



Corporate Presentation

October 2021

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Enhancing the standard of care for retinal disorders by working to achieve the first FDA approval for bevacizumab in ophthalmology

Investment Highlights

ONS-5010 (bevacizumab-vikg)¹ Targeting \$13.1 Billion Global Ophthalmic Anti-VEGF Market²

Differentiated Drug Product

- Designed to meet stringent standards required for FDA ophthalmic approval
- Eliminates risks associated with off-label repackaged bevacizumab
- Delivery through a convenient pre-filled syringe

Potential for 1st FDA Approved Bevacizumab

- Compelling pivotal data supports U.S. FDA BLA submission, targeted for calendar Q1 2022
- Launch anticipated Q1 2023

Attractive Market Opportunity

- Over 50% of the U.S. market available for conversation to ONS-5010 representing billions in yearly sales
- 12-years US regulatory exclusivity expected
- Label expansion opportunity into DME and BRVO

Goal of ONS-5010 (Bevacizumab-vikg) Program

Provide Physicians and Patients an Ophthalmic FDA Approved Alternative of a Drug Adopted from IV Use in Other Specialties

Deliver cGMP formulation to ensure essential drug strength, quality, and purity

Eliminate potential impurities and particulates from legacy re-packaging processes

Create a product offering with a differentiated ophthalmic drug solution and delivery system to enhance physician ease of use

Provide an economically elegant anti-VEGF solution for payers, patients, and doctors

Leadership Team: Global Ophthalmic Development and Commercial Launch Excellence



C. RUSSELL TRENARY III
President, CEO and Director



LAWRENCE KENYON
Chief Financial Officer and Director



JEFF EVANSON
Chief Commercial Officer



TERRY DAGNON
Chief Operating Officer



RANDY THURMAN
Executive Chairman of the Board

MARK HUMAYUN, MD, PhD
Medical Advisor



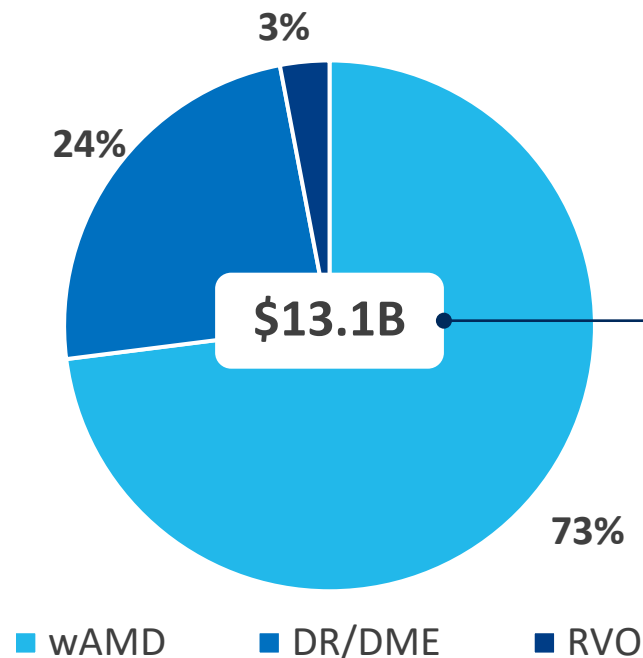
Wet AMD Landscape

Current and Future

Targeting Large and Growing Ophthalmic Markets

ONS-5010, If Approved, Will Be a Significant Therapy In the Retinal Anti-VEGF Market, Currently Estimated To Be In Excess of \$13.1 Billion Worldwide

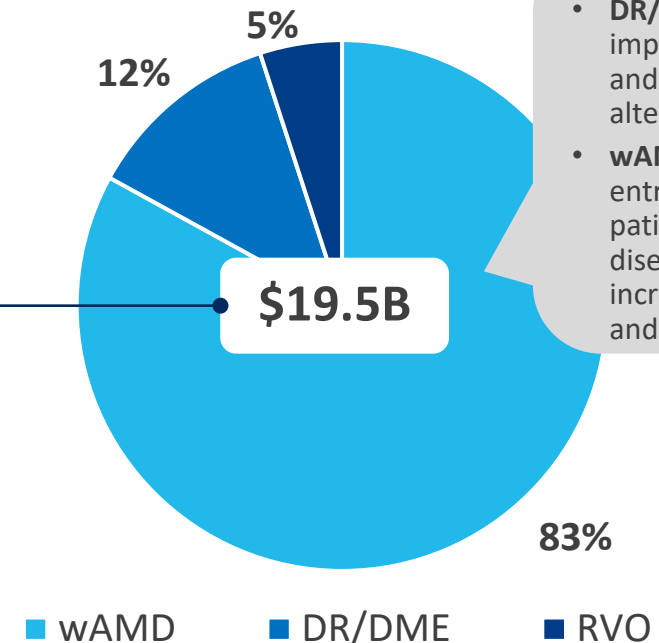
2020 9MM Anti-VEGF Revenue Share (USD)



