



Corporate Presentation

November 2022



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

Disclaimer

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Leadership Team: Global Ophthalmic Development and Commercial Launch Excellence



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President, CEO and Director



LAWRENCE KENYON
Chief Financial Officer and Director



JEFF EVANSON
Chief Commercial Officer



TERRY DAGNON
Chief Operations Officer



RANDY THURMAN
Executive Chairman of the Board

MARK HUMAYUN, MD, PhD
Medical Advisor



Investment Highlights

FDA Market Approval of ONS-5010 (bevacizumab-vikg)¹ an Investigational Therapy for the Treatment of Wet AMD with PDUFA Targeted for August 29, 2023

Targeting \$13.1 Billion Global Ophthalmic Anti-VEGF Market²

Differentiated Drug Product

- Designed to meet robust standards required for FDA ophthalmic approval
- Potential to eliminate risks associated with off-label repackaged bevacizumab, including potential impurities and particulates from compounders re-packaging processes
- Delivery ultimately through a convenient pre-filled syringe

Potential for 1st FDA Approved Ophthalmic Bevacizumab

- **U.S. FDA BLA accepted with target PDUFA action date of August 29, 2023**
- Compelling pivotal trial data
- Potential Launch in Q4 2023
- Provides an economically elegant anti-VEGF solution for patients, payers and doctors

Attractive Market Opportunity

- **Strategic commercialization agreement with AmerisourceBergen**
- Over 50% of the U.S. market available for conversion to ONS-5010, representing up to billions in potential yearly sales
- 12-years US regulatory exclusivity upon approval
- Label expansion opportunity into DME and BRVO

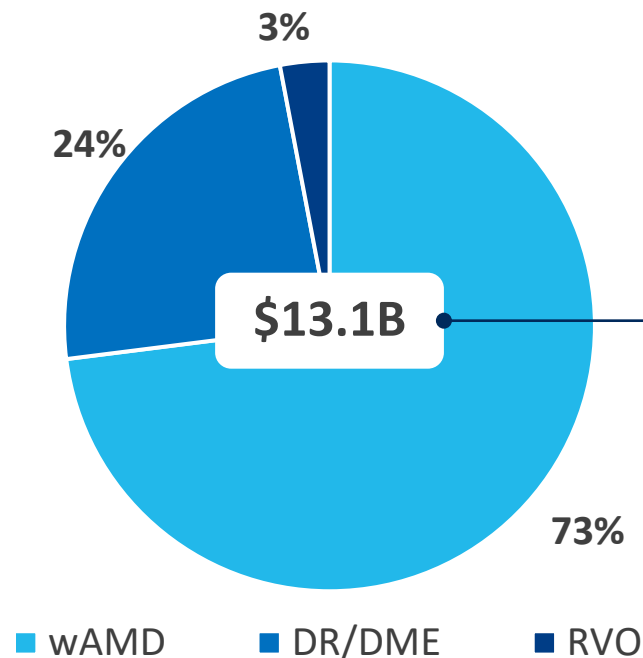
Wet AMD Landscape

Current and Future

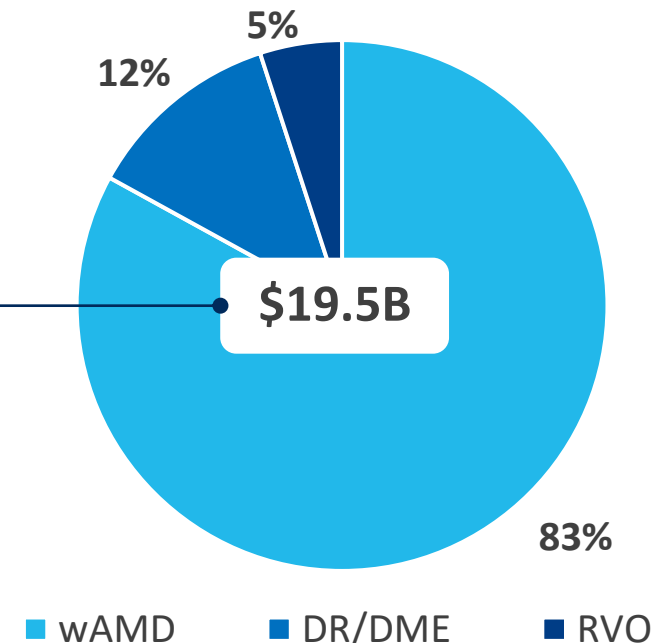
Targeting Large and Growing Ophthalmic Markets

