



# CORPORATE PRESENTATION

November 2020

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**Late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab-vikg 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 product candidate, ONS-5010 / LYTENAVA™ (bevacizumab-vikg)<sup>1</sup>, an investigational ophthalmic formulation of bevacizumab-vikg, targeting \$13.1 billion global anti-VEGF market<sup>2</sup>

### Phase 3 Clinical Program

- Demonstrated safety and efficacy in clinical experience trial
- Ongoing Phase 3 pivotal trial with topline data expected mid-2021

### Manufacturing and Regulatory

- Partnered with Fujifilm and Ajinomoto as best-in-class cGMP global manufacturers
- Tentatively granted ATC code for ophthalmic bevacizumab by the World Health Organization

### Commercial Planning Activities Underway

- Outreach to physicians, patients, KOLs and payors
- Market research indicates ONS-5010, if approved, will be a significant therapy in anti-VEGF market

### Global Strategic Partnership

- Discussions with potential strategic partners progressing
- Signing of definitive agreement could be as soon as the end of 2020

# Leadership Team: Global Ophthalmic Development and Commercial Launch Excellence



**LAWRENCE KENYON**  
President, CEO, CFO



**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

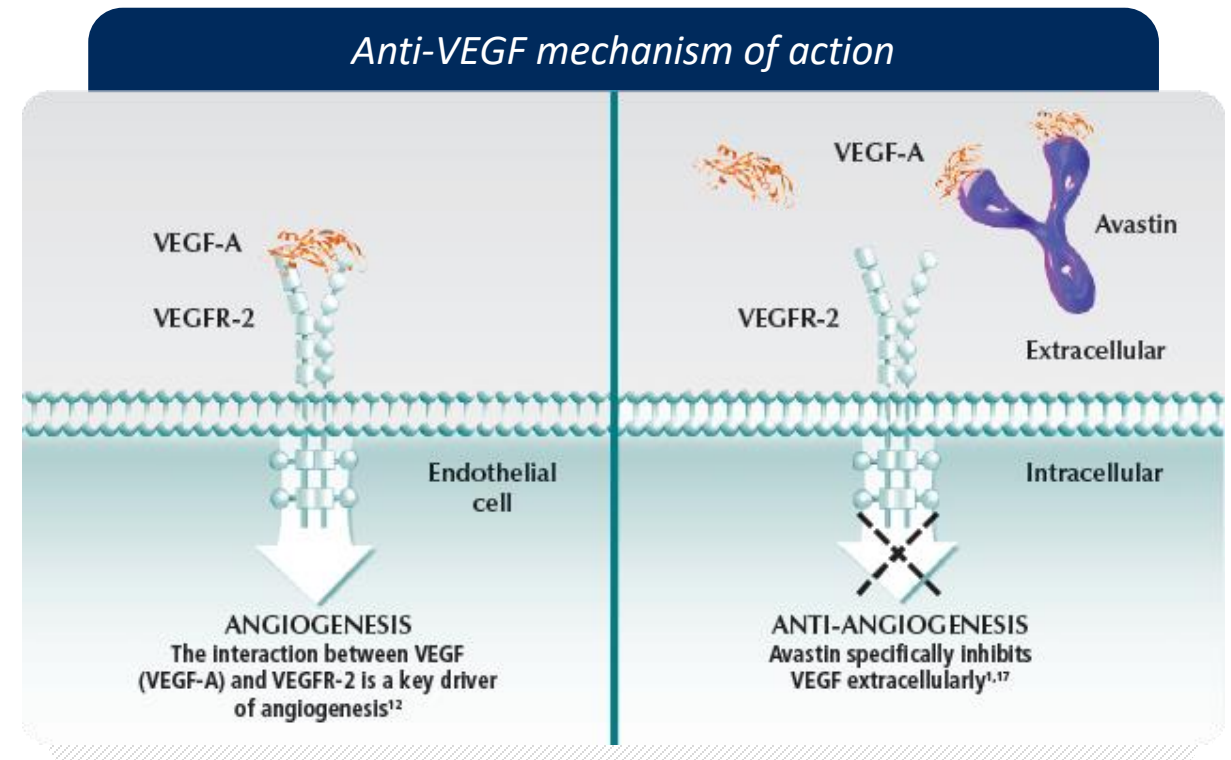
Addresses Significant Unmet Medical Need in a  
\$13.1 Billion Global Anti-VEGF Market



