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): **March 3, 2020**

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 (*see* General Instruction A.2. below):

☐ 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 exchange on which registered
Common Stock, $0.0001 par value per share	**OCUL**	**The Nasdaq Global Select 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 2.02. Results of Operations and Financial Condition.

On March 3, 2020, Ocular Therapeutix, Inc. (the "Company") issued a press release to report interim data from its ongoing Phase 1 clinical trial of its product candidate OTX-TKI and to provide net product revenue guidance for the quarters ended December 31, 2019, and ending March 31, 2020. OTX-TKI is a long-acting tyrosine kinase inhibitor intravitreal implant evaluated for the treatment of patients with wet age-related macular degeneration and other retinal diseases. The Phase 1 clinical trial is a multi-center, open-label, dose escalation trial intended to evaluate the safety, durability, tolerability and biological activity of OTX-TKI for the treatment of wet age-related macular degeneration. The trial is not powered to measure any efficacy endpoints with statistical significance.

The Company also will be attending the Cowen and Company 40th Annual Health Care Conference on March 3, 2020, to present the interim data.

A copy of the press release and an excerpt of the Company's conference presentation are included as Exhibits 99.1 and 99.2 hereto, respectively, and are incorporated by reference herein.

The information in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 attached hereto, is furnished to comply with Item 2.02 of Form 8-K, 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:

99.1	Press Release of the Company, dated March 3, 2020.
99.2	Excerpt from Company presentation, dated March 3, 2020.

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: March 3, 2020

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

Exhibit 99.1

Ocular Therapeutix™ Announces Preliminary Fourth Quarter 2019 Net Product Revenue and Provides Update on Interim Data from the OTX-TKI Phase 1 Clinical Trial at the Cowen 40th Annual Health Care Conference

BEDFORD, Mass. —(BUSINESS WIRE)—March 3, 2020—Ocular Therapeutix™, Inc. (NASDAQ: OCUL), a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye, today announced preliminary unaudited net product revenue for the fourth quarter of 2019 and interim results from its Phase 1 clinical trial for OTX-TKI, a long-acting tyrosine kinase inhibitor intravitreal implant being evaluated for the treatment of wet age-related macular degeneration and other retinal diseases. A copy of the Company's presentation from the Cowen and Company 40th Annual Health Care Conference is available on the Company's website, www.ocutx.com.

Fourth Quarter 2019 Net Revenue and First Quarter 2020 Net Revenue Guidance

Gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue was $2.3 million for the three-months ended December 31, 2019 reflecting a 172% sequential increase over total net product revenue reported in the third quarter ended September 30, 2019. Net product revenue of DEXTENZA® in the fourth quarter 2019 was $1.6 million versus $0.3 million in the third quarter ended September 30, 2019 and reflects a more than four times sequential increase. Total net product revenue for the fourth quarter of 2019 also includes net product revenue of $0.7 million from ReSure® Sealant. The Company expects to report its audited results for the 2019 fiscal year later this month.

DEXTENZA net revenue in the quarter was driven by continued increase in the number of new accounts prescribing DEXTENZA and re-order rates by existing accounts. In addition to the trends in the fourth quarter, the Company is seeing increased interest from larger accounts at the start of 2020. Based on these current trends and the 50% expansion of Key Account Managers to approximately 30 in November 2019, the Company expects DEXTENZA net revenue for the first quarter of 2020 to be in the range of $2.4 million to $2.6 million. Combined with anticipated net revenues from ReSure Sealant of approximately $0.6 million, the Company expects total net product revenue for the first quarter of 2020 to be $3.0 million to $3.2 million.

"We are pleased with our progress and with the results we are seeing in the early stages of the DEXTENZA launch," said Antony Mattessich, President and Chief Executive Officer. "Increases in new accounts, re-order rates, and average order size are all metrics we are seeing that reinforce our belief that DEXTENZA's differentiated product profile is resonating with surgeons as a novel treatment for ocular inflammation and pain following ophthalmic surgery. In addition, with encouraging interim results in OTX-TKI for the treatment of wet age-related macular degeneration and in OTX-TIC for the treatment of glaucoma that were announced today and a few weeks ago respectively, we are beginning to see the potential of our early-stage product pipeline. We look forward to providing additional updates on these programs later in the year and to a productive 2020."