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)



2030 9MM Anti-VEGF Revenue Share (USD)



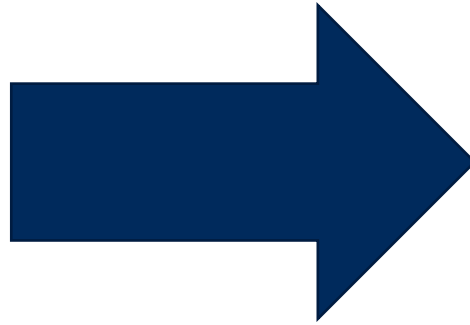
CAGR

4.1%

The Majority of New Patient Starts are Off-Label Bevacizumab

New Patient Starts

66.3% of respondents (n=990) utilize off-label bevacizumab as a first-line agent¹



Maintenance Therapy

42.8-50.2% of overall injections continue therapy on off-label^{2,3}

- **Anti-VEGF is the standard-of-care** for the treatment of wAMD, DME and BRVO globally
- **~70% of Retinal Specialists in the US use off-label Avastin first-line for wAMD**
- Despite high usage, Retinal Specialists show **concern for the quality and supply of off-label Avastin**

Source: Navigant Quantitative Survey (n=152), 2019

Public Health Concern 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**

ONS-5010

The Form of Bevacizumab the
Market Wants

ONS-5010 Ophthalmic Bevacizumab Target Product Profile

ONS-5010 (bevacizumab-vikg) Investigational Therapy

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

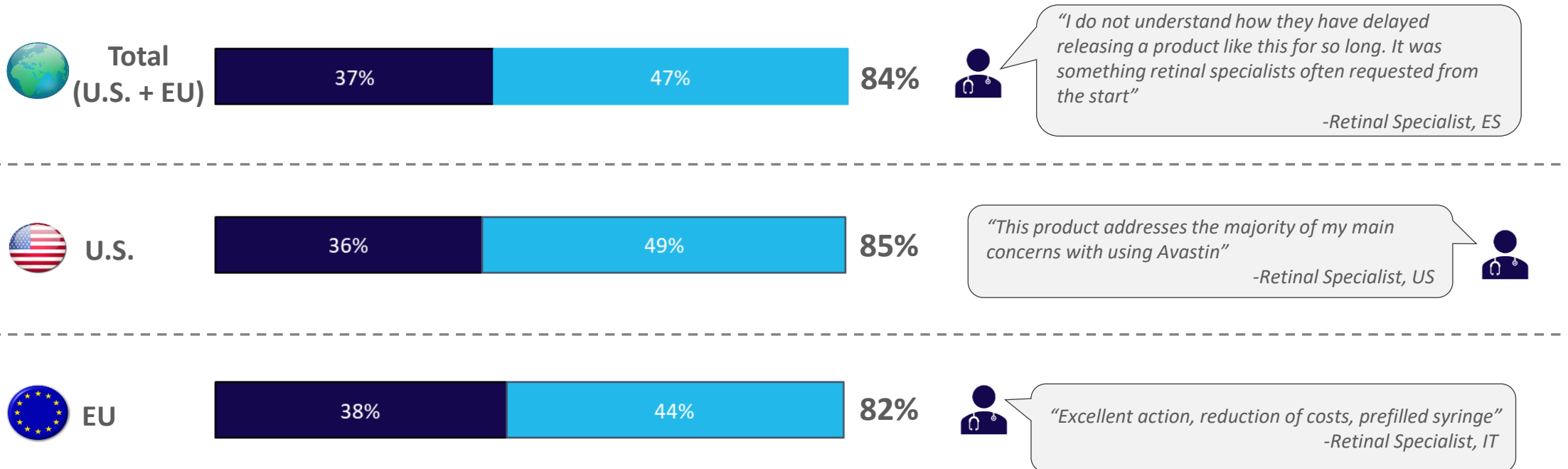
- Supplied either as **pre-filled ophthalmic syringe for intravitreal 1.25 mg injection** administered once monthly, **or in a glass vial**

