



# CORPORATE PRESENTATION

July 2021

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**Late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications.**

## Investment Highlights

# Advancing on Multiple Fronts Towards Potential FDA Approval



Potential FDA approval in wet AMD in 2022 with lead investigational product candidate ONS-5010 ophthalmic bevacizumab<sup>1</sup> targeting \$13.1 billion global ophthalmic anti-VEGF market<sup>2</sup>

### Phase 3 Clinical Program

- Ongoing Phase 3 pivotal trial with topline data expected Q3 2021



### Commercial Planning Activities Underway

- Market research indicates ONS-5010 ophthalmic bevacizumab, if approved, will be a significant therapy in ophthalmic anti-VEGF market
- Full launch readiness underway

### Manufacturing and Regulatory

- Partnered with Fujifilm and Ajinomoto as best-in-class cGMP global manufacturers
- ***ONS-5010 ophthalmic bevacizumab will be submitted as a new BLA, with 12 years of regulatory exclusivity***



### Strategic Optionality

- Launching at Outlook Therapeutics, but also...
- Evaluating options with a strategic partner

# 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



# ONS-5010

Addresses Significant Unmet Medical Need in a  
\$13.1 Billion Global Ophthalmic Anti-VEGF Market

# Anti-VEGF Therapy Has Been Standard of Care Since the Launch of LUCENTIS® and Use of Off-Label Bevacizumab

*CATT IND Study Validated Bevacizumab as Safe and Effective (2011)*

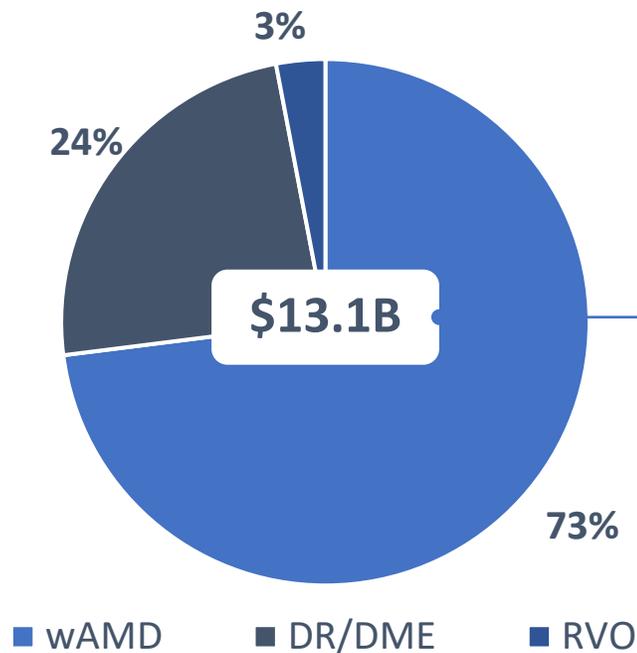


ONS-5010, if approved, will be the first on-label ophthalmic formulation of bevacizumab

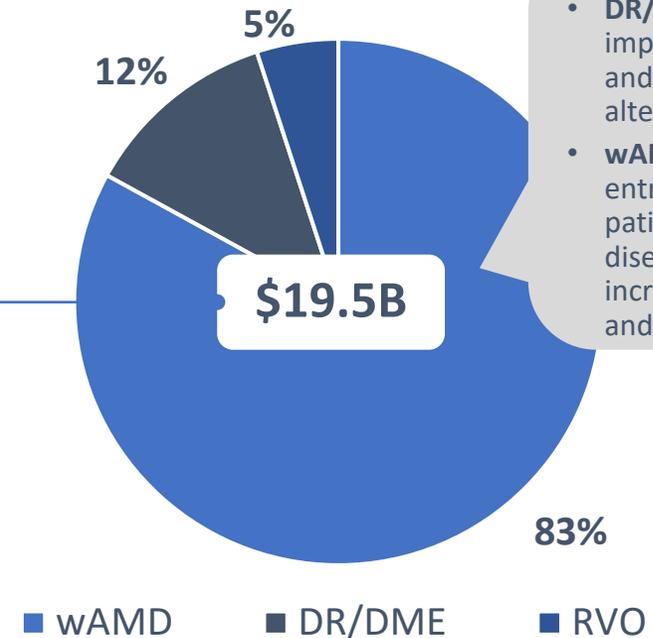
# Targeting Large and Growing Ophthalmic Markets