CAGR

4.1%

2030 9MM Anti-VEGF Revenue Share (USD)



MARKET DRIVERS:

- **DR/DME** is more directly impacted by biosimilars and lower cost alternatives (-2.2% CAGR)
- **wAMD** is buoyed by new entrants targeting patients earlier in the disease cascade, increasing awareness, and earlier diagnosis

Unapproved Bevacizumab Represents 50% of U.S. Wet AMD Market Injections

Anti-VEGF U.S. Market Share in Wet AMD¹



Used Off-Label in Retina from formulation designed for IV use

50%



36%



12%



1%



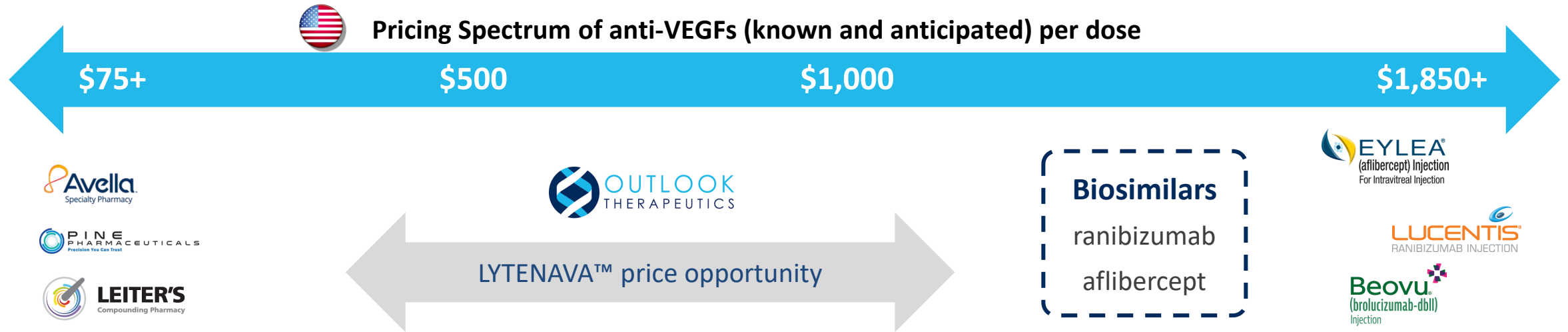
1%

Expected Drivers to Compete Across All Ophthalmic Anti-VEGF Therapeutics, if Approved by FDA

- 1 Provide cost-effective FDA approved ophthalmic bevacizumab
- 2 Become first-line “step-edit” drug of choice
- 3 12 years market exclusivity
- 4 Penetrate EU and developing markets

LYTENATM Pricing Opportunity

Optimize Uptake: Compounding Product prescribers while creating separation from biosimilars and other branded price points



Compounded Avastin (off-label)	LYTENA TM	Biosimilars to ranibizumab and/or aflibercept	Branded Premium Priced
<p>Cost of compounded Avastin is increasing due to quality issues including syringe failures.</p> <p>Cost per dose could increase to \$100/dose+</p>	<p>Pricing Strategy: Price low enough to move off-label users to branded LYTENATM, while still creating significant margin and value compared to any biosimilar and significantly less than the premium branded products.</p>	<p>Biosimilars, if approved, are likely to price at a 10-30% discount to the branded WAC.</p> <p>Mylan, Coherus and Biogen have thus far discounted ~20-30% from WAC in other biologic areas where they have launched biosimilars.</p>	<p>WAC (list) price for Lucentis is \$1,950/dose, both Beovu and Eylea are priced at \$1,850/dose.</p> <p>Practice rebates based on volume expected to continue.</p>

ONS-5010

ONS-5010 Ophthalmic Bevacizumab Target Product Profile

ONS-5010 (bevacizumab-vikg)

Patient Population

- Patients diagnosed with **wet AMD, DME, or BRVO**

Description

- Anti-VEGF **bevacizumab** designed for ophthalmic indications wet AMD, DME, and BRVO
- Known high affinity to bind to all isoforms of VEGF A

