



Corporate Presentation

February 2022



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

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MARK HUMAYUN, MD, PhD
Medical Advisor



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, including potential impurities and particulates from legacy re-packaging processes
- 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
- Provide an economically elegant anti-VEGF solution for patients, payers and doctors

Attractive Market Opportunity

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

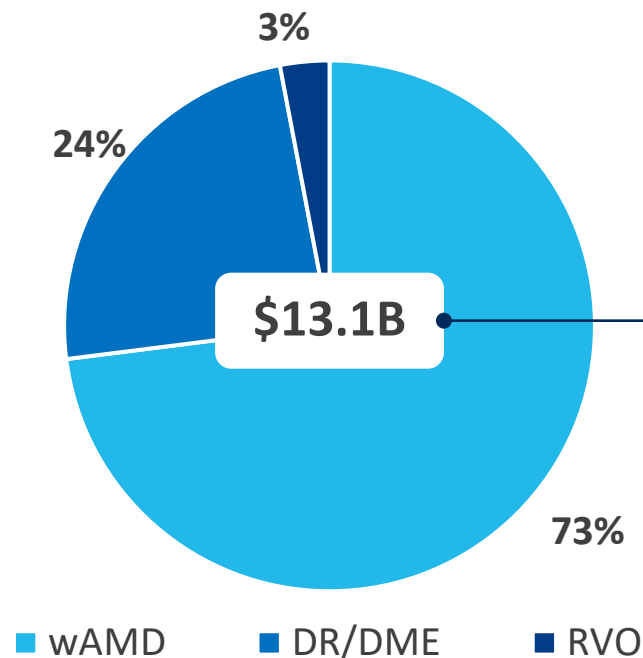
Wet AMD Landscape

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

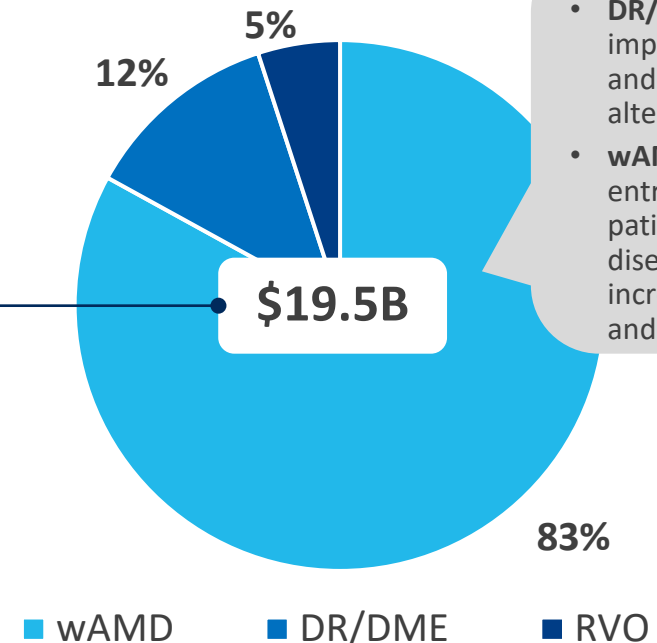
2020 9MM Anti-VEGF Revenue Share (USD)