Interim Phase 1 Data on OTX-TKI

The Phase 1, multi-center, open-label, dose escalation clinical trial being conducted in Australia is intended to evaluate the safety, durability, tolerability, and biological activity of OTX-TKI for the treatment of wet age-related macular degeneration. Two cohorts of six subjects each have been enrolled, a lower dose cohort of 200 µg and a higher dose cohort of 400 µg. In the first two fully enrolled cohorts, OTX-TKI was generally well tolerated and observed to have a favorable safety profile with no ocular serious adverse events noted. In the higher dose cohort, OTX-TKI showed a decrease in retinal fluid as measured by decreases in intraretinal and/or subretinal fluid in some subjects. The Company plans to continue long-term evaluation of the first two cohorts. This Phase 1 clinical trial is not powered to measure any efficacy endpoints with statistical significance.

“For patients with wet age-related macular degeneration and retinal diseases, there is a need for both products with new mechanisms of action and for products that are able to provide longer-acting therapy than current anti-VEGF products on the market today,” said Dr. Michael Goldstein, Chief Medical Officer of Ocular Therapeutix. "While still early, initial data from this Phase 1 study with a tyrosine kinase inhibitor indicate that OTX-TKI has the potential to decrease intraretinal and subretinal fluid in patients with wet-age-related macular degeneration. We look forward to following these patients to assess the long-term durability of the response. The safety and biological activity seen in this trial is consistent with our pre-clinical animal studies and the data support both ongoing testing as a monotherapy and in combination with other anti-VEGF injections where OTX-TKI could extend the efficacy of those products thereby requiring less frequent dosing."

About OTX-TKI

OTX-TKI (tyrosine kinase inhibitor implant) is a preformed, bioresorbable hydrogel that contains TKI particles in an injectable fiber that can be delivered through a small-gauge, sterile injection needle to the back of the eye. OTX-TKI is designed to deliver drug to the target tissues for an extended duration of up to 12 months, thereby potentially extending the dosing interval from the one to two-month frequency needed with the current standard of care. The Company has initiated an ex-U.S. multi-center, open-label, dose escalation Phase 1 study to test the safety, durability, tolerability, and biological activity.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary bioresorbable hydrogel-based formulation technology. Ocular Therapeutix’s first commercial drug product, DEXTENZA®, is FDA-approved for the treatment of ocular inflammation and pain following ophthalmic surgery. Ocular Therapeutix is conducting a Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis. OTX-TP (intracanalicular travoprost insert) is an intracanalicular insert in Phase 3 clinical development for the reduction of intraocular pressure in patients with primary open-angle glaucoma and ocular hypertension. The Company’s earlier stage assets include OTX-TIC, an extended-delivery intracameral travoprost implant for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension, as well as sustained release intravitreal implants for the treatment of retinal diseases. These intravitreal implants include OTX-TKI, containing a tyrosine kinase inhibitor (TKI), and, in collaboration with Regeneron, OTX-IVT, an extended-delivery protein-based anti-vascular endothelial growth factor (VEGF) trap. Ocular Therapeutix's first product, ReSure® Sealant, is FDA-approved to seal corneal incisions following cataract surgery.

Forward Looking Statements

Any statements in this press release about future expectations, plans, and prospects for the Company, including the commercialization of DEXTENZA®, ReSure Sealant, or any of the Company's product candidates, including the impact of and restructuring costs and potential savings associated with the Company's operational restructuring, workforce reduction and development program deferrals; the commercial launch of, and effectiveness of reimbursement codes for, DEXTENZA; the development and regulatory status of the Company's product candidates, such as the Company's development of and prospects for approvability of DEXTENZA for additional indications including allergic conjunctivitis, OTX-TP for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TIC for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-IVT as an extended-delivery formulation of the VEGF trap aflibercept for the treatment of retinal diseases including wet AMD; the ongoing development of the Company's extended-delivery hydrogel depot technology; the potential utility of any of the Company's product candidates; the potential benefits and future operation of the collaboration with Regeneron Pharmaceuticals, including any potential future payments thereunder; projected net product revenue; 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 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, those related to the implementation of the operational restructuring, the timing and costs involved in commercializing DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to retain regulatory approval of DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, the ability to maintain reimbursement codes for DEXTENZA, the initiation, timing and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's scientific approach and general development progress, the availability or commercial potential of the Company's product candidates, the Company's ability to generate its projected net product revenue on the timeline expected, if at all, 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 outcome of the Company's ongoing legal proceedings and need for additional financing or other actions 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 press release represent the Company's views as of the date of this release. 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 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 release.

