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): **June 10, 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 8.01 Other Events.

On June 10, 2023, Ocular Therapeutix, Inc. (the "Company") announced 12-month data from its Phase 1 U.S.-based clinical trial evaluating OTX-TKI for the treatment of wet age-related macular degeneration ("wet AMD"). An excerpt from the presentation of the 12-month data is included as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

An investigational, bioresorbable hydrogel intravitreal implant, OTX-TKI is designed to continuously deliver a potent tyrosine kinase inhibitor, axitinib, for the treatment of wet AMD, diabetic retinopathy and other VEGF-mediated retinal diseases. The U.S.-based Phase 1 clinical trial is a prospective, multi-center, randomized, controlled study in subjects previously treated with anti-VEGF therapy that is evaluating a 600 µg dose of OTX-TKI in a single implant, with a 2 mg aflibercept injection four weeks after the implant, compared to 2 mg aflibercept injections administered every 8 weeks. The trial is designed to assess the safety, durability and tolerability of OTX-TKI, and to assess biological activity in subjects by measuring best corrected visual acuity ("BCVA") and central subfield thickness ("CSFT") of the retina.

The clinical trial enrolled a total of 21 subjects at six clinical sites in the United States, who were randomized 3:1 to an arm receiving a single OTX-TKI implant, with a 2 mg aflibercept injection four weeks after implant injection, and an arm receiving aflibercept injections every 8 weeks. One subject in the OTX-TKI arm was not treated per protocol and has been removed from the efficacy analysis, as the subject incorrectly received aflibercept instead of a sham injection at Month 3 and 5 visits.

The 12-month data demonstrated maintenance of controlled wet AMD subjects comparable to aflibercept injections every eight weeks with a single administration of OTX-TKI. Four subjects received rescue therapy for the first time at Month 12, indicating the waning of OTX-TKI's therapeutic effect and potential disease reactivation, which helps establish a re-dosing timeline for patients.

The results showed subjects treated with a single OTX-TKI implant continued to demonstrate sustained BCVA (mean change from baseline of -1.0 letters) and CSFT (mean change from baseline of +20.2 µm) in the OTX-TKI arm at 12 months, which was comparable with the aflibercept arm (mean change from BCVA baseline of +2.0 letters; mean change from CSFT baseline of -2.2 µm). 60% of OTX-TKI subjects were rescue-free up to Month 12. At the Month 12 visit, an additional four of the subjects were rescued. Overall, an 89% reduction in treatment burden was observed in OTX-TKI treated subjects at 12 months.

As of the data cutoff of April 14, 2023, there were no drug-related ocular or systemic serious adverse events ("SAEs") observed in the OTX-TKI arm. As the Company previously announced at the 10-month data readout, one SAE of endophthalmitis was observed in the OTK-TKI arm, which occurred following the mandated aflibercept injection at Month 1 and was assessed by the investigator as related to the injection procedure. There were no retinal detachment, retinal vasculitis, or implant migration into the anterior chamber adverse events observed in the OTX-TKI arm, and no subjects had dropped out of either arm as of the data cutoff.

The Company is prepared to initiate a pivotal trial in wet AMD as early as the third quarter of 2023, subject to obtaining the necessary financing, which could be provided through a strategic alliance.

As previously announced, the Company also recently completed enrollment of its Phase 1 HELIOS clinical trial to evaluate OTX-TKI for the treatment of diabetic retinopathy. The Company expects to report 6-month interim results for the HELIOS trial in the first quarter of 2024.

Cautionary Note on Forward Looking Statements

Any statements in this Current Report on Form 8-K about future expectations, plans, and prospects for the Company, including the commercialization of DEXTENZA® or any of the Company's products or product candidates; the development and regulatory status of the Company's product candidates, such as the Company's development of and the timing of planned pivotal clinical trials for OTX-TKI for the treatment of retinal diseases including wet AMD and diabetic retinopathy; the Company's plans to advance the development of OTX-TKI; the ongoing development of the Company's extended-delivery hydrogel depot technology; the potential utility of any of the Company's product candidates; the size of the potential market for OTX-TKI; the Company's ability to fund the planned and future clinical development of its product candidates whether through strategic alliances or other fundraising; the Company's ability to enter into and perform its obligations under collaborations; the sufficiency of the Company's cash resources; and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's preclinical and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the timing and costs involved in commercializing DEXTENZA or any product or product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to retain regulatory approval of DEXTENZA or any product or product candidate that receives regulatory approval, the ability to maintain and the sufficiency of product, procedure and any other reimbursement codes for DEXTENZA, the initiation, timing, conduct and outcomes of clinical trials, whether interim clinical trial data such as the data reported in this Current Report on Form 8-K will be indicative of the results of the trial upon its completion or subsequent clinical trials in this and other indications, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's scientific approach and general development progress, the sufficiency of cash resources, the Company's existing indebtedness, the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default, the Company's ability to enter into strategic alliances or generate additional funding on a timely basis, on favorable terms, or at all, the Company's ability to recruit and retain key personnel, and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company's views as of the date of this Current Report on Form 8-K. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

99.1	Excerpt from presentation of data from Phase 1 clinical trial on June 10, 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.

