OUTLOOK THERAPEUTICS

Corporate Presentation

April 2022

NASDAQ: OTLK

outlooktherapeutics.com

OUTLOOK THERAPEUTICS

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

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RANDY THURMAN
Executive Chairman of the Board

MARK HUMAYUN, MD, PhD
Medical Advisor

Investment Highlights

Submitted U.S. FDA BLA of ONS-5010 (bevacizumab-vikg)[1] an Investigational Therapy for the Treatment of Wet AMD

Targeting $13.1 Billion Global Ophthalmic Anti-VEGF Market[2]

Differentiated Drug Product

- Designed to meet stringent standards required for FDA ophthalmic approval
- Potential to eliminate 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 support U.S. FDA BLA submission; **filed March 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

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1. ONS-5010 / LYTENAVA™ (bevacizumab-vikg) is an investigational ophthalmic formulation of bevacizumab
2. Guidehouse Triangulation of Global Data, Market Scope and Investor Forecasts (2020)

AMD = Age-Related Macular Degeneration; DME = Diabetic Macular Edema ; BRVO = Branch Retinal Vein Occlusion

Wet AMD Landscape
Current and Future

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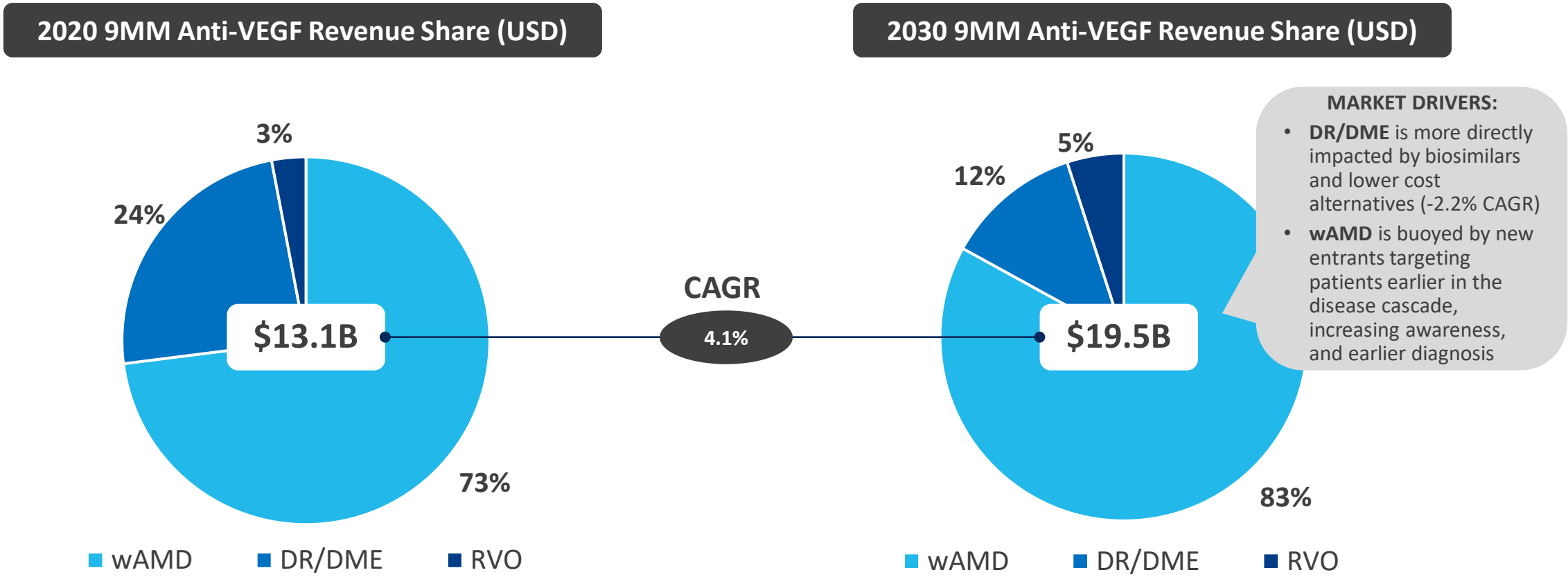
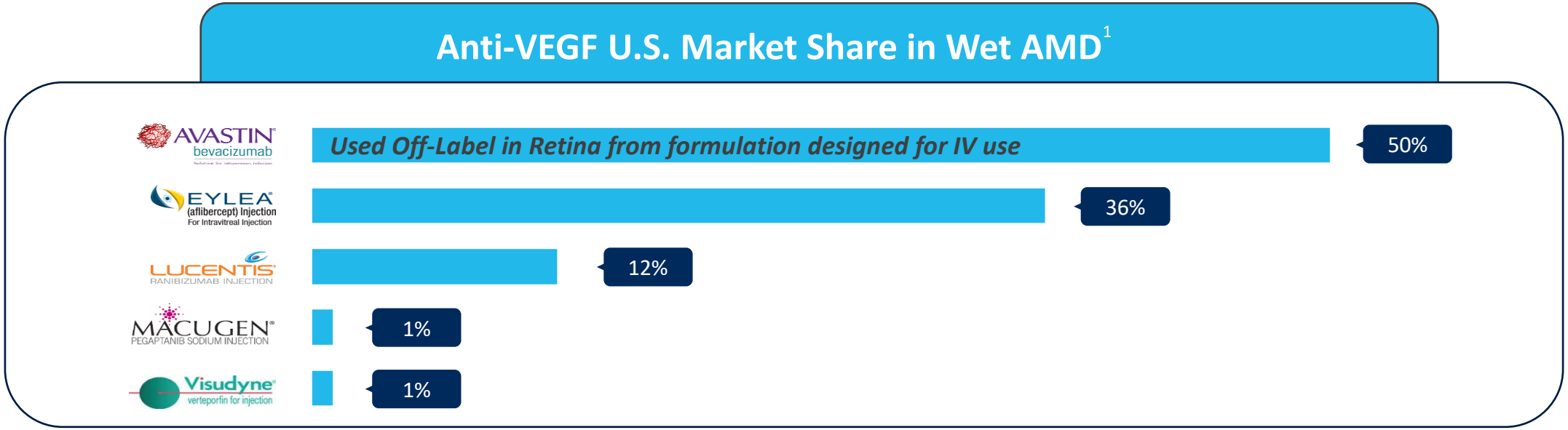
Targeting Large and Growing Ophthalmic Markets