# Standard of Care in Wet AMD

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

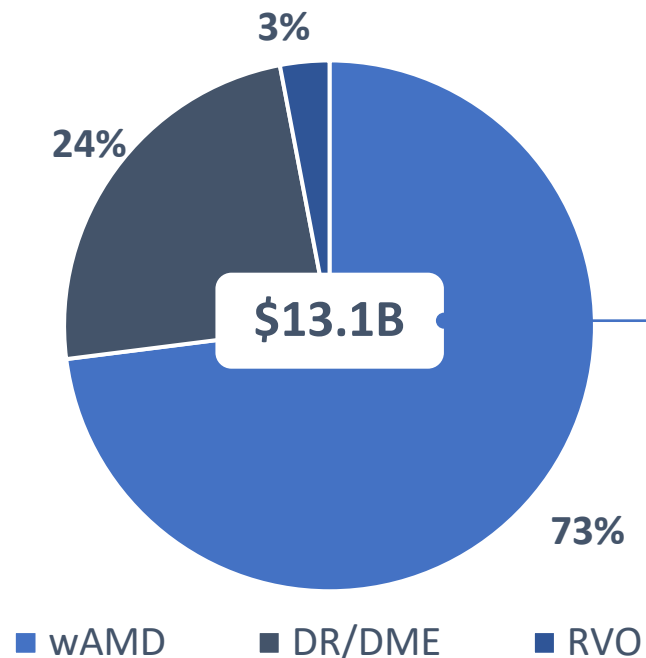
- ❑ Anti-VEGF drugs have been standard of care since 2006
  - Block growth of abnormal blood vessels and leakage of fluid from the vessels behind the retina
- ❑ Several new clinical-stage anti-VEGF drugs, including biosimilars, in development and/or recently approved
  - Require significant time and capital to achieve commercialization
  - New drugs expected to price at or near the high price points of current approved therapies



# 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

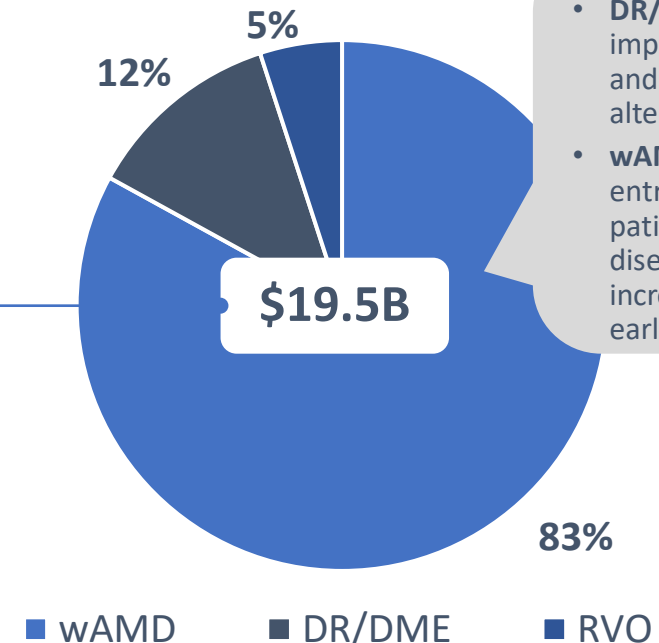
2020 9MM Anti-VEGF Revenue Share (USD)



CAGR

4.1%

2030 9MM Anti-VEGF Revenue Share (USD)