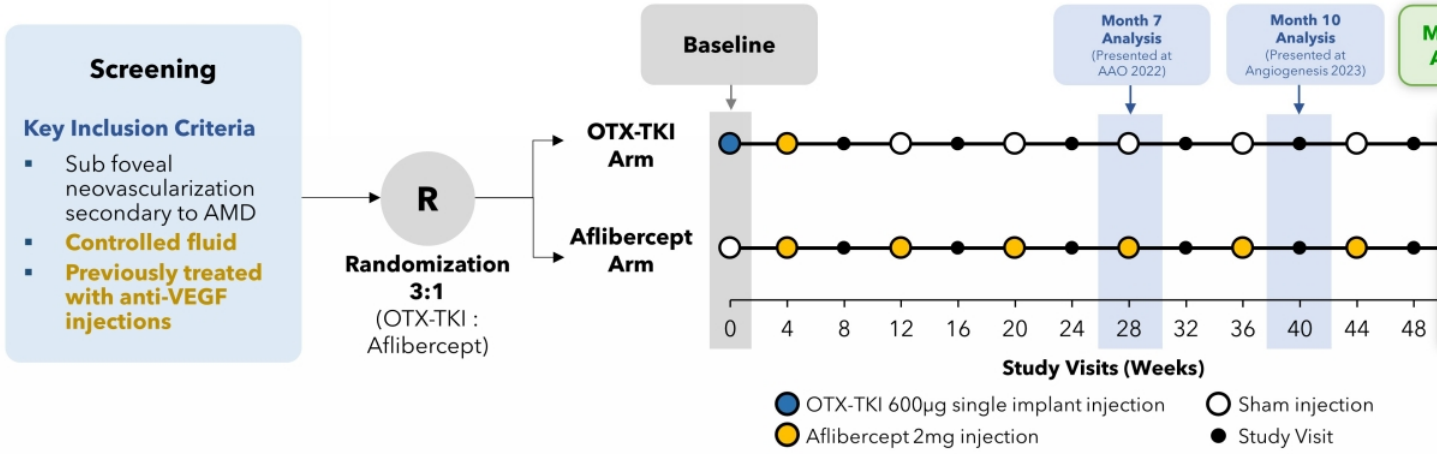
OCULAR THERAPEUTIX, INC.

Date: June 12, 2023

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

OTX-TKI U.S.-based Wet AMD Clinical Trial Design

Multicenter, Randomized, Double-masked Trial



Rescue Anti-VEGF Injection Criteria:

- Loss of ≥10 letters from best previous BCVA with current BCVA worse than baseline, or
- Evidence of ≥75µm CSFT increase from previous best value and ≥5 letters loss from best previous BCVA, or
- New macular hemorrhage

AAO=American Academy of Ophthalmology; AMD=age-related macular degeneration; BCVA=best corrected visual acuity; BL=baseline; CSFT=central subfield thickness; AMD=age-related macular degeneration; VEGF=vascular endothelial growth factor

