OUTLOOK THERAPEUTICS

CORPORATE PRESENTATION

June 2021

NASDAQ: OTLK

outlooktherapeutics.com

Disclaimer

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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[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

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

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

Visudyne® verteporfin for injection

LUCENTIS® RANIBIZUMAB INJECTION

EYLEA® (aflibercept) Injection For Intravitreal Injection

2004 | 2005 | 2006 | 2011 | 2013 | 2015 | 2017 | 2019 | >

MACUGEN® PEGAPTANIB SODIUM INJECTION

The NEW ENGLAND JOURNAL of MEDICINE

CATT Study Published; Sponsored by the National Eye Institute

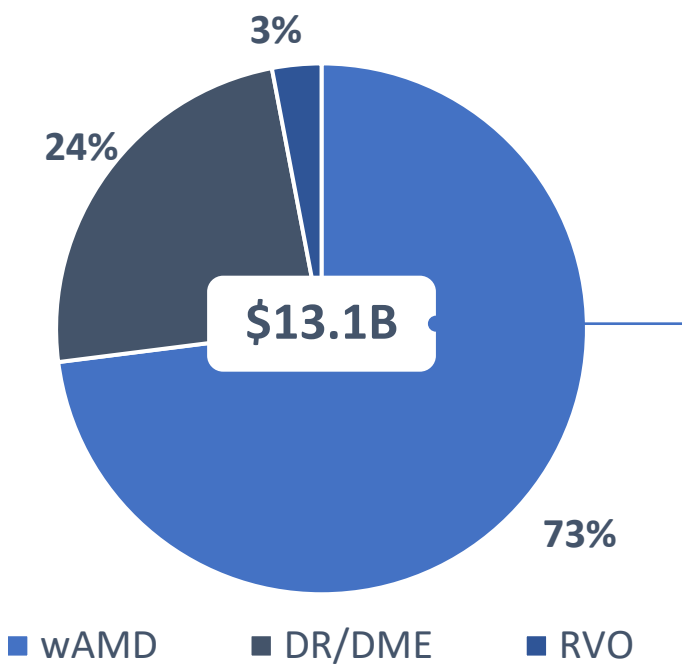
Launched with Novartis

Beovu® (brolucizumab-dbll) Injection

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

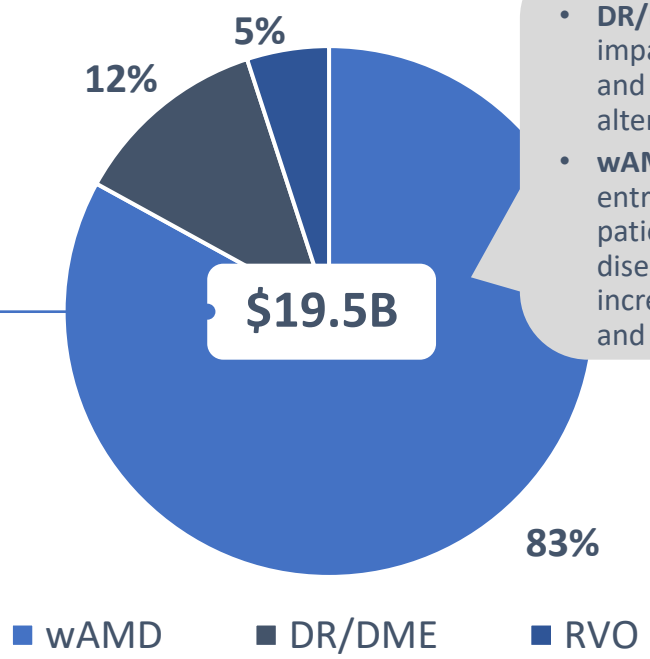
2020 9MM Anti-VEGF Revenue Share (USD)



CAGR

4.1%

2030 9MM Anti-VEGF Revenue Share (USD)