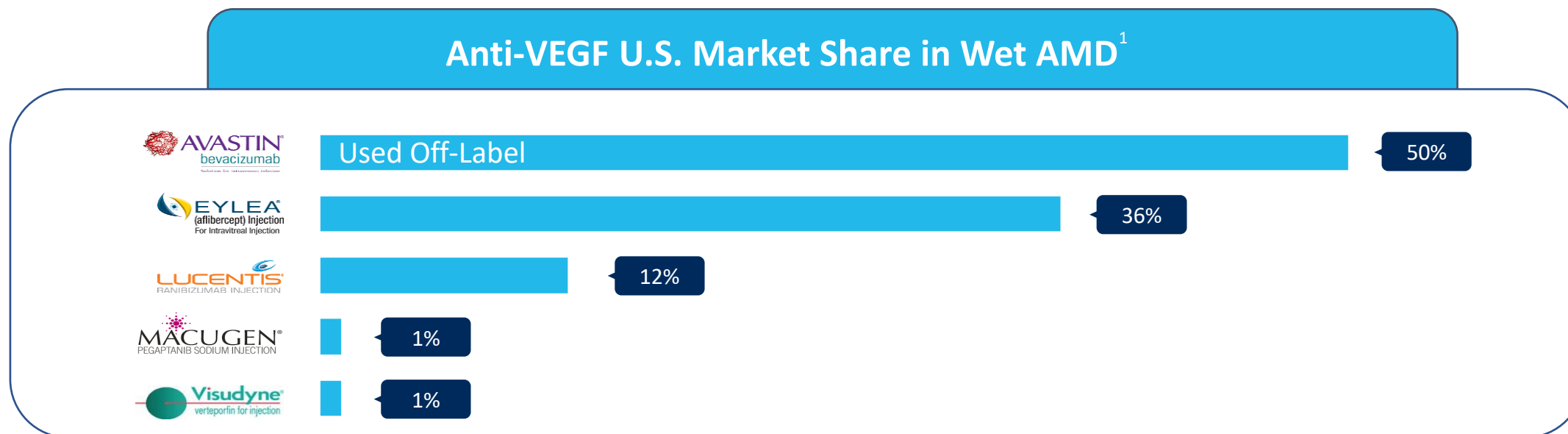


**MARKET DRIVERS:**

- **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



## Expected Drivers to Compete Across All 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

# Unapproved Repackaged IV Bevacizumab Presents Safety Issues

Once approved, ONS-5010 will reduce the need for use of unapproved repackaged IV Avastin® 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>

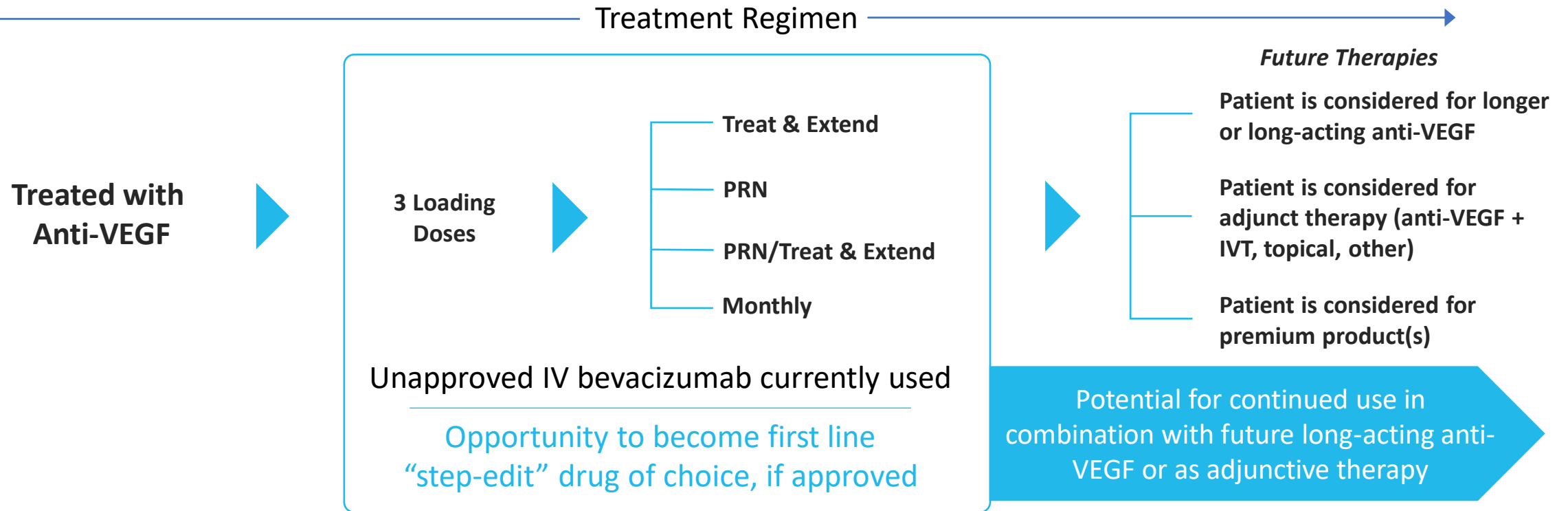
- Variability in repackaging can lower quality of syringe products, resulting in adverse events
- Silicone oil droplets may be released by the syringe into the eye