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

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 

- 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**

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

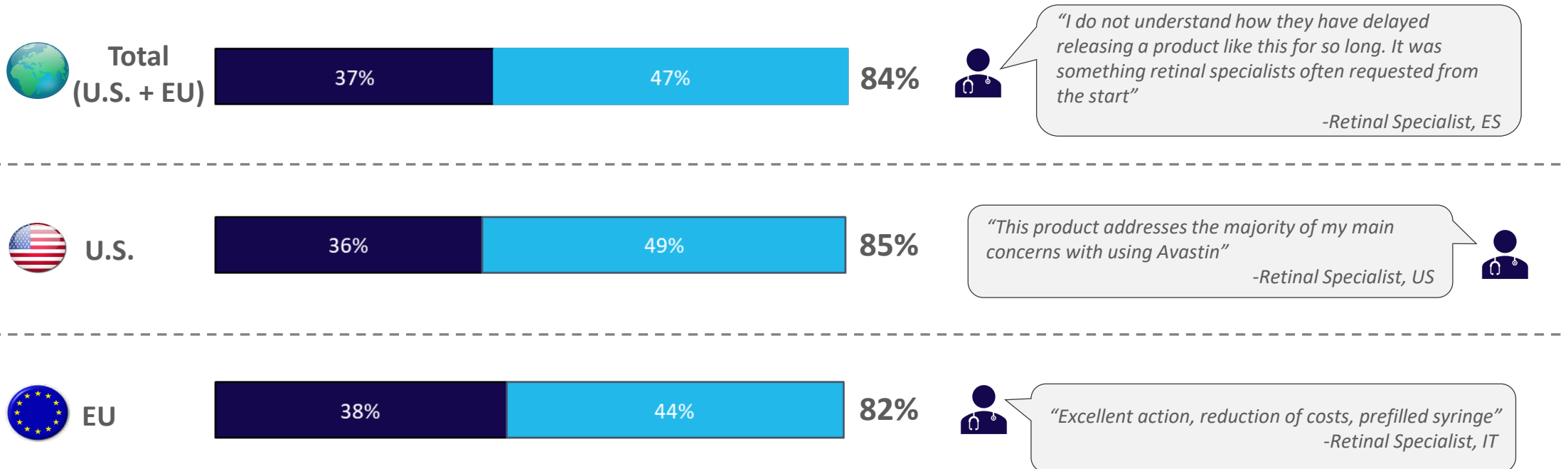
- Supplied either as **pre-filled ophthalmic syringe for intravitreal 1.25 mg injection** administered once monthly, **or in a glass vial**

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®

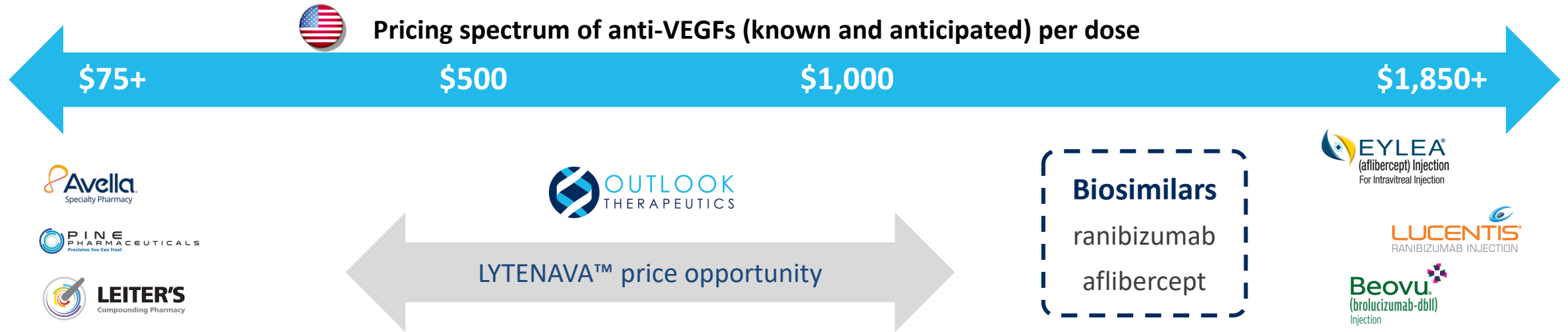
Do Physicians Want an Ophthalmic Approved Bevacizumab?

