CORPORATE PRESENTATION

August 2020

NASDAQ: OTLK

outlooktherapeutics.com

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Late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications.

Investment Highlights

Potential FDA approval in wet AMD in 2022 with lead product candidate, ONS-5010 / LYTENAVA™ (bevacizumab-vikg)[1], an investigational ophthalmic formulation of bevacizumab-vikg

Bevacizumab Was Seen to be Effective in CATT Trial

- Bevacizumab is widely accepted and used off-label for wet AMD

Well-Defined Regulatory Pathway

- PHSA 351 (a) New BLA
- Provides potential for 12 years of market exclusivity

Targeting $9.1 Billion Anti-VEGF Market[2]

- Lead Indication: wet AMD
- Follow-on indications: DME, BRVO

1: ONS-5010 / LYTENAVA™ (bevacizumab-vikg) is an investigational ophthalmic formulation of bevacizumab
2: GlobalData 2016
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

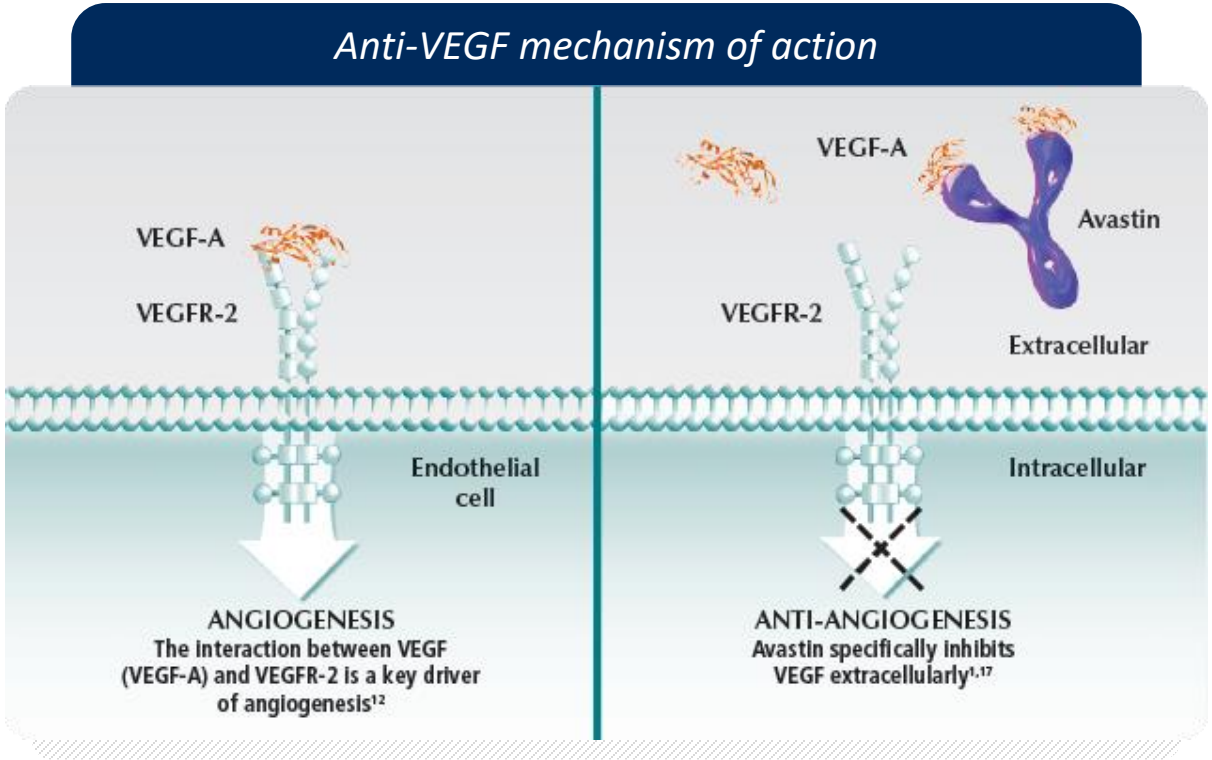
RANDY THURMAN
Executive Chairman of the Board

