OUTLOOK THERAPEUTICS

CORPORATE PRESENTATION

January 2020

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Company Highlights

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

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.

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

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*

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

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

ARNO THERAPEUTICS · TAMIR · PAR PHARMACEUTICAL

JEFF EVANSON
Chief Commercial Officer

NOVARTIS · Alcon · Medtronic · NAVIGANT

TERRY DAGNON
Chief Operating Officer

NOVARTIS · Alcon · Johnson & Johnson · DOHMEN

RANDY THURMAN
Executive Chairman of the Board

MARK HUMAYUN, MD PhD
Medical Advisor

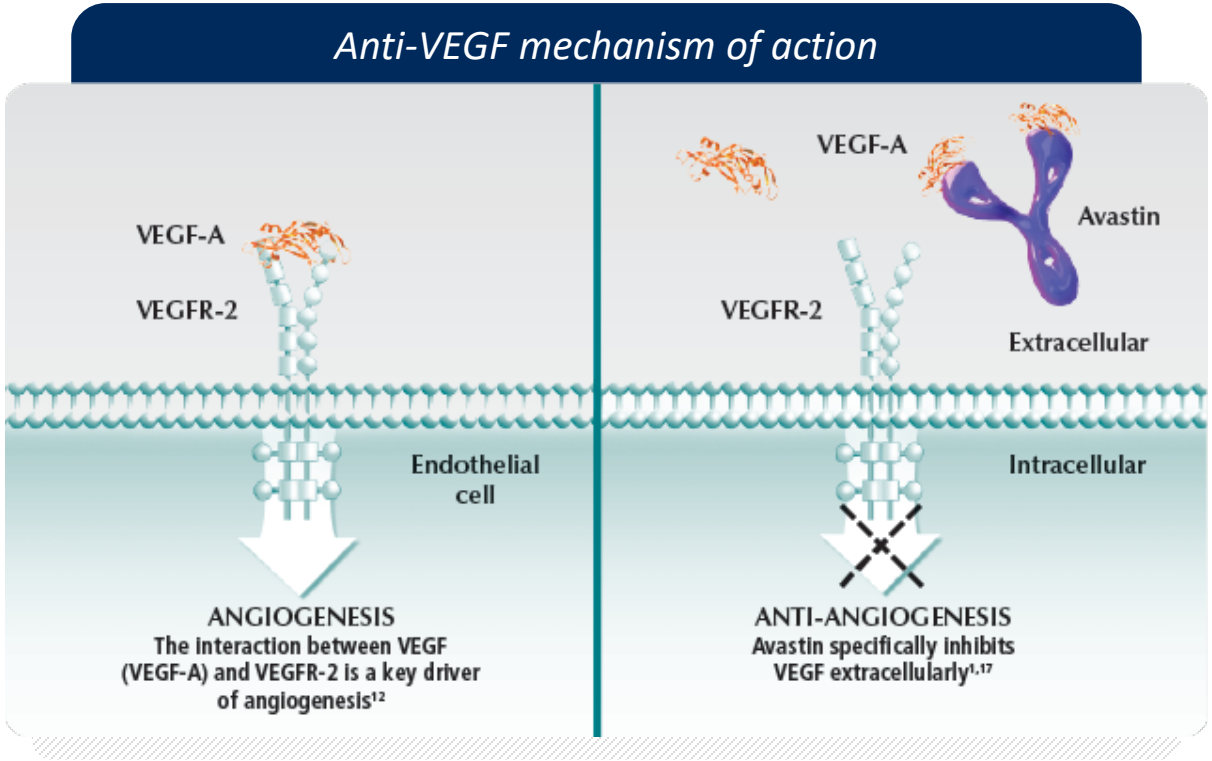
Wet AMD Standard of Care

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
  - Require significant time and capital to achieve commercialization
  - New drugs expected to target higher price points than 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