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



LYTENAVA™ Pricing Opportunity

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



| Compounded Avastin (off-label) | LYTENAVA™ | 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 LYTENAVA™, 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> |

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

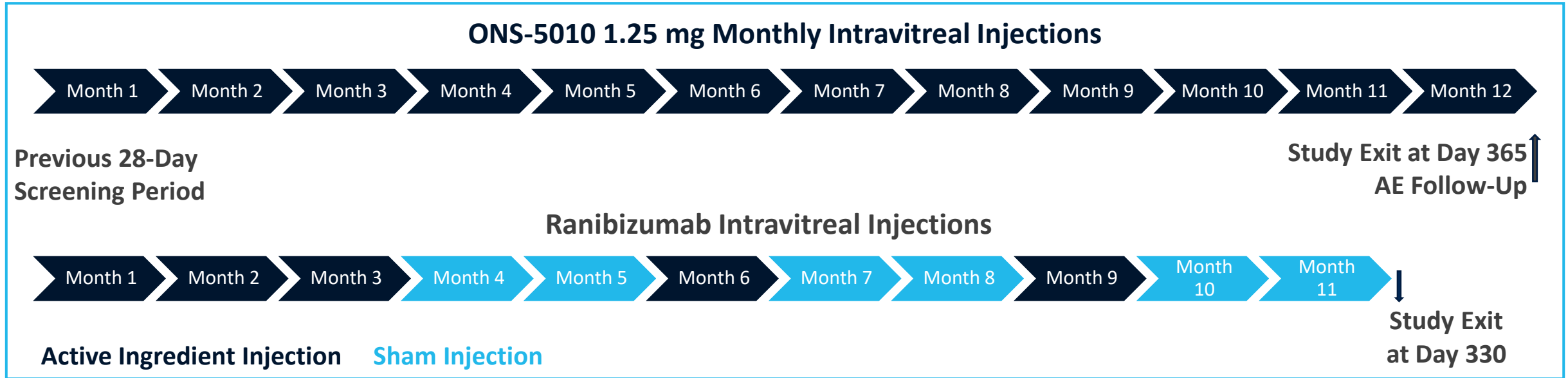


Trial Highlights:

- 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

Superiority Phase 3 Pivotal Study Design

12-Month Study of Safety and Efficacy of ONS-5010 in Subjects with Wet AMD Study Design and Statistical Analysis Plan Agreed to by U.S. FDA