MARK HUMAYUN, MD PhD
Medical Advisor

Standard of Care in Wet AMD

ONS-5010 / LYTENAVA™, if approved, will be the
first on-label ophthalmic formulation of bevacizumab-vikg

- Anti-VEGF drugs have been standard of care since 2006
  - Block growth of abnormal blood vessels and leakage of fluid from the vessels behind the retina
- 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



Targeting Large Ophthalmic Markets

$9.1 Billion Anti-VEGF Market[1]

Does not include unapproved bevacizumab

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

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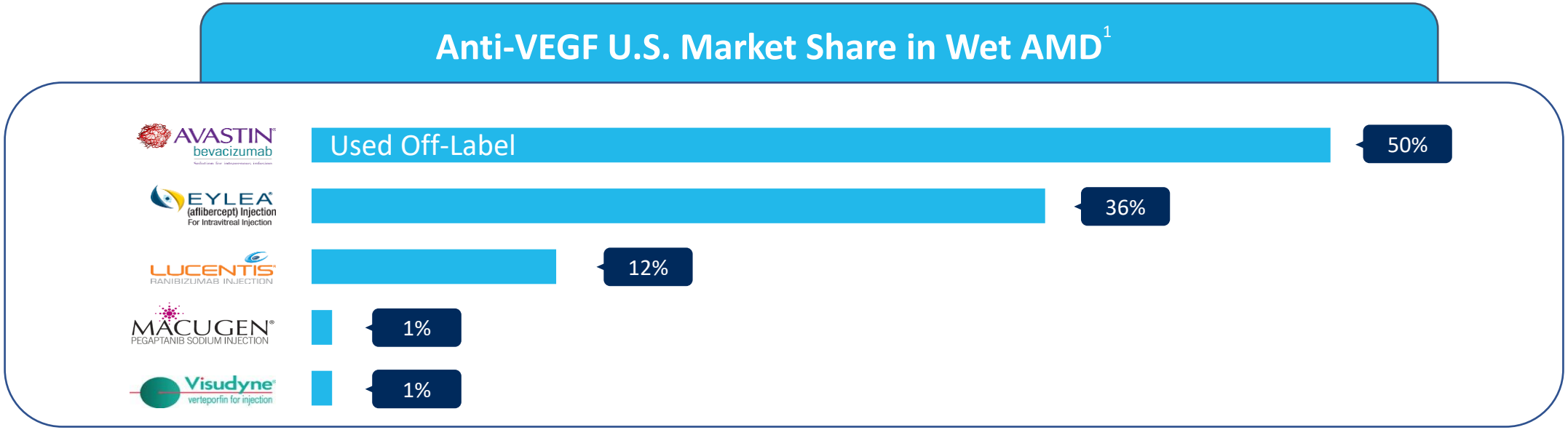
1: Source: Global Data estimates, 2016
2: EU5 consists of the UK, France, Germany, Spain, and Italy

Unapproved Bevacizumab Represents 50% of Wet AMD Market



Expected Drivers to Compete Across All 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

Unapproved Repackaged IV Bevacizumab Presents Safety Issues

Unapproved repackaged IV bevacizumab for ophthalmic injections can vary significantly when repackaged by compounding pharmacies, affecting quality, safety and access

