OUTLOOK THERAPEUTICS

CORPORATE PRESENTATION

September 2019

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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 2021/2022*

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 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

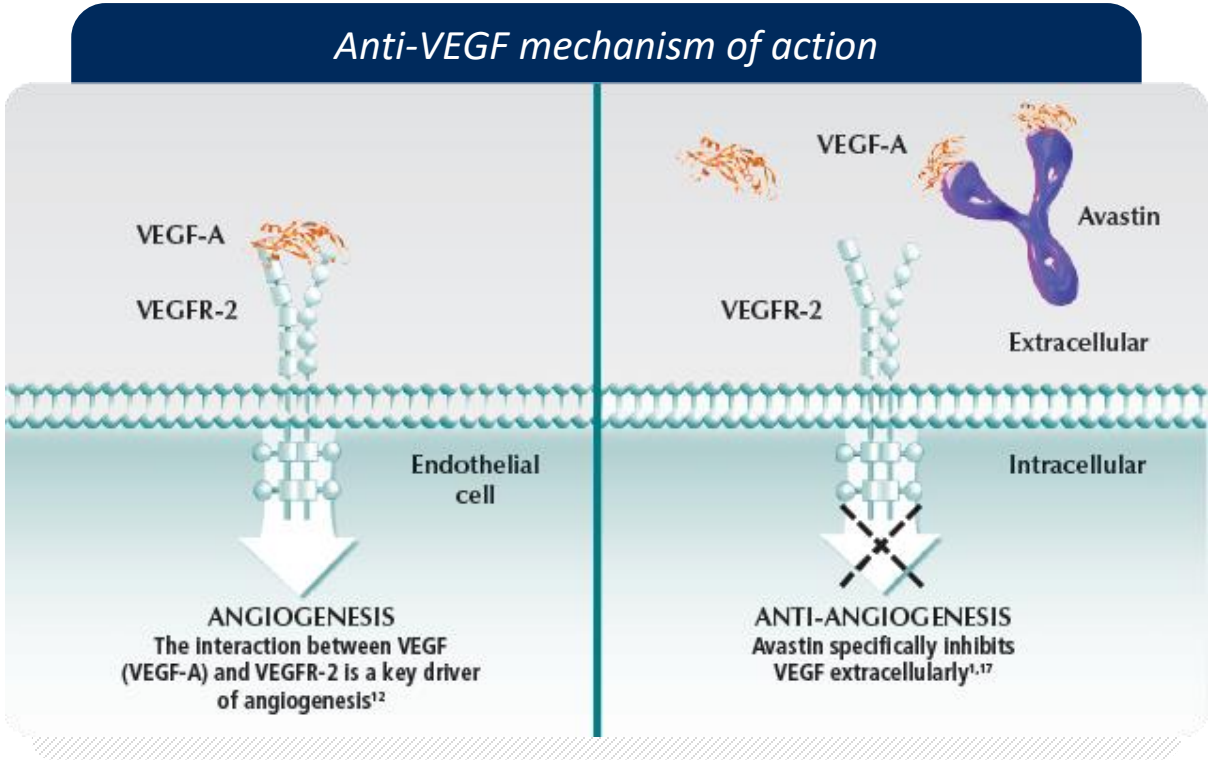
RANDY THURMAN
Executive Chairman of the Board