Study Eye Characteristics

- Active, primary CNV due to wet AMD
- Treatment-naïve
- BCVA: 20/50 – 20/320

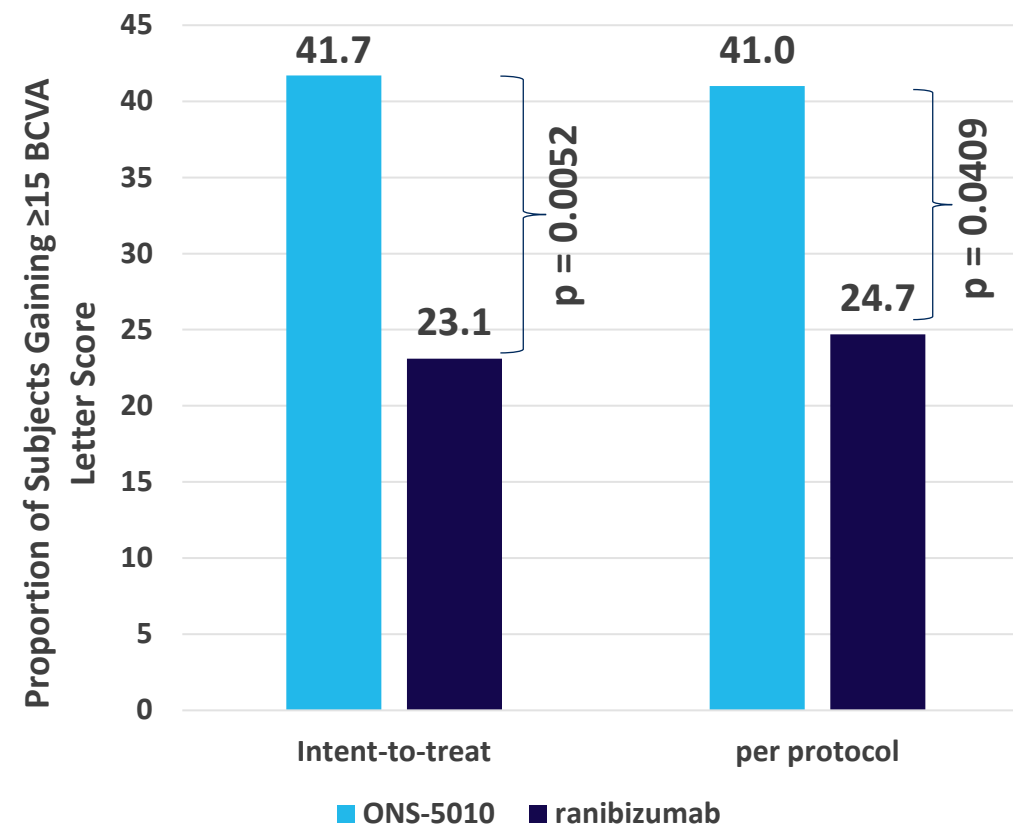
Key Study Outcomes

- Proportion of subjects who gain ≥ 15 letters in BCVA
- Mean change in BCVA from baseline to Month 11
- Frequency and incidence of AEs

Primary Endpoint Met with Statistically Significant, Clinically Relevant Results¹

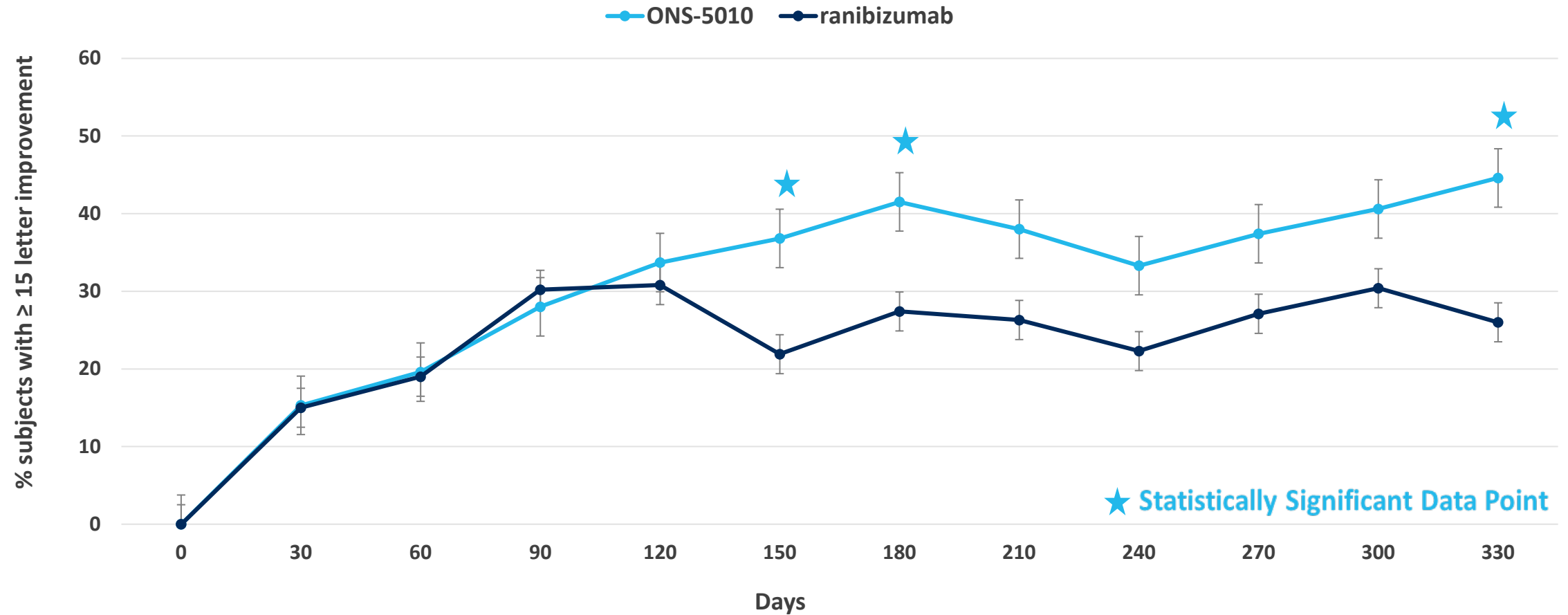
| Characteristic | Statistic | ONS-5010 (n=113) | Ranibizumab (n=115) |
|----------------------|-----------|---------------------|------------------------|
| Intent-to-Treat Pop. | | | |
| Number of Subjects | n/N (%) | 45/108 (41.7) | 24/104 (23.1) |
| Risk Difference | | 0.1859 | |
| 95% CI | | (0.0442,0.3086) | |
| p-value | | 0.0052 | |
| Per Protocol Pop. | | | |
| Number of Subjects | n/N (%) | 34/83 (41.0) | 18/73 (24.7) |
| Risk Difference | | 0.1631 | |
| 95% CI | | (0.0120, 0.3083) | |
| p-value | | 0.0409 | |

