OUTLOOK THERAPEUTICS

Virtual Clinical Day

May 20, 2021

NASDAQ: OTLK

outlooktherapeutics.com

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Medical Advisor to
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Sr. Partner, Retina-Vitreous
Associates and Assoc. Clinical
Professor of Ophthalmology, UCLA

Today's Program

- **Opening Remarks**
  - Larry Kenyon, President, CEO and CFO
- **Regulatory Strategy and Clinical Update**
  - Terry Dagnon, Chief Operating Officer
- **NORSE 2: Pivotal Phase 3 Study**
  - Mark Humayun, MD, PhD, Medical Advisor
- **Patient Safety and a Practicing Physician's Perspective**
  - Firas Rahhal, MD, Sr. Partner, Retina-Vitreous Associates and Assoc. Clinical Professor of Ophthalmology, UCLA
- **Market Opportunity and Commercialization Strategy**
  - Jeff Evanson, Chief Commercial Officer
- **Closing Remarks**
  - Larry Kenyon, President, CEO and CFO

INTRODUCTION

LAWRENCE A. KENYON

PRESIDENT, CEO & CFO, OUTLOOK THERAPEUTICS

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[1] targeting $13.1 billion global ophthalmic anti-VEGF market[2]

Phase 3 Clinical Program

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

NORSE ONE NORSE TWO NORSE THREE NORSE FOUR NORSE FIVE NORSE SIX

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

FUJIFILM Diosynth biotechnologies · Ajinomoto · BIO•PHARMA SERVICES

- 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

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1: ONS-5010™ ophthalmic bevacizumab 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

REGULATORY STRATEGY AND CLINICAL UPDATE

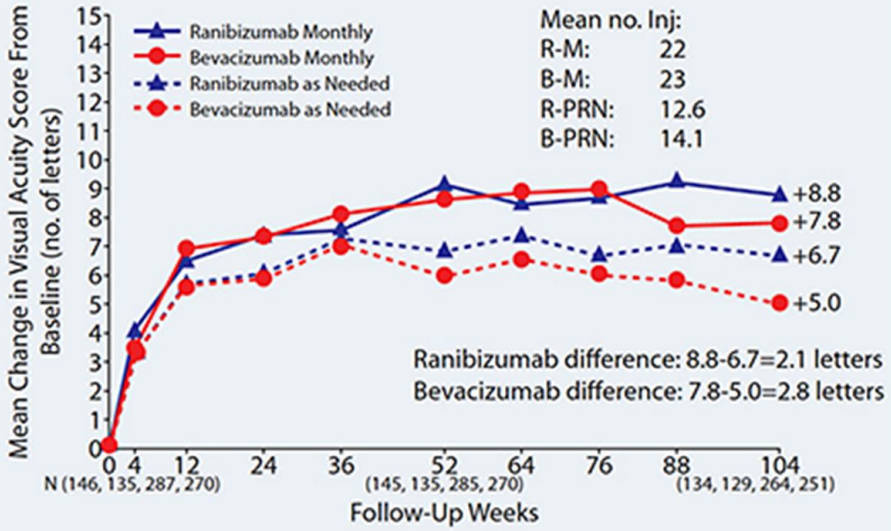
TERRY DAGNON
CHIEF OPERATING OFFICER, OUTLOOK THERAPEUTICS

