



CORPORATE PRESENTATION

October 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)¹, an investigational ophthalmic formulation of bevacizumab-vikg, targeting \$13.1 billion global anti-VEGF market²

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



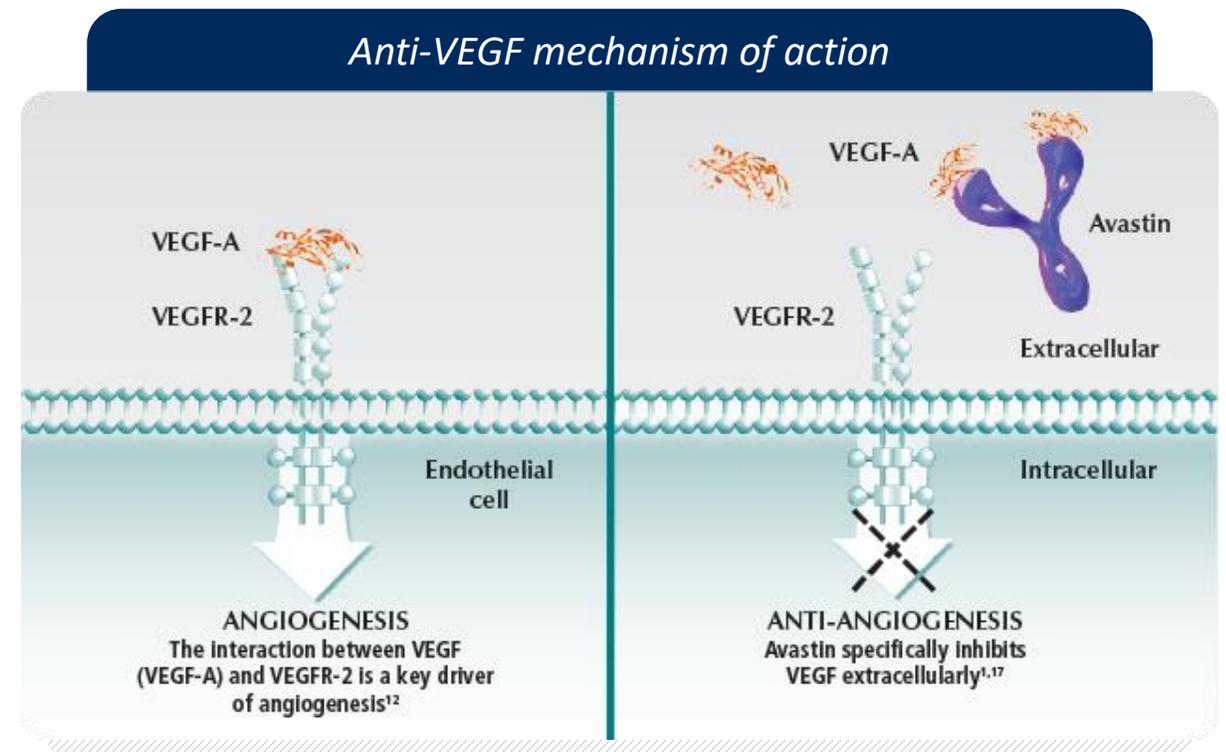
ONS-5010

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

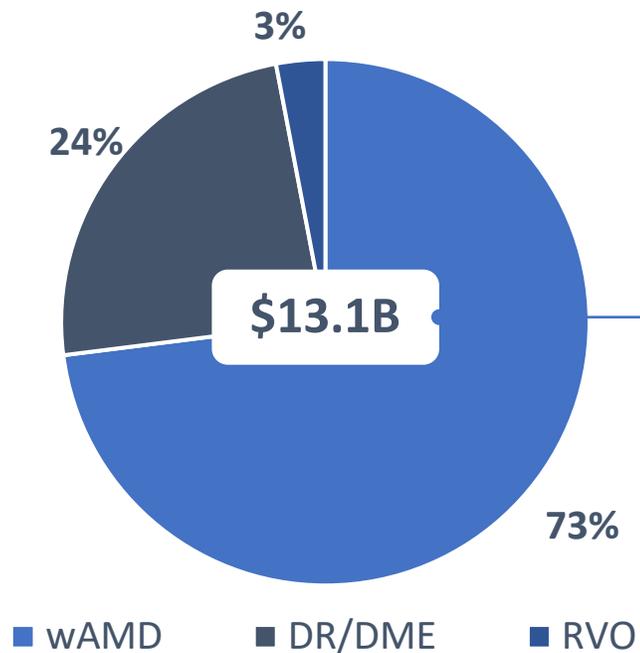
- ❑ Anti-VEGF drugs have been standard of care since 2006
 - Block growth of abnormal blood vessels and leakage of fluid from the vessels behind the retina
- ❑ Several new clinical-stage anti-VEGF drugs, including biosimilars, in development and/or recently approved
 - Require significant time and capital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