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)



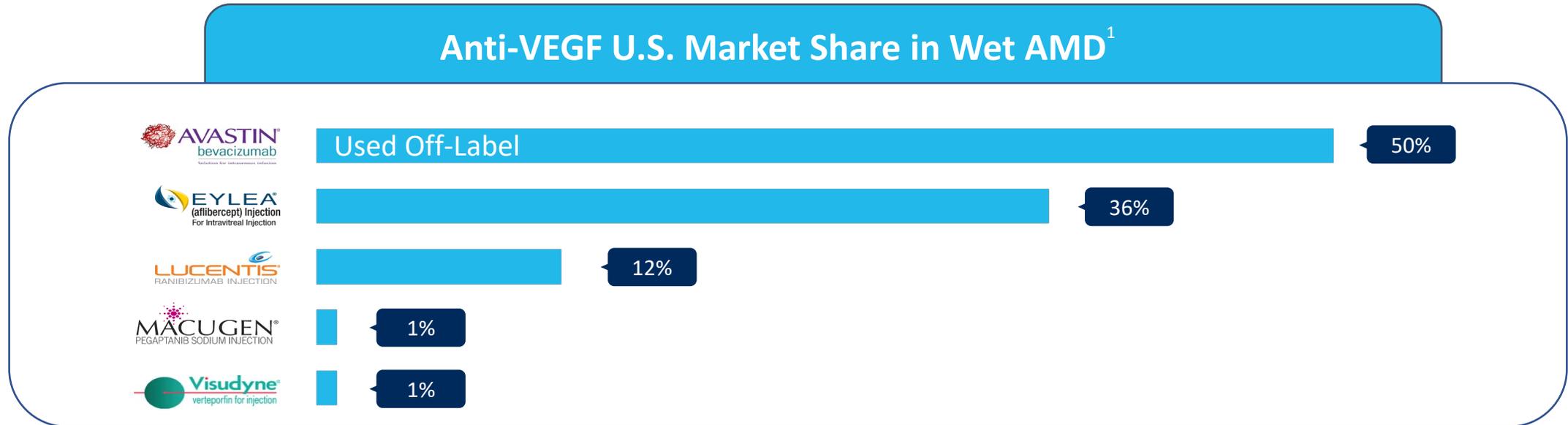
CAGR  
4.1%

**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

## Anti-VEGF U.S. Market Share in Wet AMD<sup>1</sup>



## Expected Drivers to Compete Across All Ophthalmic Anti-VEGF Therapeutics

- 1 Provide safe and cost-effective on-label bevacizumab
- 2 Become first-line "step-edit" drug of choice
- 3 12 years market exclusivity under new BLA
- 4 Penetrate EU and developing markets

# ONS-5010

Potential to be the first ophthalmic formulation of bevacizumab approved as an anti-VEGF therapy addressing vision loss from wet age-related macular degeneration (wet AMD)

# Unapproved Repackaged IV Bevacizumab Presents Safety Issues

If approved, ONS-5010 will reduce the need for use of unapproved repackaged IV Avastin<sup>®</sup> from compounding pharmacists

## Variability in Potency<sup>1</sup>

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

JAMA Ophthalmology

## Safety and Sterility Adverse Events<sup>2</sup>

- Unvalidated hold times in syringes not designed to be primary packages
- Patients have lost eyesight due to infections
- Multiple unapproved repackaged IV bevacizumab recalls due to unsterile compounding practices