MARK HUMAYUN, MD PhD
Medical Advisor

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

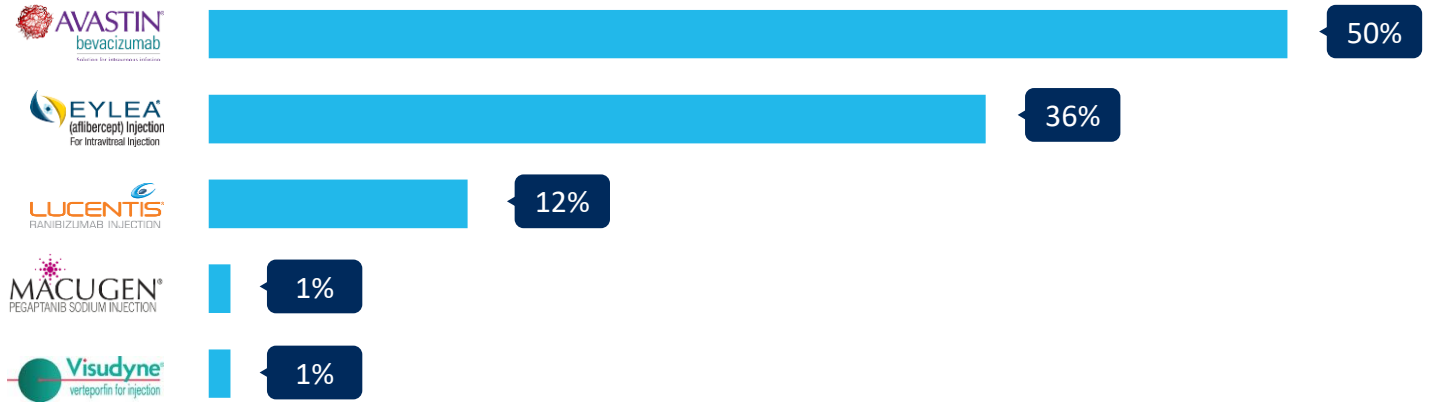
(1) Source: Global Data estimates, 2016
(2) EU5 consists of the UK, France, Germany, Spain, and Italy

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

Compounding Pharmacy Concerns

ONS-5010 expected to provide on-label option from current compounding of off-label Avastin

Issues continue to be reported with compounded bevacizumab, recently resulting in product recalls and product shortages. FDA has increasingly expressed concerns around compounded drug.

ONS-5010 could provide important benefits over off-label Avastin

- Continuity of source and quality
- Uniformity of product
- Supply chain integrity

Issues with compounding pharmacies have been well-documented


The benefits and risks of compounding pharmacies

As of the end of October, 28 deaths resulting from the use of poorly prepared compounded medications by a Massachusetts-based compounding pharmacy have been reported. These deaths have focused increased attention on the role and safety of compounded specialized medicines and dosage forms in the United States.

Pharmaceutical compounding is defined as the combining or mixing of pharmaceutical ingredients to create a customized medication product for a specific patient by a prescriber's order or prescription. Inherent in this definition is the notion that the final product is not tested for safety and efficacy by data that the FDA normally uses to assess a product. Because pharmacy school curriculums include training in the science and art of compounding, pharmacists are generally well trained in how to compound many medicines. More advanced training is also available for post-graduate pharmacists and pharmacy technicians, by organizations such as the Professional Compounding Centers of America. Although most independently owned and chain pharmacies (eg, Walgreens) do not prepare many compounded products, specialized compounding pharmacies are available that do prepare many compounded products.

SEE ALSO

FDA draft guidance on drug compounding may limit...

Addition of bovine colostrum reduces frequency ...

FDA warns against using sterile drugs from ...

Edward A. Bell

The FDA has received reports describing adverse effects from other inappropriately prepared compounded medicines in past years, but the recently reported deaths from poorly prepared injectable methylprednisolone products prepared by the New England Compounding Center has focused increased attention on pharmaceutical compounding (www.fda.gov/Drugs/DrugSafety/ucm323431.htm). The New England Compounding Center (NECC) is a specialized compounding pharmacy located in Framingham, Mass., a suburb of Boston. NECC is no longer operating, as its license to practice was suspended on Oct. 3. The product prepared by NECC that has been reported to result in significant adverse effects is preservative-free methylprednisolone 80 mg/mL, intended for epidural use.


Potential risks of pharmacy compounding.

Gudeman J, Jozwiakowski M, Chollet J, Randell M.