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



Sources: Guidehouse Triangulation of Global Data, Market Scope and Investor Forecasts (2020)
AMD = Age-Related Macular Degeneration; DME = Diabetic Macular Edema ; BRVO = Branch Retinal Vein Occlusion

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



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

1. Estimates from Global Data and ASRS PAT Surveys

Public Health Concern Due To Repackaged and Off-Label Use of Bevacizumab Designed for Other Specialties and Delivery Systems

Variability in Potency[1]

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 Events[2]

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

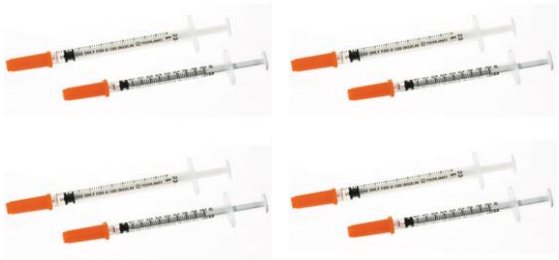
Syringe Adverse Events[3]

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



1: JAMA Ophthalmol. 2015 Jan;133(1):32-9. doi: 10.1001/jamaophthalmol.2014.3591; 2: Goldberg, Roger A et al. "An outbreak of streptococcus endophthalmitis after intravitreal injection of bevacizumab." American Journal of Ophthalmology vol. 153,2 (2012): 204-208.e1. doi:10.1016/j.ajo.2011.11.035; 3: ASRS Member Alert, April 2019

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." – FDA***[6]

- "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." – FDA[6]

- "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." – FDA[6]

- ***"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." – FDA***[6]

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1. Food Drug and Cosmetic Act 503A snd 503B & Drug Quality and Security Act of 2013; 2. Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities; Guidance for Industry; DHHS, FDA; January 2017; 3. Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application Guidance for Industry; DHHS, FDA; January 2018; 4. Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; DHHS, FDA; Draft Guidance: January 2020; 5. Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry; DHHS, FDA: January 2018; 6. Source: Compounding Laws and Policies | FDA www.fda.gov

ONS-5010

Submitted U.S. FDA BLA for the treatment of wet AMD March 2022

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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.

