OUTLOOK THERAPEUTICS

CORPORATE PRESENTATION

March 2021

NASDAQ: OTLK

outlooktherapeutics.com

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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 ophthalmic anti-VEGF market[2]

Phase 3 Clinical Program

- Initial safety and efficacy reported in clinical experience trial
- Ongoing Phase 3 pivotal trial with topline data expected Q3 2021

Commercial Planning Activities Underway

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

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

Strategic Optionality

- Evaluating options with or without strategic partners
- Sufficient capital to fund operations through a potential BLA filing

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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);*9MM is US, EU5, Japan, China & Australia

Leadership Team: Global Ophthalmic Development and Commercial Launch Excellence

LAWRENCE KENYON
President, CEO, CFO

ARNO THERAPEUTICS · TAMIR Targeting microRNAs · PAR PHARMACEUTICAL an endo international company

JEFF EVANSON
Chief Commercial Officer

NOVARTIS · Alcon · Medtronic · NAVIGANT

TERRY DAGNON
Chief Operating Officer

NOVARTIS · Alcon · Johnson & Johnson · DOHMEN LIFE SCIENCE SERVICES

RANDY THURMAN
Executive Chairman of the Board

MARK HUMAYUN, MD, PhD
Medical Advisor

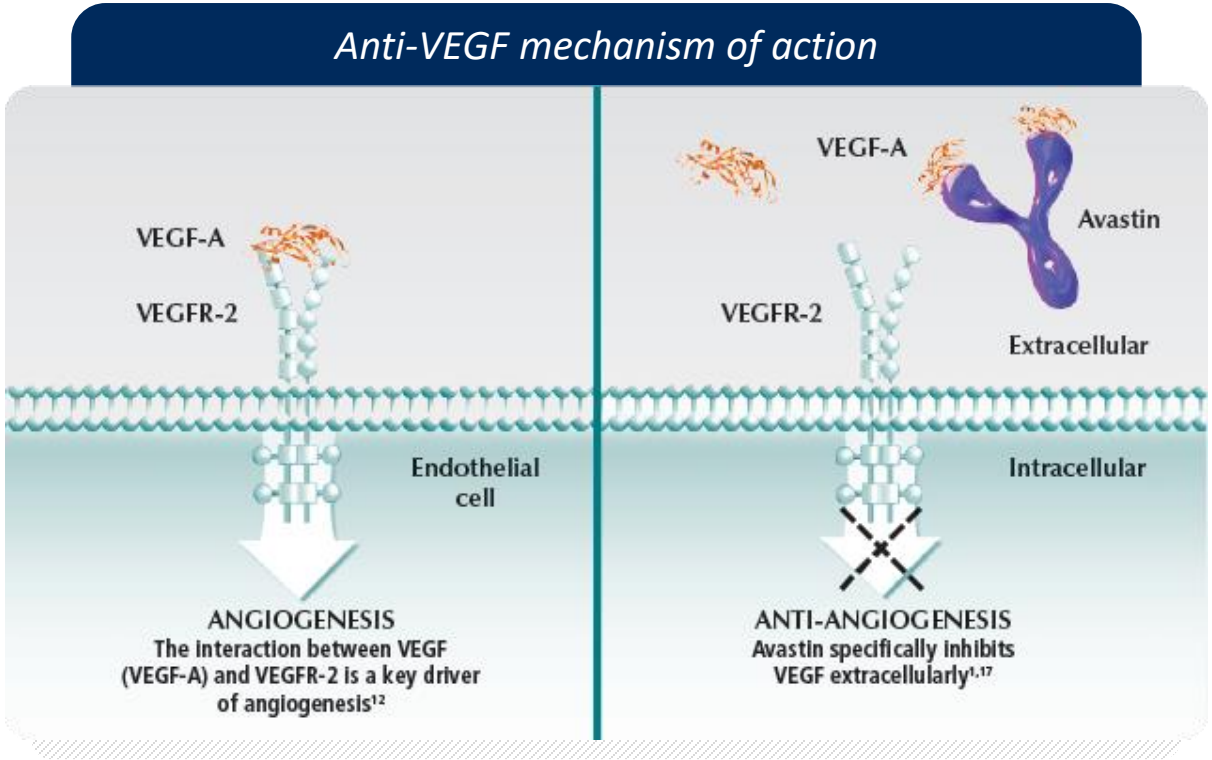
ONS-5010

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

Standard of Care in Wet AMD

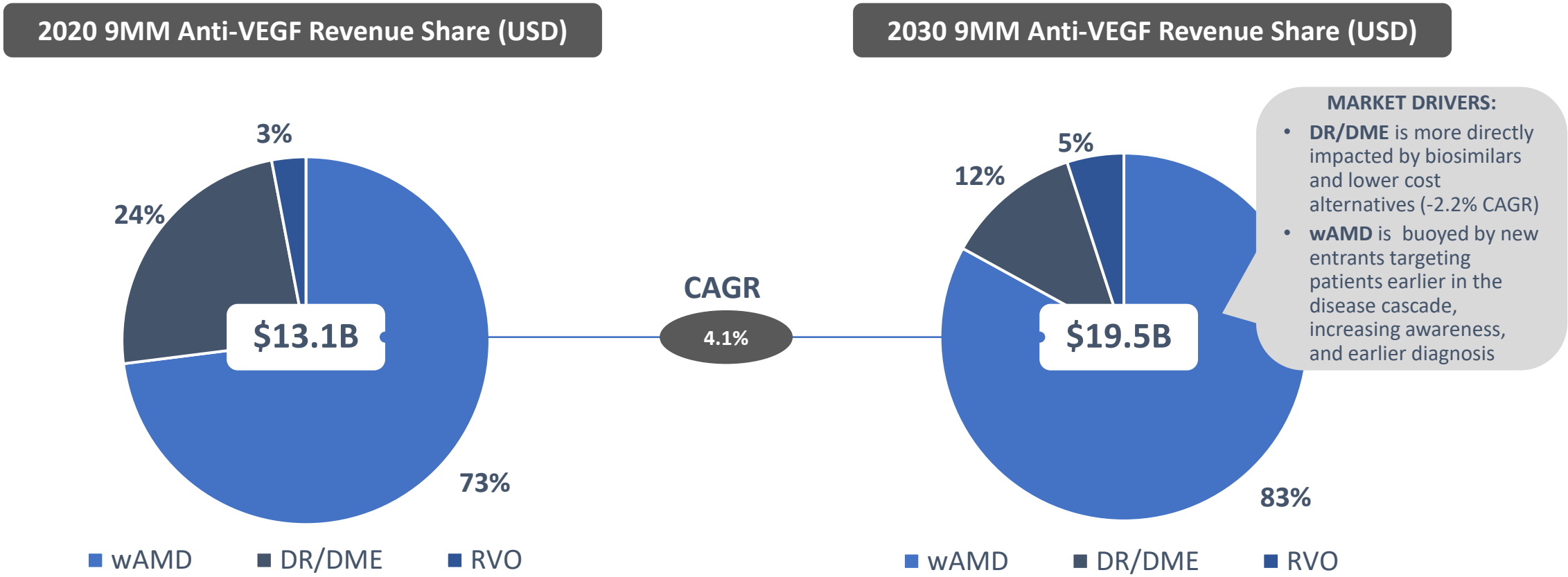
ONS-5010 / LYTENAVA™, if approved, will be the
first on-label ophthalmic formulation of bevacizumab-vikg