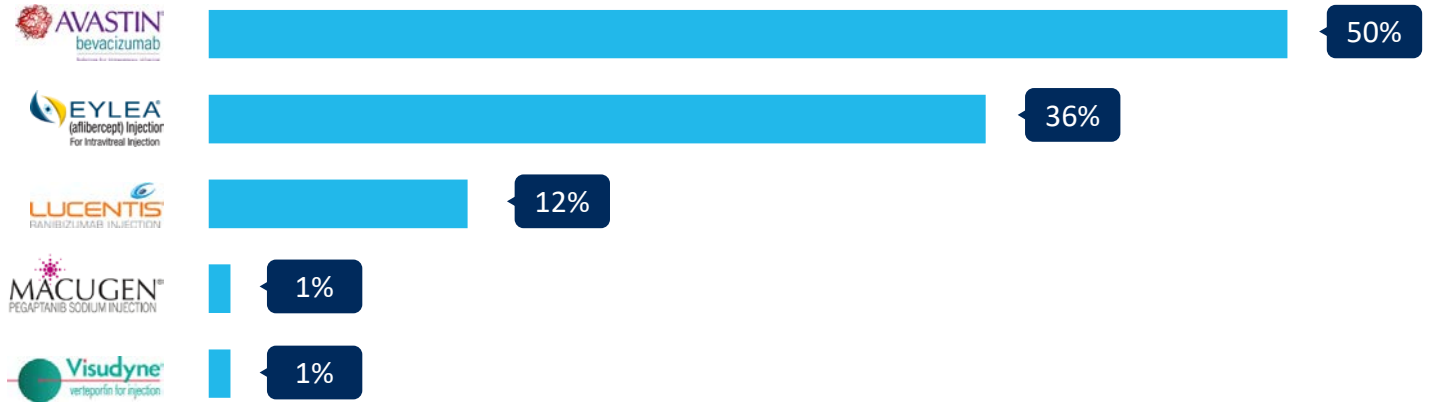
(1) Source: Global Data estimates, 2016
(2) EU5 consists of the UK, France, Germany, Spain, and Italy

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



Source: GlobalData 2016

Expected demand drivers for ONS-5010

1. Provide safe and cost-effective on-label bevacizumab
2. Penetrate EU and developing markets
3. Become first line ”step edit” drug of choice

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

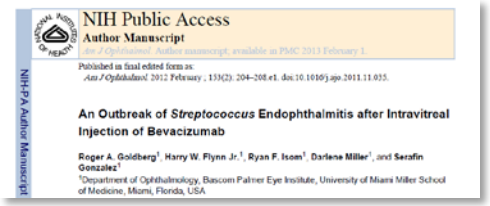

Original Investigation

Evaluation of Compounded Bevacizumab Prepared for Intravitreal Injection

- 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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Author Manuscript

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Am J Ophthalmol. 2012 February ; 153(2): 204–208.e1. doi:10.1016/j.ajo.2011.11.035.

An Outbreak of *Streptococcus* Endophthalmitis after Intravitreal Injection of Bevacizumab

Roger A. Goldberg[1], Harry W. Flynn Jr.[1], Ryan F. Isom[1], Darlene Miller[1], and Serafin Gonzalez[1]

[1]Department of Ophthalmology, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, Miami, Florida, USA

NIH-PA Author Manuscript

FDA U.S. FOOD & DRUG ADMINISTRATION

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

ASRS American Society of Retina Specialists

"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)?

CMS.gov | Centers for Medicare & Medicaid Services

Newsroom Press Kit Data Contact 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

Share

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

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.

Source: cms.gov

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

Treatment

Treated with Anti-VEGF

3 Loading Doses

ONS-5010

AVASTIN bevacizumab

biosimilars

Treat & Extend

PRN

PRN/Treat & Extend

Monthly

ONS-5010

AVASTIN bevacizumab

biosimilars

Step Edit

Patient is Considered for longer or long-acting → ONS-5010 + Long-acting anti-VEGF

Patient is considered for adjunct therapy → ONS-5010 + Adjunct (IVT, topical, other)

Patient is considered for premium product(s)