Efficacy, Safety, and AEs

- NORSE TWO demonstrated significant efficacy and safety, and when combined with NORSE ONE and NORSE THREE provides the necessary registration database. These ONS-5010 data when taken as a whole continue to be consistent with previously published results for bevacizumab.

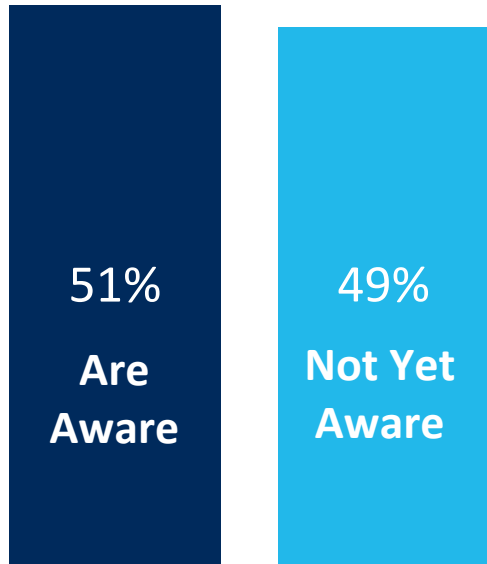
Do Physicians Want an Ophthalmic Approved Bevacizumab?

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

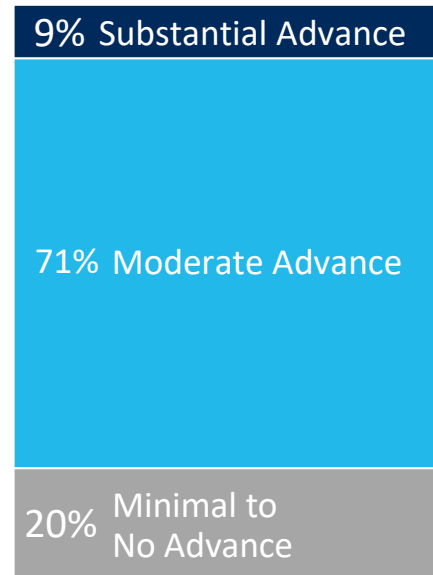


Investigational Therapy ONS-5010 Ophthalmologists Survey

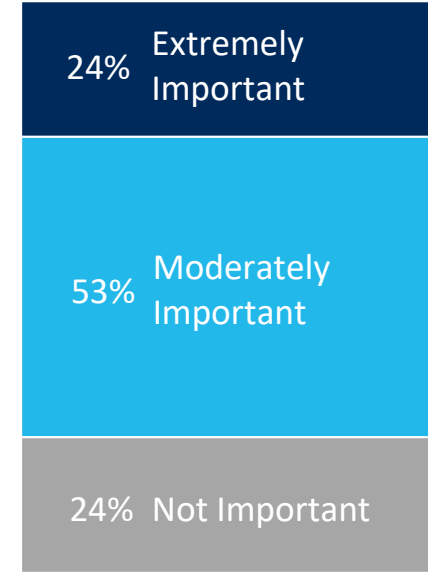
**Half of Surveyed Are
Aware of Upcoming BLA
Filing of ONS-5010**