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

OUTLOOK THERAPEUTICS

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

Step-Edit Therapy Provides Market Opportunity

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

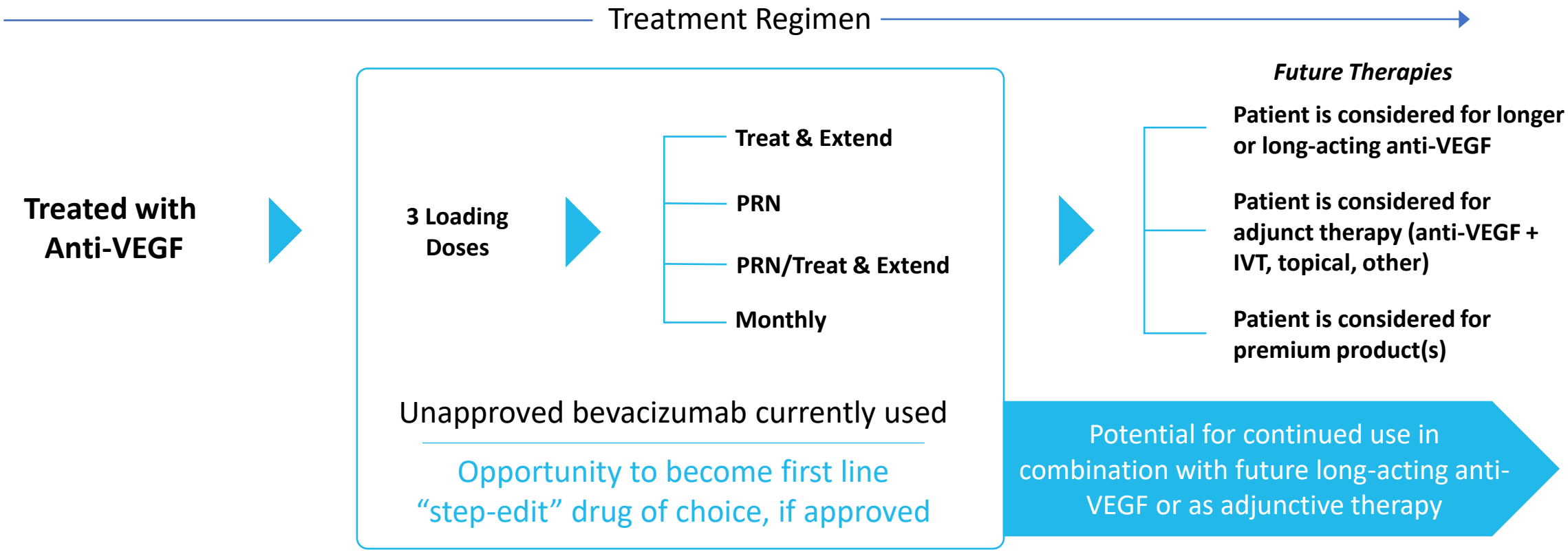
Share

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

Payor Cost Saving Measure

- Less expensive therapies are covered first
- Patient must "fail" medication before advancing to more costly treatments

Potential First Access in Treatment Paradigm with Step-Edit Therapy



Aetna now requires unapproved off-label use of bevacizumab for Medicare patients before covering more expensive, approved premium therapies (effective January 1, 2020)[1]

1: http://www.aetna.com/cpb/medical/data/700_799/0765.html

Regulatory Strategy Aligned with FDA

New Biologics License Application (BLA) submission in wet AMD expected H2 2021

- PHSA 351 (a) new BLA regulatory pathway
- FDA End-of-Phase 2 meeting completed
- Clinical protocols reflect FDA feedback
- FDA indicated study designs would be acceptable for registration

Strategy Outside of United States

EU agency meetings planned in 2020

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

ONS-5010 Clinical Program

NORSE ONE

ONS-5010-001:
Demonstrated anticipated safety and efficacy and positive proof-of-concept