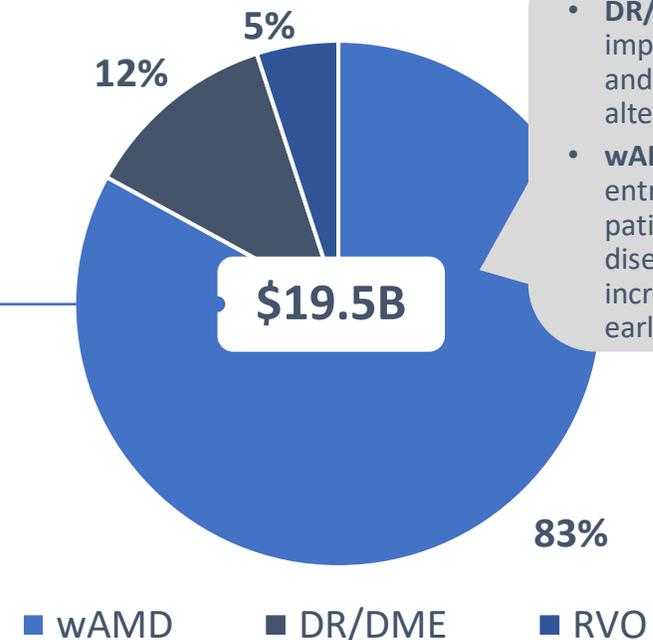
Targeting Large and Growing Ophthalmic Markets

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)



2030 9MM Anti-VEGF Revenue Share (USD)