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

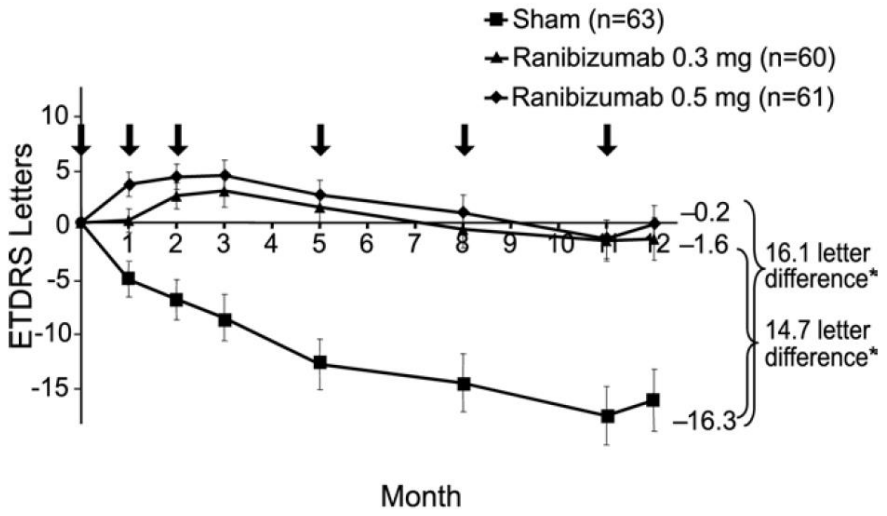
CATT IND Study Validated Bevacizumab as Safe and Effective (2011)

Bevacizumab Demonstrated to be Equivalent to LUCENTIS® in CATT Trial but Unmet Needs Remain

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.

Pathway Towards Planned BLA Filing in Wet AMD

U.S. BLA Filing Targeted Q1 2022

✓ **Completed**

NORSE ONE

Completed Clinical Experience Trial

1st Registration Trial

Topline data expected Q3 2021

NORSE TWO

Ongoing Pivotal Trial

2nd Registration Trial

✓ **Completed**

NORSE THREE

Open-Label Safety Study

Supports BLA Requirements

NORSE ONE

Completed Clinical Experience Trial

1st 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

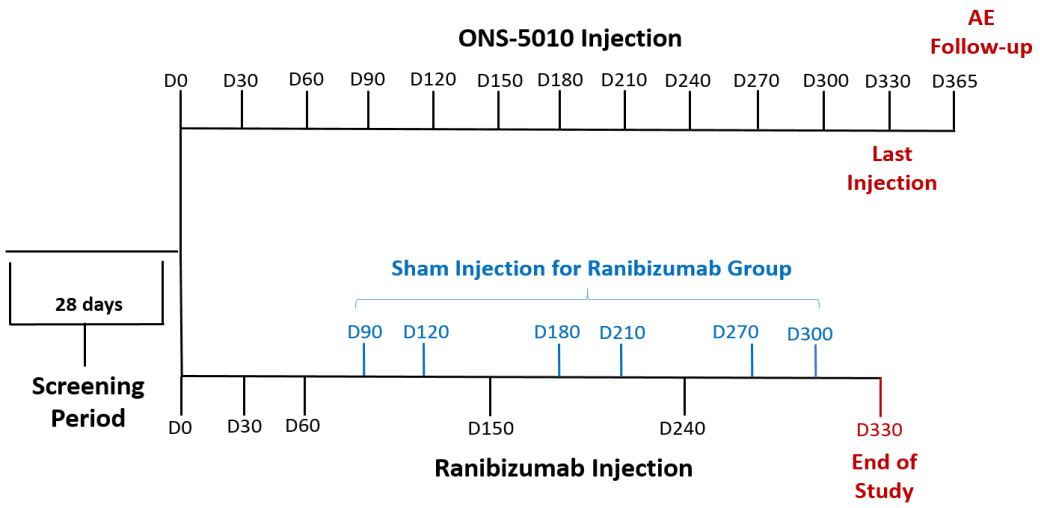
Provided successful proof of concept

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 Ophthalmic Bevacizumab 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