Author information

Abstract

Pharmacy compounding involves the preparation of customized medications that are not commercially available for individual patients with specialized medical needs. Traditional pharmacy compounding is appropriate when done on a small scale by pharmacists who prepare the medication based on an individual prescription. However, the regulatory oversight of pharmacy compounding is significantly less rigorous than that required for Food and Drug Administration (FDA)-approved drugs; as such, compounded drugs may pose additional risks to patients. FDA-approved drugs are made and tested in accordance with good manufacturing practice regulations (GMPs), which are federal statutes that govern the production and testing of pharmaceutical products. In contrast, compounded drugs are exempt from GMPs, and testing to assess product quality is inconsistent. Unlike FDA-approved drugs, pharmacy-compounded products are not clinically evaluated for safety or efficacy. In addition, compounded preparations do not have standard product labeling or prescribing information with instructions for safe use. Compounding pharmacies are not required to report adverse events to the FDA, which is mandatory for manufacturers of FDA-regulated medications. Some pharmacies engage in activities that extend beyond the boundaries of traditional pharmacy compounding, such as large-scale production of compounded medications without individual patient prescriptions, compounding drugs that have not been approved for use in the US, and creating copies of FDA-approved drugs. Compounding drugs in the absence of GMPs increases the potential for preparation errors. When compounding is performed on a large scale, such errors may adversely affect many patients. Published reports of independent testing by the FDA, state agencies, and others consistently show that compounded drugs fail to meet specifications at a considerably higher rate than FDA-approved drugs. Compounded sterile preparations pose the additional risk of microbial contamination to patients. In the last 11 years, three separate meningitis outbreaks have been traced to purportedly 'sterile' steroid injections contaminated with fungus or bacteria, which were made by compounding pharmacies. The most recent 2012 outbreak has resulted in intense scrutiny of pharmacy compounding practices and increased recognition of the need to ensure that compounding is limited to appropriate circumstances. Patients and healthcare practitioners need to be aware that compounded drugs are not the same as generic drugs, which are approved by the FDA. The risk-benefit ratio of using traditionally compounded medicines is favorable for patients who require specialized medications that are not commercially available, as they would otherwise not have access to suitable treatment. However, if an FDA-approved drug is commercially available, the use of an unapproved compounded drug confers additional risk with no commensurate benefit.

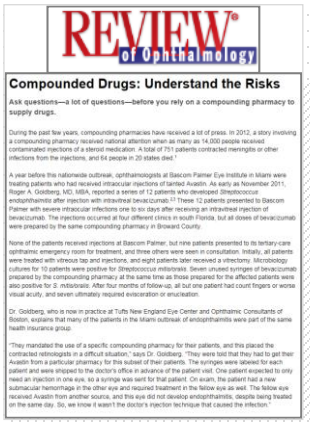

Compounding Pharmacies: A Viable Option, or Merely a Liability?

CASE SCENARIO

David O'Brien Jr, MD, Responds

Guest Discussants:

Feature Editor:


REVIEW of Ophthalmology

Compounded Drugs: Understand the Risks

Ask questions—a lot of questions—before you rely on a compounding pharmacy to supply drugs.

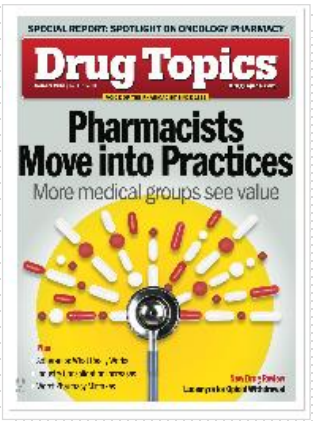
During the past few years, compounding pharmacies have received a lot of press. In 2012, a story involving a compounding pharmacy received national attention when as many as 14,000 people received contaminated injections of a steroid medication. A total of 751 patients contracted meningitis or other infections from the injections, and 64 people in 20 states died.[1]

A year before this nationwide outbreak, ophthalmologists at Bascom Palmer Eye Institute in Miami were treating patients who had received intraocular injections of tainted Avastin. As early as November 2011, Roger A. Goldberg, MD, MBA, reported a series of 12 patients who developed Streptococcus endophthalmitis after injection with intravitreal bevacizumab.[2] These 12 patients presented to Bascom Palmer with severe intraocular infections one to six days after receiving an intravitreal injection of bevacizumab. The injections occurred at four different clinics in south Florida, but all doses of bevacizumab were prepared by the same compounding pharmacy in Broward County.

None of the patients received injections at Bascom Palmer, but nine patients presented to its tertiary-care ophthalmic emergency room for treatment, and three others were seen in consultation. Initially, all patients were treated with vitreous tap and injections, and eight patients later received a vitrectomy. Microbiology cultures for 10 patients were positive for Streptococcus mitis/oralis. Seven unused syringes of bevacizumab prepared by the compounding pharmacy at the same time as those prepared for the affected patients were also positive for S. mitis/oralis. After four months of follow-up, all but one patient had count fingers or worse visual acuity, and seven ultimately required evisceration or enucleation.