NORSE TWO

ONS-5010-002:
Safety and efficacy study
Data expected: Q3 2021

NORSE THREE

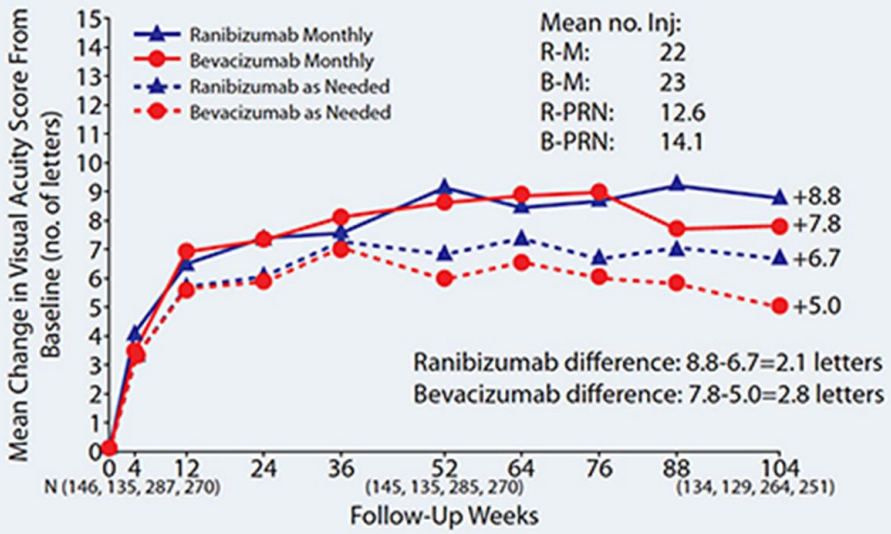
ONS-5010-003:
Open-label safety study
Initiation: Q4 2020

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

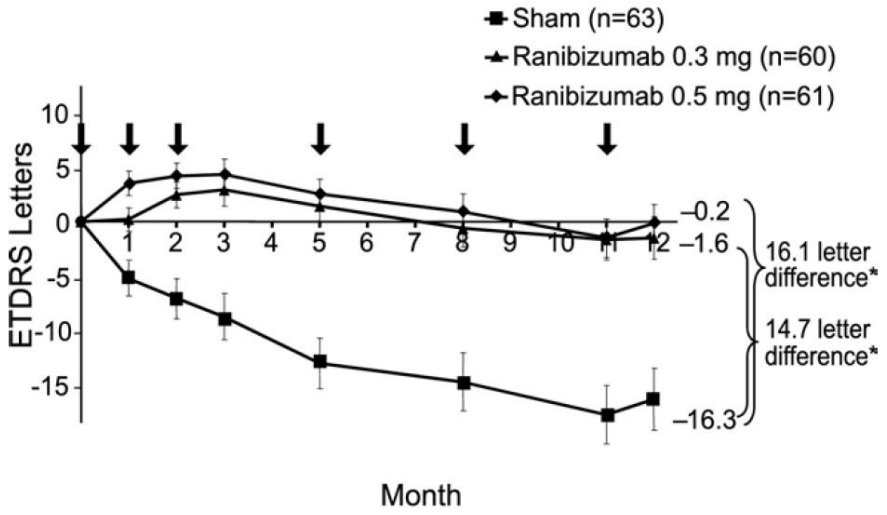
SPA agreements reached with FDA for planned DME and BRVO registration clinical studies

Bevacizumab Demonstrated to be Equivalent to LUCENTIS® in CATT Trial

CATT Study Results[1]



LUCENTIS® PIER Study[2]