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

NORSE ONE

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

NORSE TWO

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

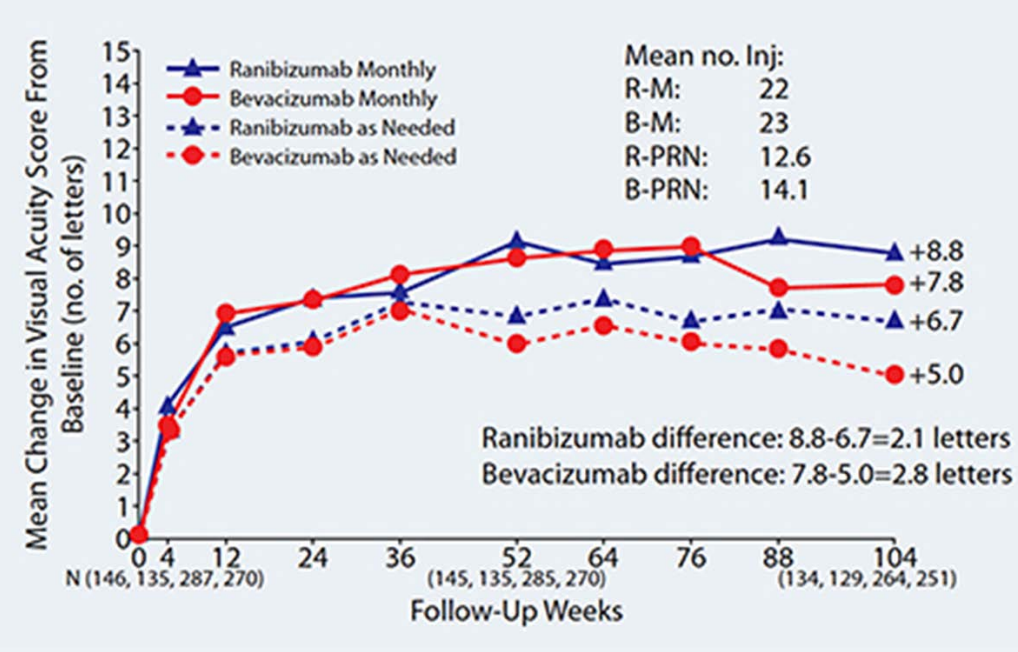
Intravitreal pharmacokinetic and immunogenicity being collected in ongoing registration trial

U.S. IND Active March 2019

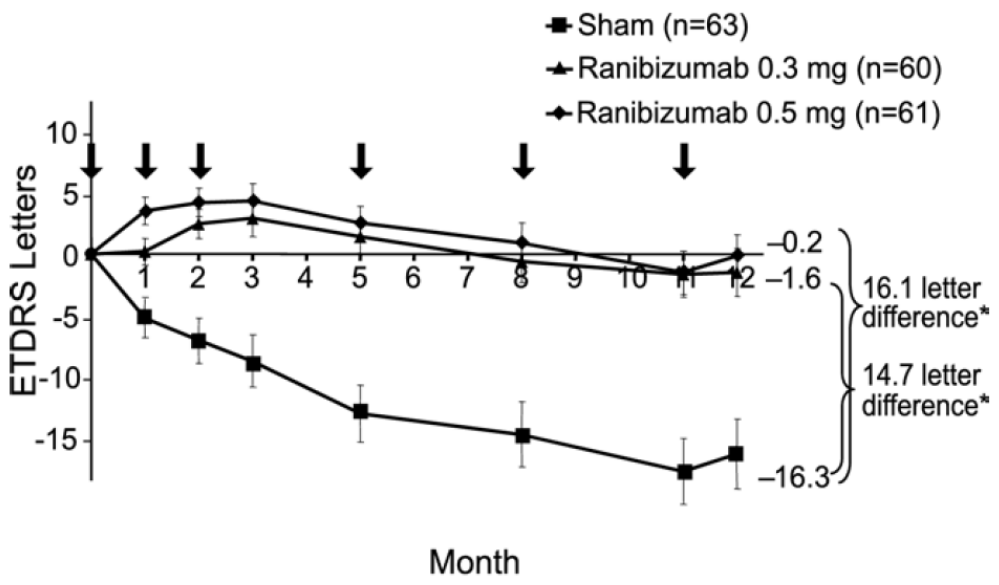
SPA agreement reached with FDA for planned DME and BRVO clinical studies