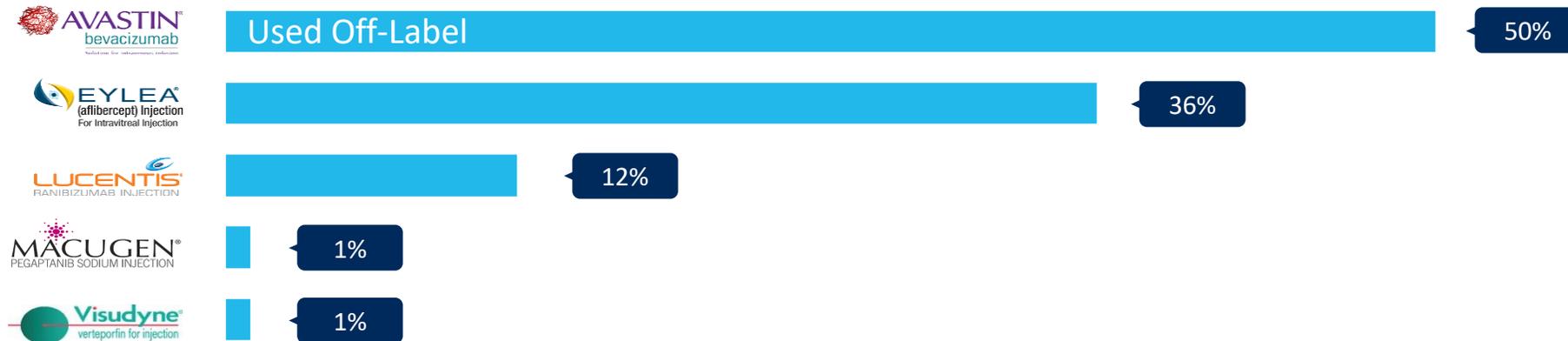
CAGR
4.1%

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 AMD¹



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 Potency¹

- 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 Events²

- 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 Malfunctioning³

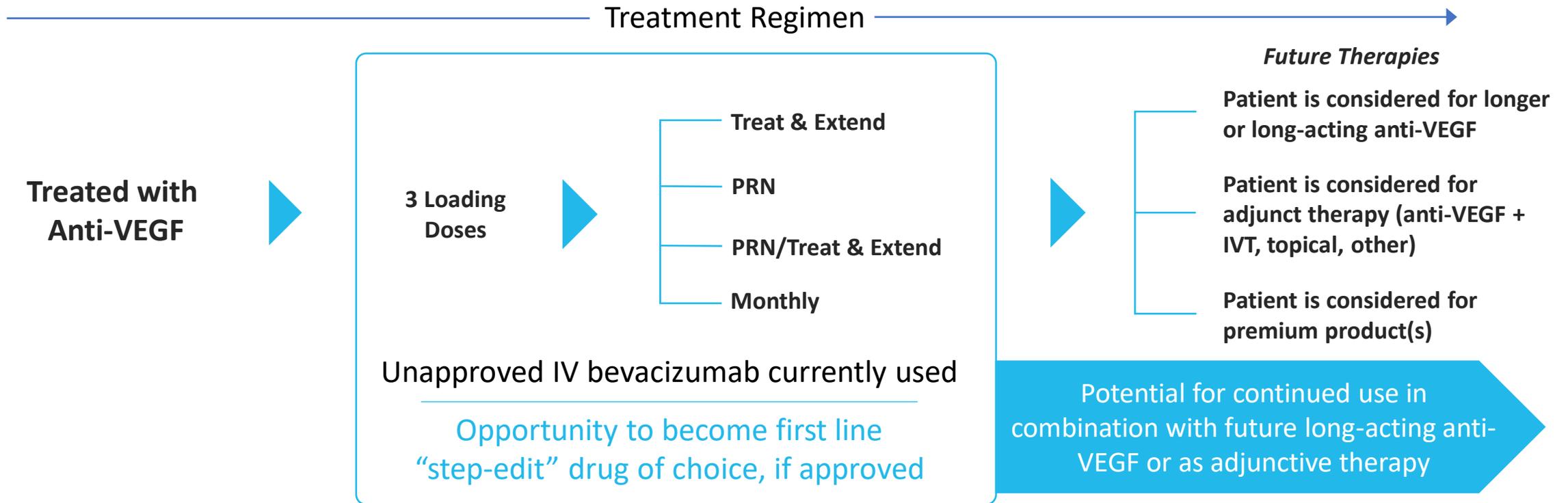
- Variability in repackaging can lower quality of syringe products, resulting in adverse events
- Silicone oil droplets may be released by the syringe into the eye