Warning Letter

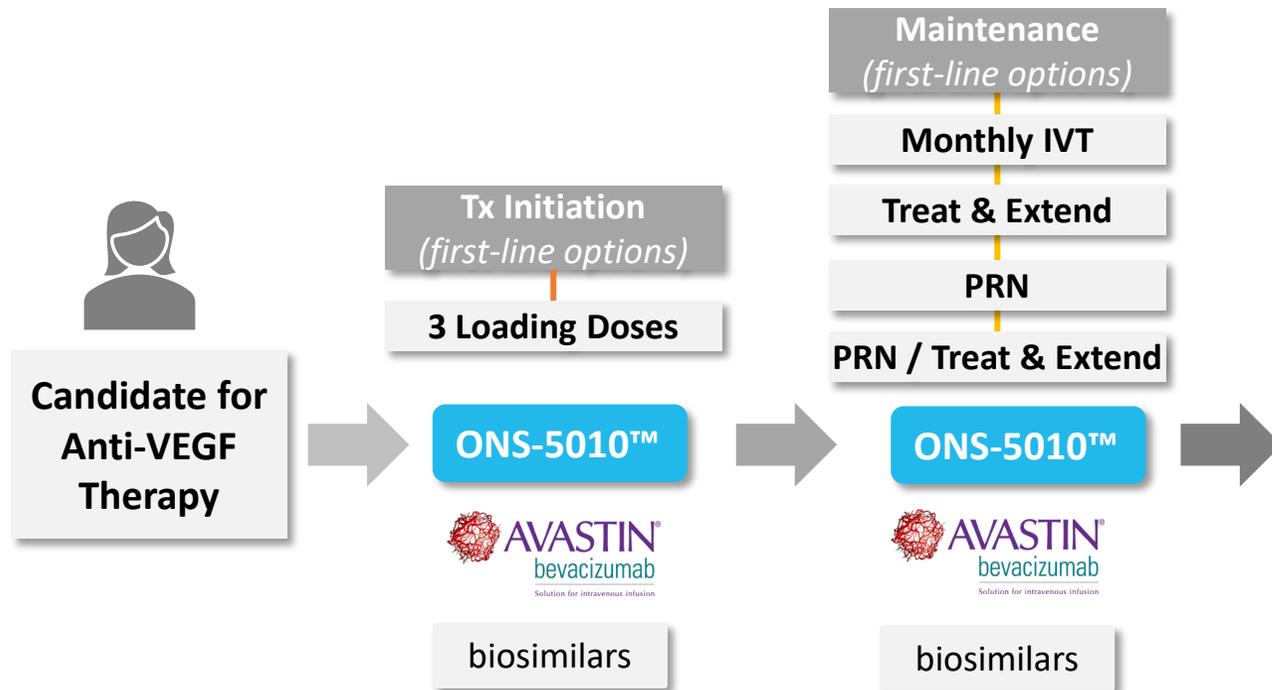
## Syringe Malfunctioning<sup>3</sup>

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



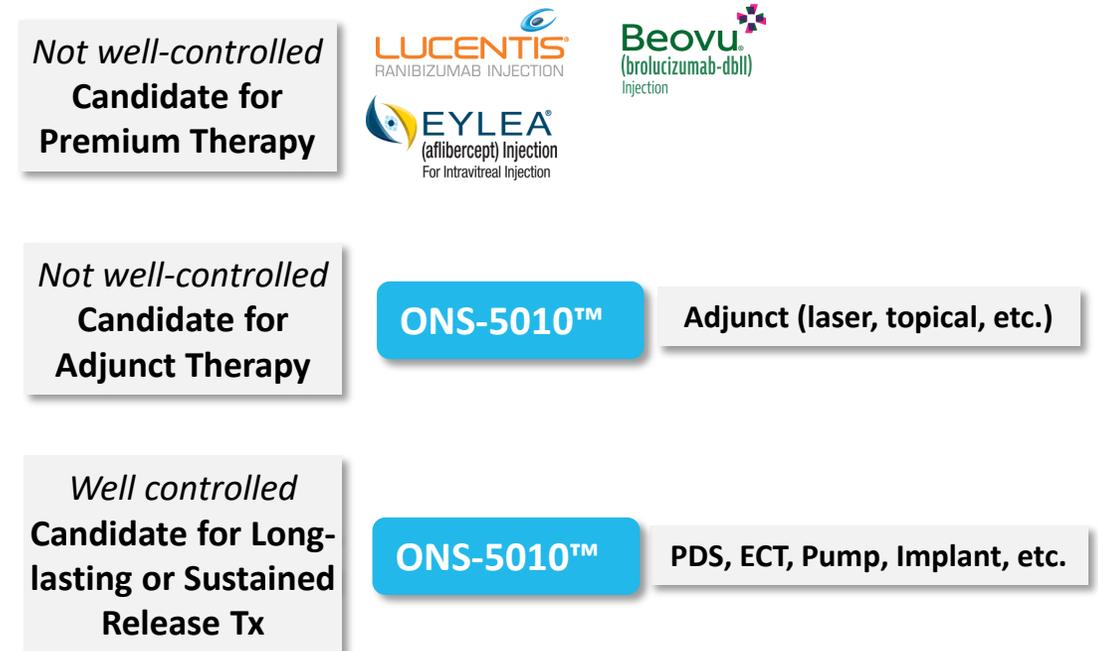
# Potential Use of ONS-5010 Ophthalmic Bevacizumab Across Wet AMD Treatment Spectrum