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



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

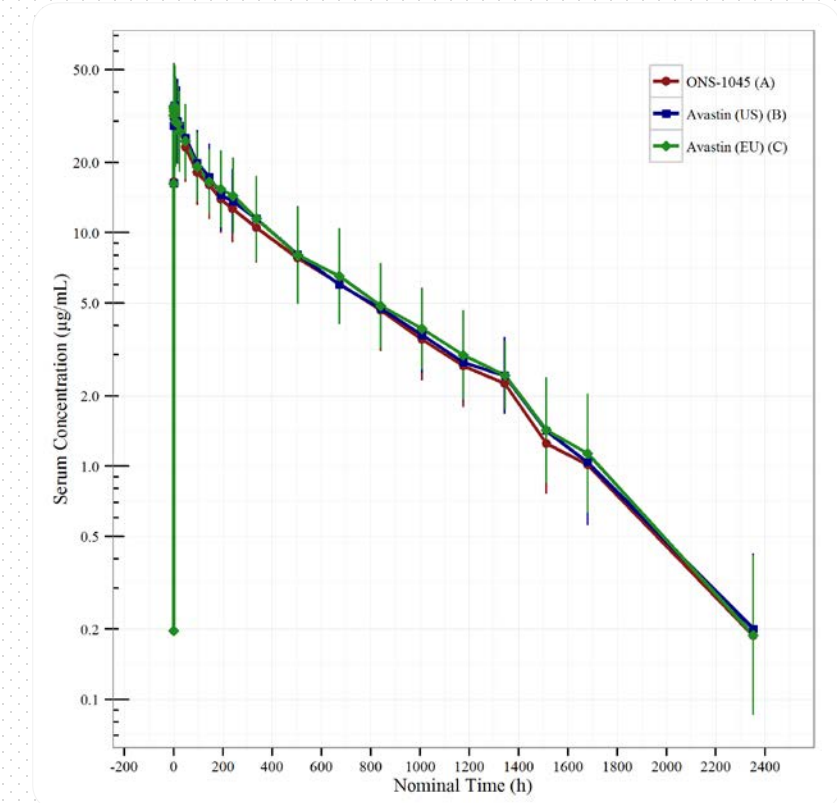
Randomized, IV double blind, single dose study vs U.S. and EU Avastin

Met primary and secondary endpoints

- Biosimilar PK
- Low immunogenicity

High degree of similarity to Avastin

Mean (±SD) bevacizumab serum concentration - log scale



NORSE ONE

Clinical Trial design

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

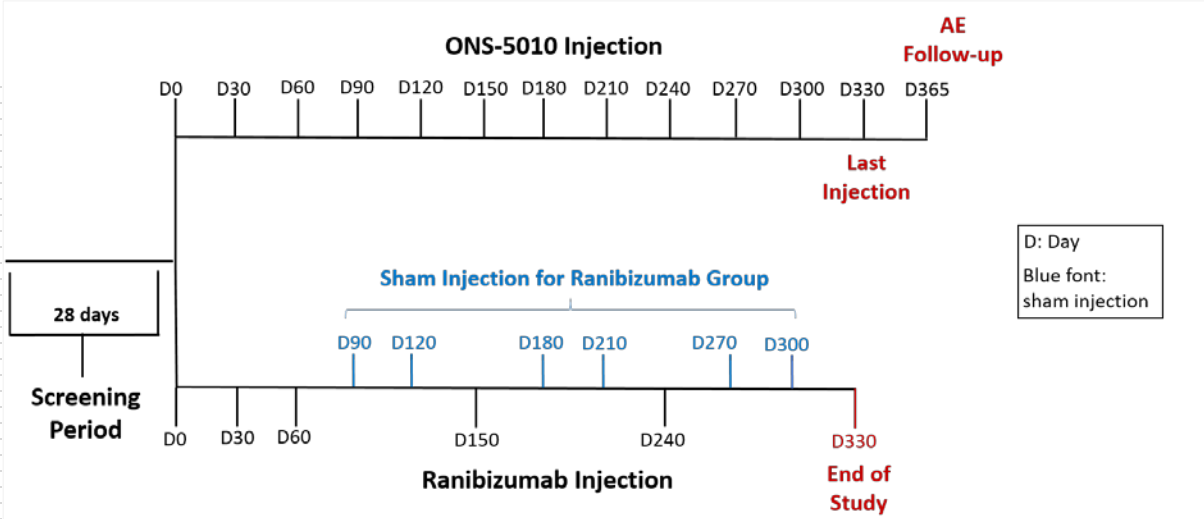
- Safety & efficacy data expected to support planned U.S. BLA filing in 2021