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Anti-VEGF - Anti–vascular endothelial growth factor therapy ; AMD – Age-related macular degeneration; DME – Diabetic macular edema; BRVO – Branch retinal vein occlusion; CATT – National Eye Institute, Comparison of Age-related Macular Degeneration Treatments Trials, 2011

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

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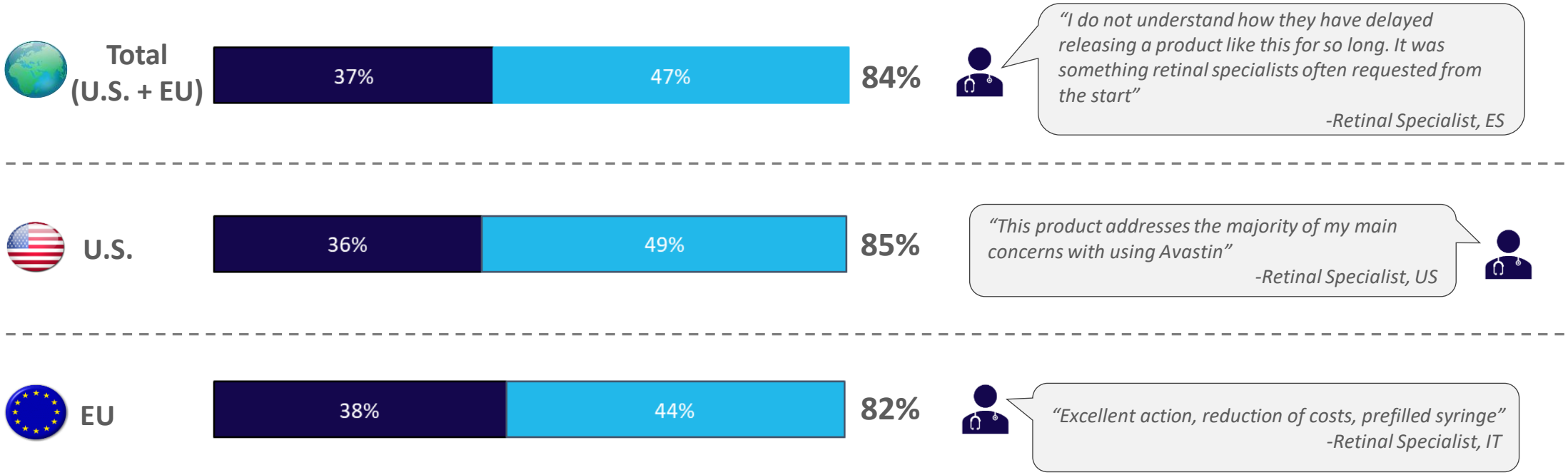
1: USP general Chapter <771> OPHTHALMIC PRODUCTS—QUALITY TESTS USP40-NF35, second supplement, June 1, 2017; 2: Aldrich, Dale S., Bach, Cynthia M., Brown, William, Chambers, Wiley, Fleitman, Jeffrey, Hunt, Desmond, Marques, Margareth R. C., Mille, Yana, Mitra, Ashim K., Platzer, Stacey M., Tice, Tom, Tin, George W.; Ophthalmic Preparations USP STIMULI TO THE REVISION PROCESS Vol. 39(5) [Sept.–Oct. 2013]; 3: Missel PJ, Lang JC, Rodeheaver DP, Jani R, Chowhan MA, Chastain J, Dagnon T. Design and evaluation of ophthalmic pharmaceutical products. In: Florence, AT, Siepmann J. Modern Pharmaceutics—Applications and Advances. New York: Informa; 2009:101–189.

Do Physicians Want an Ophthalmic Approved Bevacizumab?

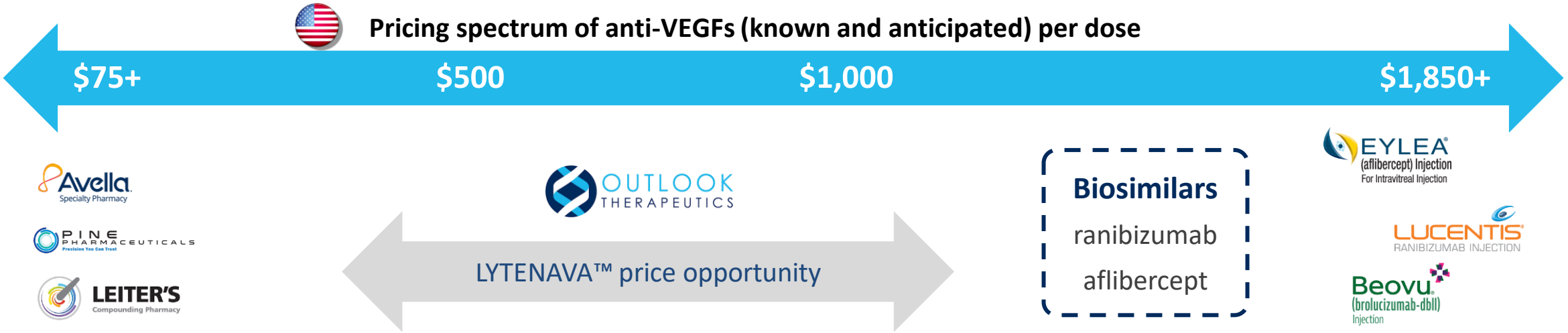
>80% of Retinal Specialists Express Interest/High Interest In an FDA-Approved Ophthalmic Bevacizumab to Treat Wet AMD, DME and BRVO



