 2023

By: /s/ Donald Notman
Donald Notman
Chief Financial Officer

Exhibit 99.1


(NASD
OCULAR THERAPEU
Transformative Investigational Tyrosine Kinase I
Therapy for Retinal Vascular D
Antony
President & Chief Execut
EURETINA Innovatio
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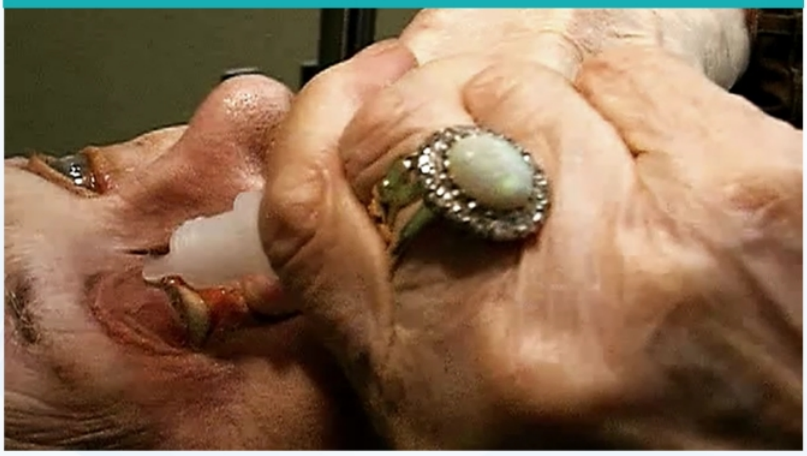
FORWARD LOOKING STATEMENTS

Any statements in this presentation about future expectations, plans, and prospects for the Company, including the commercialization of DE the Company's products or product candidates; the development and regulatory status of the Company's product candidates, including the the Company's planned pivotal trials of OTX-TKI for the treatment of wet AMD; the Company's plans to advance the development of OTX-TK runway and sufficiency of the Company's cash resources; and other statements containing the words "anticipate," "believe," "estimate," "exp "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, consti statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicate looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that c Company's preclinical and clinical development programs, future results, performance or achievements to differ significantly from those exp the forward-looking statements. Such risks and uncertainties include, among others, the timing and costs involved in commercializing DEXT or product candidate that receives regulatory approval, including the conduct of post-approval studies; the ability to retain regulatory appro any product or product candidate that receives regulatory approval; the ability to maintain and the sufficiency of product, procedure and an reimbursement codes for DEXTENZA; the initiation, design, timing, conduct and outcomes of clinical trials including the first pivotal trial of C treatment of wet AMD; uncertainties as to the response from the FDA regarding the SPA submission for OTX-TKI, including the risk that the F with the design of the first pivotal trial under the SPA; the risk that even if the FDA agrees with the design of the first pivotal trial under the SP agree that the data generated by the trial could support marketing approval; uncertainty as to whether the data from earlier clinical trials will data of later clinical trials, particularly later clinical trials that have a different design than the earlier trials; availability of data from clinical trial regulatory submissions and approvals; the Company's scientific approach and general development progress; uncertainties inherent in esti cash runway, future expenses and other financial results, including its ability to fund future operations, including clinical trials; Company's exi and the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default; to enter into strategic alliances or generate additional funding on a timely basis, on favorable terms, or at all; and other factors discussed in t section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forwa statements included in this presentation represent the Company's views as of the date of this presentation. The Company anticipates that su developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statemer the future, the Company specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise, exc law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the dat

This presentation discusses investigational product candidates in development. Their efficacy and safety profiles have not been esta have not been approved for marketing by the FDA.

OCULAR THERAPEUTIX AIMS TO TRANSFORM OPHTHALM
BRINGING ADVANCED THERAPIES TO PHYSICIANS AND PA

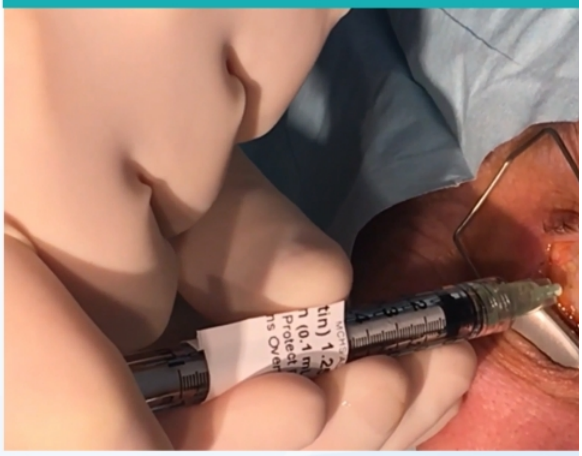
OBSOLETE EYE DROPS



Video Courtesy Dr. Alan Robin

Focused on developing physician-administered, preservative-free, and compliance-improved treatments for ophthalmic diseases that improve outcomes and practice economics