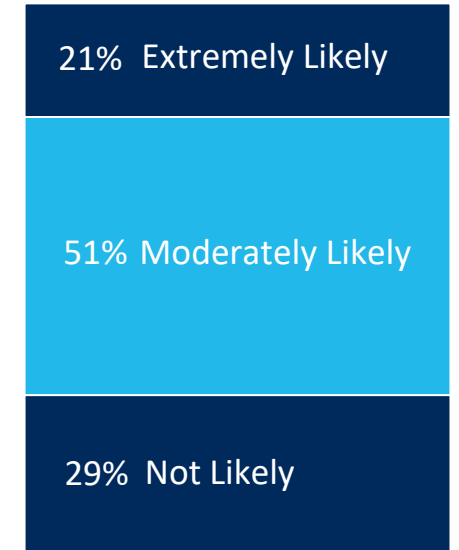
**80% of Surveyed Perceive
ONS-5010 as an Advancement**



**77% of Surveyed Believe an
FDA Approved Bevacizumab
for Wet AMD is Important**



**71% of Surveyed Are Likely
to Prescribe ONS-5010
If Approved**

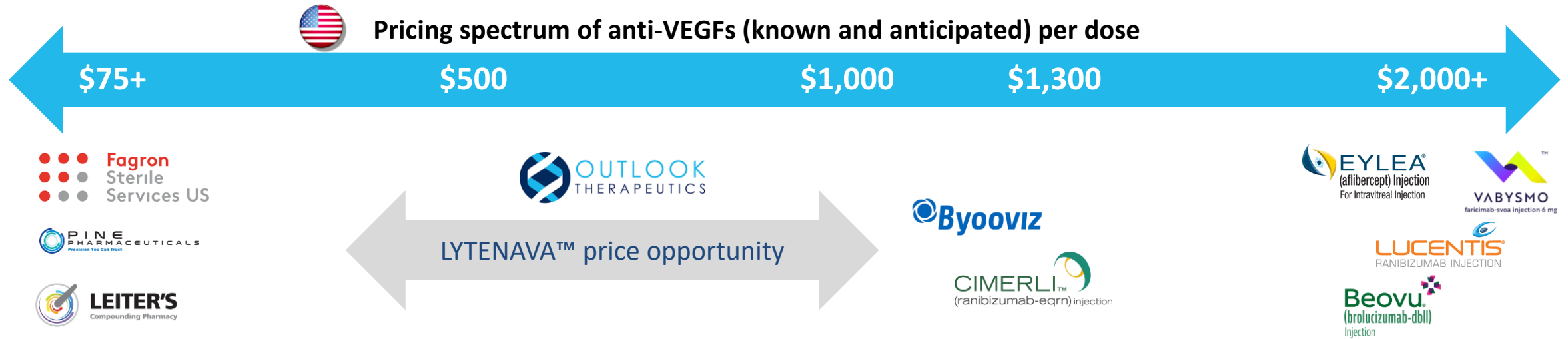


FDA Approval Requirements vs Compounded Bevacizumab

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

LYTENAVA™ Pricing Opportunity

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



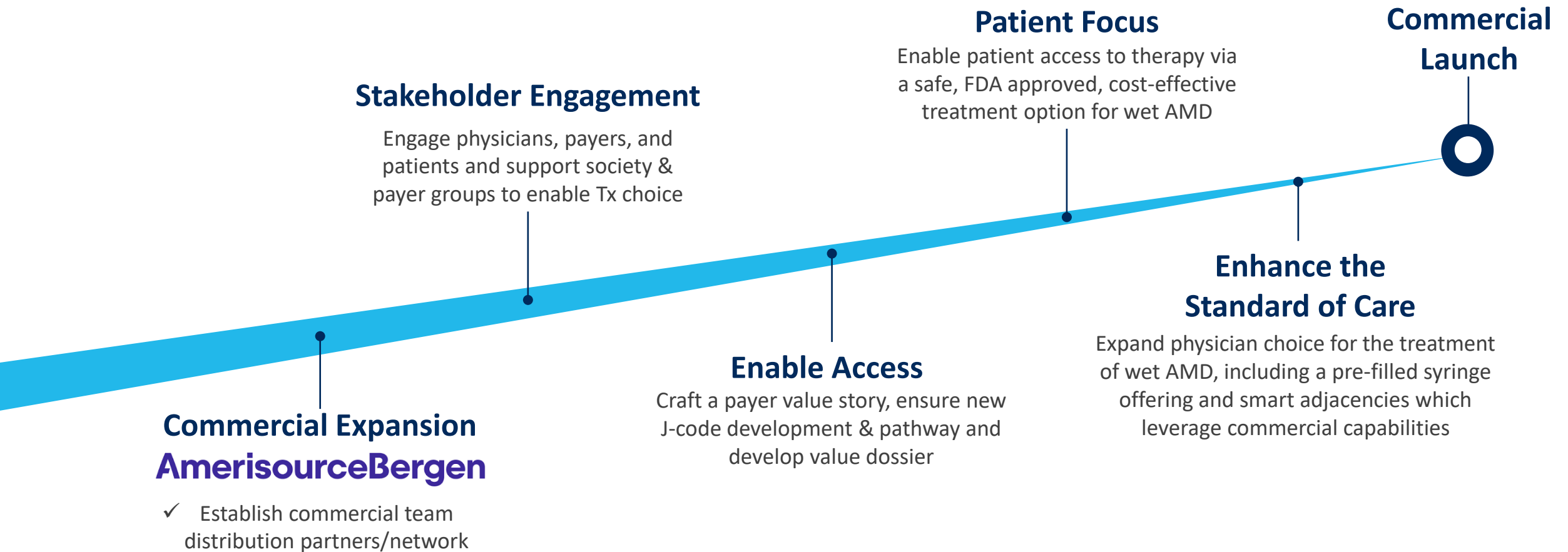
Compounded Avastin (off-label)	LYTENAVA™	Biosimilars to ranibizumab and/or aflibercept	Branded Premium Priced
<p>Cost of compounded Avastin is increasing due to quality issues including syringe failures.</p> <p>Cost per dose could increase to \$100/dose+</p>	<p>Pricing Strategy: Price low enough to move 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>First LUCENTIS biosimilar launched in July 2022 at a 40% discount to the branded WAC.</p> <p>Second biosimilar to LUCENTIS launches in October 2022 at 33% discount to branded WAC.</p> <p>EYLEA biosimilars remain several years from approval and launch.</p>	<p>WAC (list) price for Vabysmo is \$2,200/dose, Lucentis is \$1,950/dose, and both Beovu and Eylea are priced at \$1,850/dose</p> <p>Practice rebates based on volume expected to continue.</p>

ONS-5010

Commercial Activities

Charting a Path To a Successful Launch

Focus on Shaping the Market by Creating Awareness and Educating Physicians



Strategic Commercialization Partnership in U.S. with Preeminent Leader in Specialty Pharma Distribution

AmerisourceBergen

Establishes Commercial Depth in Advance of Potential ONS-5010 Commercial Launch

- ✓ Third-Party Logistics Services and Distribution
- ✓ Medical Information and Pharmacovigilance Services