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UNMET NEED IN RETINAL DISEASE

PROBLEM WITH IMMEDIATE-RELEASE INJECTIONS

- While anti-VEGF drugs are effective, they are also rapidly cleared from the vitreous humor; therefore, to reach and to maintain effective concentrations, repeated administrations every 4-8 weeks are necessary[1]
- Repeated intravitreal injections may cause side effects such as infection, endophthalmitis, hemorrhage, damage to the lens, retinal detachment, and poor patient tolerance over time[1]
- Discomfort, eye pain, decreased vision, increased photosensitivity, and floaters are just some of the patient complaints with injections[1]
- Repeated injections also have a significant impact on patients emotionally and financially as well as the time and transportation burden placed on care givers[2]

A New Therapy is Needed.

New Mechanism of Action
TKIs act upstream of Anti-VEGF

Longer Duration of Action
TKIs are potent small molecules

Research Question:

Does axitnib (a tyrosine kinase inhibitor) injected into the eye have biological activity?

1. Bochot A, Fattal E. Liposomes for intravitreal drug delivery: a state of the art. *J Control Release*. 2012;161(2):628-634.
2. Boyle J, Vukicevic M, Koklanis K, Itsiopoulos C, Rees G. Experiences of patients undergoing repeated intravitreal anti-vascular endothelial growth factor injections for neovascular age-related macular degeneration. *Psychol Health Med*. 2018;23(2):127-140.

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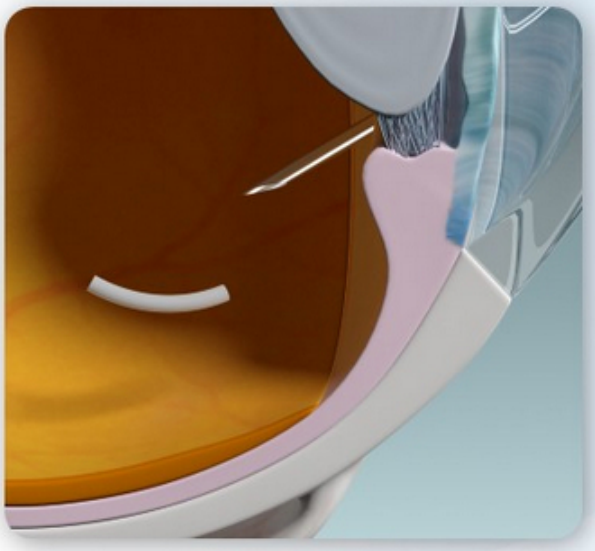
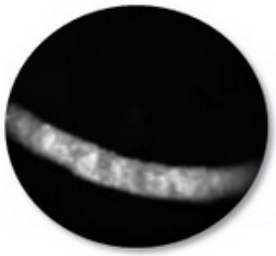
DRUG DELIVERY TO THE INTRAVITREAL SPACE

FACTORS FOR CONSIDERATION IN DESIGNING A LONG DURATION INTRAVITREAL IMPLANT:

- **Clinically-meaningful decrease in retinal fluid**
  Well-tolerated with clinically-meaningful efficacy
- **Extended duration of therapy**
  3 months or more
- **Consistently bioresorbable**
  Duration of drug and duration of carrier vehicle
- **Implant location and limited movement**
  Compact geometry, designed to avoid optical impact, but able to be monitored