Dosing and Administration

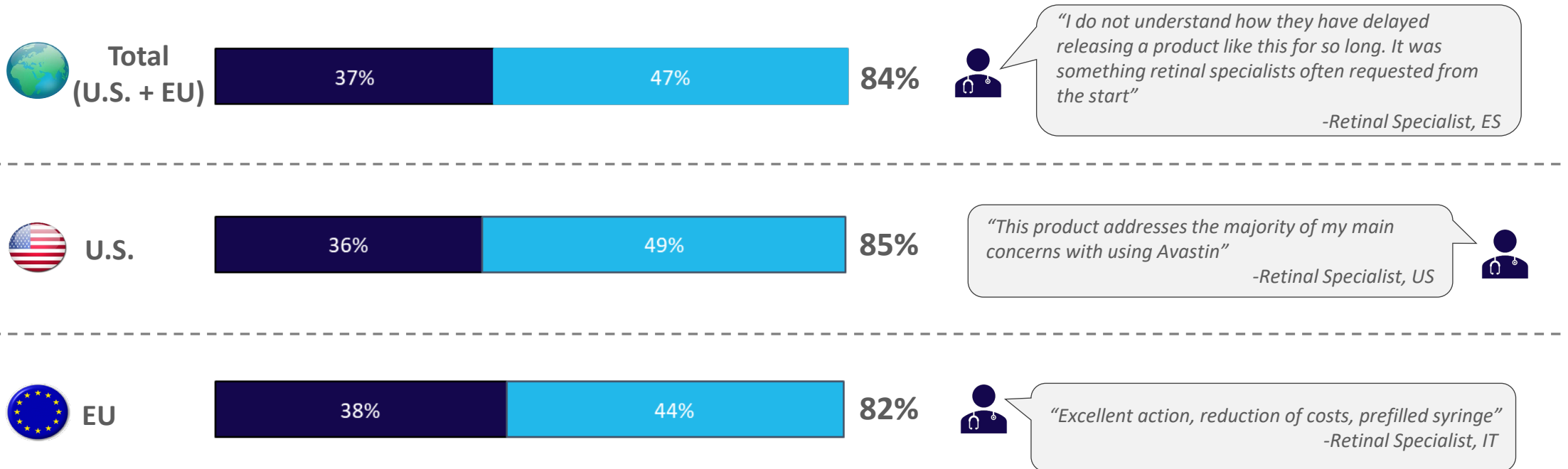
- Supplied either as **pre-filled ophthalmic syringe for intravitreal 1.25 mg injection** administered once monthly, **or in a glass vial**

Efficacy, Safety, and AEs

- Demonstrated significant efficacy and safety in NORSE ONE, TWO, and THREE trials
- Comparable to data from the National Eye Institute (NEI) Comparison of Age-Related Macular Degeneration Treatments Trials (CATT) study as equivalent to LUCENTIS®

Do Physicians Want an Ophthalmic Approved Bevacizumab?

>80% of Retinal Specialists Express Interest/High Interest In an FDA-Approved Ophthalmic Bevacizumab to Treat Wet AMD, DME and BRVO



ONS-5010 Ophthalmic Bevacizumab Value Proposition

ONS-5010 (bevacizumab-vikg)

Potential Value Proposition

- Potential FDA approved bevacizumab for the treatment of wet AMD
- **Priced to allow a cost-effective FDA approved option for first-line**
- Ability for **bilateral administration with malpractice insurance coverage**
- **Addresses compounding pharmacy quality control issues** causing potential AEs, product shortages, and liability risks associated with off-label repackaged IV Avastin[®]
 - Ensures cGMP quality and delivery system designed for retinal disorders

Compounded Bevacizumab Compared to FDA Approved

Ophthalmic Solution Requirement	Off-Label Compounded Repackaged IV Solution	FDA Approved Ophthalmic Solution for Intravitreal Injection
Sterile USP <71> ¹	?	Yes
FDA approved ophthalmic package consistent with USP <771> ¹	No	Yes
FDA reviewed stability data supporting shelf life ^{2,3}	No	Yes
Particulates per USP <789> for ophthalmic solutions ¹	?	Yes
pH FDA approved and consistent with USP <771> ^{1,2,3}	No	Yes
Potency FDA approved specifications for shelf life ^{2,3}	No	Yes
Osmolarity specification for ophthalmic solution ^{2,3}	No	Yes
Bacterial endotoxins USP <85> ¹	?	Yes
GMP ^{2,3}	?	Yes

Unmet Medical Needs Due To Repackaged and Off-Label Use of Bevacizumab Designed for Other Specialties and Delivery Systems

Variability in Potency¹

JAMA Ophthalmology

- 81% of samples had lower protein concentrations than required
- Samples had statistically significant variations in protein concentration among samples

Safety and Sterility Adverse Events²

Warning Letter FDA

- Unvalidated hold times in syringes
- Patients have lost eyesight due to infections
- Multiple unapproved repackaged IV bevacizumab recalls due to unsterile compounding practices

Syringe Adverse Events³

ASRS American Society of Retina Specialists

- Variability in repackaging can lower quality of syringe products, resulting in adverse events
- Silicone oil droplets may be released from the syringe into the eye