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

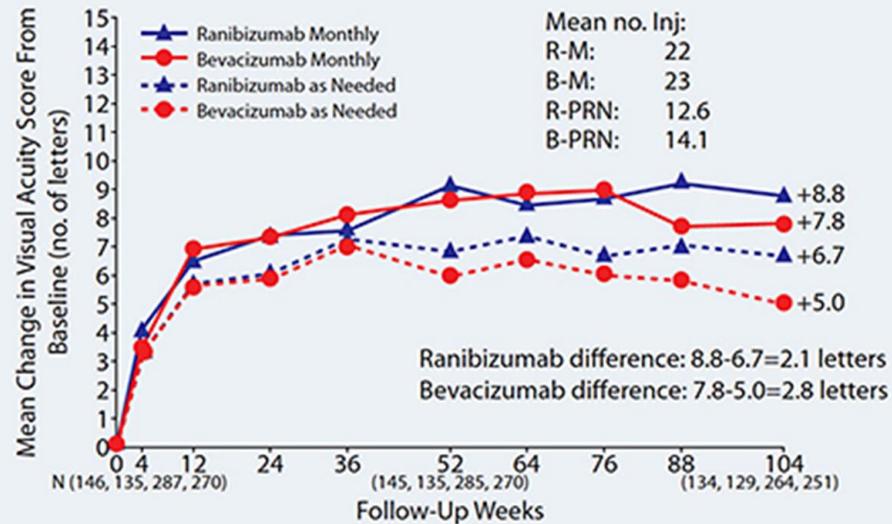


Regulatory Strategy Aligned With FDA

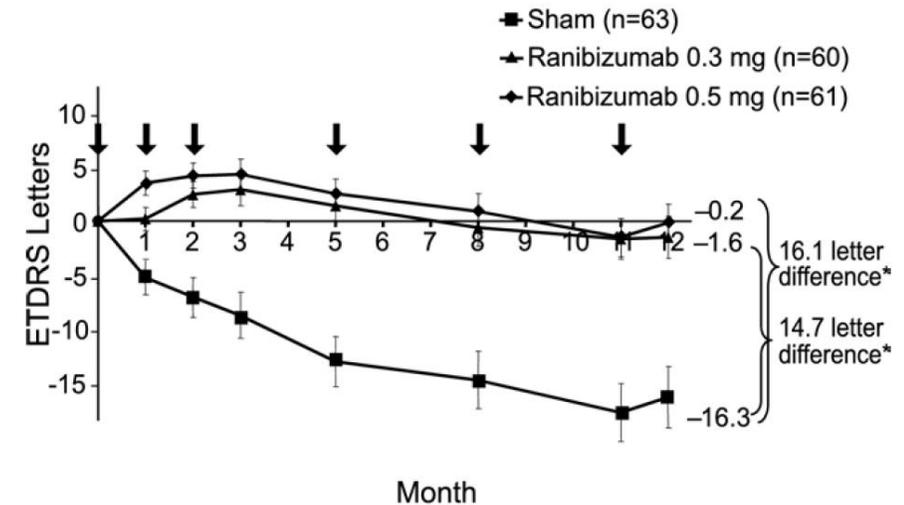
- Pursuing New Biologics License Application (BLA) submission in wet AMD

Bevacizumab Demonstrated to be Equivalent to LUCENTIS® in CATT Trial

CATT Study Results¹



LUCENTIS® PIER Study²



Completed Clinical Experience Trial

Phase 3 Clinical Program



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

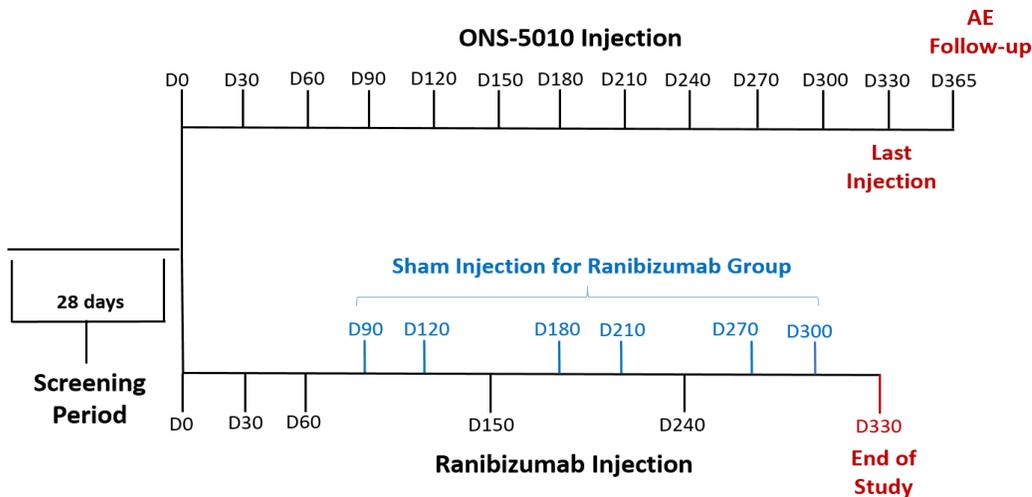
Demonstrated anticipated safety and efficacy signals consistent with previously published results for ophthalmic bevacizumab