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 age-related macular degeneration indication

NORSE TWO

Clinical Trial design

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

NORSE TWO

Randomized Masked Controlled Trial with 220 subjects

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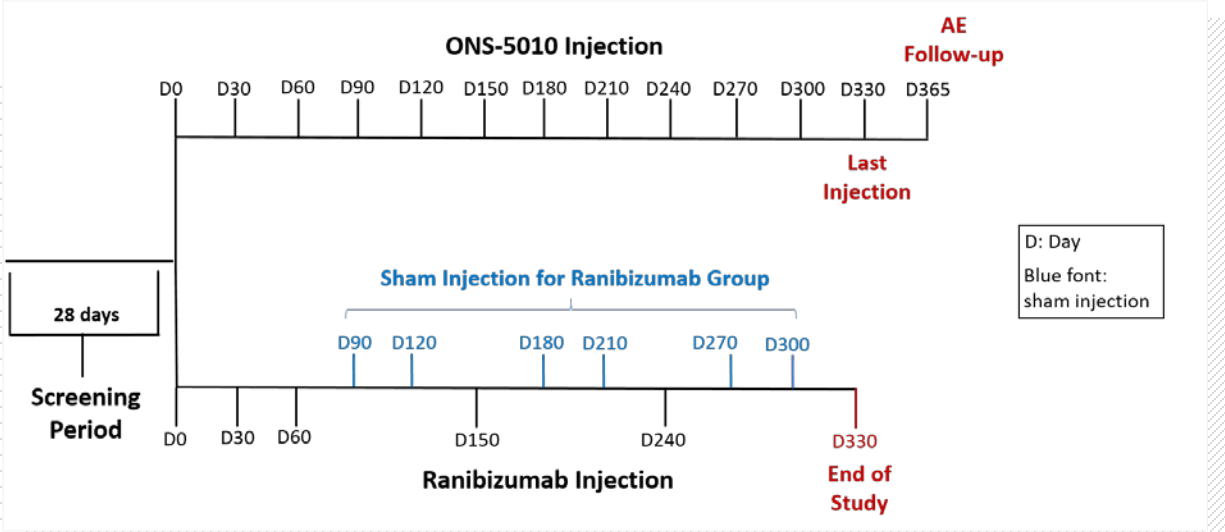


Study Design / size confirmed in April 2018 FDA EOP2 acceptable as one of two adequate and well controlled trials that will support approval of exudative age-related macular degeneration indication

Commercial Strategy

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

Provide safe and cost-effective on-label 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)

Total (US + 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

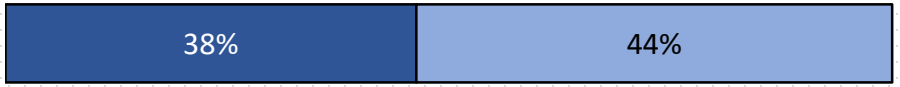
US

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

Key Insight

>80% of respondents in the US and EU are highly interested in using ONS-5010 to treat wAMD, DME and BRVO

*Other survey options not shown *were "neutral, not likely to use, and not interested at all"*

Source: Navigant Quantitative Survey (n=152), 2019

Milestones

Milestone	Target
U.S. IND submission and Approval	Completed
Enrollment begins in 2nd Wet AMD clinical trial	Ongoing
Commenced Contract Manufacturing with FUJIFILM Diosynth Biotechnologies	Q2 2019
Meet with European regulatory authorities and Initiate DME and BRVO clinical trials	H2 2019
	H1 2020
NORSE ONE Primary outcome data	Q3 2020
BLA submission	Q1 2021
NORSE TWO Primary outcome data	Q1 2021

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
- 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