Source: Navigant Quantitative Survey (n=152), 2019, **Respondents who have interest or high interest in ONS-5010**
*Other survey options not shown were "neutral, not likely to use, and not interested at all"

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
Cost of compounded Avastin is increasing due to quality issues including syringe failures. Cost per dose could increase to **$100/dose+**	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.	Biosimilars, if approved, are likely to price at a 10-30% discount to the branded WAC. Mylan, Coherus and Biogen have thus far discounted ~20-30% from WAC in other biologic areas where they have launched biosimilars.	WAC (list) price for Lucentis is **$1,950/dose**, both Beovu and Eylea are priced at **$1,850/dose**. Practice rebates based on volume expected to continue.

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 – **BLA submitted March 2022**
- 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

Charting a Path To a Successful Launch

Building The Commercial Foundation

Commercial Expansion

Establish commercial team

Finalize distribution partners/network

Stakeholder Engagement

Engage physicians, payers, and patients to deliver meaningful value

Support key stakeholders including society & payer groups to enable Tx choice

Enabling Access

Craft a payer value story including data/tools to support the value prop

Ensure new J-code development & pathway

Develop value dossier with robust data to enable access

Patient Focus

Enable patient access to therapy via a safe, FDA approved, cost-effective treatment option for wet AMD

Create patient education and service offerings (HUB)