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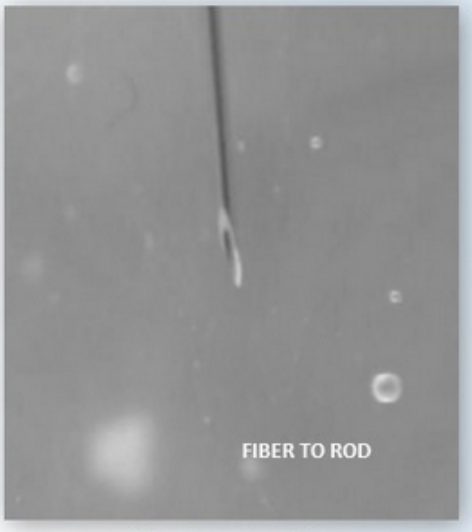
INTRAVITREAL INJECTION IN A PHASE 1 CLINICAL TRIAL FOR THE TREATMENT OF AGE-RELATED MACULAR DEGENERATION

OTX-TKI (tyrosine kinase inhibitor implant) for intravitreal injection

DESCRIPTION:

- Targeting sustained release for 3 to 6+ months
- Broader anti-angiogenic profile than anti-VEGF alone and longer duration (small molecule)
- Systemic TKI efficacy established in oncology
- Small fiber (27-30G needle) with minimal/no visual impact; product candidate can be monitored by physician
- Potential to provide an additional option for patients and providers
- Different target than traditional VEGF therapies
- Preservative-free



Video shown in real time
in simulated vitreous humor

IN PRECLINICAL MODELS (RABBIT CHALLENGE):

- Sustained, steady state in vitro and in vivo release for up to 12 months with a single insert
- PK, PD and tolerability with no negative safety signals reported to date

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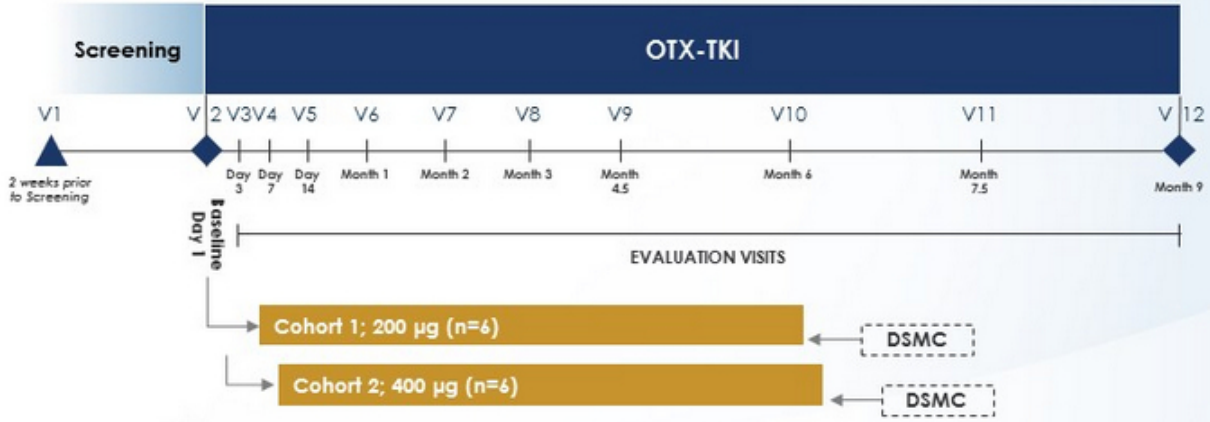
OTX-TKI PHASE 1 STUDY

DESIGN

- Open-label, dose-escalation, feasibility study
- 5 sites in Australia
- 9-month study
- One eye per patient will be treated
- Key Inclusion criteria:
  - ✓ Active primary SFNV secondary to AMD

OBJECTIVES

- Safety, tolerability, and biological activity
- Safety evaluations at all visits; mean change in CSFT measured by SD-OCT, BCVA, and clinically-significant leakage on FA and/or OCT-A at 6 months



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MEAN CHANGE IN CENTRAL SUBFIELD THICKNESS VALUES

STUDY EYE BY COHORT

*Cohort 1 subjects 02-001 and 01-001 CSFT compared to Baseline visit; remainder of subjects CSFT compared to Screening visit