Difference in % Subjects Gaining 3 Lines Vision



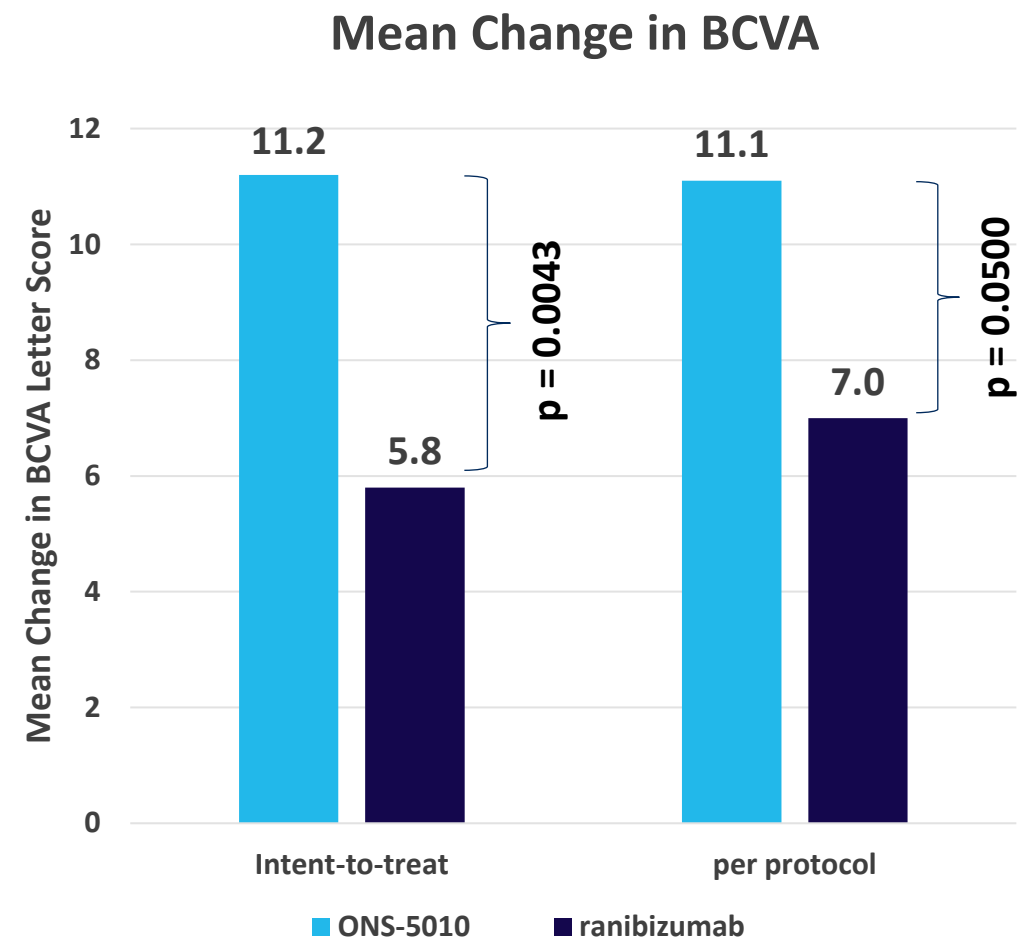
ONS-5010 Rapid Onset of Action with Sustained Significance Over Time