Not Held to FDA Ophthalmic Quality Standards When Repackaged



400 mg/16 mL, single-use vial;
100 mg/4 mL, single-use vial



U.S. Law and FDA Regulations for Compounding and Repackaging

- The Food Drug and Cosmetic Act (FD&CA) and Drug Quality and Security Act of 2013 define what is legal for 503A and 503B Compounding Pharmacies.¹
 - **Once a drug or biologic is FDA approved and commercially available compounding is no longer authorized.**^{2,3,4,5}
 - 503A Compounding pharmacies are regulated by federal regulations and state laws and can only compound or repackage for individual prescriptions in limited quantities and cannot distribute across state lines for > 5% of business.
 - 503B Compounding pharmacies / outsourcing facilities must comply with CGMP regulations, are inspected by FDA and must adhere to reporting requirements.
 - Neither 503A nor 503B pharmacies can compound or repackage commercially available drugs unless they appear on the official FDA drug shortage list.
- **“Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality.” – FDA⁶**
- “The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product.” – FDA⁶
- “Such a practice would create significant public health risks because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared under substandard manufacturing conditions.” – FDA⁶
- **“Under the statutory scheme, only very rarely should a compounded drug product that is essentially a copy of a commercially available drug product be offered to a patient.” – FDA⁶**

Pathway Towards Potential FDA Approval in Wet AMD – NORSE TWO Top-Line Results Recently Unveiled

U.S. BLA Submission Targeted Calendar Q1 2022

✓ Positive Signals



Clinical Experience Trial
1st Registration Trial

✓ Positive Top-Line Data



Pivotal Trial
2nd Registration Trial

✓ Completed



Open-Label Safety Study
Supports BLA Requirements



Pivotal Trial

2nd Registration Trial



Trial Highlights:

- Randomized masked controlled trial
- ONS-5010 (bevacizumab-vikg) vs LUCENTIS® (ranibizumab)
- 228 patients enrolled
- Trial conducted in the United States
- Trial arms included >95% treatment-naïve patients
- Safety & efficacy data support planned U.S. BLA submission in calendar Q1 2022

NORSE TWO Pivotal Trial Design



Randomized masked controlled trial with 228 subjects



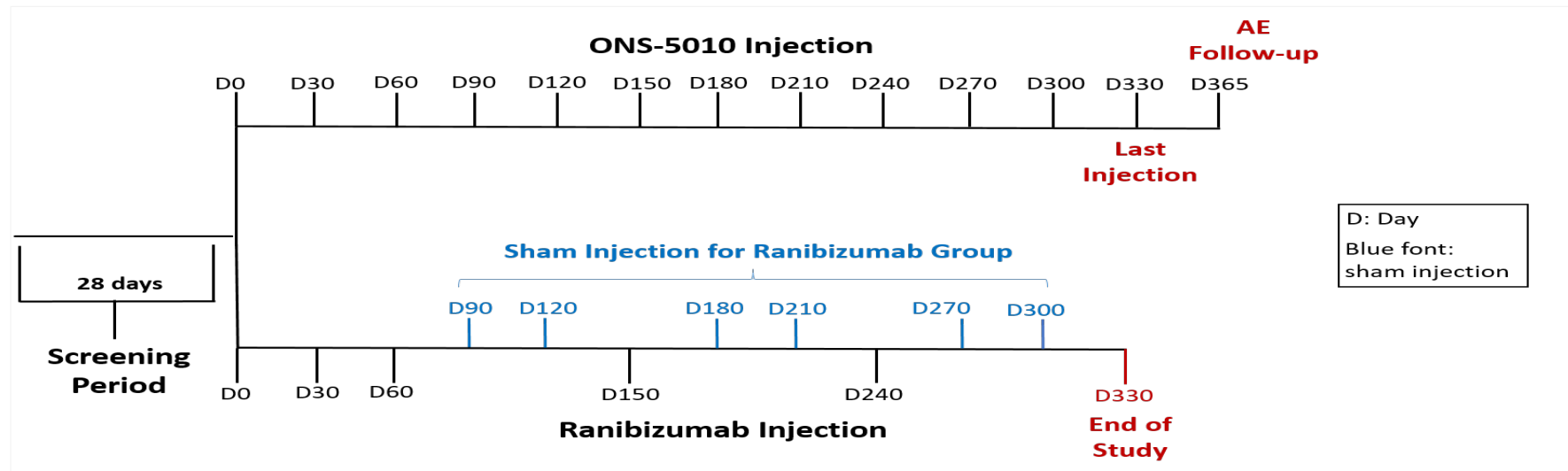
ONS-5010 (bevacizumab-vikg) administered monthly X 12



LUCENTIS dosing arm (PIER dosing) – Three initial monthly injections followed by fixed quarterly dosing with sham injections at monthly intervals in between



Primary endpoint difference in proportion of subjects gaining 15 letters of BCVA at Day 330



NORSE TWO: Positive Efficacy Data

Unprecedented 41% ONS-5010 with 3-Line Gainers¹

Statistically Significant Difference Across Both Primary and Key Secondary Endpoints

	ONS-5010 (bevacizumab-vikg)	LUCENTIS® (ranibizumab)	p-value
Primary Endpoint:			
Difference in subjects who gained at least 15 letters in the best corrected visual acuity (BCVA) at 11 months ²			
Intent-to-Treat (ITT) Primary Dataset	41%	23%	p = 0.0052
Secondary Per-Protocol (PP) Dataset	41%	24%	p = 0.04
Key Secondary Endpoint:			
Mean change in the BVCA through 11 months ²			
Intent-to-Treat (ITT) Primary Dataset	11.2 letters	5.8 letters	p = 0.0043
Secondary Per-Protocol (PP) Dataset	11.1 letters	7.0 letters	p = 0.05