*Cohort 2 subjects CSFT all compared to Baseline visit

*All BCVA values compared to Baseline visit

NOTE: Values shown are Mean ± SEM;
Interim review, unmonitored data

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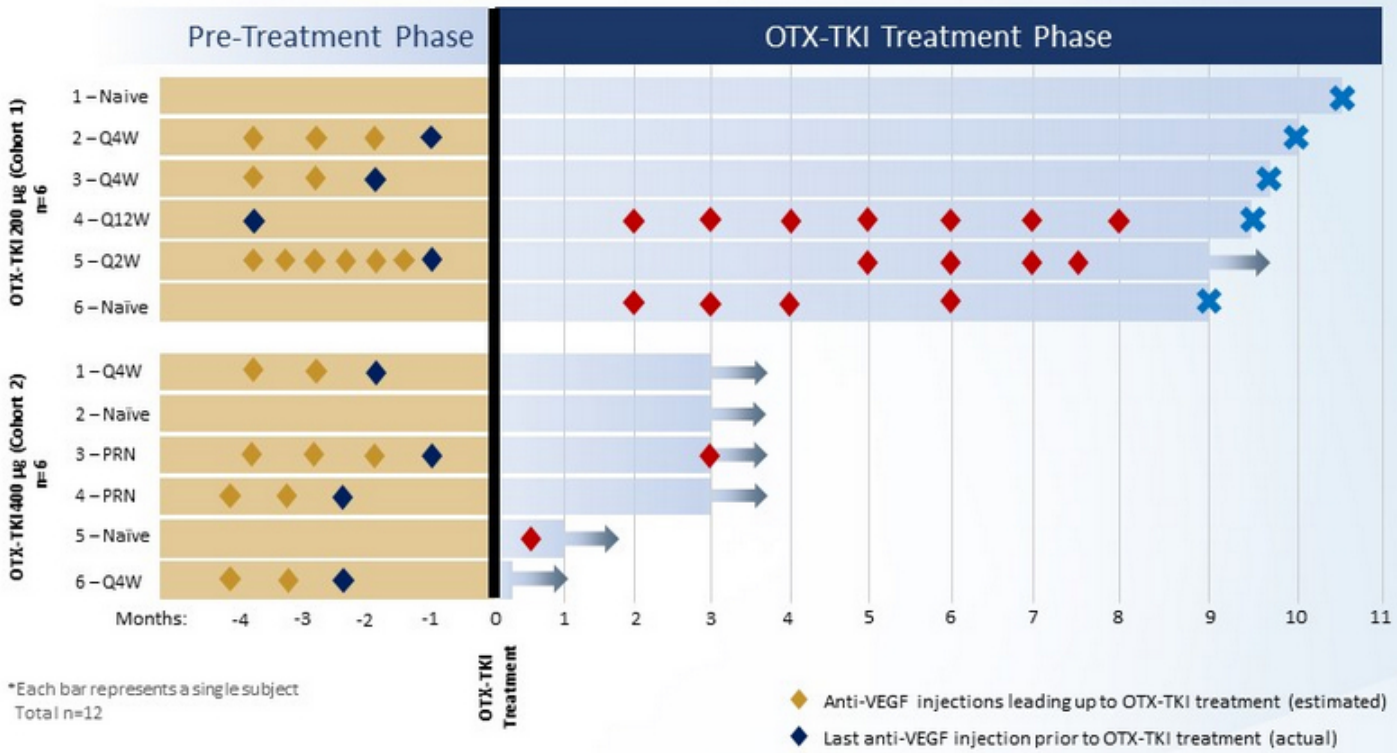
INDIVIDUAL SUBJECT DURABILITY ASSESSMENT



*Each bar represents a single subject
Total n=12

- Anti-VEGF injections leading up to OTX-TKI treatment (estimated)
- Last anti-VEGF injection prior to OTX-TKI treatment (actual)
- Rescue treatment
- Implant no longer visible
- Continuing follow-up