- 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



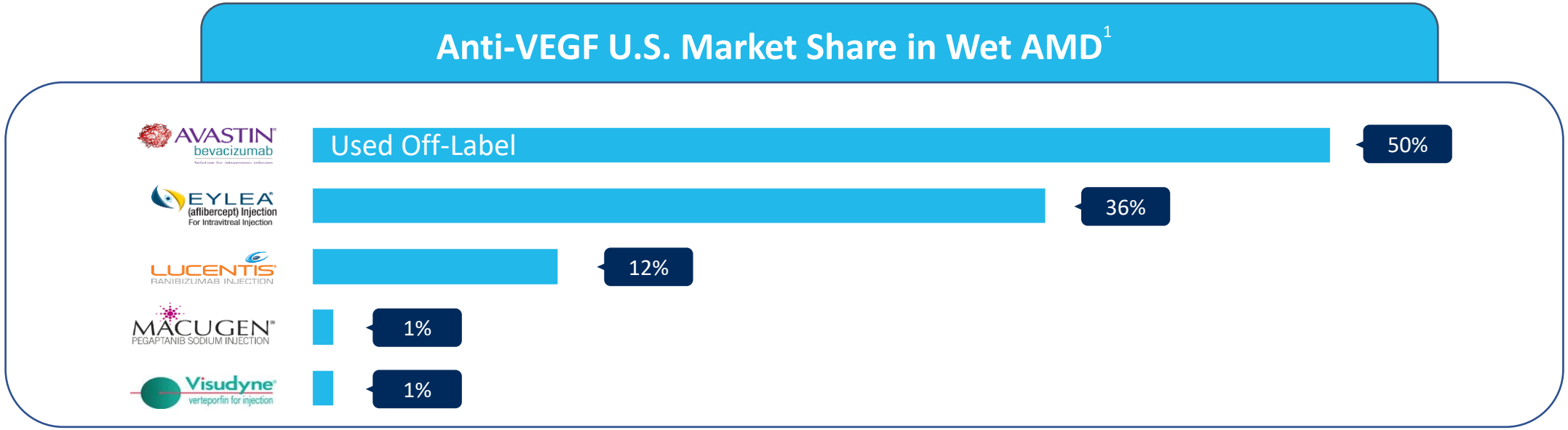
Targeting Large and Growing Ophthalmic Markets

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



Sources: Guidehouse Triangulation of Global Data, Market Scope and Investor Forecasts (2020);*9MM is US, EU5, Japan, China & Australia
AMD = Age-Related Macular Degeneration; DME = Diabetic Macular Edema ; BRVO = Branch Retinal Vein Occlusion

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



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

1: Source: Global Data estimates, 2016

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)

Unapproved Repackaged IV Bevacizumab Presents Safety Issues

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

Variability in Potency[1]

- 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[2]

- 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

FDA
Warning Letter

Syringe Malfunctioning[3]

- 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

ASRS American Society of Retina Specialists

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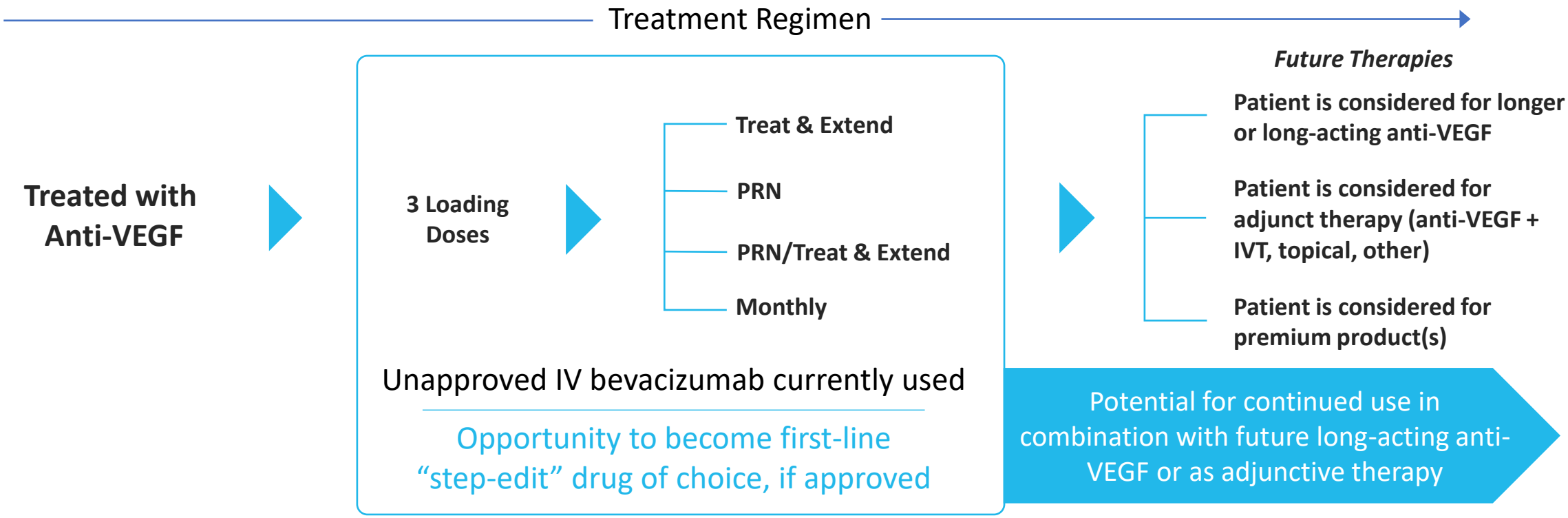
1: JAMA Ophthalmol. 2015 Jan;133(1):32-9. doi: 10.1001/jamaophthalmol.2014.3591; 2: Goldberg, Roger A et al. “An outbreak of streptococcus endophthalmitis after intravitreal injection of bevacizumab.” American Journal of Ophthalmology vol. 153,2 (2012): 204-208.e1. doi:10.1016/j.ajo.2011.11.035; 3: ASRS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