OBSOLETE IMMEDIATE RELEASE I



Video Courtesy Dr. Leonid Skorin

Create more durable treatments for retinal disea
the need for multiple injections into the eye resu
compliance and potentially better preservation o

OPHTHALMOLOGY IS RIPE FOR DISRUPTION

WE ARE ADVANCING A BROAD OPHTHALMOLOGY POR
USING ELUTYX FOR CONTINUOUS DRUG DELIVERY

PROGRAM	THERAPEUTIC FOCUS	PRECLINICAL	EARLY/MID CLINICAL STAGE (PHASE 1 – PHASE 2)	PIVOTAL CLINICAL TRIAL STAGE (PHASE 3)	FDA APPROVAL	NEXT MILESTONES
Dextenza® (dexamethasone ophthalmic insert) 0.4 mg for intracanalicular use	Post surgical ocular inflammation and pain Ocular itching associated with allergic conjunctivitis				●	
OTX-TKI (axitinib intravitreal implant)	Wet AMD*			●		**Q4 2023** Screen first su
OTX-TKI (axitinib intravitreal implant)	Diabetic Retinopathy		●			**Q1 2024** Interim data f and prepare to initiate
OTX-TIC (travoprost intracameral implant)	Glaucoma and ocular hypertension		●			**Q1 2024** Top-line data
OTX-DED (dexamethasone intracanalicular insert)	Episodic dry eye disease		●			Phase 1 trial completed **H1 2024** Complete enro determine placebo comp
OTX-CSI (cyclosporine intracanalicular insert)	Dry eye disease		●			Phase 1/2 trial complete **H1 2024** Complete enro determine placebo comp
Complement Modulator (product candidate)	Intermediate and late dry AMD*	●				
Gene Delivery (intravitreal and suprachoroidal delivery)	Inherited retinal degenerations and protein biofactory indications	●				

*Age-related Macular Degeneration (AMD)
†Subject to receipt of FDA response to Special Protocal Assessment; ‡Subject to FDA discussions of future clinical trial requirements and obtaining necessary financing §Subject to confirmatory Phase 1 readout

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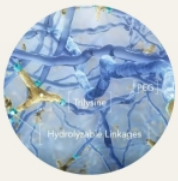
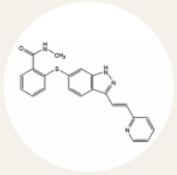
OTX-TKI IS DESIGNED TO DELIVER CONTINUOUS CONTI
OVER WET AMD

OTX-TKI is a combination of Elutyx and axitinib designed to sustain drug release for



Elutyx Technology: targeted sustained drug delivery platform

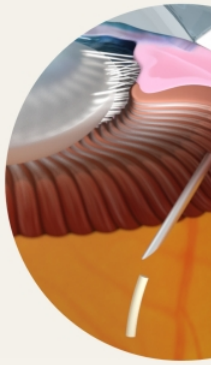
- Designed to deliver axitinib for 9-12 months with a single implant
- Completely bioresorbable
- Formulated from biocompatible and inert components