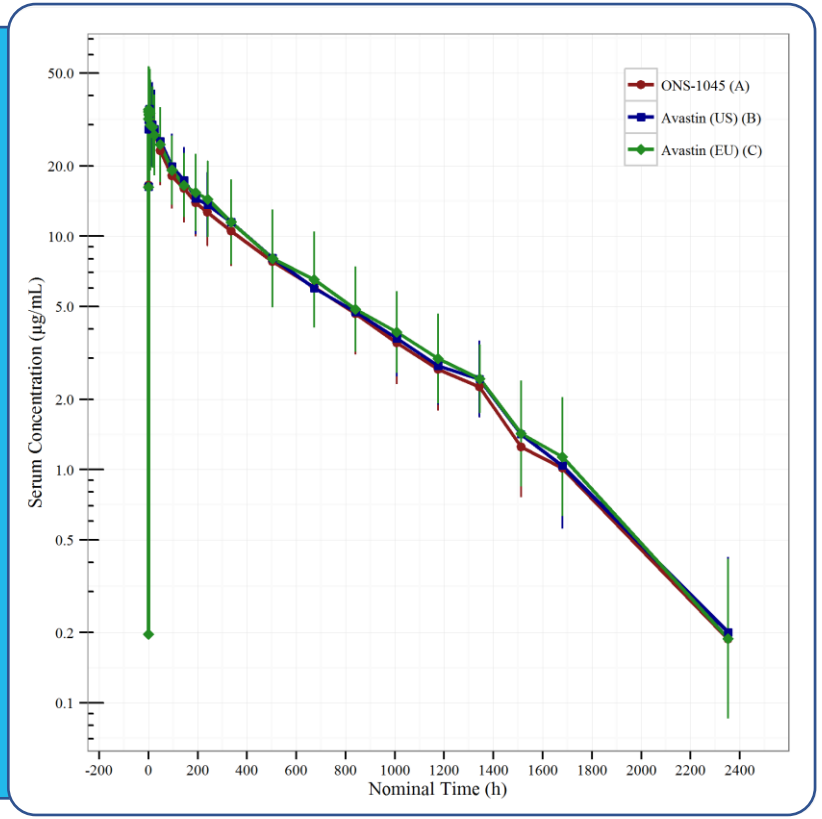
1: Comparison of Age-related Macular Degeneration Treatments Trials (CATT) Research Group, Daniel F. Martin, Ophthalmology, July 2012 Volume 119, Issue 7, Pages 1388–1398
2: Am J Ophthalmol. 2010 Sep;150(3):315-324.e1. doi: 10.1016/j.ajo.2010.04.011. Epub 2010 Jul 3.

Outlook Bevacizumab Demonstrated PK Biosimilarity to Avastin®

Phase 1 PK Study

- OTLK IV bevacizumab vs. U.S. and EU Avastin®
- Randomized, IV double-masked, single dose study
- Met primary and secondary endpoints
  - Biosimilar PK
  - Low immunogenicity

Mean (±SD) bevacizumab serum concentration - log scale



NORSE ONE

First Registration, Clinical Experience Study

Phase 3 Clinical Program

Positive proof-of-concept

Demonstrated anticipated safety and efficacy consistent with previously published results for ophthalmic bevacizumab

Study Highlights:

- Randomized Masked Controlled Trial
- ONS-5010 vs LUCENTIS® (ranibizumab)
- 61 subjects enrolled
- Study conducted in Australia
- Expected to support planned new U.S. BLA filing in 2021