Baseline Characteristics

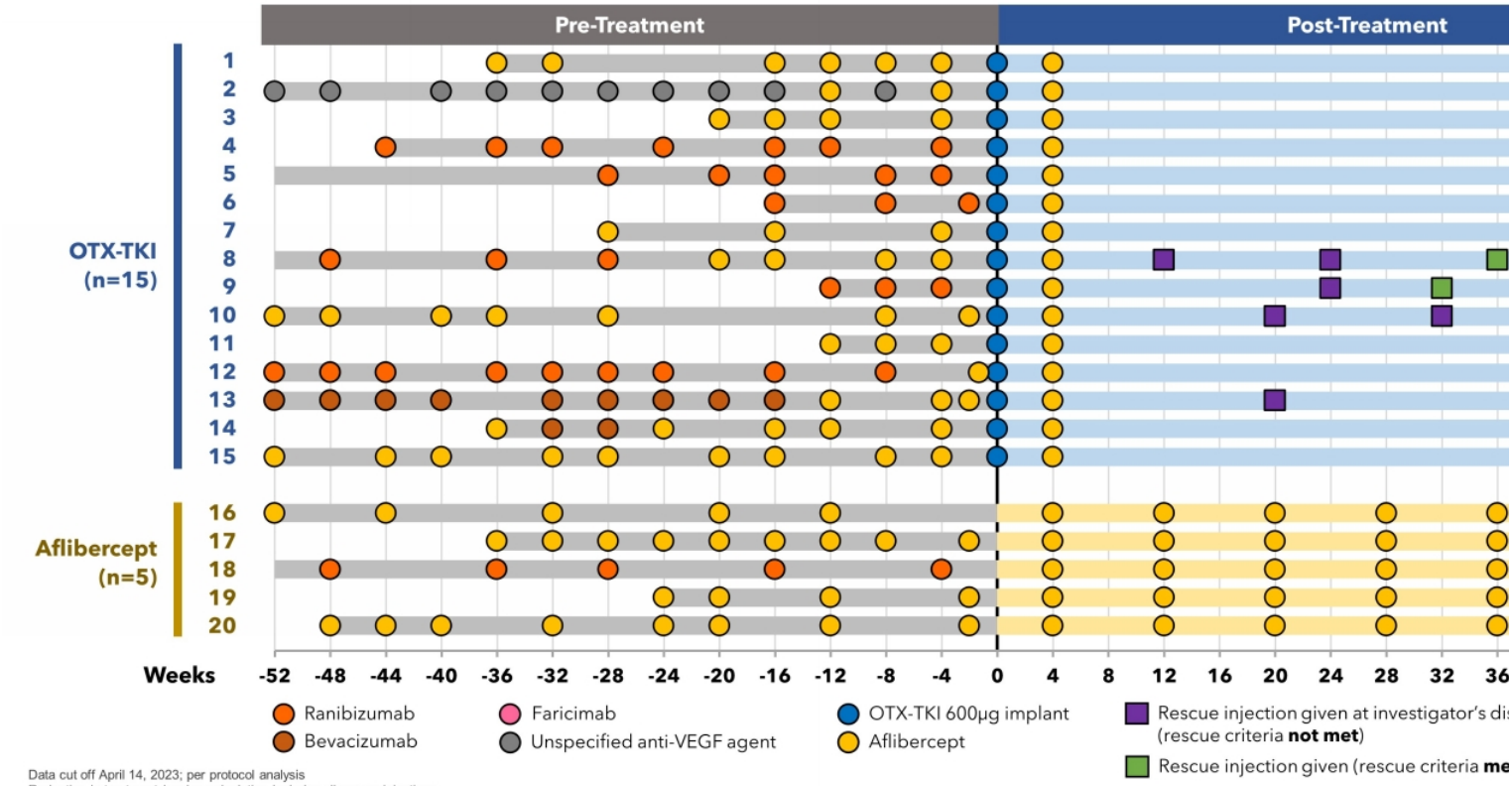
Baseline Characteristic	OTX-TKI (N=16)†	Aflib (N
Mean (SD) Age, Years	76 (8)	84
Male, n (%) **Female, n (%)**	8 (50) 8 (50)	3 (2 (
Mean (SD) Months since wet AMD diagnosis	18 (12)	18
Mean (SD) Number of anti-VEGF Injections within 12 Months Prior to baseline*	8 (3)	8 (
Mean (SD) BCVA in ETDRS Letters	70.9 (17.7)	73.8
Mean (SD) CSFT, µm	273.8 (43.0)	240.6

*Annualized data
† Includes one subject not treated per protocol who has been removed from efficacy analysis as subject incorrectly received aflibercept instead of sham injection visits

Data cut off April 14, 2023
BCVA=best corrected visual acuity; CSFT=central subfield thickness; ETDRS=Early Treatment Diabetic Retinopathy Study; AMD=age-related macular degeneration; SD=standard deviation; VEGF=vascular endothelial growth factor