NORSE TWO

Ongoing Pivotal Trial

2nd Registration Trial

Enrollment completed

Topline data expected Q3 2021

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

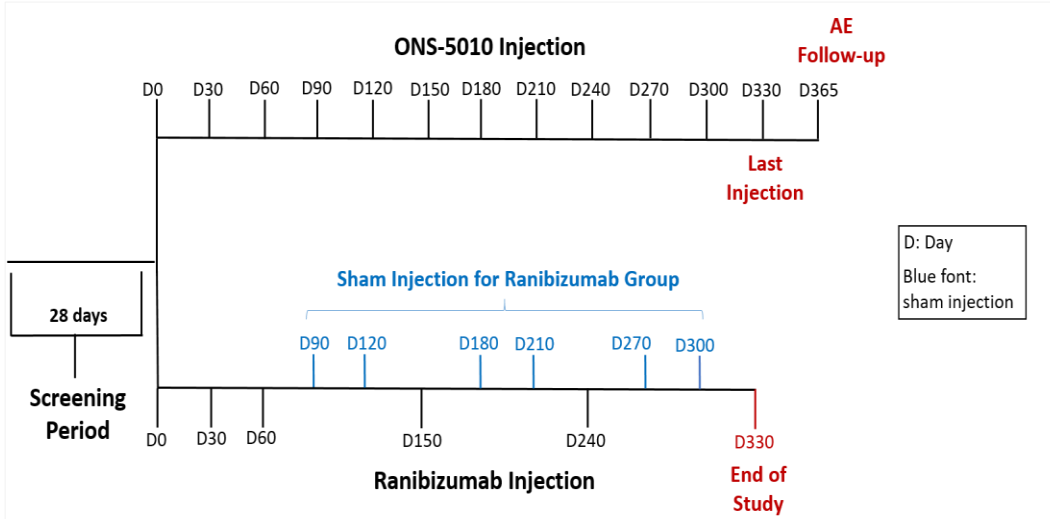
Ongoing Pivotal Trial Design Informed by Clinical Experience Trial – With Larger Sample Size

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 ≥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

NORSE THREE

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

Q&A

NORSE TWO: PIVOTAL PHASE 3 STUDY

MARK A. HUMAYUN, MD, PHD

MEDICAL ADVISOR TO OUTLOOK THERAPEUTICS; OPHTHALMOLOGIST, ENGINEER, INVENTOR; NATIONAL MEDAL OF TECHNOLOGY AND INNOVATION AWARDED BY PRESIDENT BARACK OBAMA, 2016; TOP 1% OPHTHALMOLOGIST (U.S. NEWS & WORLD REPORT); MEMBER, U.S. NATIONAL ACADEMICS OF MEDICINE AND ENGINEERING; PYRON AWARD, AMERICAN SOCIETY OF RETINA SPECIALISTS; PAST PRESIDENT, AMERICAN SOCIETY OF RETINA SPECIALISTS; CO-INVENTOR OF ARGUS II, WHICH OFFERS FUNCTIONAL SIGHT TO PATIENTS WITH COMPLETE RETINAL BLINDNESS

NORSE TWO

Ongoing Pivotal Trial

2nd Registration Trial

Registration clinical trial designed to meet regulatory purposes, not to introduce new science

Previously validated molecule and study designs with over a decade of clinical use

The clinically relevant primary endpoint is the difference in the proportion of participants who gain at least 15 letters at month 11

Study is powered for statistical significance

Unmet needs to be addressed:

- Demonstrate that ONS-5010 behaves in the eye as Avastin® does, as shown in the CATT trial and other studies
- Ophthalmic formulation, cGMP produced as part of regulated supply chain
- Approved responsibly priced ANTI-VEGF product

Q&A

PATIENT SAFETY AND A PRACTICING PHYSICIAN'S PERSPECTIVE

FIRAS M. RAHHAL, MD

SENIOR PARTNER, RETINA-VITREOUS ASSOCIATES MEDICAL GROUP IN LOS ANGELES AND
ASSOCIATE CLINICAL PROFESSOR OF OPHTHALMOLOGY AT THE UCLA GEFFEN SCHOOL OF MEDICINE

Off-Label Repackaged IV Bevacizumab Can Present Safety Issues

If approved, ONS-5010 ophthalmic bevacizumab will reduce the need for off-label 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 exist 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

Unmet Needs to be Met by ONS-5010

Potential Benefits to Clinicians and Their Patients

- Address concerns reported with off-label repackaged IV bevacizumab
- Allow clinicians to continue to rely on a well-known molecule that is provided in a specific ophthalmic formulation
- Potentially expand patient access to care with a responsibly priced approved ophthalmic therapy
- Increase patient satisfaction and improve clinical outcomes while potentially avoiding serious adverse events