NORSE TWO Safety Results:

Consistent with Previously Reported Results from NORSE ONE and NORSE THREE

In All Three Studies Only One Subject has Reported Ocular Inflammation

Characteristic	Statistic	ONS-5010 (Masked Data) (N=113)	Ranibizumab (N=115)	Overall (Masked Data) (N=228)
At Least 1 TEAE	n (%)	83 (73.5)	88 (76.5)	171 (75.0)
At Least 1 Related TEAE	n (%)	6 (5.3)	2 (1.7)	8 (3.5)
Maximum Severity				
CTCAE Grade 1 Mild	n (%)	46 (40.7)	45 (39.1)	91 (39.9)
CTCAE Grade 2 Moderate	n (%)	23 (20.4)	30 (26.1)	53 (23.2)
CTCAE Grade 3 Severe	n (%)	11 (9.7)	9 (7.8)	20 (8.8)
CTCAE Grade 4 Life-threatening	n (%)	0	2 (1.7)	2 (0.9)
CTCAE Grade 5 Death	n (%)	3 (2.7)	2 (1.7)	5 (2.2)
At Least 1 Ocular TEAE	n (%)	55 (48.7)	60 (52.2)	115 (50.4)
At Least 1 Ocular TEAE in Study Eye	n (%)	47 (41.6)	47 (40.9)	94 (41.2)
At Least 1 Non-Ocular TEAE	n (%)	55 (48.7)	57 (49.6)	112 (49.1)
At Least 1 >= Grade 3 Related TEAE	n (%)	2 (1.8)	1 (0.9)	3 (1.3)
At Least 1 Serious TEAE	n (%)	14 (12.4)	16 (13.9)	30 (13.2)
At Least 1 Related Serious TEAE	n (%)	2 (1.8)	1 (0.9)	2 (0.9)
At Least 1 TEAE Leading to Study Withdrawal	n (%)	2 (1.8)	4 (3.5)	6 (2.6)

NORSE ONE and NORSE THREE Results



Completed Clinical Experience Trial

Demonstrated anticipated safety and efficacy signals consistent with previously published results for ophthalmic use of bevacizumab

Trial Highlights:

- Desired proportion of 3-line visual acuity gainers achieved
- Desired mean gain in visual acuity achieved
- Zero ocular inflammation observed
- Safety was comparable to published bevacizumab studies, such as CATT



Open-Label Safety Study

Positive safety profile reinforces previously reported safety data for ONS-5010 (bevacizumab-vikg)

Trial Highlights:

- Provided adequate number of patient exposure required for BLA submission
- No unexpected safety trends
- Zero cases of ocular inflammation

Manufacturing and Regulatory Progress Towards Commercialization



Manufacturing

Best-in-class cGMP
manufacturing partners



Pre-Filled Syringes

Supply agreement for a convenient
pre-filled ophthalmic syringe



Regulatory

Achieved clinical requirements
agreed upon with the FDA

The Outlook Therapeutics Opportunity for Patients, Physicians, and Payers



Mission is to enhance the standard of care



Plan is to be the first FDA approved bevacizumab in ophthalmology



Market opportunity is billions in yearly sales with potential for significant momentum upon approval



Data are compelling and statistically significant



Aim is to launch directly in the U.S. and consider OUS licensing



Company Summary

- **Targeting \$13.1 billion global ophthalmic anti-VEGF market¹**
 - *Initial U.S. target segment worth potentially billions in yearly revenue are served by compounding pharmacies which by law should give way to Outlook Therapeutics' ONS 5010, if FDA approved*
- **Potential for first FDA approved ophthalmic formulation of bevacizumab**
- **U.S. FDA BLA submission targeted for calendar Q1 2022 with anticipated approval to follow 9-12 months later**
- **Management team with proven ophthalmic commercial launch expertise**

Appendix

Bevacizumab Solution Injection Options

- **Off label - IV Solutions Given via IV Administration**

Does Not Meet Requirements for FDA Approved Ophthalmic Dosage Form

- Bascom Palmer (Dr. Rosenfeld) initially employed bevacizumab intravenously as a therapy for wet age-related macular degeneration and showed it was successful, however it was concluded intravitreal injection should be investigated¹

- **Off label – Not FDA Approved - Compounded Repackaged IV Solution for Intravitreal Injection**

Does Not Meet Requirements for FDA Approved Ophthalmic Dosage Form

- The National Eye Institute conducted the landmark CATT clinical trial under an FDA IND with FDA oversight on a single manufacturing/repackaging process
- Subsequent to the CATT Trial, many Compounding Pharmacies have supplied compounded repackaged AVASTIN with a long history of ocular safety issues, recalls, FDA Warning letters, with peer reviewed publications demonstrating a concerning lack of potency and other concerns^{2,3}