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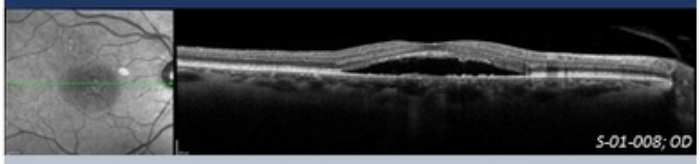
COHORT 2: SD-OCT EVALUATION

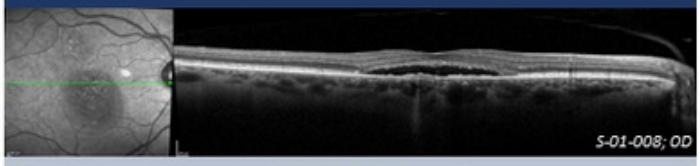
Subject 1: History of EYLEA Q4 Weeks

BASELINE



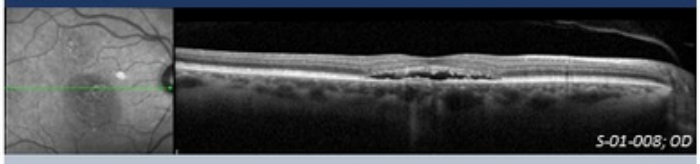
CSFT: 473 µm

MONTH 2



CSFT: 368 µm

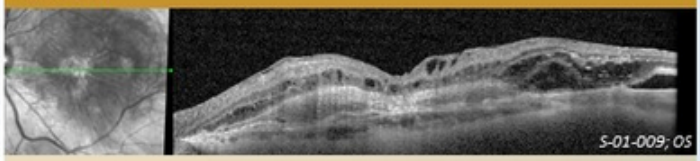
MONTH 3



CSFT: 337 µm

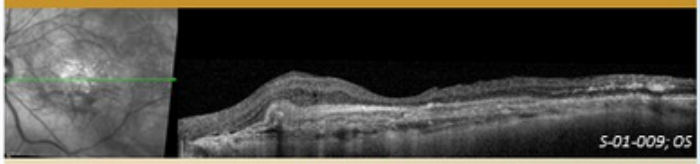
Subject 2: Treatment Naïve

BASELINE



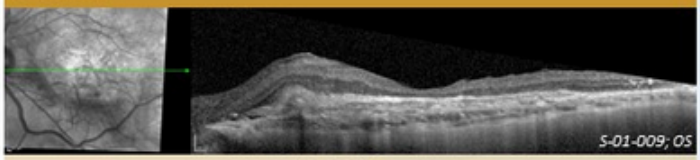
CSFT: 513 µm

MONTH 2



CSFT: 343 µm

MONTH 3



CSFT: 316 µm

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COHORT 1 & 2
SAFETY OVERVIEW

TOTAL ADVERSE EVENTS

Number of subjects with:	OTX-TKI 200 µg N=6	OTX-TKI 400 µg N=6	Total (n=12)
Adverse Events (AEs)	17	12	29
Treatment-related AEs	2	1	3
Injection procedure-related AEs	1	4	5
By severity			
Mild	*14*	*10*	*24*
Moderate	*2*	*2*	*4*
Severe	*0*	*0*	*0*
Ocular AEs	15	8	23
Ocular AEs in the study eye	11	6	17
Ocular Serious AEs	0	0	0
Treatment-related SAEs	0	0	0
Injection procedure-related SAEs	0	0	0

Interim look; Unmonitored data.

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OTX-TKI CONCLUSIONS: TO BE CONFIRMED

- **Clinically-meaningful decrease in retinal fluid**
  To date, OTX-TKI was generally well tolerated and observed to have a favorable safety profile in both cohorts. In the higher dose cohort, some subjects showed a decrease in intraretinal or subretinal fluid at 2 months
- **Extended duration of therapy**
  Patients still being followed in cohort 2, to be determined
- **Consistently bioresorbable**
  Implant biodegraded in 5 of 5 subjects by 9-10 months in cohort 1
- **Implant location and limited movement**
  Implant was able to be monitored; patients did not report visual impact

Study is ongoing; continued long-term evaluation of both cohorts

- Need to establish durability of treatment
- Identify Maximum Tolerated Dose (MTD)
- Understand utility of OTX-TKI with anti-VEGF injection

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