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 safety and efficacy signals for confidence in the outcome of the ongoing fully-enrolled pivotal trial

Ongoing U.S.-based Phase 3 pivotal trial

- Completed enrollment of 228 patients
- Pivotal data are expected Q3 2021

Demonstrated safety and efficacy

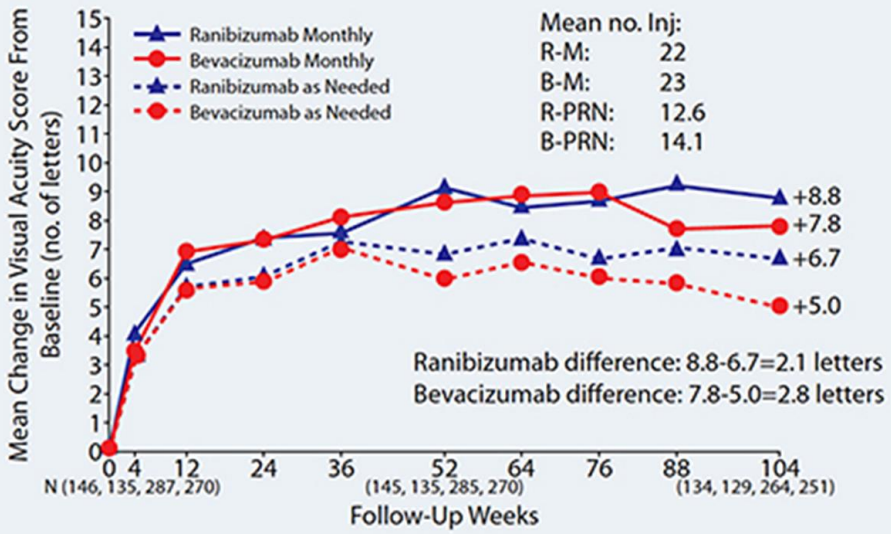
- Recently reported data from clinical experience trial

Regulatory strategy aligned with FDA

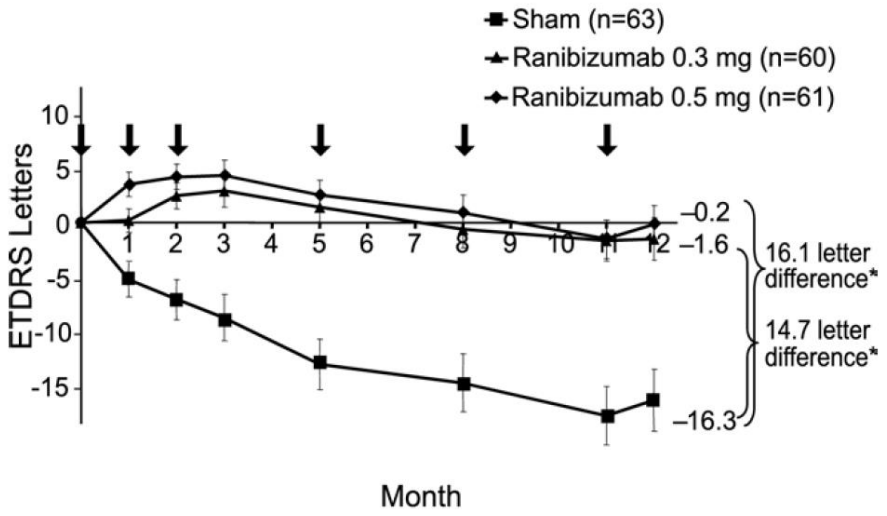
- Pursuing new Biologics License Application (BLA) submission in wet AMD

