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Company Highlights



Phase 3 clinical stage biopharmaceutical company uniquely positioned to excel in the large and growing ophthalmology market



Lead candidate ONS-5010 is an ophthalmic formulation of bevacizumab (Avastin) with a well defined regulatory pathway

Streamlined clinical program allowing for potential approval in 2022



Potential for 12 years of market exclusivity protection from biosimilar competition as first approved ophthalmic bevacizumab in the U.S. and 8+2 in the E.U.



ONS-5010 targets an estimated \$9.1B Anti-VEGF therapy market in wet AMD, DME, BRVO in 2018 (GlobalData 2016)



If approved, ONS-5010 has potential to mitigate inherent risks associated with off-label compounding of drugs such as Avastin



Management team with extensive clinical/ regulatory ophthalmology & drug development expertise

AMD = Age-Related Macular Degeneration; DME = Diabetic Macular Edema; BRVO = Branch Retinal Vein Occlusion



Leadership Team: Global Ophthalmic Development and Commercial Launch Excellence



LAWRENCE KENYON President, CEO, CFO







RANDY THURMAN



JEFF EVANSON Chief Commercial Officer











TERRY DAGNON Chief Operating Officer









Executive Chairman of the Board



MARK HUMAYUN, MD PhD Medical Advisor

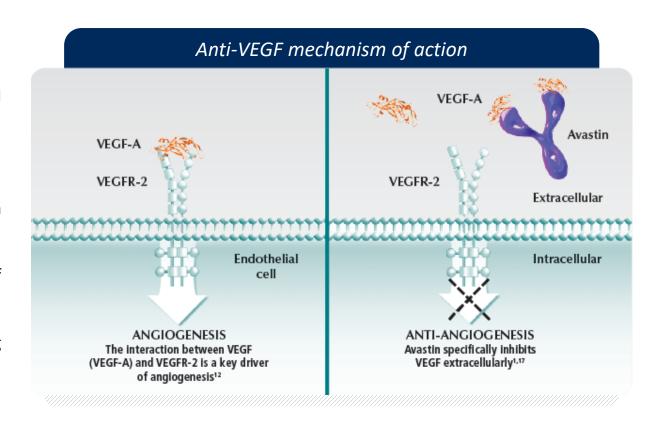




Wet AMD Standard of Care

ONS-5010, if approved, will be the first ophthalmic on-label version of bevacizumab

- ☐ Use of anti-VEGF drugs have represented the standard of care in retina since 2006
 - Block growth of abnormal blood vessels and leakage of fluid from the vessels
 - Leading anti-VEGF drugs include bevacizumab (Avastin), ranibizumab (Lucentis), and aflibercept (Eylea)
- 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
- ONS-5010 is the only version of bevacizumab (Avastin) being developed for regulatory approval specifically for wet-AMD, DME and BRVO





Prevalence in target indications (2018)(1)

ONS-5010 has the potential to address large markets in wet AMD, DME and BRVO

Assumption	U.S.	EU5 ⁽²⁾	Japan
Prevalence: Wet AMD Patients	697,041	1,724,946	365,709
Diagnosed: DME Patients	324,064	338,011	376,414
Prevalence: BRVO Patients	119,042	135,206	61,852



⁽¹⁾ Source: Global Data estimates, 2016

⁽²⁾ EU5 consists of the UK, France, Germany, Spain, and Italy

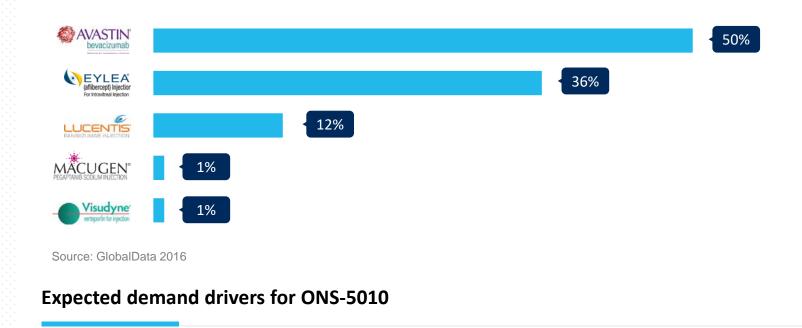
Significant Opportunity in Targeted Indications



\$9.1 Billion estimated 2018 anti-VEGF market in wet AMD, DME and BRVO

As Avastin, Eylea and Lucentis lose patent protection, ONS-5010 will provide retina physicians and their patients with an important option that will be safe and cost-effective