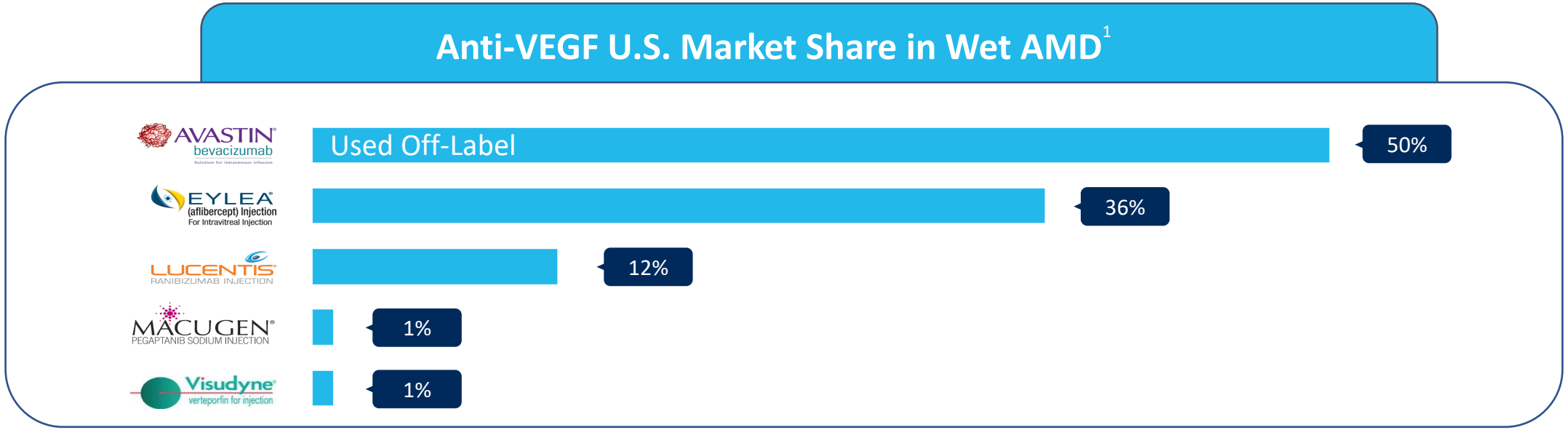


MARKET DRIVERS:

- **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

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 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

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

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

First-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

→

Second-line Treatment Scenarios

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**

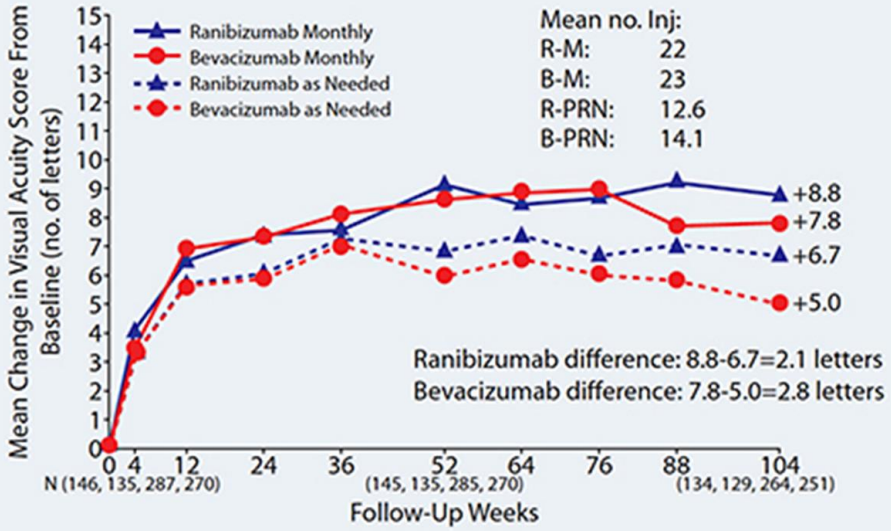
ONS-5010™ — **PDS, ECT, Pump, Implant, etc.**

As option for Tx Guidelines and/or Step Edit

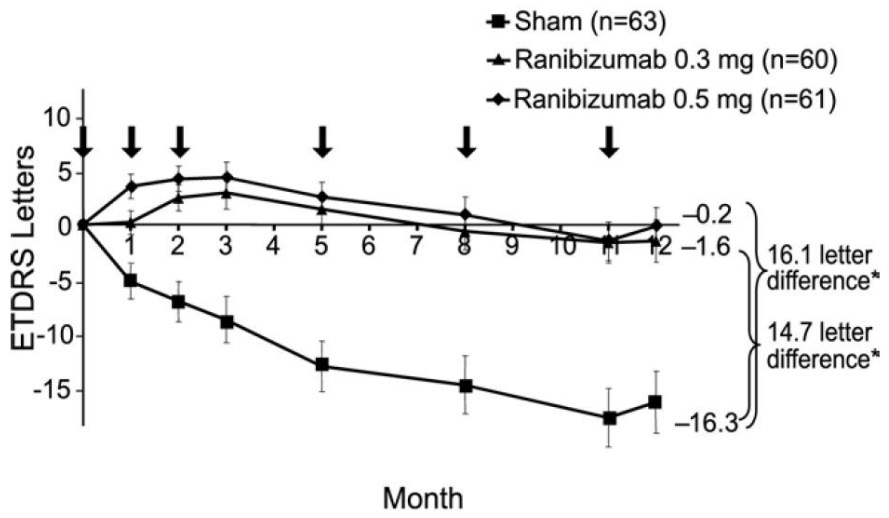
As synergistic option to future sustained delivery or adjunct therapies

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.