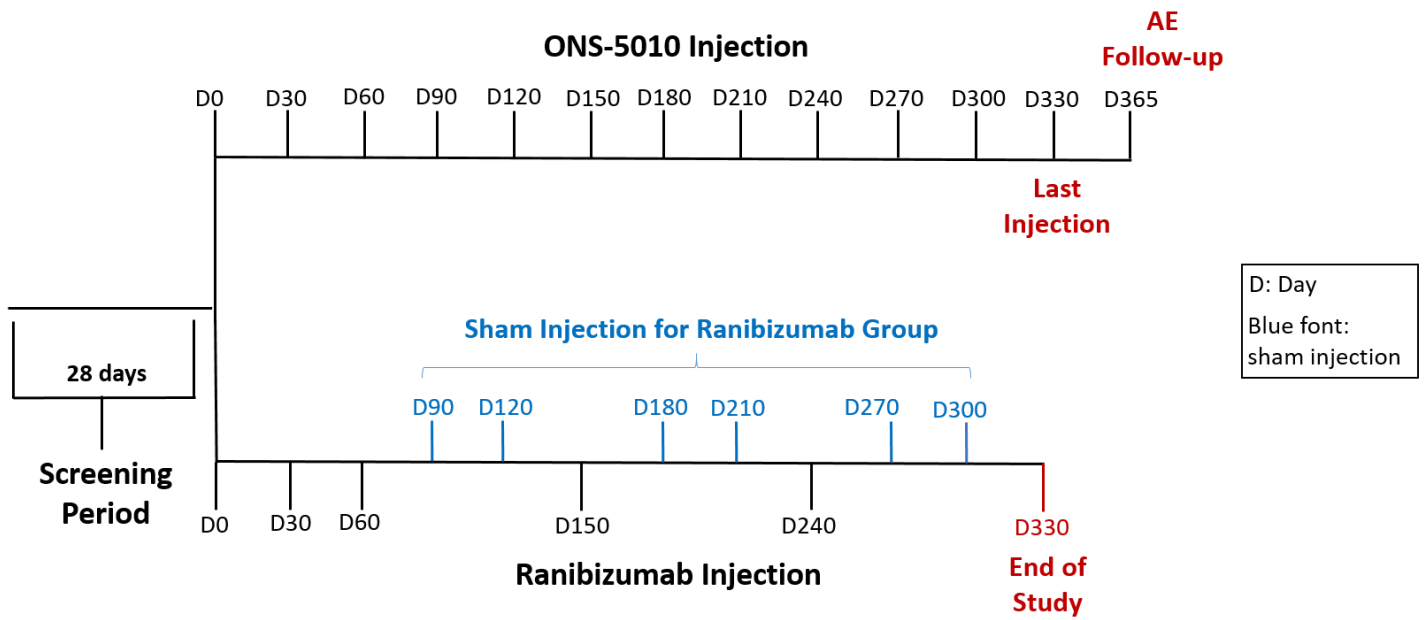
Study Supports Design of Ongoing Pivotal NORSE 2 Registration Trial

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:
Difference in proportion of patients who gain at least 15 letters in BCVA from baseline at day 330



Study design / size confirmed in April 2018 by FDA at EOP2 meeting as acceptable as one of two adequate and well-controlled registration clinical trials that may support approval of exudative age-related macular degeneration indication

Positive Proof-of-Concept of ONS-5010

- ONS-5010 demonstrated anticipated safety and efficacy consistent with previously published ophthalmic bevacizumab research
- There were no significant statistical differences in efficacy and safety in this small clinical experience trial
- The results from NORSE 1 provide support for the established design and protocol for the ongoing pivotal NORSE 2 clinical trial
- No adverse events associated with inflammation, a concern for other anti-VEGFs in treating retinal diseases

Study Enrollment

Parameter		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%)

Overall Response

	ONS-5010	Ranibizumab
Subjects achieving > 15 letters BCVA at Month 11	2/25 (8%)	5/23 (22%)

Subgroup Analysis of Treatment-Naïve Subjects

	ONS-5010	Ranibizumab
Subjects achieving > 15 letters BCVA at Month 11	2/6 (33%)	4/13 (31%)

Subgroup Analysis

	ONS-5010	Ranibizumab
Proportion of Subjects with baseline visual acuity of <67 Letters (20/50 or worse)	2/4 (50%)	4/9 (44%)

NORSE TWO

Pivotal Study

Phase 3 Clinical Program

Enrollment Completed

Topline Data Expected Q3 2021

Study Highlights:

- Randomized Masked Controlled Trial
- ONS-5010 vs LUCENTIS® (ranibizumab)
- 227 patients enrolled
- Study conducted in United States
- Both study arms include predominantly treatment-naïve patients with baseline VA less than 20/50 at study start
- Safety & efficacy data expected to support planned new U.S. BLA filing in 2021