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

Parameter		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%)

Overall Response

	ONS-5010	Ranibizumab
Subjects achieving > 15 letters BCVA at Month 11	2/26 (7.7%)	5/24 (20.8%)

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%)

Results From Clinical Experience Trial Align With Historical Bevacizumab Data & Pivotal Trial Population

- ONS-5010 ITT BCVA Subgroup Summary
 - Treatment-naïve **7.3** (historical **CATT 8.0**)
 - Treatment-naïve & 20/50 or worse **8.3** (historical **CATT 8.0**)
- 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**)

Historical Comparison

- Martin D.F., Maguire M.G., Fine S.L. et al. Comparison of Age-related Macular Degeneration Treatments Trials (CATT) Research Group Ranibizumab and bevacizumab for treatment of neovascular age-related macular degeneration: two-year results. *Ophthalmology*. 2012; 119: 1388-1398
- Regillo C.D., Brown D.M., Abraham P., et al. PIER Study Group Randomized, double-masked, sham-controlled trial of ranibizumab for neovascular age-related macular degeneration: PIER Study year 1. *Am J Ophthalmol*. 2008; 145: 239-248
- Schmidt-Erfurth U., Eldem B., Guymer R. et al. EXCITE Study Group Efficacy and safety of monthly versus quarterly ranibizumab treatment in neovascular age-related macular degeneration: the EXCITE study. *Ophthalmology*. 2011; 118: 831-839

Clinical Experience Trial Provides Confidence in Design and Sample Size of Pivotal Trial

Historical Comparison

Study	Endpoint	Ranibizumab	Bevacizumab	Sham	
Clinical Experience Trial (33.3% 20/40 or better) (N = 21)	% ≥15 letters BCVA mean change in BCVA letters	Treatment-naïve, quarterly 28.6% +12.0 ITT / +11.9 PP	3	Treatment-naïve, monthly 33.3% +7.3 ITT / +8.4 PP	1
PIER (18.5% 20/40 or better) (N = 184)	% ≥15 letters BCVA mean change in BCVA letters	Quarterly 13.1% -0.2	3		9.5% -16.3
EXCITE (19.8% 20/40 or better) (N = 353; 3 arms)	% ≥15 letters BCVA mean change in BCVA letters	14.2% quarterly / 28.7% monthly +4.0 quarterly / +8.0 monthly	3		
CATT (34.3% 20/40 or better) (N = 1185)	% ≥15 letters BCVA mean change in BCVA letters	34.2% monthly / 24.9% PRN +8.5 monthly / +6.8 PRN		31% monthly / 28% PRN +8.0 monthly / +5.9 PRN	1

Take-home messages:

- 1 Clinical experience trial provided the expected level of treatment effect based on historical data
Safety data are consistent with other intravitreally administered anti-VEGF therapies
- 2 Our pivotal trial sample size was powered on data from PIER and EXCITE studies
Our pivotal trial population (N = 227) is almost all treatment-naïve with 20/50 as best VA entry criteria rather than 20/40 as in our clinical experience trial
- 3 Ranibizumab over-performed in this small study compared to larger, published trials; unlikely to see the same in our larger pivotal trial; if more subjects in our pivotal trial compared to historical studies are capable of demonstrating a visual acuity gain ≥15 letters, then randomization should distribute these subjects equally across both study arms