Axitinib: potent tyrosine kinase inhibitor

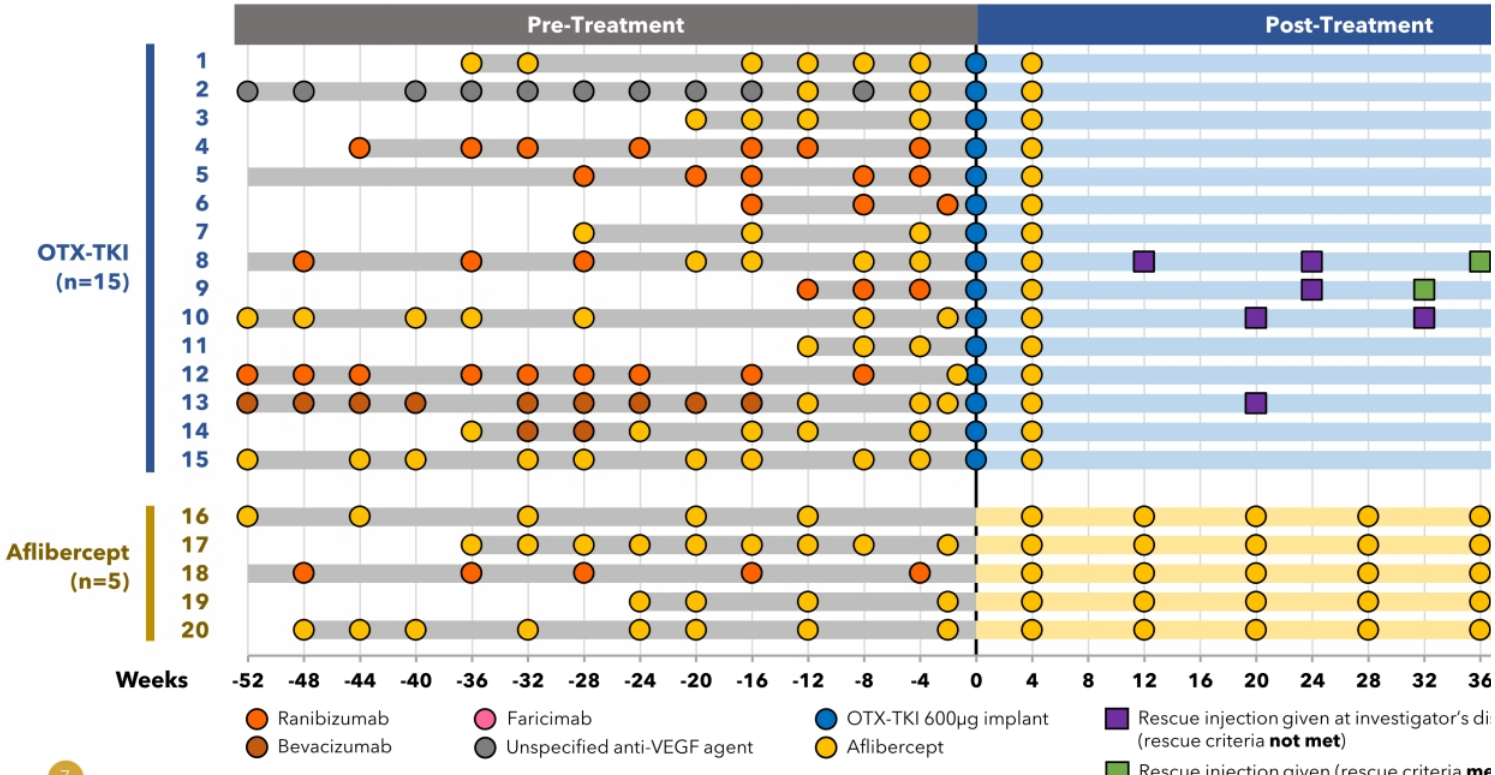
- Highly potent, pan-VEGF receptor inhibitor
- Acts within the intracellular space

OTX-TKI: axitinib
Elutyx techr



References: 1. Zhao Y, et al. *Oncologist*. 2015;20(6):660-673. **2.** Gross-Goupil M, et al. *Clin Med Insights Oncol*. 2013;7:269-277. **3.** Liang C, et al. *Mol Ther Oncolytics*. 2022;24:577-584. **4.** Blizzard CD, Driscoll A, El-Hayek R, et al. Ocular implant containing a tyrosine kinase inhibitor. Published online September 13, 2022. Accessed September 26, 2022. Patent