Reduction in Anti-VEGF Injections Following OTX-TKI at 12 Months

89% reduction in treatment burden with OTX-TKI at 12 months

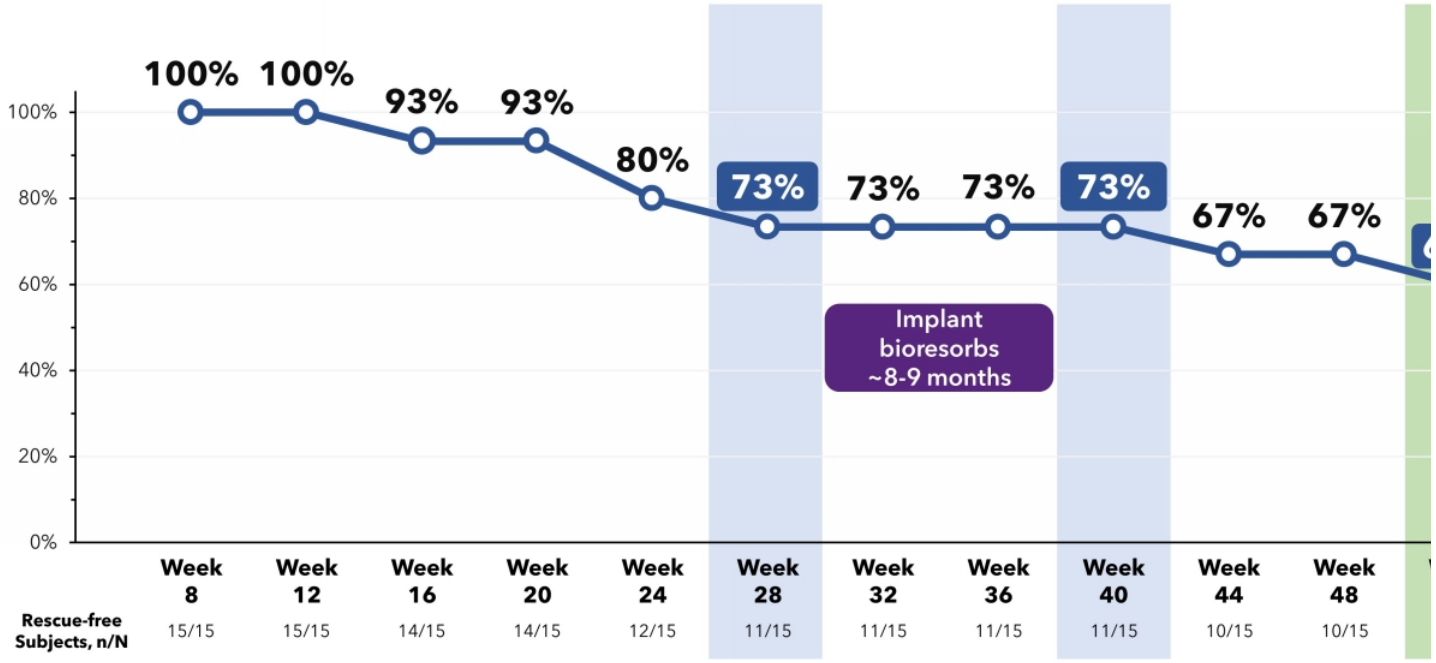


Data cut off April 14, 2023; per protocol analysis
Reduction in treatment burden calculation includes all rescue injections
Sham injection was given at Week 0 in the Aflibercept Arm and at Weeks 12, 20, 28, 36 and 44 in the OTX-TKI Arm (not shown). At Week 52, subjects in the aflibercept group were treated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

OTX-TKI Demonstrated Extended Duration of Action

60% were rescue-free up to 12 months with 4 additional subjects rescued at 12 mont