Bevacizumab Demonstrated to be Equivalent to LUCENTIS® in CATT Trial

CATT Study Results[1]



LUCENTIS® PIER Study[2]



1: Comparison of Age-related Macular Degeneration Treatments Trials (CATT) Research Group, Daniel F. Martin, Ophthalmology, July 2012 Volume 119, Issue 7, Pages 1388–1398
2: Am J Ophthalmol. 2010 Sep;150(3):315-324.e1. doi: 10.1016/j.ajo.2010.04.011. Epub 2010 Jul 3.

Completed Clinical Experience Trial

1st Registration Trial

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

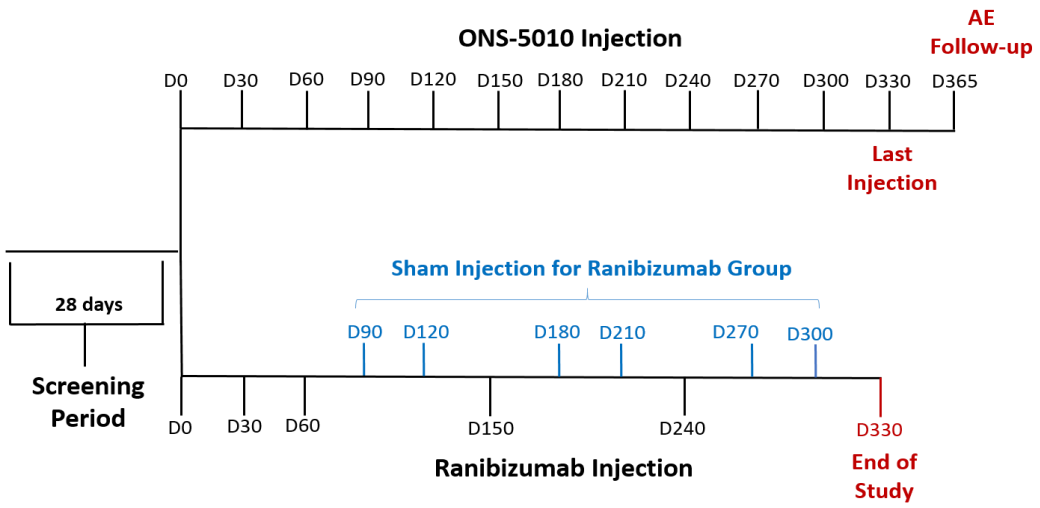
Demonstrated anticipated safety and efficacy signals consistent with previously published results for ophthalmic bevacizumab

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

2nd Registration Trial

Enrollment completed

Topline data expected Q3 2021

Trial Highlights:

- Randomized Masked Controlled Trial
- ONS-5010 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 2021

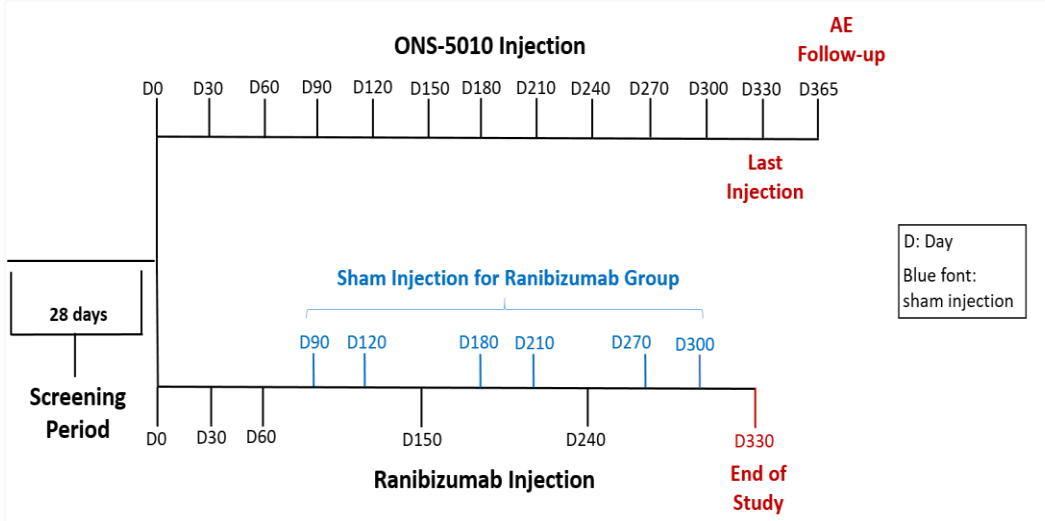
Ongoing Pivotal Trial Design Informed by Clinical Experience Trial – With Larger Sample Size