- **Investigational Ophthalmic Solution - Dosage Form**

FDA oversight under FDA IND

- ONS-5010 bevacizumab-vikg an investigational ophthalmic solution has been investigated in NORSE ONE, NORSE TWO and NORSE THREE under an FDA IND and a new BLA is planned to be submitted in Q1/2022. Clinical trials and manufacturing has been conducted under an IND and FDA oversight

AAO Addressing Compounding Pharmacy Concerns

AAO is monitoring Avastin shortages and pricing



Issues continue to be reported with compounded bevacizumab:

- Change in syringe type to comply with USP 789 standards for particulate matter in ophthalmic solutions (i.e. eliminating silicone oil droplets in insulin syringes)



ONS-5010 could provide important benefits over off-label Avastin

- Continuity of source and quality
- Uniformity of product
- Supply chain integrity
- FDA approved delivery vehicle/syringe



Email from AAO dated May 30 , 2019

Academy Communication

The Facts About the Avastin Shortage

The Academy continues to seek new information on the ongoing Avastin shortages that are affecting the drug's supply nationwide. Today, we're sharing with you the latest information and a comprehensive document to explain this issue and actions the Academy is taking.

Avastin is a critically important treatment option for ophthalmology patients facing sight threatening diseases, including AMD, macular edema, neovascular glaucoma and others. It is the most commonly administered intravitreal drug worldwide and therefore any disruption to its availability has a major impact on patients.

The basics:

- A shortage of Avastin has affected access to the drug and prices.
- The shortage is related to a change in syringe type to comply with Food and Drug Administration guidance and with USP 789 standards for particulate matter in ophthalmic solutions.
- Suppliers are providing the Academy with updates on supplies and prices.
- The Academy has asked CMS to modify Avastin reimbursement rates to protect physicians from financial risk.

Get the latest details below on the impact of the shortage, and visit the [AAO.org Avastin Shortages and Reimbursements page](https://www.aao.org/Avastin-Shortages-and-Reimbursements) for our comprehensive report on this issue. We will update that page regularly with new information.

Commercial Planning Activities Underway



If ONS-5010 (bevacizumab-vikg) is FDA approved and has a cost-effective profile, Outlook Therapeutics expects ONS-5010 to be widely adopted by payors and clinicians worldwide and to become the first-line drug of choice for payor-mandated “step-edit” in the United States for retinal indications