89% REDUCTION IN ANTI-VEGF TREATMENT BURDEN FOLLOWING OTX-TKI AT 12 MONTHS



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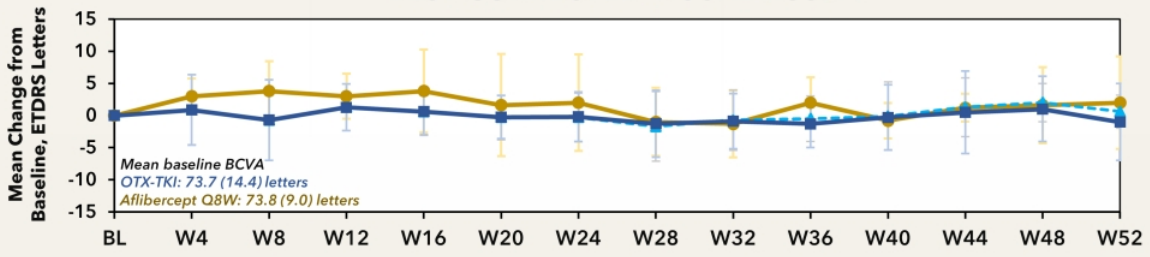
Data cut off April 14, 2023; per protocol analysis
Reduction in treatment burden calculation includes all rescue injections
Sham injection was given at Week 0 in the Aflibercept Arm and at Weeks 12, 20, 28, 36 and 44 in the OTX-TKI Arm (not shown). At Week 52, subjects in the aflibercept group were treated with wet AMD standard of care at the investigator

VISION AND CSFT WITH OTX-TKI WERE COMPARABLE T STANDARD OF CARE AFLIBERCEPT Q8W

OTX-TKI U.S. randomized trial evaluating wet AMD subjects with controlled retinal fluid

BEST CORRECTED VISUAL ACUITY



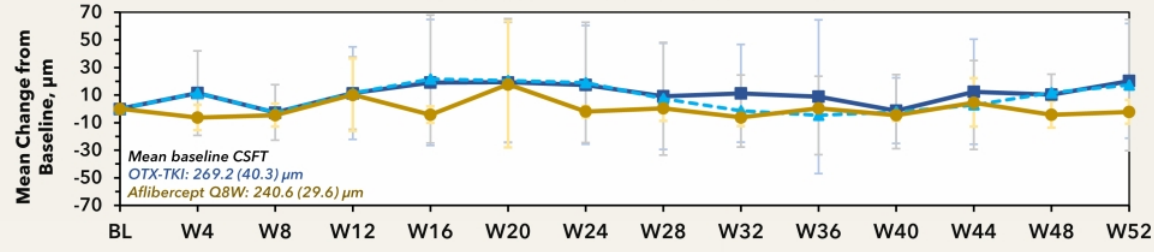
Mean (SD) change i from baseline to W

OTX-TKI: -1.0 (6.0) lette

OTX-TKI: +0.6 (2.6) lett (censoring rescued subjects)

Aflibercept Q8W: +2.0

CENTRAL SUBFIELD THICKNESS



Mean (SD) change i from baseline to W

OTX-TKI: +20.2 (41.6) µ

OTX-TKI: +17.2 (47.6) µ (censoring rescued subjects)

Aflibercept Q8W: -2.2 (

OTX-TKI arm*(N=15) — OTX-TKI arm (censoring rescued subjects)† — Aflibercept Q8W (N=5)

Data cut off April 14, 2023; Error bars represent standard deviation

* OTX-TKI arm received OTX-TKI at baseline and a single aflibercept injection at Week 4; n=14 in OTX-TKI arm at Weeks 8, 28, 40 and 48 due to missed visits

† Sample size for OTX-TKI arm (censoring rescued subjects): n=15 at Baseline and Weeks 4 and 12; n=14 at Week 8 (missed visit) and Weeks 16 and 20; n=12 at Week 24 and n=11 at Weeks 28, 32, 36 and 40; n=10 at Week 44; n=9 at Weeks 48 and 52

BCVA=best corrected visual acuity; BL=baseline; CSFT=central subfield thickness; ETDRS=Early Treatment Diabetic Retinopathy Study; W, week