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

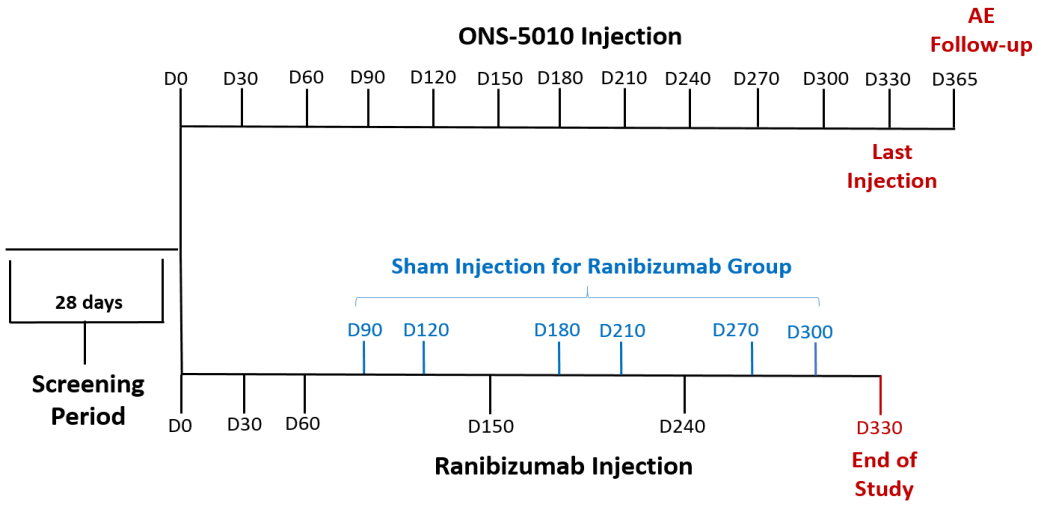
- Provided high level of confidence in the outcome of the ongoing fully-enrolled pivotal trial
- Demonstrated anticipated safety and efficacy signals consistent with previously published results for ophthalmic bevacizumab
- Provided successful proof of concept

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 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**)

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

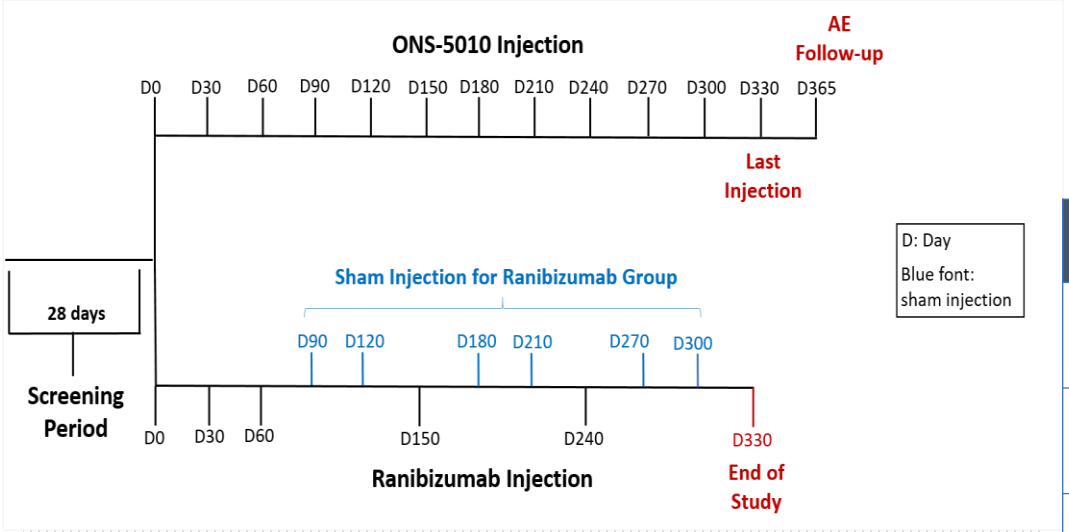
Ongoing Pivotal Trial Design Informed by Clinical Experience Trial – With Larger Sample Size

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

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

Physicians Want Approved Bevacizumab

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

Total (U.S. + EU)

84%

"I do not understand how they have delayed releasing a product like this for so long. It was something retinal specialists often requested from the start"
-Retinal Specialist, ES

U.S.

85%

"This product addresses the majority of my main concerns with using Avastin"
-Retinal Specialist, US

EU

82%

"Excellent action, reduction of costs, prefilled syringe"
-Retinal Specialist, IT

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 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

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