# ONS-5010

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

# ONS-5010: If Approved, Potential First Access in Treatment Paradigm with Step-Edit Therapy



## Step-Edit is a Payor Cost Saving Measure

- Less expensive therapies are covered first
- Patient must “fail” medication before advancing to more costly treatments

# Clinical Progress Drives ONS-5010 Towards U.S. and EU Filings in 2021

Recently completed clinical experience trial provides a high level of confidence in the outcome of the ongoing fully-enrolled pivotal trial



## Ongoing U.S.-based Phase 3 pivotal trial

- Completed enrollment of 227 patients
- Pivotal data are expected mid-2021



## Demonstrated safety and efficacy

- Recently reported data from clinical experience trial

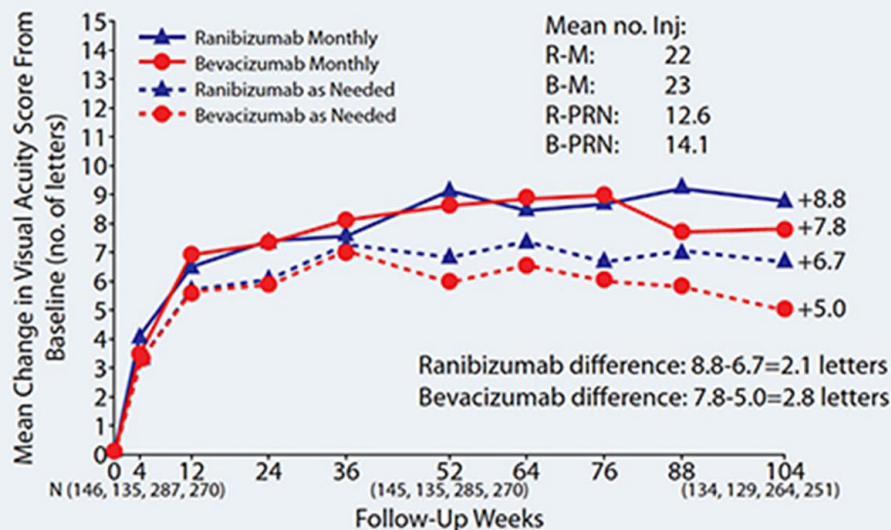


## Regulatory Strategy Aligned With FDA

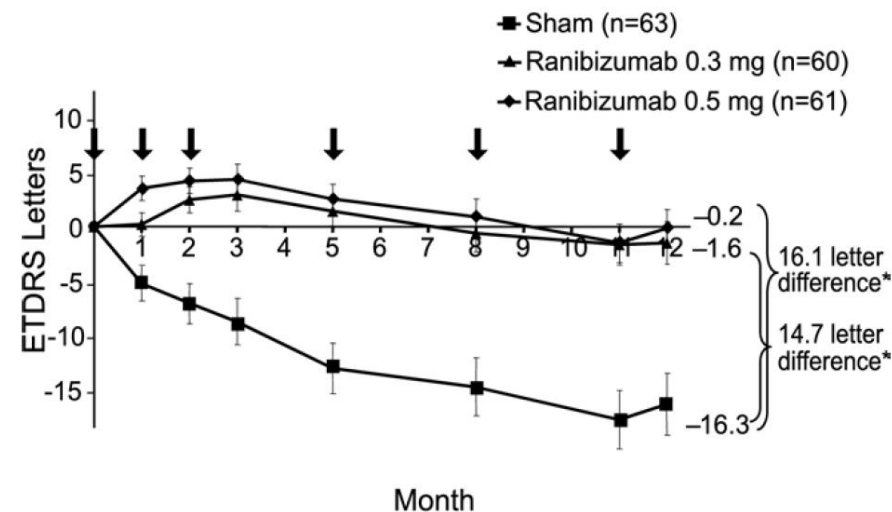
- Pursuing New Biologics License Application (BLA) submission in wet AMD