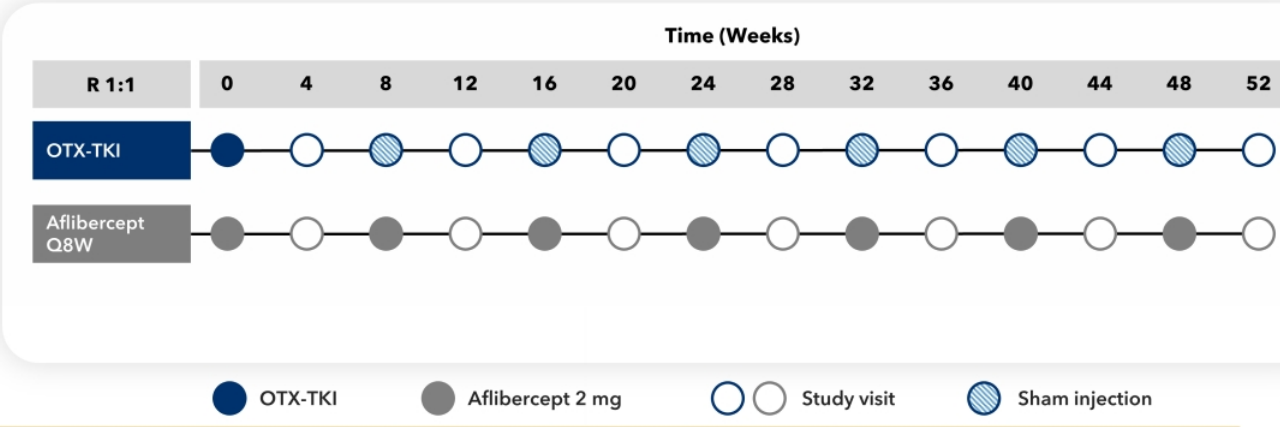
Reference: Khanani AM. 12-Month Update on Randomized, Controlled, Trial of OTX-TKI (Axitinib Intravitreal Implant) for the Treatment of Wet AMD. Presented at the Clinical Trials at the Summit Meeting. June 10, 2023. Park City, UT>

WET AMD NONINFERIORITY TRIALS USING SHAM INJECTIONS SEEM NO LONGER ACCEPTABLE TO T

FDA recommends a comparative arm in which "dosing frequency, criterion for dosing adjust criterion for interventions are the same" for investigational arm[1]

TRIAL DESIGN CHALLENGES

- Aflibercept Q8W arm has a different dosing frequency than OTX-TKI arm
- FDA does not recommend sham injections
- Saline injections increase risk of safety events (repeated use as seen below not preferred)



Reference: 1. Neovascular Age-Related Macular Degeneration: Developing Drugs for Treatment Guidance for Industry. US Food and Drug Administration. Published February 6, 2023. Accessed September 21, 2023. https://www.fda.gov/media/165606/download.

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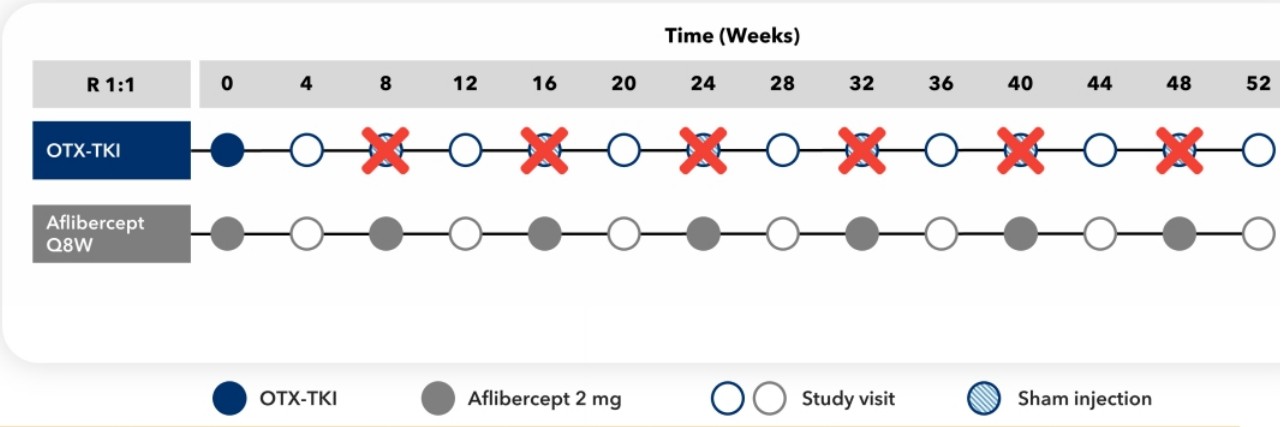

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TO MAINTAIN MASKING, TRIAL WOULD REQUIRE A THIRD
WITH CONTROL INJECTION MATCHING INVESTIGATIONAL

With the addition of a second control arm, OTX-TKI would need to demonstrate non-inferio aflibercept Q8W arm and superiority over control injection arm