Dr. Goldberg, who is now in practice at Tufts New England Eye Center and Ophthalmic Consultants of Boston, explains that many of the patients in the Miami outbreak of endophthalmitis were part of the same health insurance group.

"They mandated the use of a specific compounding pharmacy for their patients, and this placed the contracted retinologists in a difficult situation," says Dr. Goldberg. "They were told that they had to get their Avastin from a particular pharmacy for this subset of their patients. The syringes were labeled for each patient and were shipped to the doctor's office in advance of the patient visit. One patient expected to only need an injection in one eye, so a syringe was sent for that patient. On exam, the patient had a new submacular hemorrhage in the other eye and required treatment in the fellow eye as well. The fellow eye received Avastin from another source, and this eye did not develop endophthalmitis, despite being treated on the same day. So, we know it wasn't the doctor's injection technique that caused the infection."


SPECIAL REPORT: SPOTLIGHT ON ONCOLOGY PHARMACY

Drug Topics

Pharmacists Move into Practices

More medical groups see value

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 calendar Q4 2019

Additional Ex-U.S. regulatory agency meetings expected in calendar Q4 2019

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

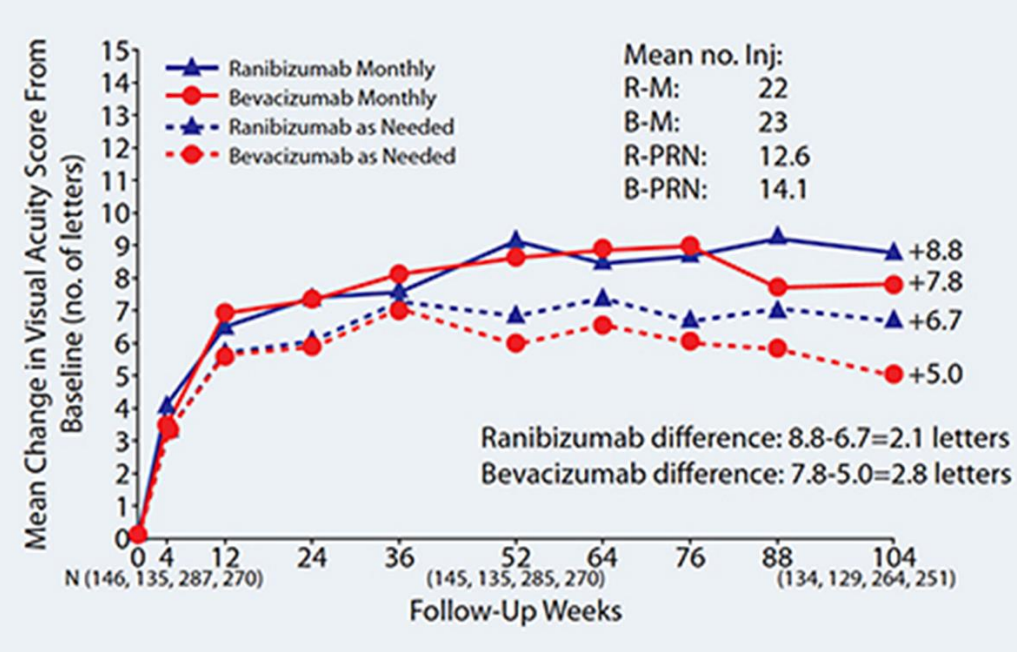
Intravitreal pharmacokinetic and immunogenicity being collected in ongoing registration trial