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

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



## LUCENTIS® PIER Study<sup>2</sup>



# Completed Clinical Experience Trial

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



Provides 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



### Trial Design 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 2021





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

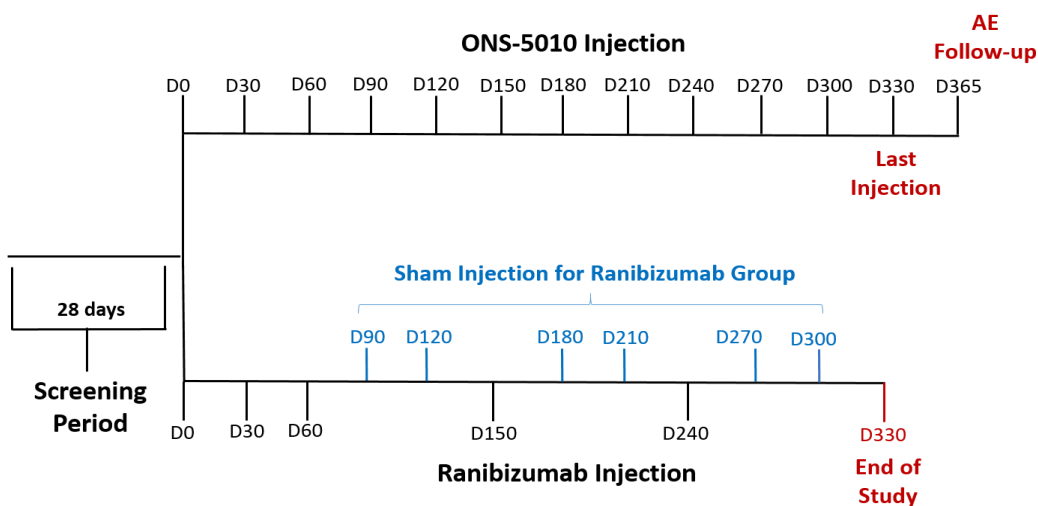
**Title:** A clinical effectiveness, multicenter, randomized, double-masked, controlled trial of the efficacy and safety of ONS-5010 in subjects with subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration

## Trial Design:

- 30 treatment-naïve or previously treated wet AMD patients per arm
- Baseline visual acuity 20/40 to 20/320
- ONS-5010 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

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



Enrollment completed



Topline data expected mid-2021



### Trial Highlights:



- Randomized Masked Controlled Trial
- ONS-5010 vs LUCENTIS® (ranibizumab)
- 227 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 2021



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



Randomized masked controlled trial with 227 subjects



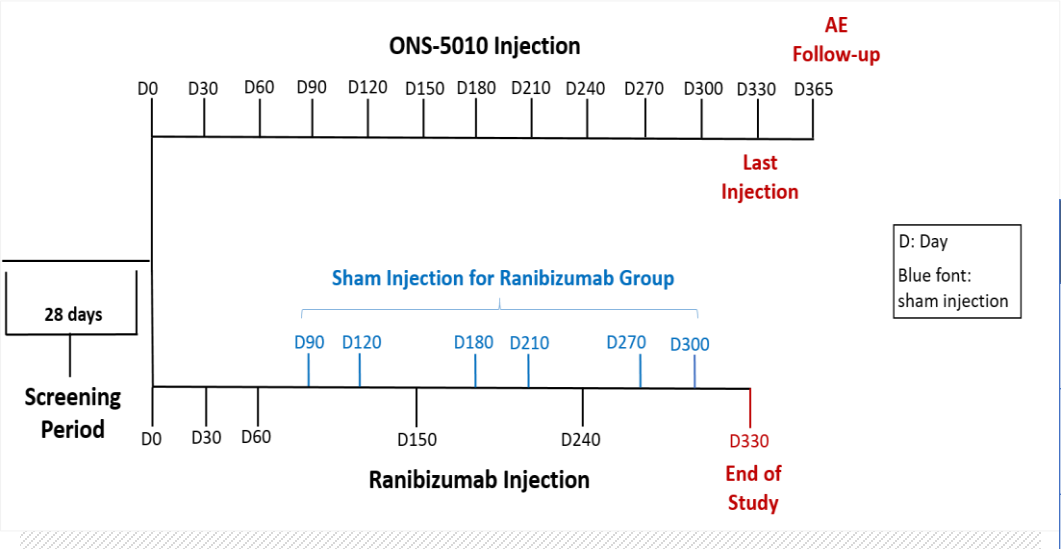
ONS-5010 administered monthly X 12



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 ≥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