Enhance the Standard of Care

Expand physician choice for the treatment of wet AMD

Build LCM roadmap including a pre-filled syringe offering

Explore smart adjacencies which leverage commercial capabilities

Focus on Shaping the Market by Creating Awareness and Educating Physicians

Pathway Towards Potential FDA Approval in Wet AMD

✓ U.S. FDA BLA Submitted March 2022

✓ Positive Signals

NORSE ONE

Clinical Experience Trial

1st Registration Trial

✓ Positive Top-Line Data

NORSE TWO

Pivotal Trial

2nd Registration Trial

✓ Completed

NORSE THREE

Open-Label Safety Study

Supports BLA Requirements

NORSE ONE and NORSE THREE Results

NORSE ONE — 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

NORSE THREE — 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 TWO

Pivotal Trial

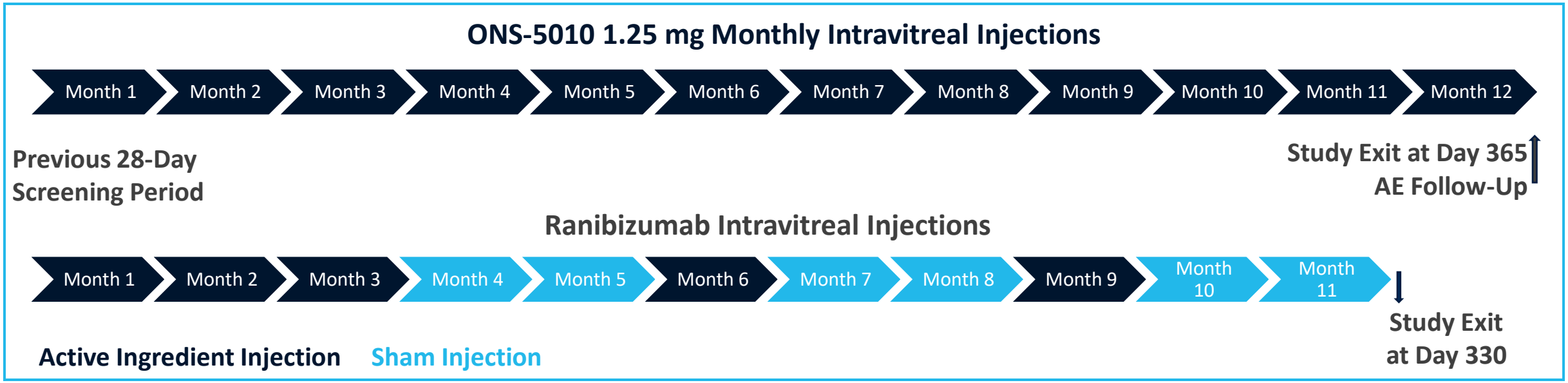
2nd Registration Trial

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

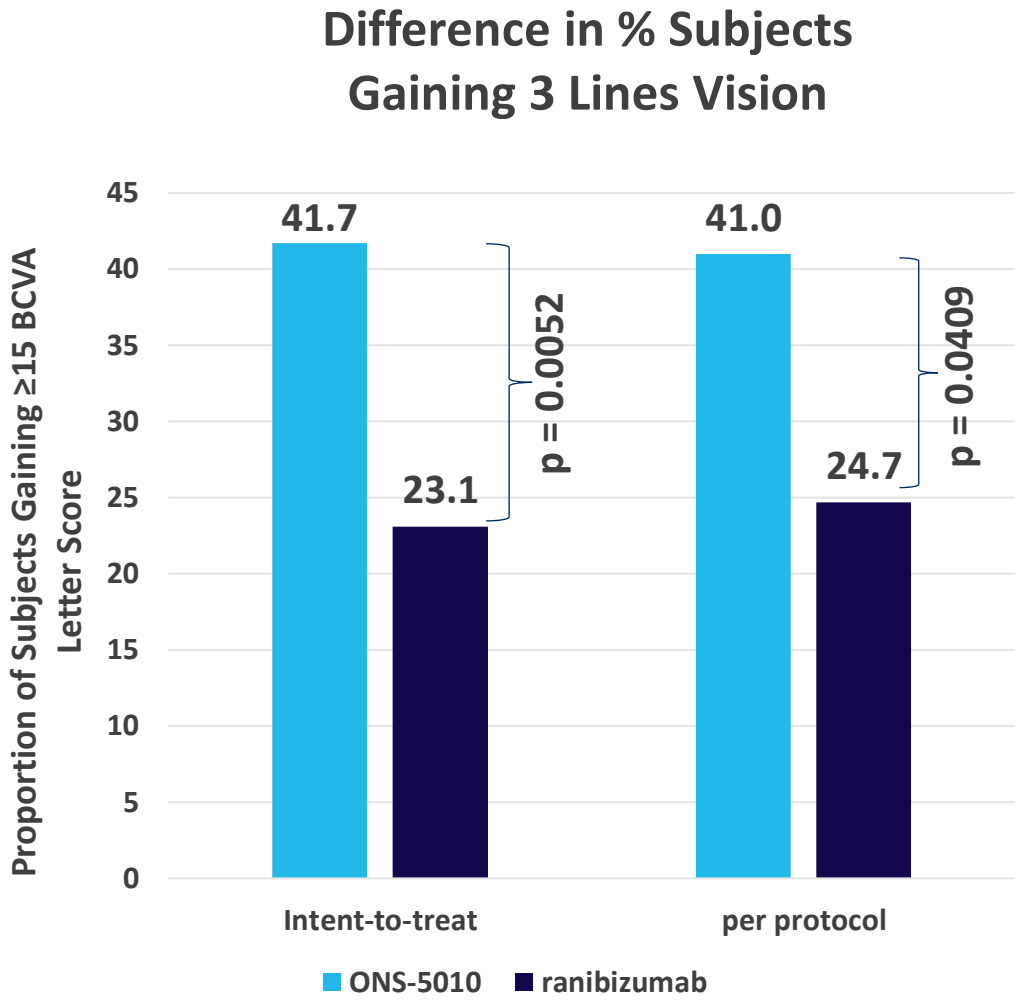
- Active, primary CNV due to wet AMD
- Treatment-naïve
- BCVA: 20/50 – 20/320