U.S. IND Active March 2019

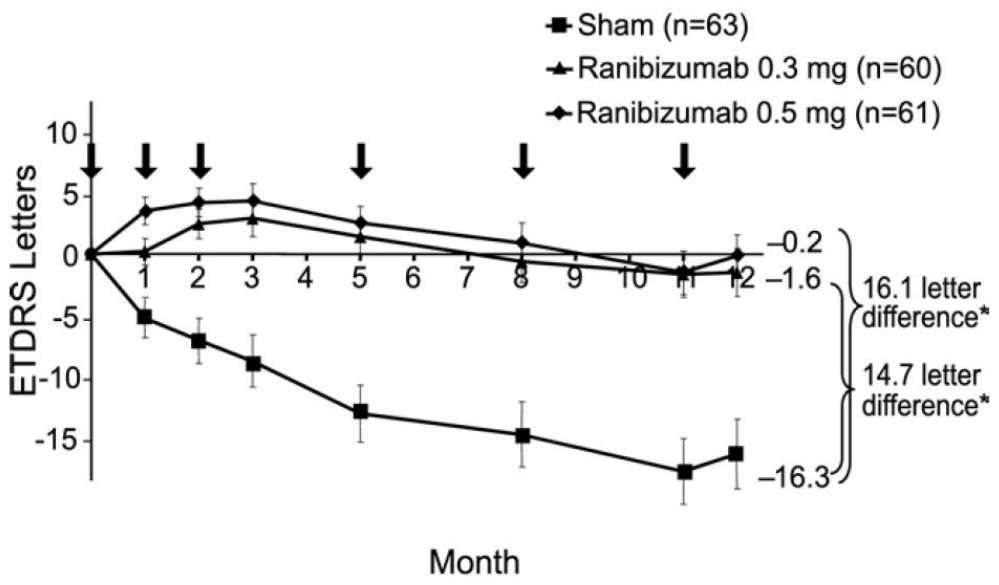
DME and BRVO clinical studies planned to begin later in 2019

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

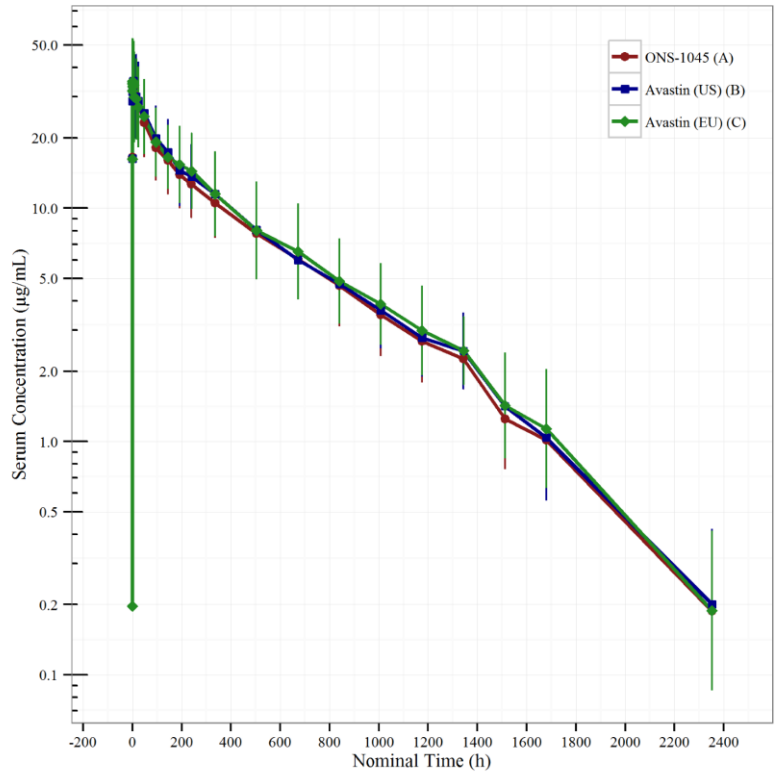
Randomized, IV double blind, single dose study vs U.S. and EU Avastin