Randomized masked controlled trial with 228 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 am	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

Completed last patient visit with topline data expected Q2 2021

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

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 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 an enhanced safety and cost-effectiveness 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

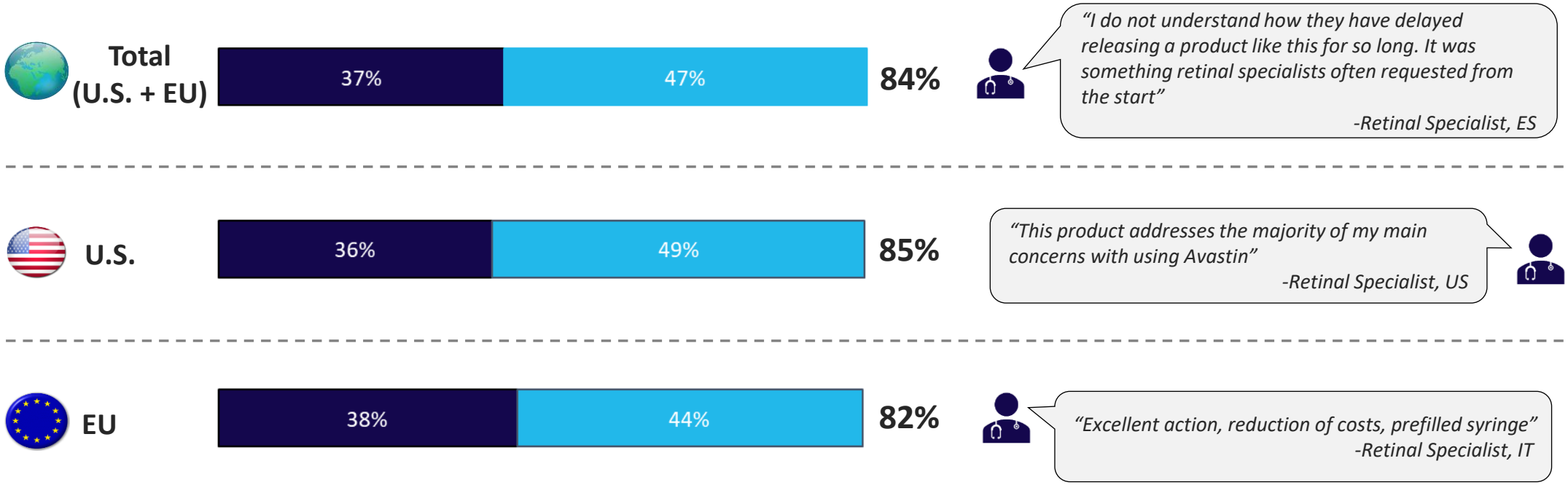
Physician and Patient Outreach

Aligning Key Opinion Leaders

Payor Community Engagement

Physicians Want Approved Bevacizumab

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



Source: Navigant Quantitative Survey (n=152), 2019
*Other survey options not shown *were "neutral, not likely to use, and not interested at all"*

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 Ophthalmic Anti-VEGF Market[1]
- Potential for 12 Years of Market Exclusivity
- Management Team with Extensive Clinical/Regulatory Ophthalmology & Drug Development Experience

1: Guidehouse Triangulation of Global Data, Market Scope and Investor Forecasts (2020);*9MM is US, EU5, Japan, China & Australia