1: OMIC. Accessed March 22, 2021. https://www.omic.com/

Q&A

MARKET OPPORTUNITY, COMMERCIALIZATION STRATEGY

JEFF EVANSON
CHIEF COMMERCIAL OFFICER, OUTLOOK THERAPEUTICS

ONS-5010 Ophthalmic Bevacizumab Target Product Profile

ONS-5010 Ophthalmic Bevacizumab	
Patient Population	• Patients diagnosed with **wet AMD, DME, or BRVO**
Description	• ONS-5010 ophthalmic bevacizumab is the anti-VEGF **bevacizumab designed for ophthalmic indications** wet AMD, DME, and BRVO
Dosing and Administration	• Supplied either as **pre-filled ophthalmic syringe for intravitreal 1.25 mg injection** administered once monthly, **or as a glass vial with an accessory kit (including a companion ophthalmic syringe)**
Efficacy, Safety, and AEs	• Efficacy and safety comparable to that demonstrated in the National Eye Institute (NEI) Comparison of Age-Related Macular Degeneration Treatments Trials (CATT) Study as equivalent to Lucentis®

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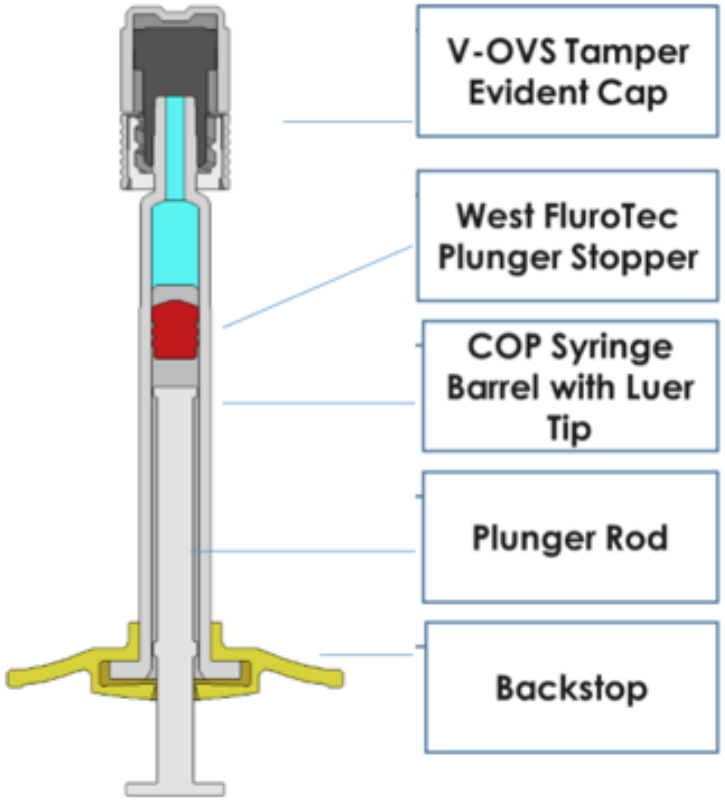
Anti-VEGF - Anti–vascular endothelial growth factor therapy ; AMD – Age-related macular degeneration; DME – Diabetic macular edema; BRVO – Branch retinal vein occlusion; CATT – National Eye Institute, Comparison of Age-related Macular Degeneration Treatments Trials, 2011