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

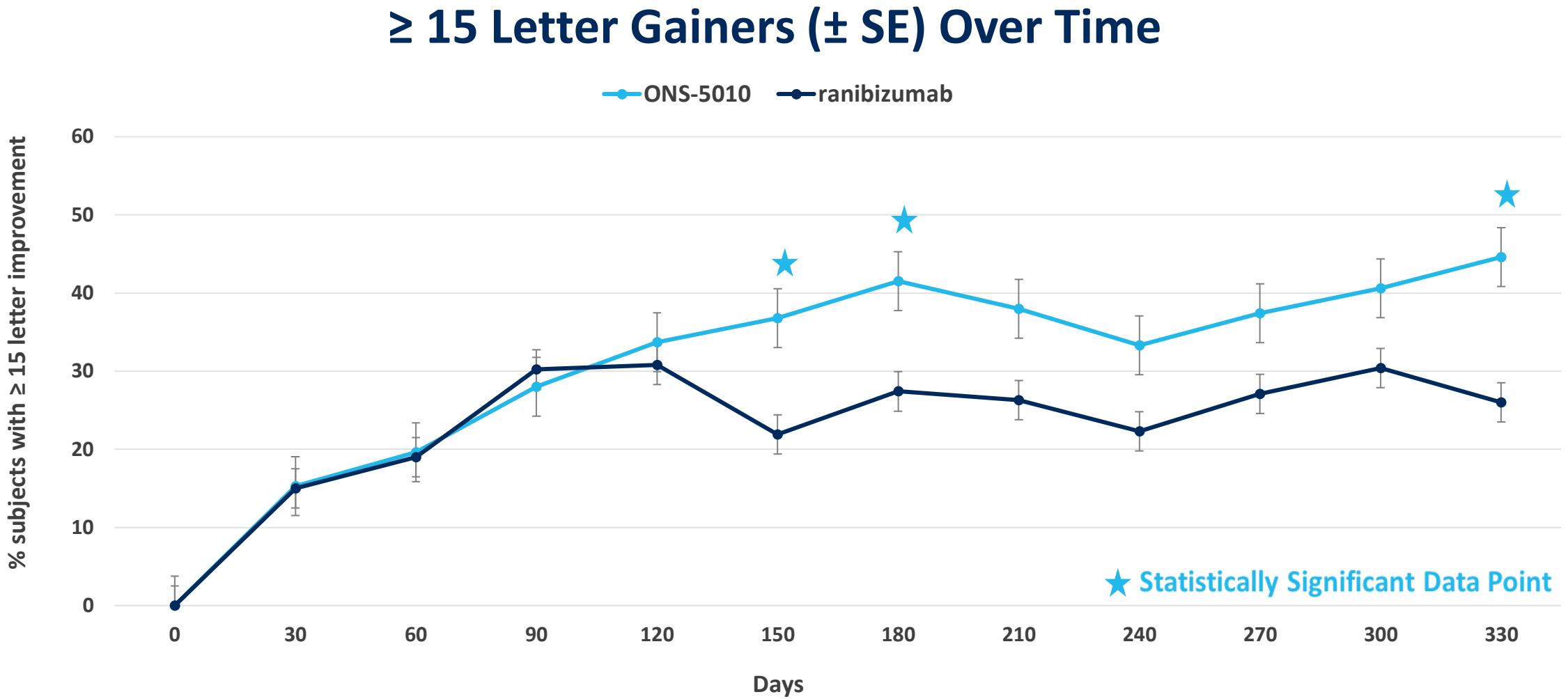
Primary Endpoint Met with Statistically Significant, Clinically Relevant Results[1]