**Physician and
Patient Outreach**

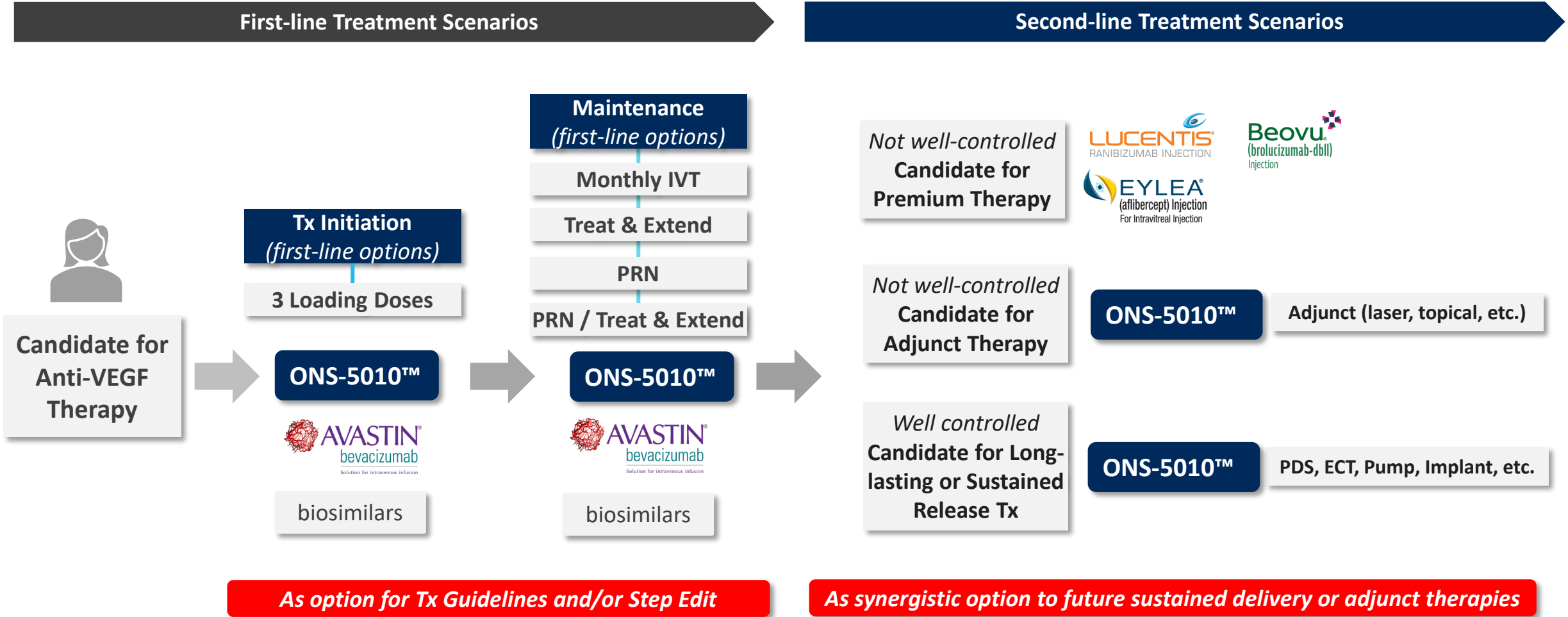


**Aligning Key
Opinion Leaders**



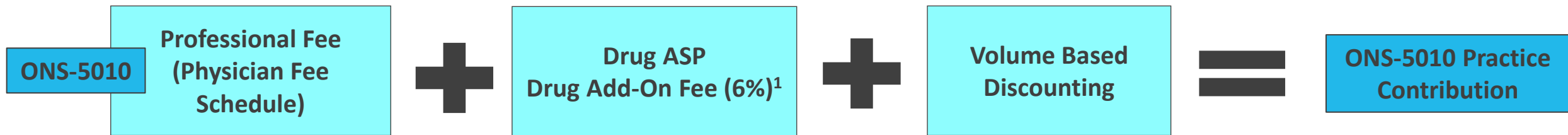
**Payor Community
Engagement**

Potential Use of ONS-5010 Ophthalmic Bevacizumab Across Wet AMD Treatment Spectrum



Compelling and Predictable Physician Economics Compared to Unapproved Compounded Bevacizumab

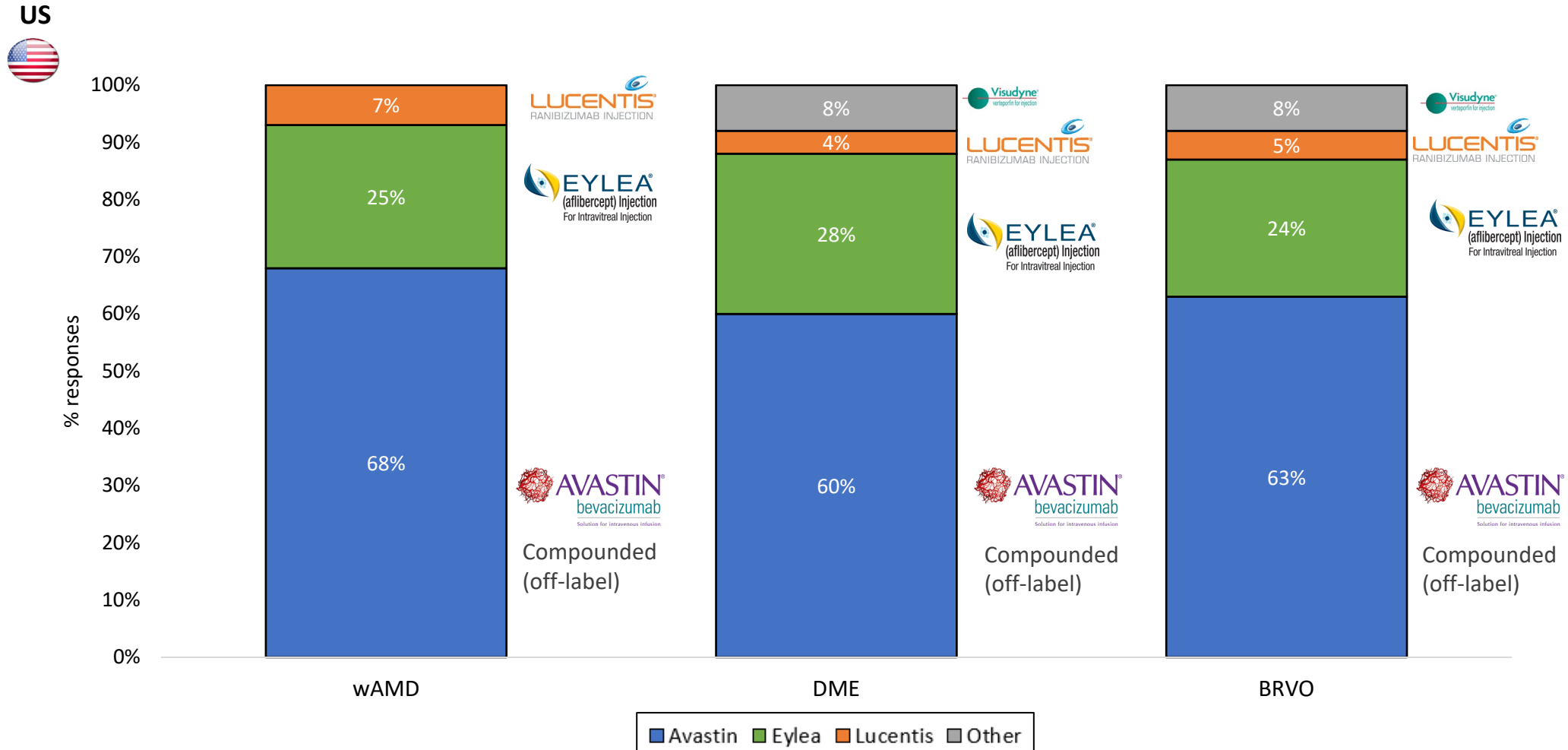
Per Injection Revenue (unilateral)