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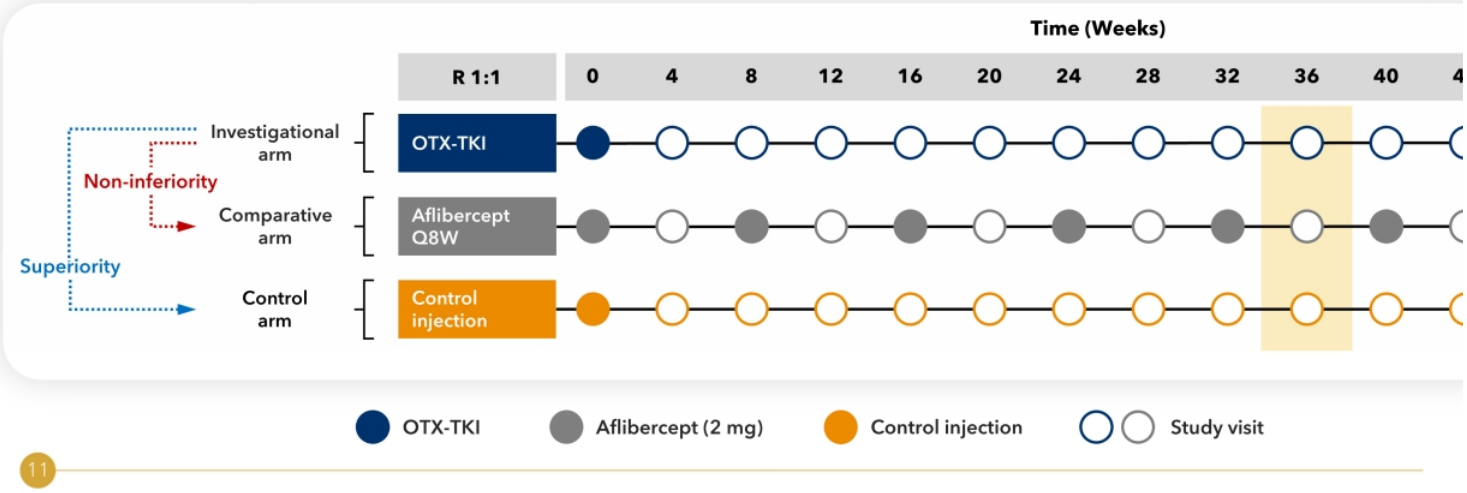

CURRENT FDA GUIDANCE ALLOWS THREE WAYS DEMONSTRATE SUPERIORITY

FDA RECOMMENDS ENDPOINTS DEMONSTRATING THE FOLLOWING FOR SUPERIORITY TRIALS[1]

≥15 LETTER *DECREASE*

Statistically significant smaller percentage of patients with ≥15 letter decrease at 9 months or later

≥15 LETTER *INCREASE*

Statistically significant greater percentage of patients with ≥15 letter increase at 9 months or later

≥15 LETTER *DIFFERENCE*

Statistically significant difference between groups in mean BCVA of ≥15 letter at 9 months or later

We plan to continue to collaborate with the FDA and the retina community to identify other endpoints that align with current treatment approaches

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PATIENT SAFETY, ENROLLMENT FEASIBILITY & OTX LIKELIHOOD OF SUCCESS WERE KEY CONSIDERATI

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≥15 LETTER *DIFFERENCE*

Statistically significant difference between groups in mean BCVA of ≥15 letter at 9 months or later

Factors Considered in Endpoint Selection

1 SAFETY OF STUDY PARTICIPANTS

- Screen **treatment-naïve subjects who have reasc** and improve their VA to 20/20, with the goal of ma above baseline level
- KOLs and clinical trialists generally find it permissi **control arm treated with single dose aflibercept** 15 letter loss in this specific patient population is e

2 ENROLLMENT FEASIBILITY

- Clinical trialists acknowledge this **subset of wAMI available** and commonly excluded from other clin screen fails

3 BEST DEMONSTRATES OTX-TKI'S POTENT AND DURABILITY

- **Durability of OTX-TKI is illustrated best** with this superiority design

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SOL: OTX-TKI PIVOTAL CLINICAL TRIAL IN WET A