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**	



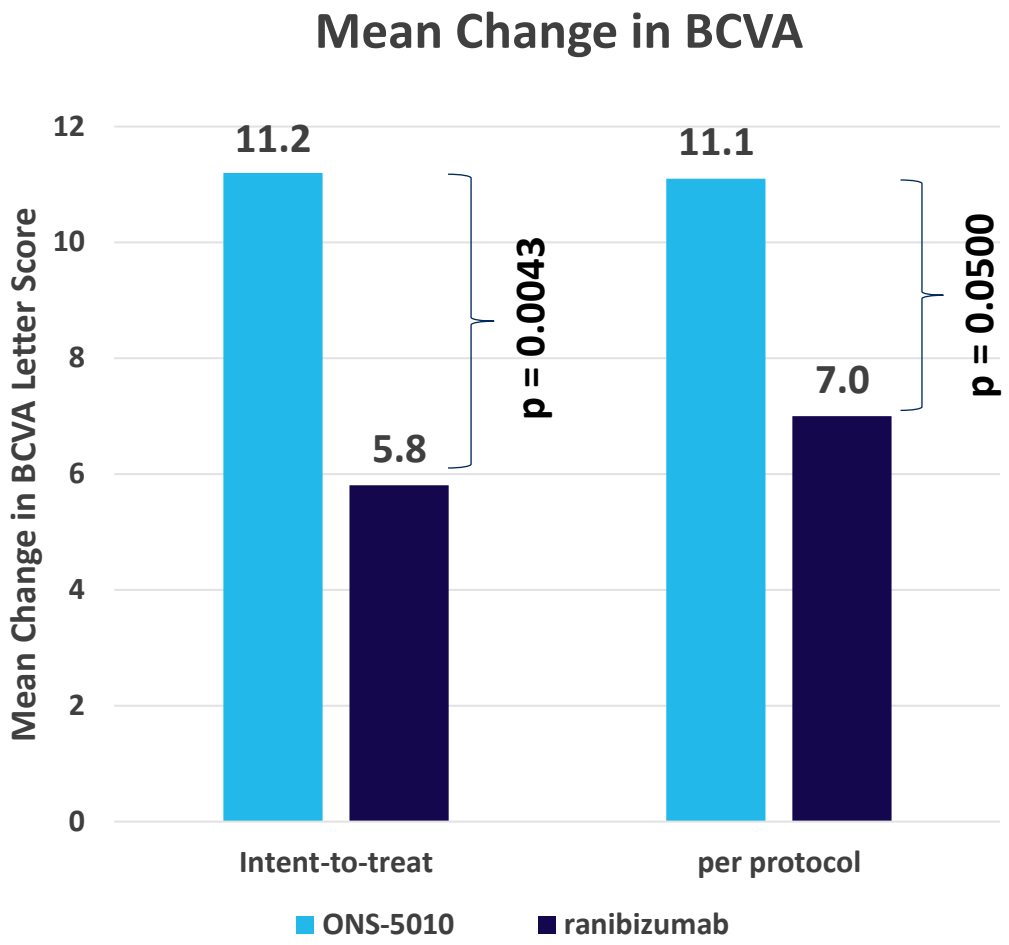
1. Primary endpoint at Month 11

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



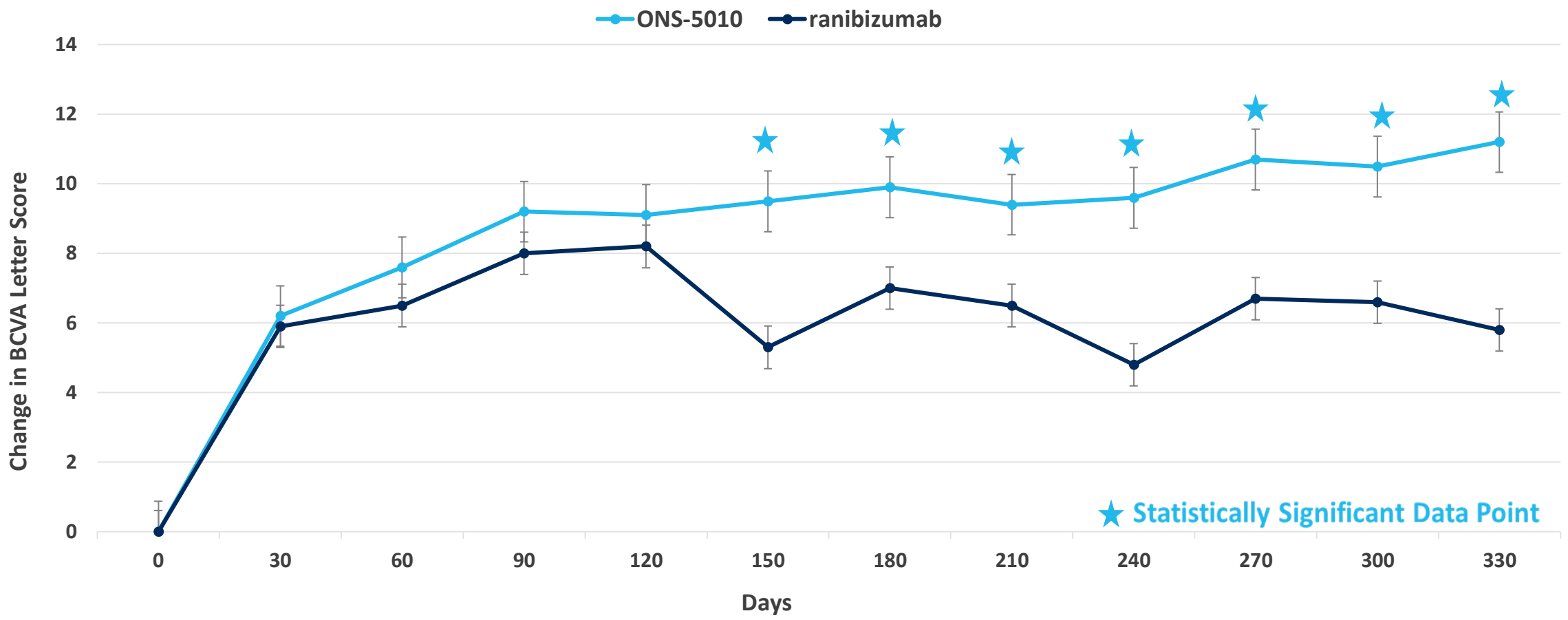
Key Secondary Endpoints Met with Highly Statistically Significant, Clinically Relevant Results