Wet AMD U.S. treated patient market share (est 2018) and ONS-5010 opportunity



- Provide safe and cost-effective onlabel bevacizumab
- Become first line "step edit" drug of choice
- 2 Penetrate EU and developing markets



THERE ARE SIGNIFICANT UNMET NEEDS WITH OFF-LABEL AVASTIN DUE TO QUALITY AND SYRINGE ISSUES AS WELL AS CONSISTENT POTENCY OF DRUG

Recent clinical research has shown that Avastin injection dosages can vary significantly when prepared by compounding pharmacies, leading to consequences that affect product quality, safety, and access such as:



Variability in Potency

A 2015 JAMA study demonstrated significant variability in the protein concentration of Avastin prepared for ophthalmic use in compounding pharmacies in the US



- 81% of samples collected from compounding pharmacies had lower protein concentrations than Avastin acquired from Genentech
- Samples collected from the same compounding pharmacies had statistically significant variations in protein concentration between samples
- Concern remains that variable product could potentially impact Avastin clinical efficacy and potency



Safety and Sterility Adverse Events

Several incidents nationwide have called attention to the association between unsterile Avastin compounding and infectious endophthalmitis





WARNING LETTER

- Endophthalmitis clusters have been traced to unsafe practices at multiple compounding pharmacies in the US, EU and Asian Pacific
- The FDA was prompted to issue a formal warning in 2011 concerning compounding practices after 12 patients lost their eyesight due to infections gained from unsterile Avastin in Florida
- Since, multiple Avastin recalls have occurred due to FDA inspections revealing unsterile compounding practices



Syringe Malfunctioning

Variability in repackaging of Avastin at compounding pharmacies can lower the quality of syringe products, resulting in adverse events



"AmEx Pharmacy Recalls 1 Lot of Bevacizumab"

According to the company, the syringe of this product may become difficult to express, and when additional force is applied while the needle is in the eye, the syringe may injure the patient.

AmEx pharmacy notes that it has received 3 reports associated with the recalled lot as being difficult to express, **resulting in 2 Adverse Drug Events**"

ASRS Member Alert, April 2019



What is step edit (step therapy)?



Centers for Medicare & Medicaid Services

Newsroom

Press Kit

Blog

Fact sheet

Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs

Aug 07, 2018 | Leadership, Medicare Part C, Medicare Parts A & B, Prescription drugs





Today, the Centers for Medicare & Medicaid Services (CMS) introduced much-needed competition and negotiation into the market for physician-administered and other Part B medications that will result in better deals and lower drug costs for patients. As part of the agency's ongoing activities to deliver on President Trump's promises outlined in his American Patients First Blueprint, CMS will provide Medicare Advantage plans the option of applying step therapy for physician-administered and other Part B drugs in a way that lowers costs and improves the quality of care for Medicare beneficiaries, Medicare Advantage (MA) plans will have the choice of implementing step therapy to manage Part B drugs, beginning January 1, 2019 as

Source: cms.gov

CMS will provide Medicare Advantage plans the option of applying step therapy for physician-administered and other Part B drugs in a way that lowers costs and improves the quality of care for Medicare beneficiaries.

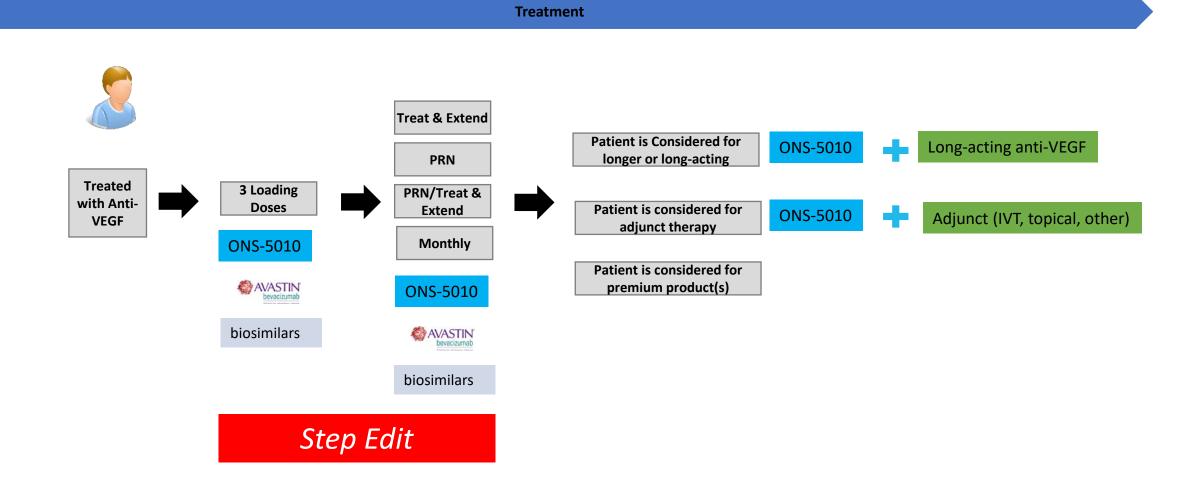


What is Step Therapy?