≥ 15 Letter Gainers (± SE) Over Time



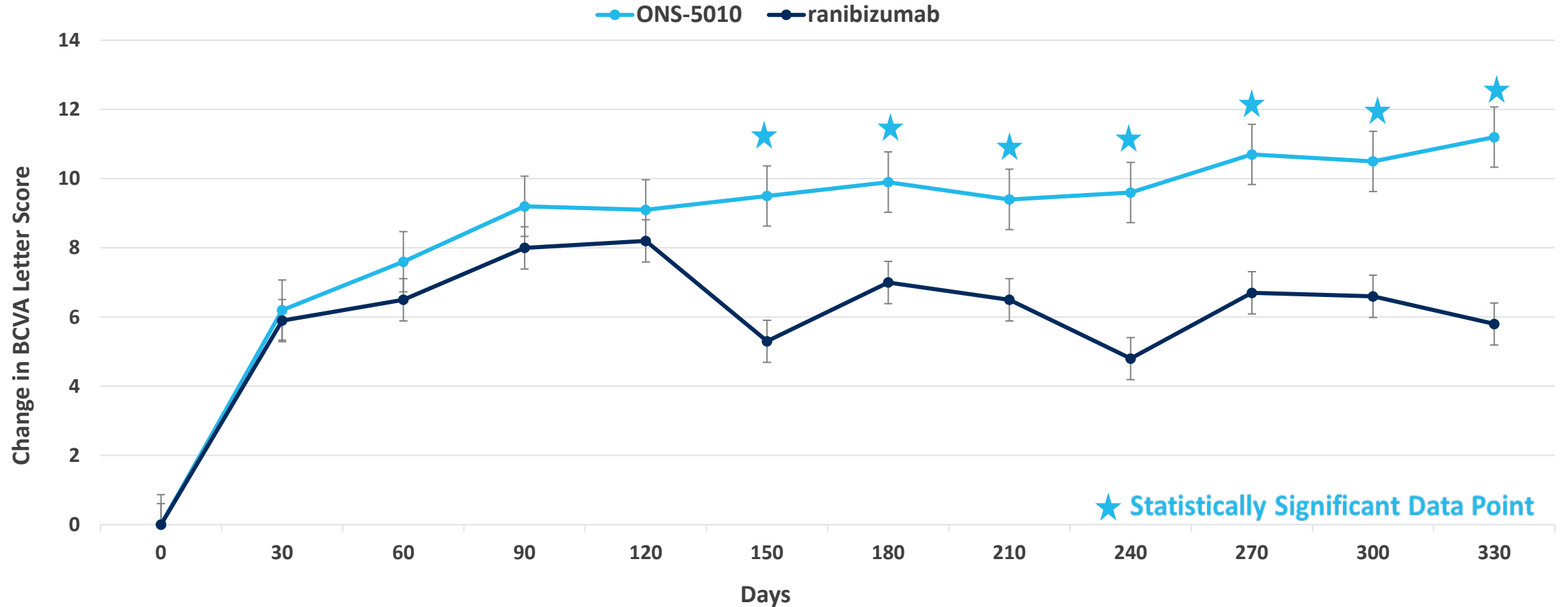
Key Secondary Endpoints Met with Highly Statistically Significant, Clinically Relevant Results

| Characteristic | Statistic | ONS-5010 (n=113) | Ranibizumab (n=115) |
|---|-----------|---------------------|------------------------|
| BCVA Score Change from Baseline to Month 11 (ITT) | n | 104 | 96 |
| | Mean (SD) | 11.2 (12.19) | 5.8 (14.80) |
| p-value | | 0.0043 | |
| BCVA Score Change from Baseline to Month 11 (PP) | n | 80 | 68 |
| | Mean (SD) | 11.1 (12.77) | 7.0 (14.56) |
| p-value | | 0.0500 | |