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

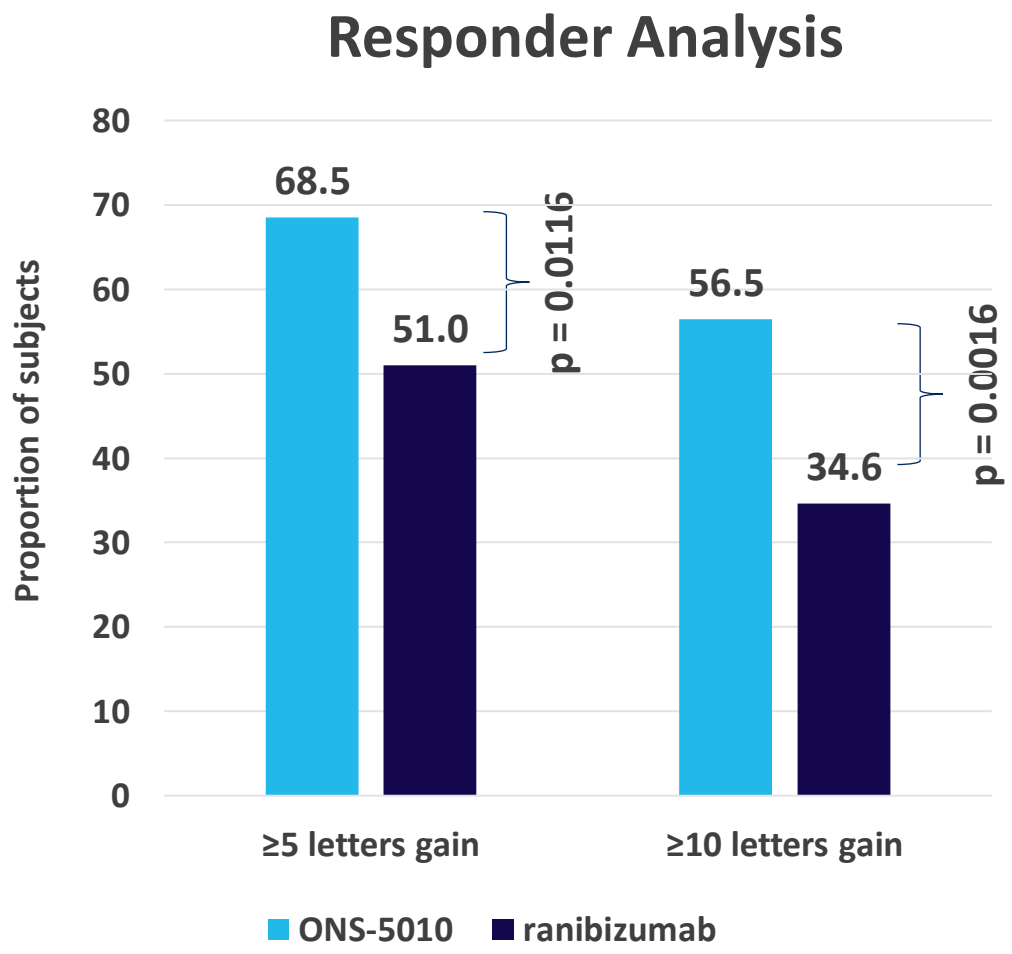
Mean (± SE) Change in BCVA Over Time



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**



1. Primary endpoint at Month 11

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)

1. Primary endpoint at Month 11

Safety Results: Frequency and Incidence of Ocular AEs ≥ 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 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

Financial Highlights

NASDAQ: OTLK

Sufficient capital through the anticipated approval of the ONS-5010 BLA expected in the first calendar quarter of 2023[1]

$70.2M	~$412M	~224M	~1.5M
Cash Balance[2]	Market Cap[3]	Shares Outstanding[2]	Average Volume[3]

1: Based off management's current expectations; 2: As of December 31, 2021; 3: As of April 10, 2022

Company Summary

- **Targeting $13.1 billion global ophthalmic anti-VEGF market[1]**
  - *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**

- **U.S. FDA BLA submitted March 2022 with anticipated approval to follow 9-12 months later**

- **Sufficient capital through the anticipated approval of the ONS-5010 BLA**

- **Management team with proven ophthalmic commercial launch expertise**

1. Guidehouse Triangulation of Global Data, Market Scope and Investor Forecasts (2020)