**Besse Medical is One of the Largest Specialty
Pharmaceutical Distributors to Retina Specialists**

ONS-5010

Clinical Data

Compelling Clinical Data Support Potential FDA Approval in Wet AMD

✓ U.S. FDA BLA Accepted with Target PDUFA of August 29, 2023

✓ 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

NORSE ONE and NORSE THREE Results



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



Pivotal Trial

2nd Registration Trial

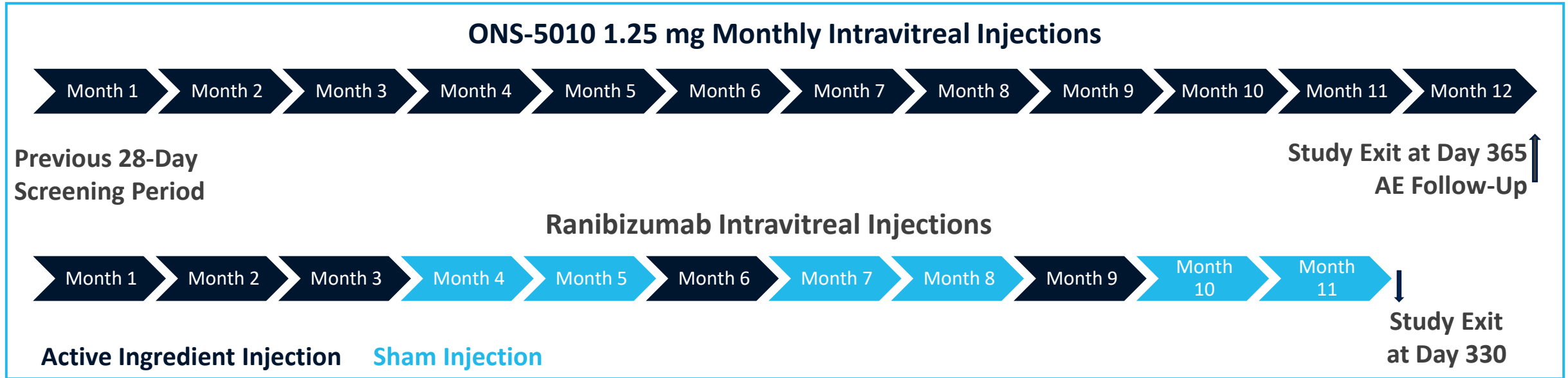


Trial Highlights:

- 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

Phase 3 Pivotal Study Design – Registration Strategy

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

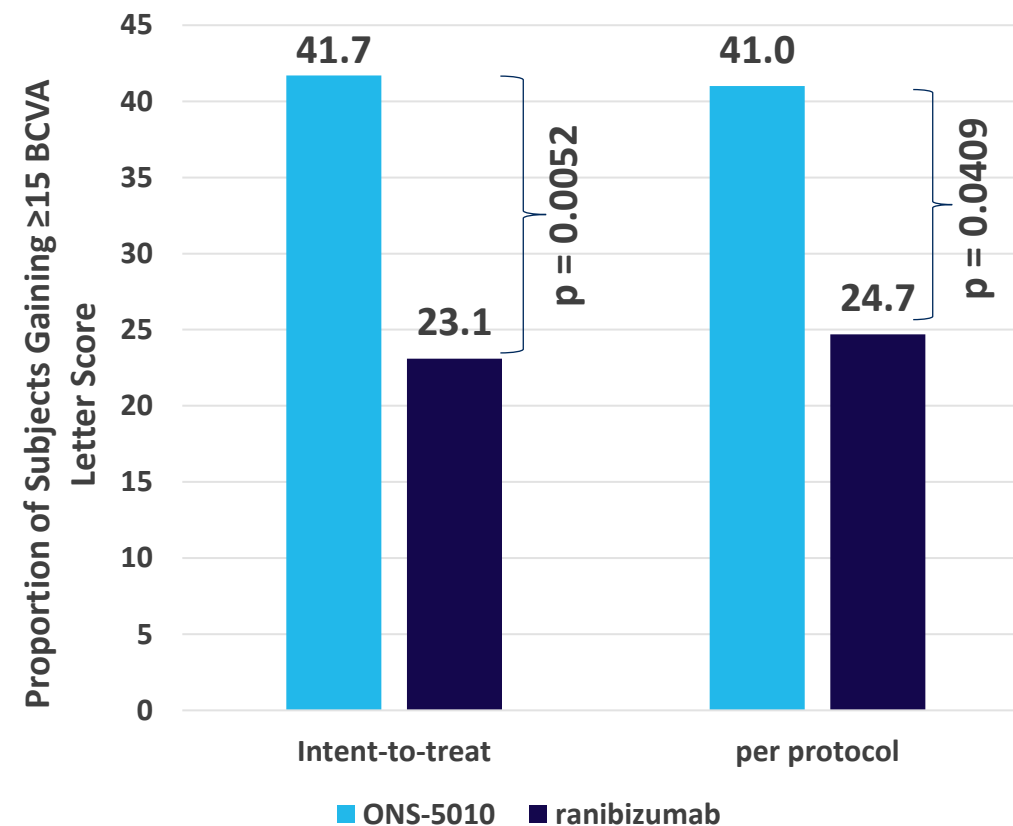
Key Study Outcomes

- 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

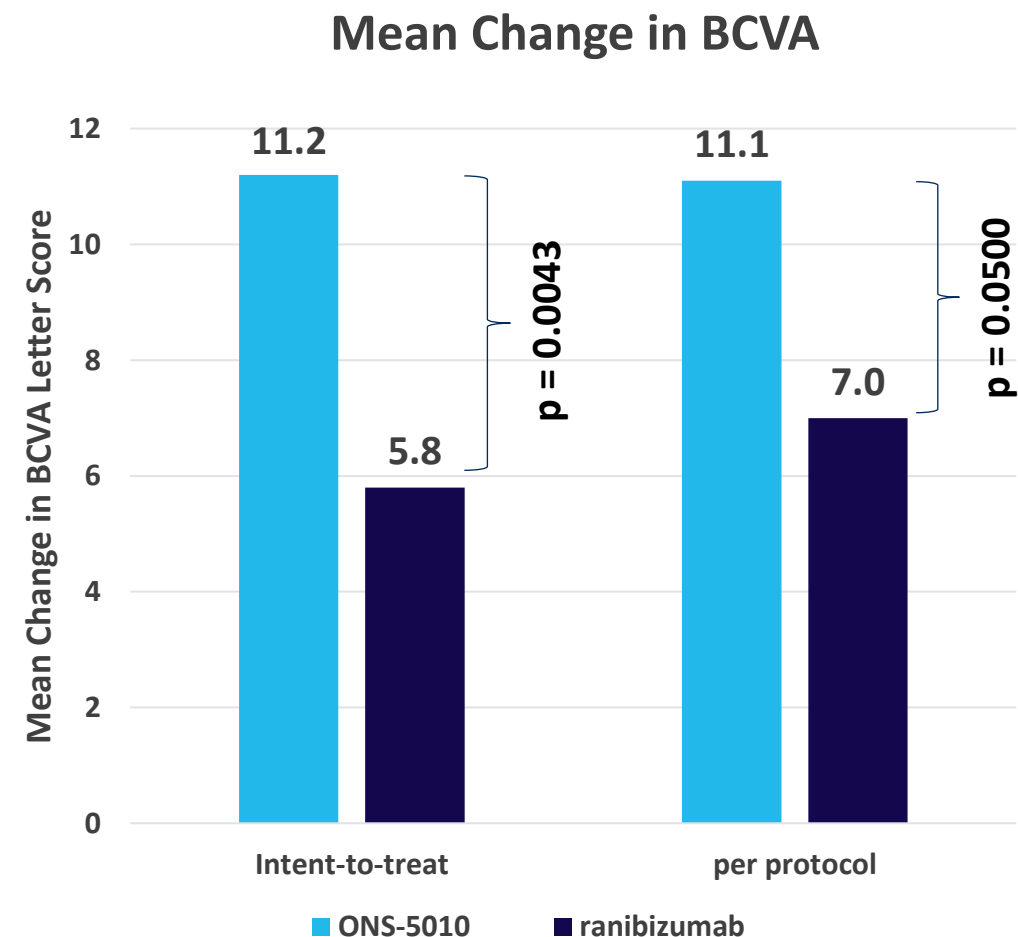
Characteristic	Statistic	ONS-5010 (n=113)	Ranibizumab (n=115)
Intent-to-Treat Pop.			
Number of Subjects	n/N (%)	45/108 (41.7)	24/104 (23.1)
Risk Difference		0.1859	
95% CI		(0.0442,0.3086)	
p-value		0.0052	
Per Protocol Pop.			
Number of Subjects	n/N (%)	34/83 (41.0)	18/73 (24.7)
Risk Difference		0.1631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