Benefits of the ONS-5010 Ophthalmic Bevacizumab O.5mL Syringe

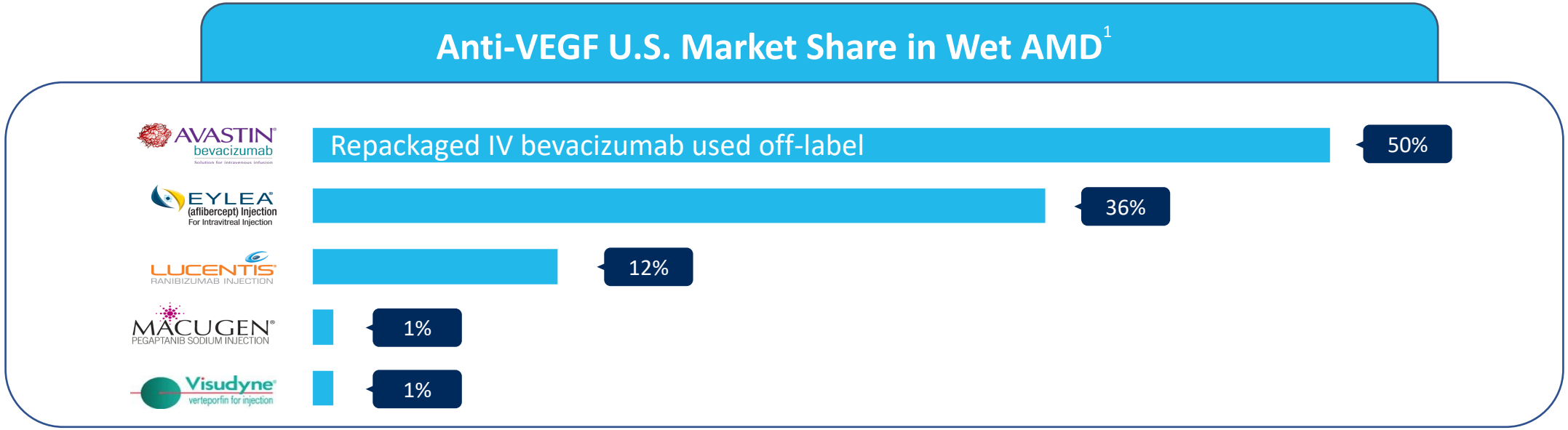


Benefits of the 0.5ml Syringe

1. **Freedom to operate (clearance)** – Designed and developed with a focus on patent clearance of the final product.
2. **No breakage** – Shatter resistant, safer for injection near the eye.
3. **Silicone oil free** – Low sub-visible particles – better drug stability, lower protein aggregation.
4. **Uses Standard Plunger Stopper** -- The SMP syringe supports the use of industry standard plungers (stoppers).
5. **Gas Tight --** Gas and solute barrier properties of the syringe assembly enable terminal ethylene oxide sterilization with no migration of the ethylene oxide into the drug product. SMP syringe assembly also provides a barrier to oxygen.
6. **No Tungsten** – No possibility of tungsten residue – tungsten not used in the syringe manufacturing process.
7. **No Delamination –** Metals found in traditional Type 1 glass that can cause glass delamination are not present in the SMP syringe.
8. **Virtually No Leachables** -- Extractables that are below the Analytical Evaluation Threshold (< 0.15µg/ml) for a broad range of solvents. Barrier coating blocks leachables from the polymer into the drug product.
9. **Six Sigma Quality** -- Provide six sigma quality for all critical dimensions and critical defects. Tight dimensional tolerances enable the optimization of the syringe barrel and plunger interference to provide low/consistent plunger forces and container closure integrity (CCI).
10. **Dose Accuracy** – Due to tight dimensional tolerances and consistent plunger forces.

The 0.5mL Syringe represents a significant improvement in medication administration over existing repackaged bevacizumab products