Multi-center, double-masked, randomized, parallel-group Phase 3 tria

DESIGN

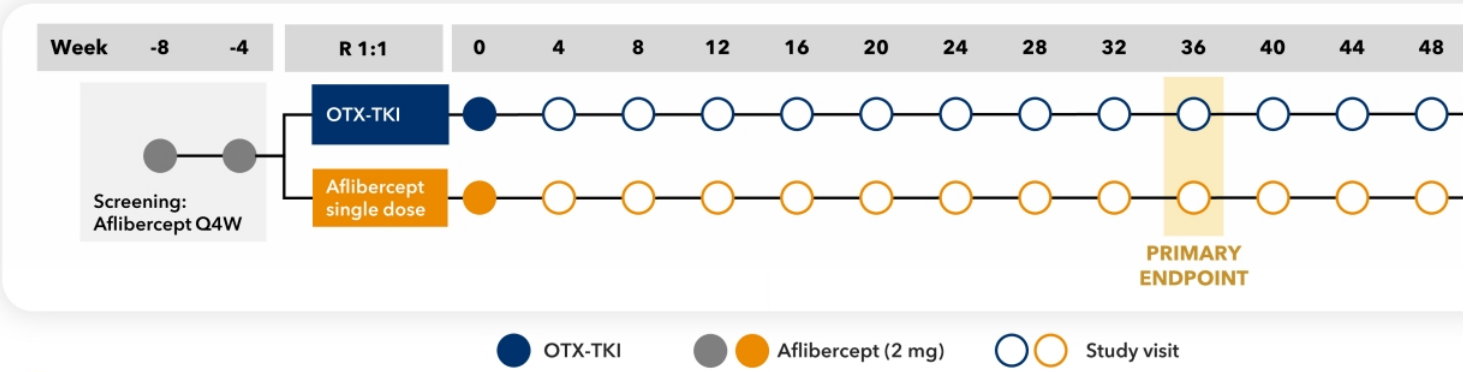
- Primarily conducted in the U.S.
- Two arm trial with ~150 subjects per group

KEY INCLUSION CRITERIA

- Subjects who are treatment naïve in the study eye with a diagnosis of choroidal neovascularization or sub foveal neovascularization at screening
- Visual acuity of **20/20 at Day 1**

PRIMARY ENDPOIN

Proportion of subjects wh
maintained visual acuity, defi
<15 ETDRS letters of BCVA f
Week 36



OTX-TKI Aflibercept (2 mg) Study visit

14 Trial design is pending confirmation of a Special Protocol Assessment submitted to the US Food and Drug Administration (FDA)

UPCOMING WET AMD PROGRAM MILESTONES

SEP 2023

- ☑ Submit Special Protocol Assessment (SPA)
- ☑ IRB Approval
- ☑ Initiate contracting with study sites