## First-line Treatment Scenarios



**As option for Tx Guidelines and/or Step Edit**

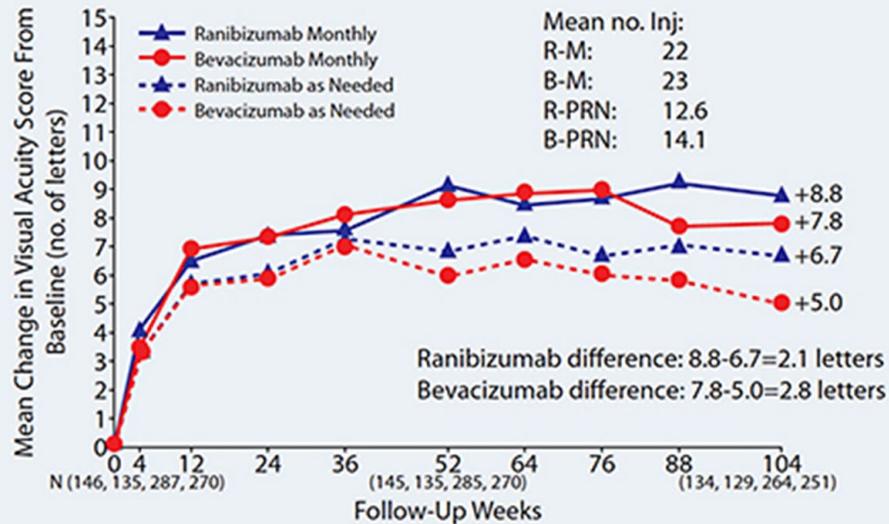
## Second-line Treatment Scenarios



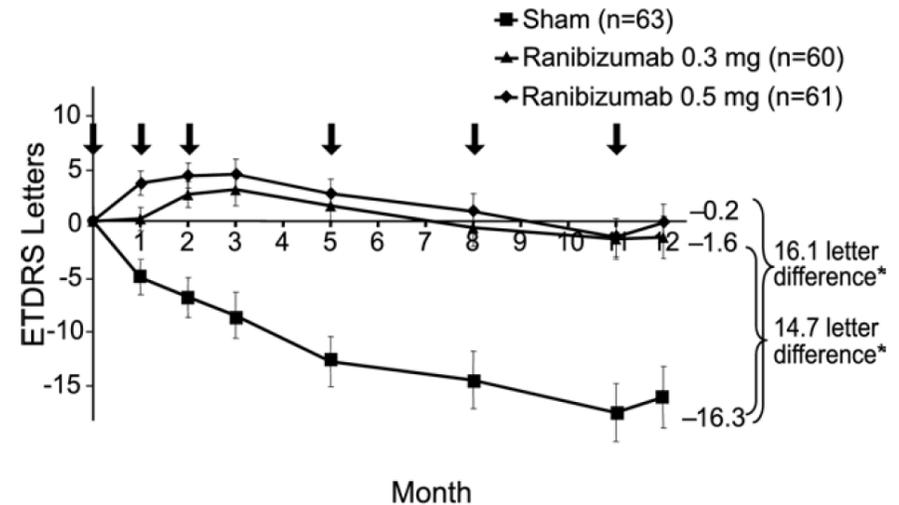
**As synergistic option to future sustained delivery or adjunct therapies**

# Bevacizumab Demonstrated to be Equivalent to LUCENTIS® in CATT Trial

## CATT Study Results<sup>1</sup>



## LUCENTIS® PIER Study<sup>2</sup>



# Pathway Towards Planned BLA Filing in Wet AMD

U.S. BLA Filing Targeted Q1 2022

✓ Completed



Completed Clinical  
Experience Trial  
1<sup>st</sup> Registration Trial

Topline data  
expected Q3 2021



Ongoing Pivotal Trial  
2<sup>nd</sup> Registration Trial

✓ Completed



Open-Label Safety Study  
Supports BLA Requirements



# Completed Clinical Experience Trial

## 1<sup>st</sup> Registration Trial



Provided high level of confidence in the outcome of the ongoing fully-enrolled pivotal trial