Ongoing Pivotal Trial

Phase 3 Clinical Program



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



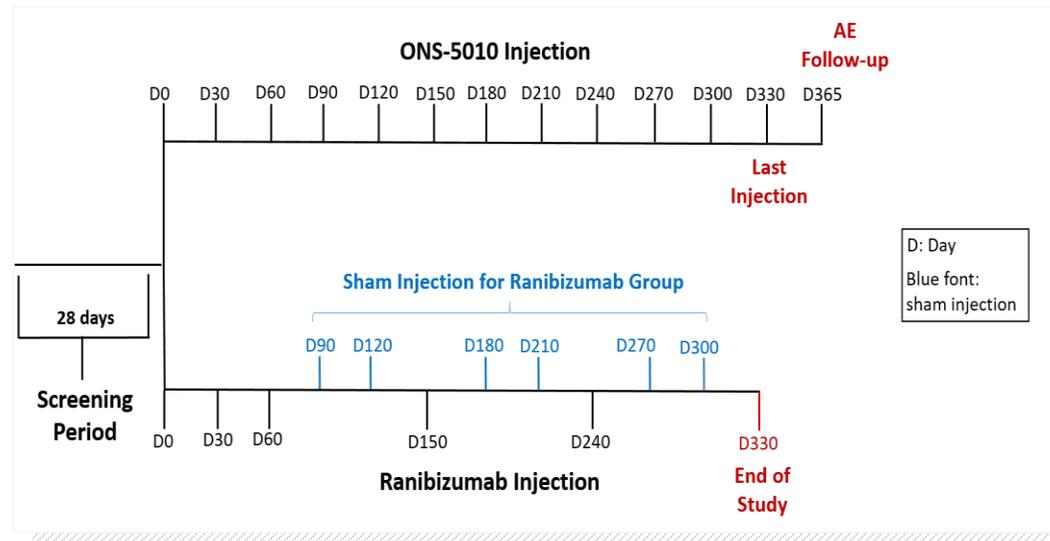
ONS-5010 administered monthly X 12



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

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**



**Aligning Key
Opinion Leaders**



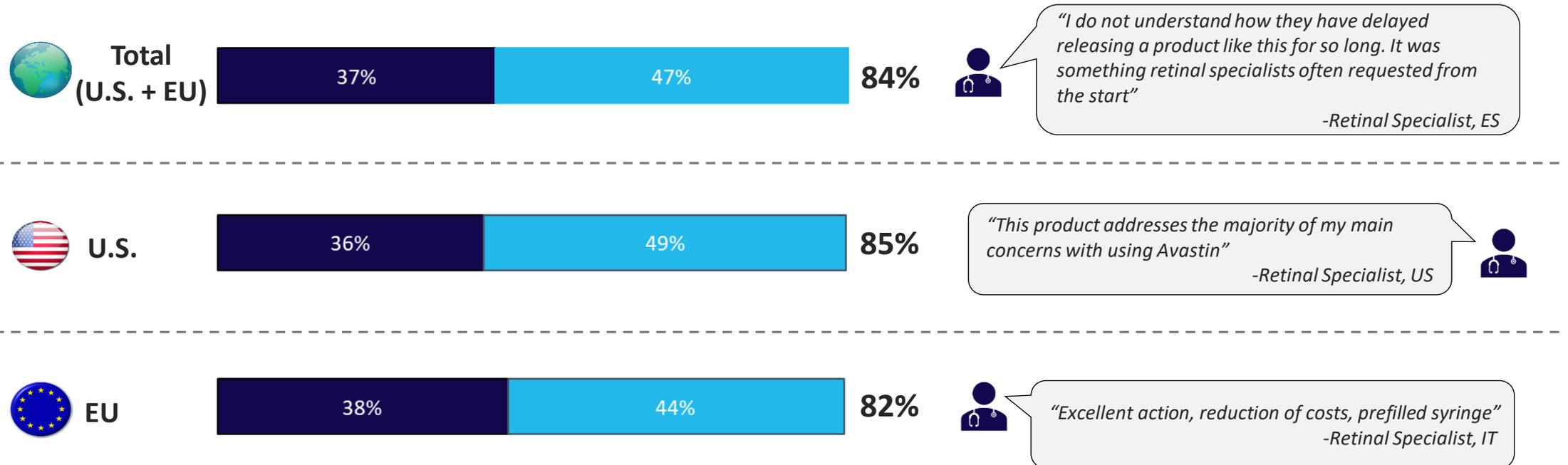
**Payor Community
Engagement**

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



Pre-Filled Syringes

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



Regulatory

Tentatively granted ATC code for ophthalmic bevacizumab



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 Market¹
- Potential for 12 Years of Market Exclusivity
- Management Team with Extensive Clinical/Regulatory Ophthalmology & Drug Development Experience