# Ongoing

## Open-Label Safety Study

### Supports BLA Requirements



Full enrollment of 195 subjects achieved in less than one month, significantly ahead of planned four-month schedule

Data from study to be included in complete data package to support BLA for wet AMD

#### Trial Highlights:

- Open-label safety study
- Enrolled 195 subjects with wet age-related macular degeneration (AMD), diabetic macular edema (DME) or branch retinal vein occlusion (BRVO)
- Subjects to receive three doses of ONS-5010 over a three-month period
- Conducted to ensure adequate number of safety exposures to ONS-5010 / LYTENAVA™ (bevacizumab-vikg)

# Commercial Planning Activities Underway



With enhanced safety and 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

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## Aligning Key Opinion Leaders

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## Payor Community Engagement

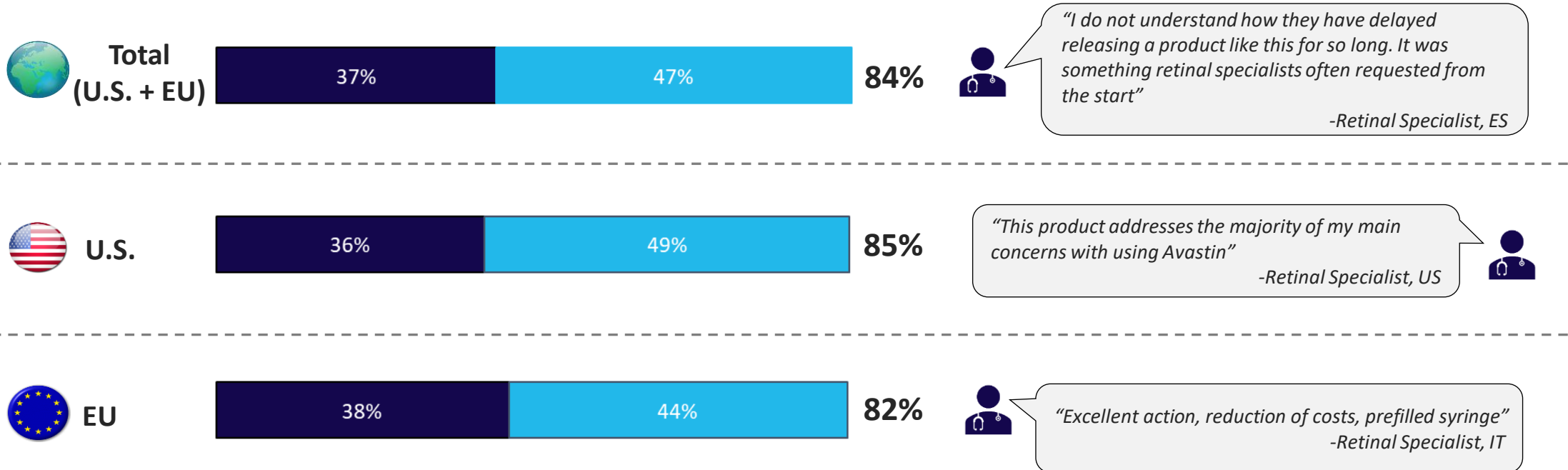
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### Discussions with Potential Strategic Partners Progressing

- Engaged with several life sciences companies that could result in a strategic partnership and definitive agreement for ONS-5010 as soon as the end of 2020
- Established joint venture with Syntone Technologies for commercializing ONS-5010 in Greater China

# Physicians Want Approved Bevacizumab

>80% of retinal specialists express interest in an FDA-approved 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 / LYTENAVA™ has potential to be first FDA-approved ophthalmic formulation of bevacizumab for use in multiple retinal indications
- Potential FDA Approval in 2022
- Targeting \$13.1 Billion Global Anti-VEGF Market<sup>1</sup>
- Potential for 12 Years of Market Exclusivity
- Management Team with Extensive Clinical/Regulatory Ophthalmology & Drug Development Experience