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



Provided successful proof of concept



### Trial Highlights:

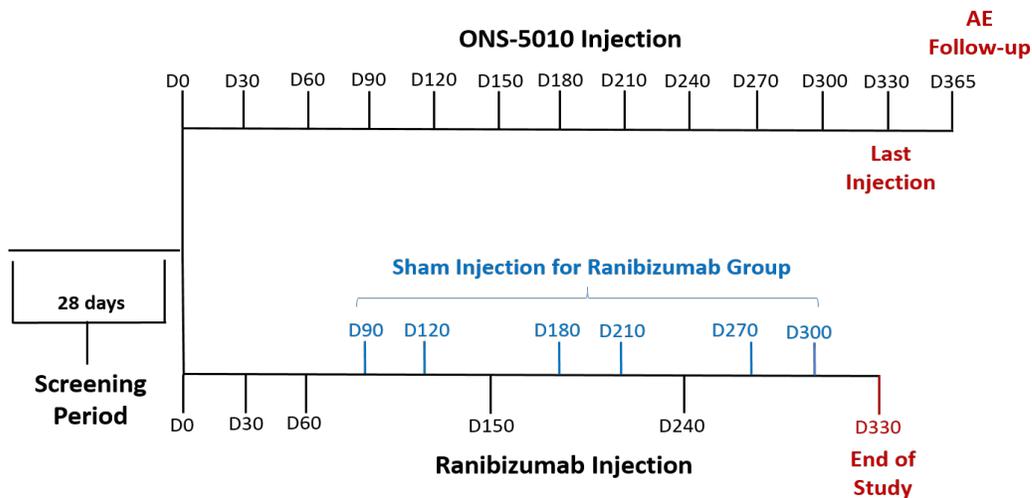


- Randomized masked controlled trial
- ONS-5010 vs LUCENTIS® (ranibizumab)
- 61 subjects enrolled
- Trial conducted in Australia
- Expected to support planned new U.S. BLA filing in Q1 2022



# ONS-5010 Demonstrated Safety and Efficacy in Clinical Experience Trial

**Title:** A clinical effectiveness, multicenter, randomized, double-masked, controlled trial of the efficacy and safety of ONS-5010 in subjects with subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration



## Trial Design

- 30 treatment-naïve or previously treated wet AMD patients per arm
- Baseline visual acuity 20/40 to 20/320
- ONS-5010 ophthalmic bevacizumab dosed monthly vs ranibizumab dosed 3 initial monthly injections, followed by quarterly dosing
- Efficacy read-out at the Month 11 visit

## Proof-of-Concept Achieved

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

# Positive Results From Clinical Experience Trial

- ONS-5010 demonstrated anticipated safety and efficacy signals consistent with previously published ophthalmic bevacizumab research
- No significant statistical differences in efficacy and safety
- Results provide support for the established design and protocol for ongoing U.S.-based Phase 3 pivotal trial
- No ocular adverse events of intraocular inflammation, vasculitis or retinal artery occlusion such as those recently reported for other anti-VEGFs in treating retinal diseases

Trial Enrollment		ONS-5010 (N=31)	Ranibizumab (N=30)	Overall (N=61)
Prior Anti-VEGF Treatment	Yes	25 (80.6%)	15 (50.0%)	40 (65.6%)
	No	6 (19.4%)	15 (50.0%)	21 (34.4%)

Subgroup Analysis of Treatment-Naïve Subjects	ONS-5010	Ranibizumab
Subjects achieving > 15 letters BCVA at Month 11	2/6 (33%)	4/14 (28.6%)

Subgroup Analysis	ONS-5010	Ranibizumab
Proportion of treatment-naïve Subjects with baseline visual acuity of <67 Letters (20/50 or worse)	2/4 (50%)	4/10 (40%)