ONS-5010 Rapid Onset of Action with Sustained Significance Over Time

Mean (\pm SE) Change in BCVA Over Time

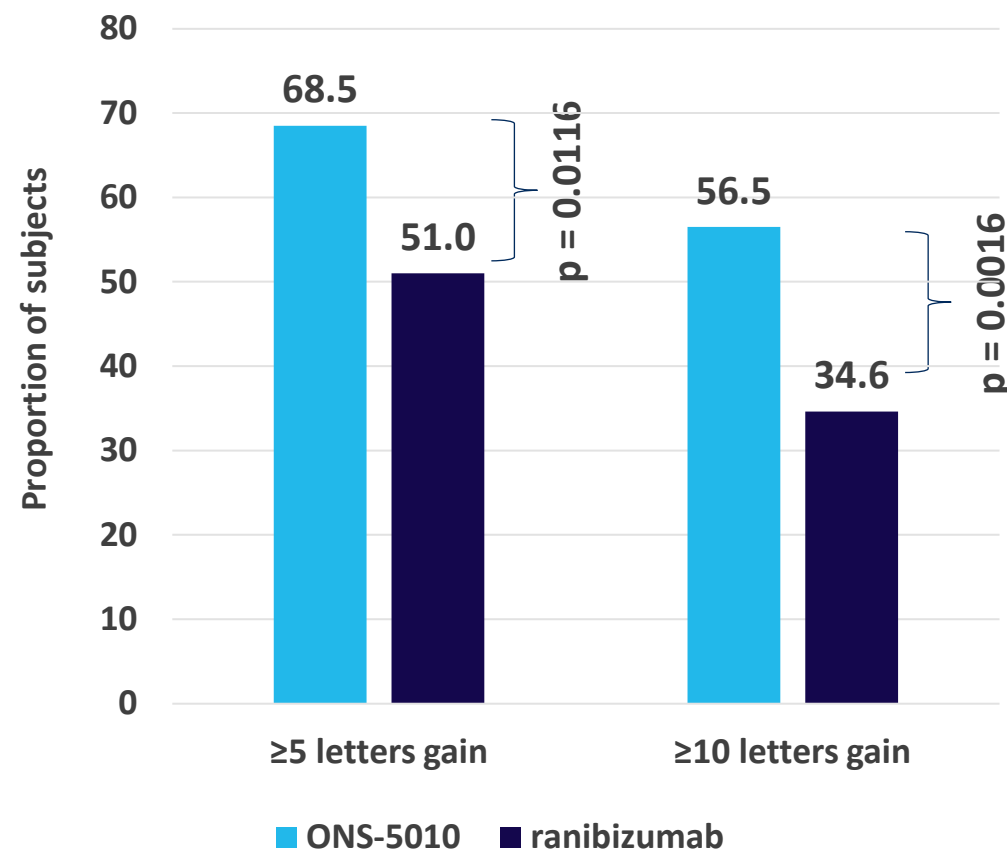


Statistically Significant, Clinically Relevant Secondary Endpoints

| Characteristic | Statistic | ONS-5010 (n=113) | Ranibizumab (n=115) |
|------------------------------|-----------|---------------------|------------------------|
| Subjects Gaining ≥5 letters | | | |
| Number of Subjects | n/N (%) | 74/108 (68.5) | 53/104 (51.0) |
| Risk Difference | | 0.1756 | |
| 95% CI | | (0.0315,0.3052) | |
| p-value | | 0.0116 | |
| Subjects Gaining ≥10 letters | | | |
| Number of Subjects | n/N (%) | 61/108 (56.5) | 36/104 (34.6) |
| Risk Difference | | 0.2187 | |
| 95% CI | | (0.0726,0.3487) | |
| p-value | | 0.0016 | |