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

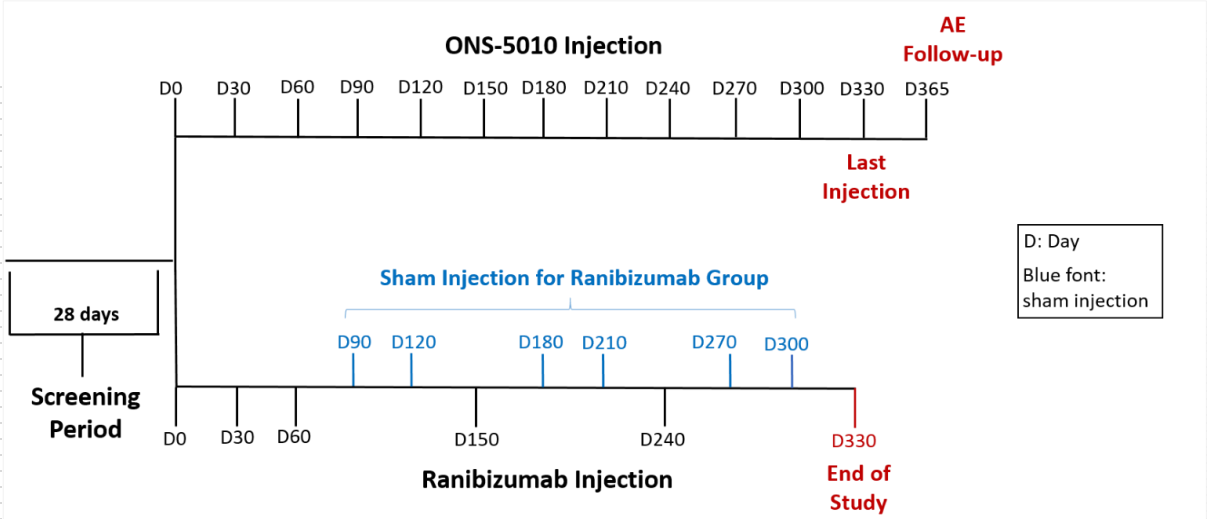
- Safety & efficacy data expected to support planned U.S. BLA filing in 2020

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 2020

NORSE TWO

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

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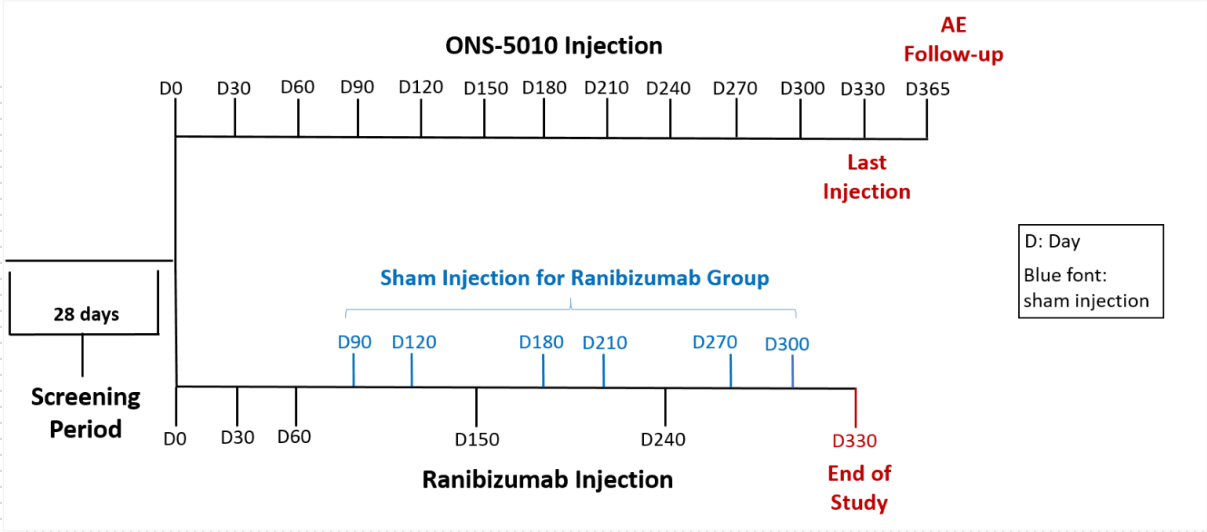

Study Design / size confirmed in April 2018 FDA EOP2 acceptable as one of two adequate and well controlled trials that will support approval of exudative age-related macular degeneration indication

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

Milestones

Milestone	Completed	Ongoing	Q2 2019	H2 2019	H1 2020	Q3 2020	Q4 2020
Target	U.S. IND submission and Approval	Enrollment begins in 2nd Wet AMD clinical trial	Commenced Contract Manufacturing with FUJIFILM Diosynth Biotechnologies	Meet with European regulatory authorities and Initiate DME and BRVO clinical trials		NORSE ONE Primary outcome data	BLA submission NORSE TWO Primary outcome data

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 2021/2022
- 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