Off-Label Repackaged IV Bevacizumab Represents 50% of U.S. Wet AMD Market



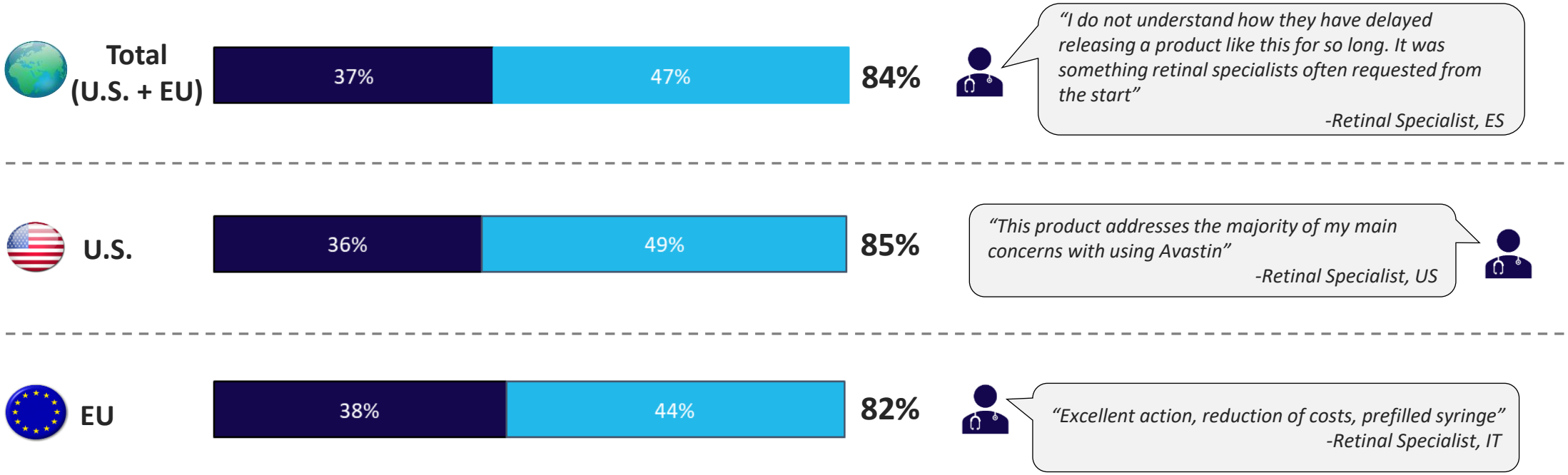
Expected Drivers to Compete Across All Ophthalmic Anti-VEGF Therapeutics

1. Provide safe and cost-effective on-label bevacizumab
2. Become a first-line option for retina physicians
3. 12 years market exclusivity under new BLA
4. Penetrate US, EU and developing markets

1: Source: Global Data estimates, 2016

Market Research Shows 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"

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

First-line Treatment Scenarios

Second-line Treatment Scenarios

Candidate for Anti-VEGF Therapy

Tx Initiation *(first-line options)*

3 Loading Doses

ONS-5010™

AVASTIN® bevacizumab Solution for intravenous infusion

biosimilars

Maintenance *(first-line options)*

Monthly IVT

Treat & Extend

PRN

PRN / Treat & Extend

ONS-5010™

AVASTIN® bevacizumab Solution for intravenous infusion

biosimilars

Not well-controlled **Candidate for Premium Therapy**

LUCENTIS® RANIBIZUMAB INJECTION

Beovu® (brolucizumab-dbll) Injection

EYLEA® (aflibercept) Injection For Intravitreal Injection

Not well-controlled **Candidate for Adjunct Therapy**

ONS-5010™ — **Adjunct (laser, topical, etc.)**

Well controlled **Candidate for Long-lasting or Sustained Release Tx**

ONS-5010™ — **PDS, ECT, Pump, Implant, etc.**

As option for Tx Guidelines and/or Step Edit

As synergistic option to future sustained delivery or adjunct therapies

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

Aligning Key Opinion Leaders

Payor Community Engagement

ONS-5010 Ophthalmic Bevacizumab Potential Value Proposition

ONS-5010 Ophthalmic Bevacizumab	
Potential Value Proposition	• Upon approval, will allow **bilateral administration** • Ophthalmic FDA-approved formulation of bevacizumab will **address cGMP/quality control issues** causing potential AEs, product shortages, and liability risks associated with off-label repackaged IV Avastin® (eg, USP 789 standards for particulate matter in ophthalmic solutions) • Ensures potency, sterility, and accurate and safe syringe for injection • Addresses issue of the AAO requesting that CMS modify Avastin® reimbursement rates to **protect physicians from financial risk** • **Responsibly priced to allow a cost-effective option for first-line** use should Medicare or other government agencies require such usage as a result of new treatment guidelines developed by the AAO or ASRS • Provides **synergies with future long-acting agents and adjunct therapies** for enhanced treatment of these conditions • Will provide **commercial rebates and volume discounting** consistent with currently available branded anti-VEGFs for retinal diseases

Q&A

CLOSING REMARKS

LAWRENCE A. KENYON

PRESIDENT, CEO & CFO, OUTLOOK THERAPEUTICS

Summary

- 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

THANK YOU!