68.5% (p = 0.0116) ONS-5010 subjects gained ≥ 5 letters of vision
 56.5% (p = 0.0016) ONS-5010 subjects gained ≥ 10 letters of vision
 41.7% (p = 0.0052) ONS-5010 subjects gained ≥ **15 letters of vision**

Responder Analysis



Safety Results: Consistent with Previously Reported Results from NORSE ONE and NORSE THREE

Only One ONS-5010 Ocular Inflammation AE Reported in NORSE TWO (Iritis)

| Characteristic | Statistic | ONS-5010 (n=113) | Ranibizumab (n=115) | Overall (n=228) |
|--------------------------------------|--------------|---------------------|------------------------|--------------------|
| ≥ 1 Adverse Event | n (%) | 85 (75.2) | 85 (73.9) | 170 (74.6) |
| ≥ 1 ocular Adverse Event | n (%) | 59 (52.2) | 61 (53.0) | 120 (52.6) |
| ≥ 1 non-ocular Adverse Event | n (%) | 56 (49.6) | 52 (45.2) | 108 (47.4) |
| ≥ 1 Serious Adverse Event | n (%) | 14 (12.4) | 16 (13.9) | 30 (13.2) |
| ≥ 1 ocular Serious Adverse Event | n (%) | 1 (0.9) | 0 | 1 (0.4) |
| ≥ 1 non-ocular Serious Adverse Event | n (%) | 13 (11.5) | 16 (13.9) | 29 (12.7) |

Safety Results: Frequency and Incidence of Ocular AEs $\geq 3\%$

Low Incidence of Ocular AEs, Despite More Injections in ONS-5010 Arm

| Characteristic | Statistic | ONS-5010 (n=113) | Ranibizumab (n=115) | Overall (n=228) |
|---|--------------|---------------------|------------------------|--------------------|
| ≥ 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) |
| Corneal abrasion | n (%) | 4 (3.5) | 1 (0.9) | 5 (2.2) |
| Dry eye | n (%) | 2 (1.8) | 5 (4.3) | 7 (3.1) |
| Intraocular pressure increased | n (%) | 7 (6.2) | 1 (0.9) | 8 (3.5) |
| Neovascular AMD | n (%) | 0 | 4 (3.5) | 4 (1.8) |
| Retinal hemorrhage | n (%) | 4 (3.5) | 6 (5.2) | 10 (4.4) |
| Subretinal fluid | n (%) | 3 (2.7) | 4 (3.5) | 7 (3.1) |
| Visual acuity reduced | n (%) | 4 (3.5) | 14 (12.2) | 18 (7.9) |
| Vitreous detachment | n (%) | 4 (3.5) | 2 (1.7) | 6 (2.6) |
| Vitreous floaters | n (%) | 4 (3.5) | 1 (0.9) | 5 (2.2) |

Only One ONS-5010 Ocular Inflammation AE Reported in All Three ONS-5010 Studies

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

NORSE SEVEN

Pre-Filled Syringe

Vials Versus
Pre-Filled Syringe



Trial Highlights:

- 3-month study to compare the safety of ONS-5010 in vials versus pre-filled syringe
- Enrolling ~120 subjects with visual impairment due to retinal disorders
 - Wet AMD
 - BRVO
 - DME

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

Financial Highlights

NASDAQ: OTLK

Sufficient capital through the anticipated approval of the ONS-5010 BLA expected in the first calendar quarter of 2023¹

~\$311M

Market Cap²

~224M

Shares Outstanding³

~1.6M

Average Volume²

Cash Balance

~\$14.5M

As of September 30, 2021

\$54.0M

Cash balance does not include net proceeds from public offering which closed on November 29, 2021

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**
- **Sufficient capital through the anticipated approval of the ONS-5010 BLA expected in the first calendar quarter of 2023**
- **Management team with proven ophthalmic commercial launch expertise**