Step therapy is a type of prior authorization for drugs that begins treatment for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary, promoting better clinical decisions. For example, using step therapy plans could ensure that a senior who is newly diagnosed with a condition begins treatment with a cost-effective biosimilar before progressing to a more costly drug therapy if the initial treatment is ineffective. By implementing step therapy along with care coordination and drug adherence programs in Medicare Advantage plans, it will lower costs and improve the quality of care for Medicare beneficiaries.



ONS-5010 can be an important new on-label option for physicians treating patients with anti-VEGF





Regulatory strategy



Outlook Therapeutics has met with FDA and confirmed an innovative clinical trial strategy, which we believe will expedite the clinical development of ONS-5010 for wet AMD

PHSA 351 (a) New BLA regulatory pathway

FDA End-of-Phase 2 meeting completed

Recommendations have been implemented

Protocols reflect FDA feedback



New BLA expected to have 12 years of regulatory exclusivity as first approved ophthalmic bevacizumab



EU agency meetings planned in 2020



Additional Ex-U.S. regulatory agency meetings expected in 2020



ONS-5010 Clinical program design

Two Phase 3 registration clinical trials have been initiated in wet AMD



ONS-5010-001: Enrollment completed in first adequate and well controlled study in wet AMD



ONS-5010-002: Second wet AMD trial initiated & enrollment ongoing



Clinical program for wet AMD, DME & BRVO reviewed by FDA at End-of-Phase 2 meeting in 2018

FDA has indicated the study designs would be acceptable for registration



Completed Phase 1 IV pharmacokinetic (PK) study comparing to Avastin



Intravitreal pharmacokinetic and immunogenicity being collected in ongoing registration trial



U.S. IND Active March 2019



SPA agreement reached with FDA for planned DME and BRVO clinical studies

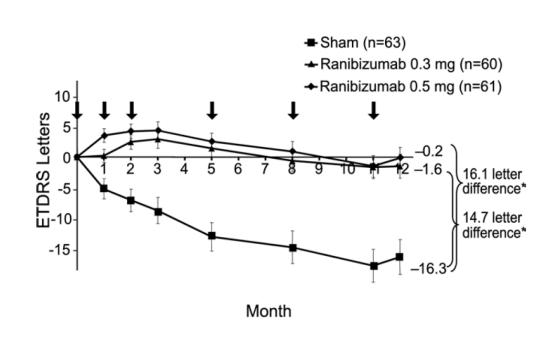


CATT Study Results: bevacizumab was proven to be as safe and effective as Lucentis. Lucentis PIER study indicates quarterly dosing is inferior to monthly injections.

CATT Study Results

Mean Change in Visual Acuity Score From Mean no. Inj: Ranibizumab Monthly 14 R-M: 22 Bevacizumab Monthly 13 23 B-M: Ranibizumab as Needed 12 R-PRN: 12.6 Bevacizumab as Needed Baseline (no. of letters) 11 B-PRN: 14.1 10-9 8-Ranibizumab difference: 8.8-6.7=2.1 letters Bevacizumab difference: 7.8-5.0=2.8 letters 52 64 (145, 135, 285, 270) 24 36 76 88 104 (134, 129, 264, 251) 0 4 12 N (146, 135, 287, 270) Follow-Up Weeks

Lucentis PIER Study



Source: Comparison of Age-related Macular Degeneration Treatments Trials (CATT) Research Group, Daniel F. Martin, Ophthalmology, July 2012 Volume 119, Issue 7, Pages 1388–1398



Bevacizumab phase 1 PK

Phase 1 PK data demonstrated biosimiliarity between Outlook's formulation of bevacizumab vs. U.S. and EU versions of Avastin

Phase 1 PK study was conducted using ONS-1045, a formulation of bevacizumab developed by Outlook Therapeutics