DEC 2023

- Agreement on protocol and analysis with FDA
- Screen first subject*

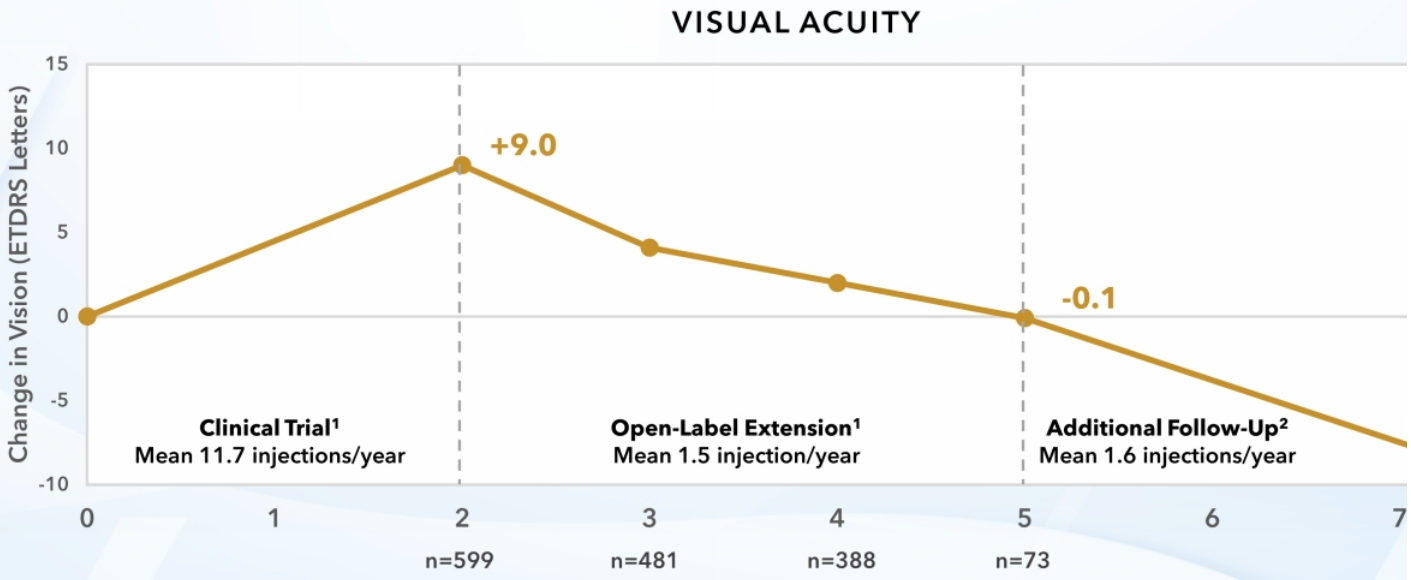
H2 2024

Prepare to i
second pi
wAMD tr

*Subject to receipt of FDA response to Special Protocol Assessment; †Subject to obtaining necessary financing

PRESSING NEED FOR A MORE DURABLE WET AMD TH

Anti-VEGF injections are effective, however, their dosing frequencies are a cha wet AMD leading to vision loss over time



References: 1. Singer MA, Awh CC, Sadda S, et al. *Ophthalmology*. 2012;119(6):1175-1183. 2. Rofagha S, Bhisitkul RB, Boyer DS, et al. *Ophthalmology*. 2013;120(11):2292-2299.

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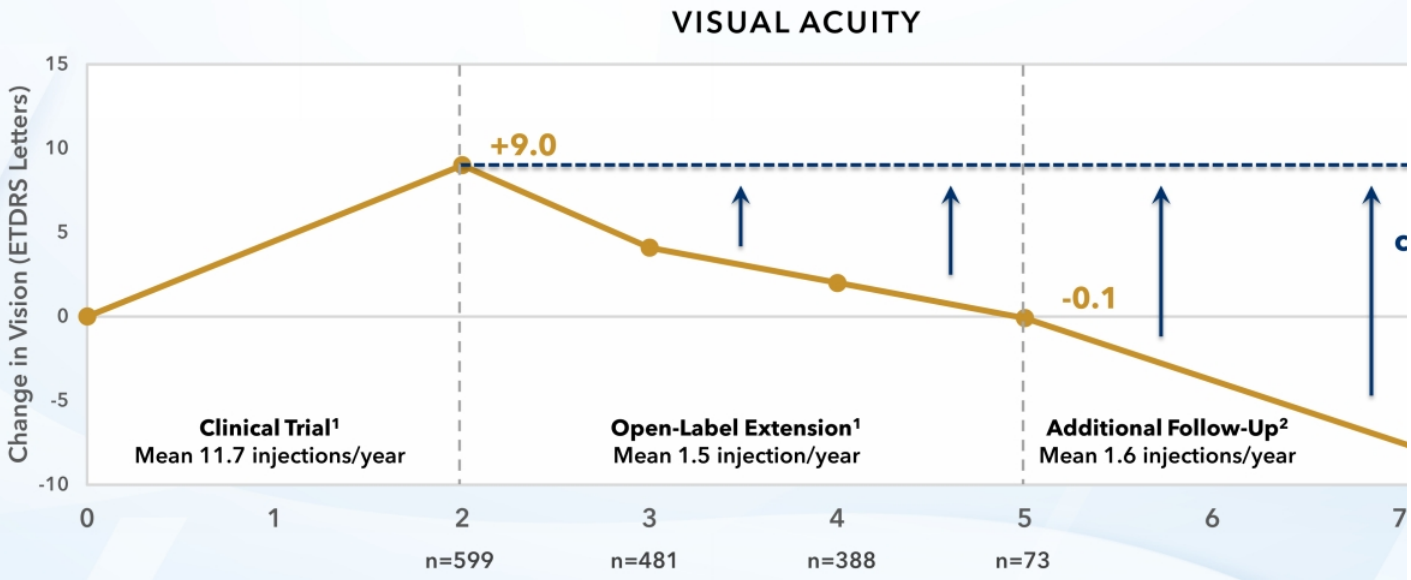

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Ocular
Therapeutix™
Committed to safeguarding vision
and enhancing lives