- ONS-5010 ITT 3-line Visual Acuity Gainers Subgroup Summary
  - Treatment-naïve ONS-5010: **2/6 - 33.3%** (historical **CATT 31% bevacizumab monthly** historical **PIER 13.1% ranibizumab quarterly** historical **EXCITE 14.2% ranibizumab quarterly**)
  - Treatment-naïve & 20/50 or worse ONS-5010: **2/4 - 50%** (historical **CATT 31% bevacizumab monthly** historical **PIER 13.1% ranibizumab quarterly** historical **EXCITE 14.2% ranibizumab quarterly**)
- ONS-5010 ITT BCVA Subgroup Summary
  - Treatment-naïve **+7.3 letters** (historical **CATT +8.0**)
  - Treatment-naïve & 20/50 or worse **+8.3 letters** (historical **CATT +8.0**)



# Ongoing Pivotal Trial

## 2<sup>nd</sup> Registration Trial



Enrollment completed

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Topline data expected Q3 2021

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### Trial Highlights:



- Randomized masked controlled trial
- ONS-5010 ophthalmic bevacizumab vs LUCENTIS® (ranibizumab)
- 228 patients enrolled
- Trial conducted in the United States
- Both trial arms include predominantly treatment-naïve patients with baseline VA less than 20/50 at trial start
- Safety & efficacy data expected to support planned new U.S. BLA filing in Q1 2022



# Ongoing Pivotal Trial Design Informed by Clinical Experience Trial – With Larger Sample Size



Randomized masked controlled trial with 228 subjects



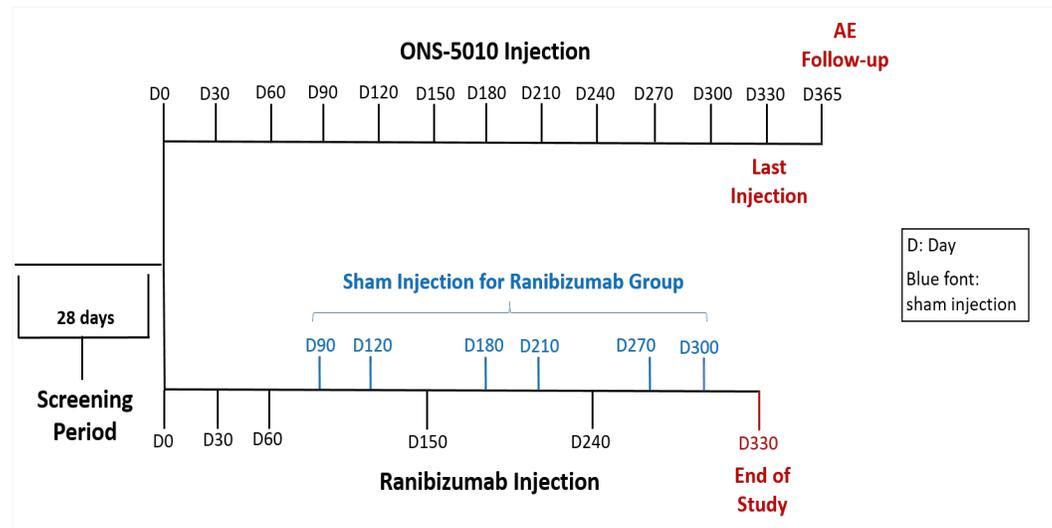
ONS-5010 ophthalmic bevacizumab administered monthly X 12



LUCENTIS dosing arm (PIER dosing) – Three initial monthly injections followed by fixed quarterly dosing



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



Comparison of trial Parameters	Clinical Experience Trial	Pivotal Trial	Rationale for Change from Clinical Experience Trial to Pivotal Trial Parameters
Prior Treatment	Both treatment-naïve and previously treated	Treatment-naïve, only	Treatment-naïve subjects have more active disease (leakage on fluorescein angiography) and worse vision; more room to improve
Baseline Visual Acuity	20/40 to 20/320 BCVA (73 to 25 letters)	20/50 to 20/320 BCVA (67 to 25 letters)	Better baseline VA (20/40 or better) is associated with less gain in VA and a lower proportion gaining $\geq 3$ -lines compared to worse VA (20/50 or worse)
Planned Sample Size	25 per arm	110 per arm	To support 90% power to detect a difference between arms in the proportion of responders



# Completed

## Open-Label Safety Study

### Supports BLA Requirements



Positive safety profile reported in NORSE 3 reinforces previously reported safety data for ONS-5010 ophthalmic bevacizumab