Difference in % Subjects Gaining 3 Lines Vision



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	

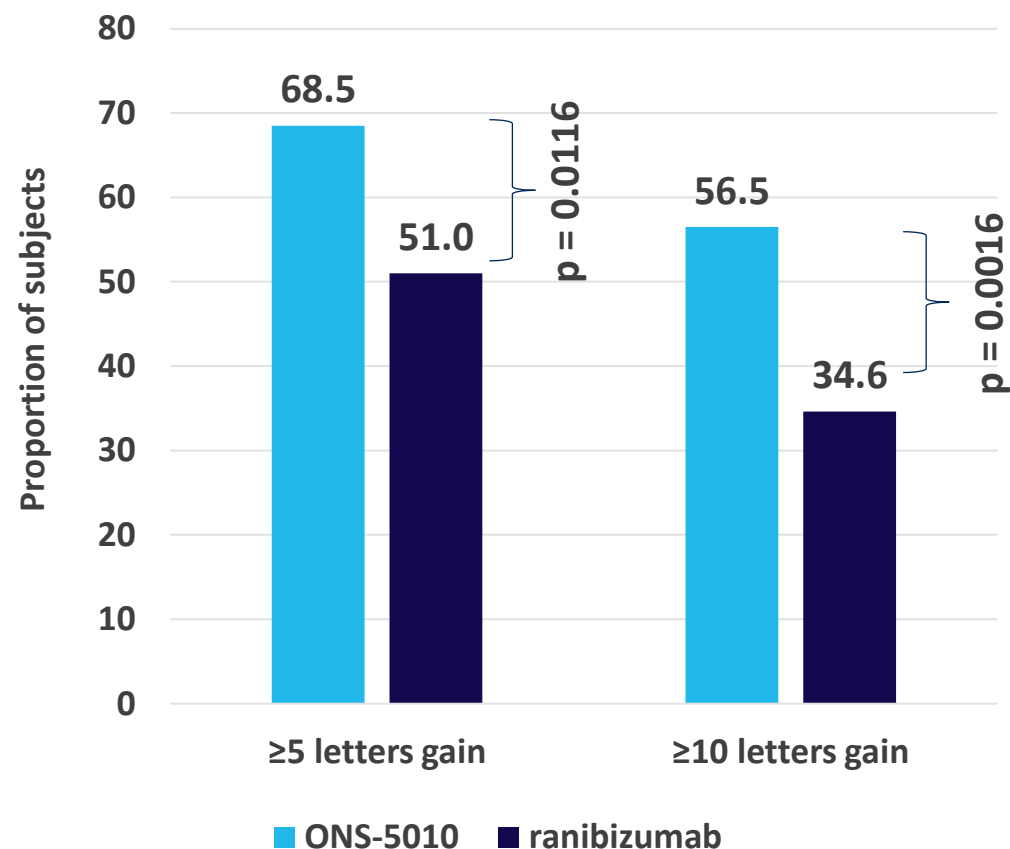


Statistically Significant, Clinically Relevant Secondary Endpoints

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)

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 Outlook Therapeutics investigational pre-filled syringe
 - Vial arm (n= has been fully enrolled and is now complete)
- Enrolling ~120 subjects with visual impairment due to retinal disorders
 - Wet AMD
 - BRVO
 - DME

Financial Highlights

NASDAQ: OTLK

**Sufficient Capital to Support Pre-launch Activities for ONS-5010
And a Pathway to Potentially Support Launch If Approved¹**

\$26.0M

Cash Balance²

~\$270M

Market Cap³

~226M

Shares Outstanding⁴

~481K

Average Volume³



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 be converted to Outlook Therapeutics' LYTENAVA, if FDA approved*
- **Potential for first FDA approved ophthalmic formulation of bevacizumab**
- **Potential FDA approval August 29, 2023**
- **Sufficient capital for pre-launch activities**
- **Management team with proven ophthalmic commercial launch expertise**
 - *Leveraging strategic commercialization agreement with AmerisourceBergen to preserve capital and enhance commercial reach*