Randomized, IV double blind, single dose study vs U.S. and EU Avastin

Met primary and secondary endpoints

- Biosimilar PK
- Low immunogenicity

High degree of similarity to Avastin

entration (µg/mL) Mean (±SD) bevacizumab serum concentration - log scale







First of two adequate and well controlled Phase 3 trial designs in wet AMD subjects

Study approved in August of 2018 by Australian authorities

Study initiated and first subjects enrolled in September 2018

Study conducted in Australia

61 patients enrolled

ONS-5010 vs ranibizumab (Lucentis)

Safety and efficacy data to be collected

 Safety & efficacy data expected to support planned U.S. BLA filing in 2021







Randomized Masked Controlled Trial with 61 subjects



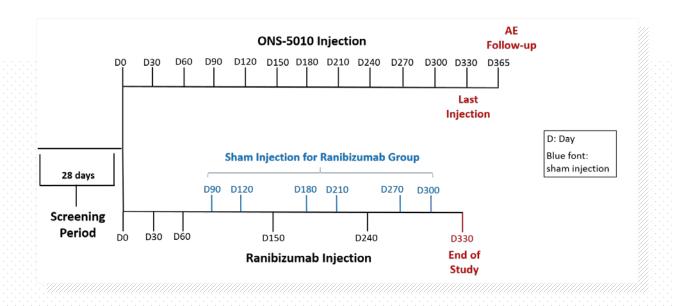
ONS 5010 Administered Monthly X 12



LUCENTIS Dosing Arm (PIER Dosing) – Three initial monthly injections followed by fixed quarterly dosing



Primary endpoint mean change in BCVA at Day 330





Study Design / size confirmed in April 2018 FDA EOP2 acceptable as one of two adequate and well controlled trials that will support approval of exudative agerelated macular degeneration indication







Second of two adequate and well controlled Phase 3 trial designs in wet AMD subjects

US IND active March 31 2019

US Investigator Meeting held April 6th in Dallas Texas

Study is being conducted in the U.S.

Approximately 220 patients to be enrolled

ONS-5010 vs ranibizumab (Lucentis)

Safety and efficacy data to be collected

 Safety & efficacy data expected to support U.S. BLA filing expected in 2021







Randomized Masked Controlled Trial with 220 subjects



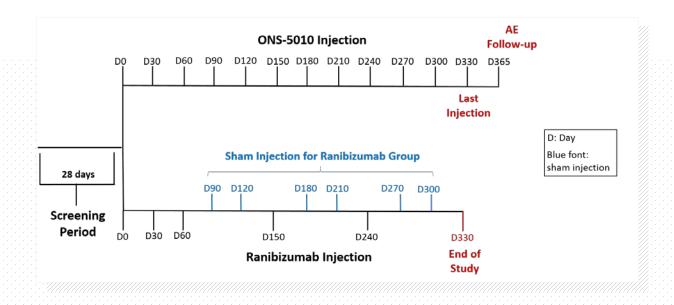
ONS 5010 Administered Monthly X 12



LUCENTIS Dosing Arm (PIER Dosing) – Three initial monthly injections followed by fixed quarterly dosing



Primary endpoint difference in proportion of participants who gain at least 15 letters in BCVA





Study Design / size confirmed in April 2018 FDA EOP2 acceptable as one of two adequate and well controlled trials that will support approval of exudative agerelated macular degeneration indication



Commercial Strategy

Commercial Launch will be led by Jeff Evanson, Chief Commercial Officer of Outlook Therapeutics. Former V.P. and Global Pharma Franchise Head of Novartis Alcon division.



Provide safe and cost-effective onlabel bevacizumab



Responsible pricing for physicians and patients aimed to maximize utilization



Pre-filled syringe expected to provide convenience and safety (post-approval change)



Collaborative payor strategy (e.g., "not to exceed" per patient agreements)



Become first-line "step edit" drug of choice for branded (Eylea, Lucentis) and long acting options (e.g., brolucizumab, abicipar, GNE PDS)