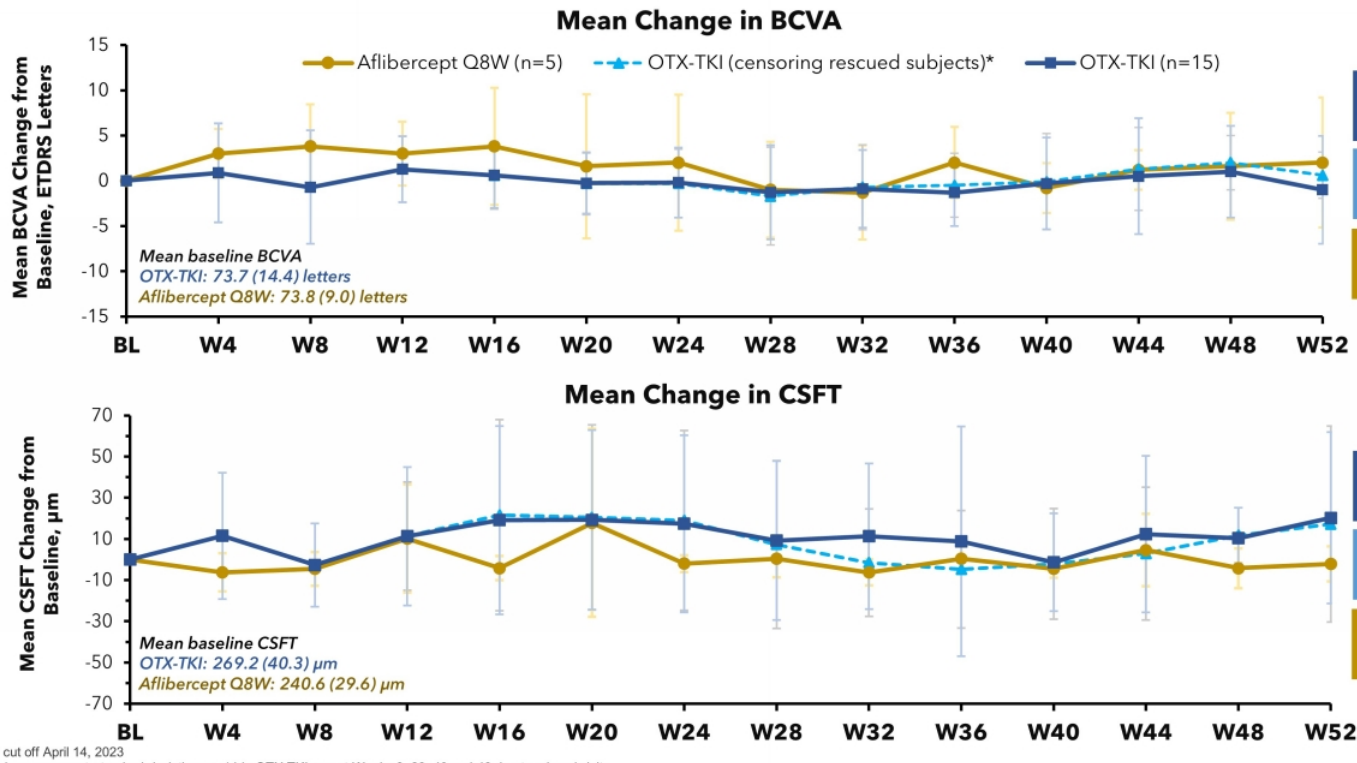
Percentage of OTX-TKI Subjects Rescue-Free Up to Each Visit (n=15)



	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48
Rescue-free Subjects, n/N	15/15	15/15	14/15	14/15	12/15	11/15	11/15	11/15	11/15	10/15	10/15

Data cut off April 14, 2023
Rescue-free rate calculations: If subjects received rescue anti-VEGF therapy at a study visit, those were reflected to count at the following study visit in the graph above
Percentages presented in the graph above represent rescue-free rates up to each study visit, except for the 33% at Week 52 which includes rescue injections given at the Week 52 study visit

Vision and CSFT with OTX-TKI were Comparable to Aflibercept Q8



Data cut off April 14, 2023

Error bars represent standard deviation; n=14 in OTX-TKI arm at Weeks 8, 28, 40 and 48 due to missed visits

*Sample size for OTX-TKI (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

Safety Summary

- No reports of drug-related ocular or systemic SAEs in either arm
- One event of acute endophthalmitis in OTX-TKI arm which occurred following mandated aflibercept injection at Month 1
  - Reported as moderate
  - Injection procedure related
  - Unrelated to the study drug
  - Resolved after intravitreal antibiotic injection, with vision returning to baseline
- All events were mild except
  - Acute endophthalmitis SAE (moderate and resolved) and worsening of cataract (moderate) in OTX-TKI arm
  - Elevated IOP in aflibercept arm (moderate and resolved)

	OTX-TKI n=16
Subjects with Adverse Events in the Study Eye, n (%)	
Elevated IOP	2 (12.5)
Retinal detachment	0
Retinal vasculitis	0
Implant migration into the anterior chamber	0
Acute endophthalmitis	1 (6.25)*
Subjects with Ocular Adverse Events in the Study Eye Severity, n (%)	
Ocular AEs	16 (100.0)
Mild	14 (87.5)
Moderate	2 (12.5)*
Severe	0
Serious AEs	1 (12.5)*

*Moderate and serious ocular AE in OTX-TKI arm was Acute Endophthalmitis 6 days a injection at Month 1
**Moderate AE in Aflibercept arm was Elevated Intraocular pressure

Data cut off April 14, 2023
IOP=intraocular pressure; SAE=serious adverse event