- In contrast, ASRS has identified that compounded off-label bevacizumab is not adequately reimbursed at the national level
- Costs of compounding have continued to rise due to increased efforts to meet UPS 789 criteria. Physicians have shared that there is reduced margin for physicians choosing to compound bevacizumab due to these changes
- Additionally, several large compounding pharmacies have either moved away from compounding (AMEX) or have had to issue recalls and product safety bulletins
- **ONS-5010 can directly address this economic and quality dilemma for physicians and patients alike**

New Patient Starts (U.S.)

If approved, ONS-5010 could have direct access to up to 60-68% of new patient starts (initial injections)



Safety Results: Frequency and Incidence of Ocular AEs > 1%

Characteristic	Statistic	ONS-5010 (Total Data) (N=113)	Ranibizumab (N=115)	Overall (Total Data) (N=228)
At Least 1 Ocular TEAE in Study Eye	n (%)	51 (45.1)	48 (41.7)	99 (43.4)
Cataract	n (%)	6 (5.3)	3 (2.6)	9 (3.9)
Conjunctival hemorrhage	n (%)	10 (8.8)	3 (2.6)	13 (5.7)
Conjunctival hyperemia	n (%)	0	2 (1.7)	2 (0.9)
Corneal abrasion	n (%)	5 (4.4)	1 (0.9)	6 (2.6)
Cystoid macular edema	n (%)	1 (0.9)	2 (1.7)	3 (1.3)
Dermatochalasis	n (%)	2 (1.8)	2 (1.7)	4 (1.8)
Detachment of retinal pigment epithelium	n (%)	0	2 (1.7)	2 (0.9)
Dry age-related macular degeneration	n (%)	0	3 (2.6)	3 (1.3)
Dry eye	n (%)	3 (2.7)	5 (4.3)	8 (3.5)
Eye pain	n (%)	3 (2.7)	2 (1.7)	5 (2.2)
Eye irritation	n (%)	2 (1.8)	0	2 (0.9)
Hordeolum	n (%)	1 (0.9)	2 (1.7)	3 (1.3)
Intraocular pressure increased	n (%)	7 (6.2)	1 (0.9)	8 (3.5)
Lacrimation increased	n (%)	0	2 (1.7)	2 (0.9)
Metamorphopsia	n (%)	1 (0.9)	4 (3.5)	5 (2.2)
Neovascular age-related macular degeneration	n (%)	9 (8.0)	12 (10.4)	21 (9.2)
Photopsia	n (%)	2 (1.8)	0	2 (0.9)

Safety Results: Frequency and Incidence of Ocular AEs > 1%

Characteristic	Statistic	ONS-5010 (Total Data) (N=113)	Ranibizumab (N=115)	Overall (Total Data) (N=228)
At Least 1 Ocular TEAE in Study Eye	n (%)	51 (45.1)	48 (41.7)	99 (43.4)
Posterior capsule opacification	n (%)	1 (0.9)	3 (2.6)	4 (1.8)
Procedural pain	n (%)	0	2 (1.7)	2 (0.9)
Punctate keratitis	n (%)	3 (2.7)	2 (1.7)	5 (2.2)
Retinal degeneration	n (%)	1 (0.9)	2 (1.7)	3 (1.3)
Retinal hemorrhage	n (%)	3 (2.7)	8 (7.0)	11 (4.8)
Retinal edema	n (%)	0	4 (3.5)	4 (1.8)
Retinal vein occlusion	n (%)	0	2 (1.7)	2 (0.9)
Subretinal fibrosis	n (%)	2 (1.8)	2 (1.7)	4 (1.8)
Subretinal fluid	n (%)	4 (3.5)	5 (4.3)	9 (3.9)
Vision blurred	n (%)	2 (1.8)	2 (1.7)	4 (1.8)
Visual acuity reduced	n (%)	3 (2.7)	17 (14.8)	20 (8.8)
Vitreous detachment	n (%)	3 (2.7)	2 (1.7)	5 (2.2)
Vitreous floaters	n (%)	5 (4.4)	1 (0.9)	6 (2.6)
Vitreous hemorrhage	n (%)	2 (1.8)	1 (0.9)	3 (1.3)