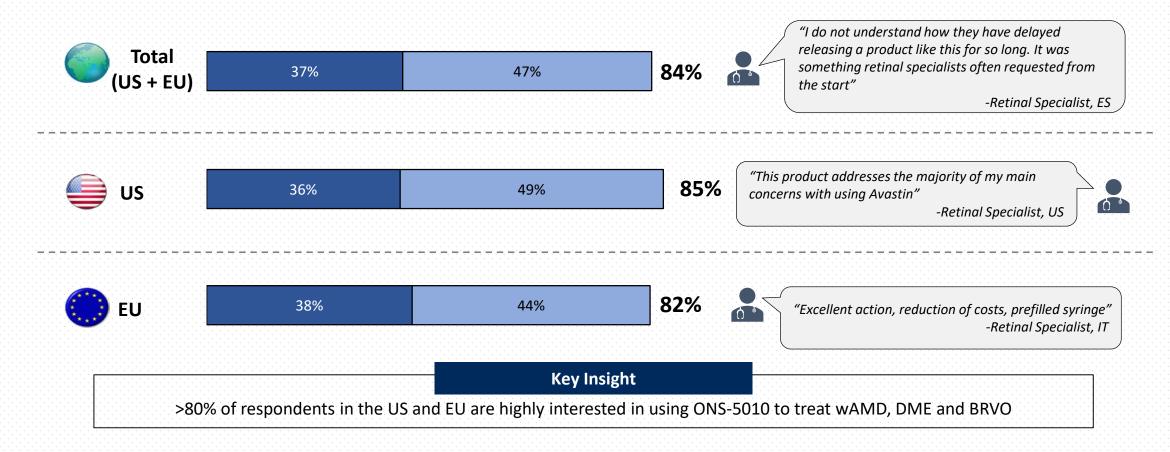


Penetrate EU5 and developing markets where off-label Avastin use has been restricted



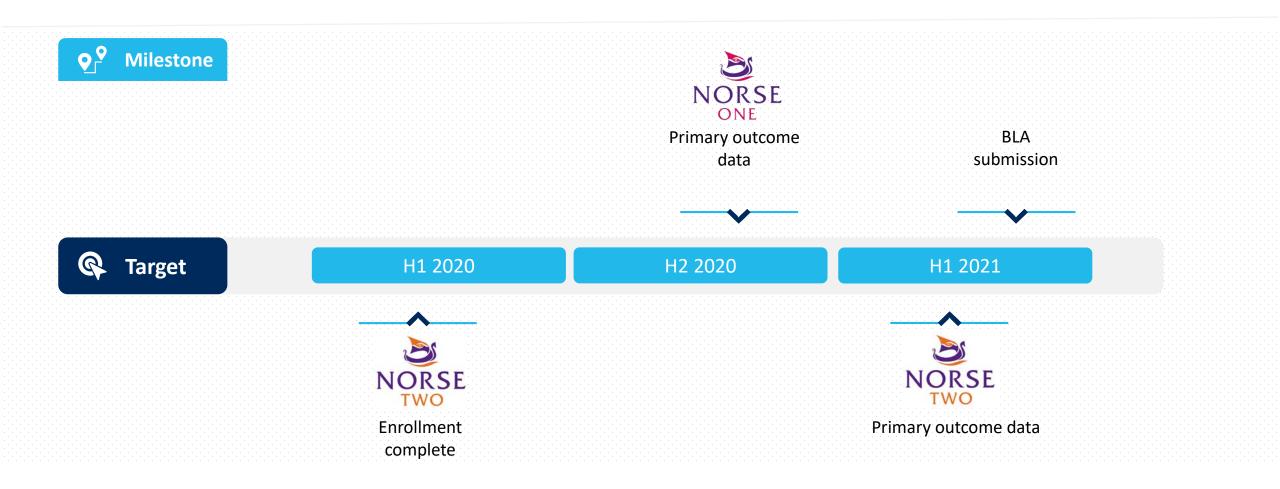
PRIMARY MARKET RESEARCH (BLINDED TARGET PRODUCT PROFILE), RETINAL SPECIALISTS INDICATE A HIGH LEVEL OF INTEREST IN ONS-5010

% of Retinal Specialists Expressing High Interest in ONS-5010 (Top 2 Box Ratings)



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

Key Upcoming Milestones







- Phase 3 clinical stage biopharmaceutical company uniquely positioned to excel in the large and growing ophthalmology market
- Lead candidate ONS-5010 is an ophthalmic formulation of bevacizumab (Avastin) with a well defined regulatory pathway
 - Streamlined clinical program allowing for potential approval in 2022
- Potential for 12 years of market exclusivity protection from biosimilar competition as first approved ophthalmic bevacizumab
- ONS-5010 targets an estimated \$9.1B Anti-VEGF therapy market in wet AMD, DME, BRVO in 2018 (GlobalData 2016)
- If approved, ONS-5010 has potential to mitigate inherent risks associated with off-label compounding of drugs such as Avastin
- Management team with extensive clinical/regulatory ophthalmology & drug development