No unexpected safety trends, safety profile consistent with prior published data on the use of bevacizumab for ophthalmic conditions

Zero cases of ocular inflammation in NORSE 3, a concern that has emerged for other anti-VEGF therapies to treat retinal conditions

#### Trial Highlights:

- Open-label safety study
- Enrolled 197 subjects with wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) or branch retinal vein occlusion (BRVO)
- Subjects received three doses of ONS-5010 ophthalmic bevacizumab over a three-month period
- Conducted to ensure adequate number of safety exposures to ONS-5010 ophthalmic bevacizumab

# Commercial Planning Activities Underway



With an enhanced safety and cost-effectiveness profile, Outlook Therapeutics expects ONS-5010 ophthalmic bevacizumab, if approved, 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**

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**Aligning Key  
Opinion Leaders**

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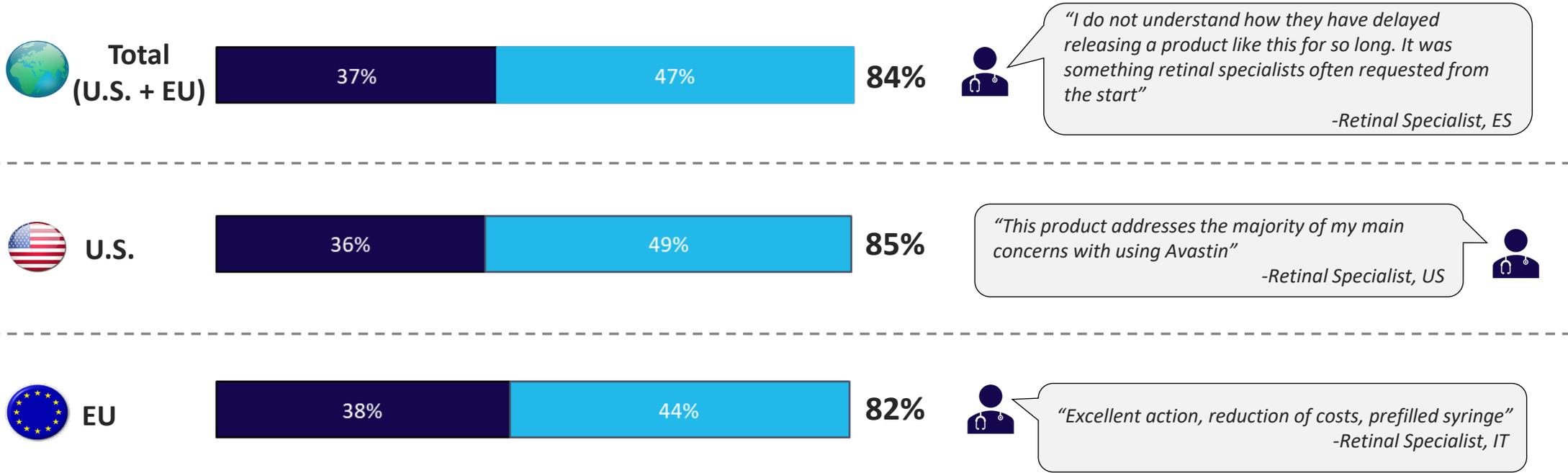


**Payor Community  
Engagement**

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# Physicians Want Approved Bevacizumab

>80% of retinal specialists express interest in an FDA-approved ophthalmic bevacizumab to treat wet AMD, DME and BRVO



# Manufacturing and Regulatory Progress Towards Commercialization



## Manufacturing

Best-in-class cGMP manufacturing partners

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## Pre-Filled Syringes

Supply agreement for a best-in-class pre-filled ophthalmic syringe

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## Regulatory

Tentatively granted ATC code for ophthalmic bevacizumab

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## Company Highlights

- Lead product candidate ONS-5010 has potential to be the first FDA-approved ophthalmic formulation of bevacizumab for use in multiple retinal indications
- ***Strong physician and payor support***, for an approved, responsibly priced, cGMP ophthalmic bevacizumab
- Pivotal Phase 3 clinical data to be reported in calendar Q3 2021
- BLA submission planned for wet AMD in calendar Q1 2022
- Management team with extensive commercial, R&D and regulatory ophthalmology experience