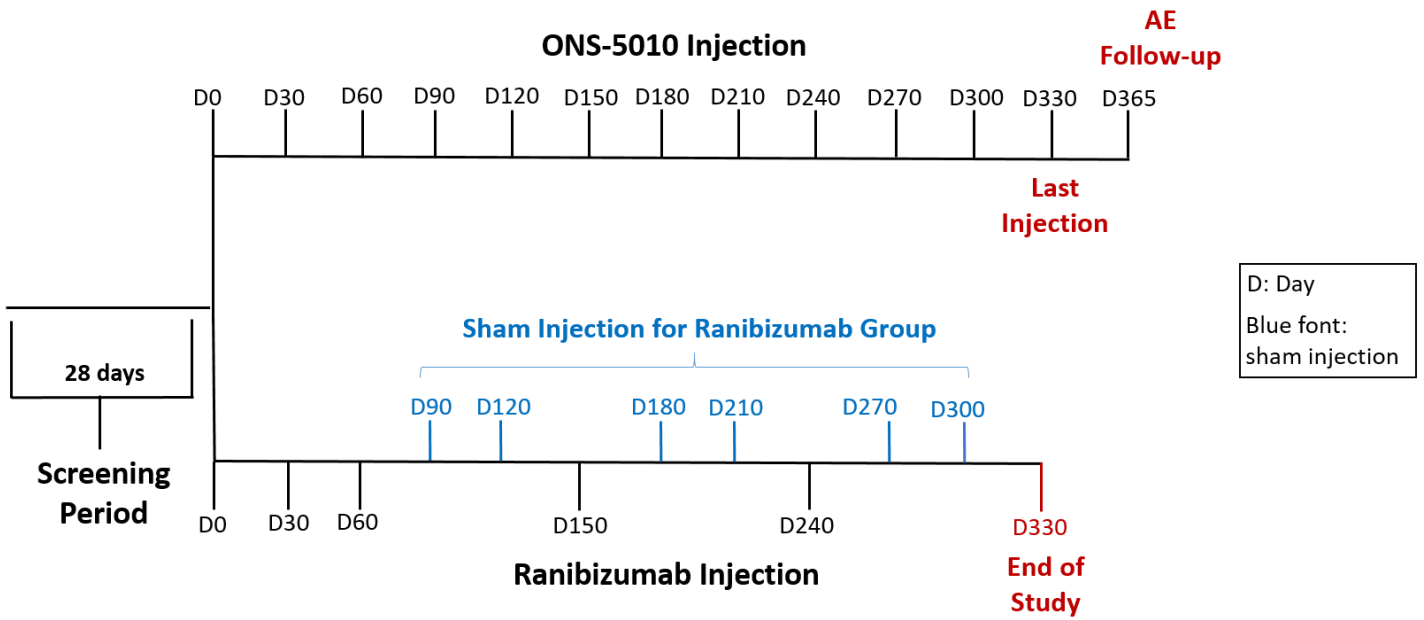
Study Design

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 patients who gain at least 15 letters in BCVA from baseline at day 330



Study design / size confirmed in April 2018 by FDA at EOP2 meeting as acceptable as one of two adequate and well-controlled registration clinical trials that may support approval of exudative age-related macular degeneration indication

NORSE THREE

Open-Label Safety Study

Phase 3 Clinical Program

Expect to Commence Study Q4 2020

Topline Data Expected Q3 2021

Study Highlights:

- Open-Label Safety Study
- ~180 patients to be enrolled
- Safety study to ensure adequate number of safety exposures to ONS-5010 to support planned new U.S. BLA filing in 2021

Commercial Strategy

Commercial launch will be led by Jeff Evanson, Chief Commercial Officer. Former V.P., Head, Global Pharmaceutical Franchise and Global Director, Alcon

NOVARTIS Alcon Medtronic NAVIGANT

Commercial Drivers

- Provide safe and cost-effective approved bevacizumab
- Responsible pricing (collaborative payor strategy)
- Pre-filled syringes expected to provide convenience and safety
- Market exclusivity (new BLA)
  - 12 years in United States
  - 8+2 years in EU

Step-Edit Therapy

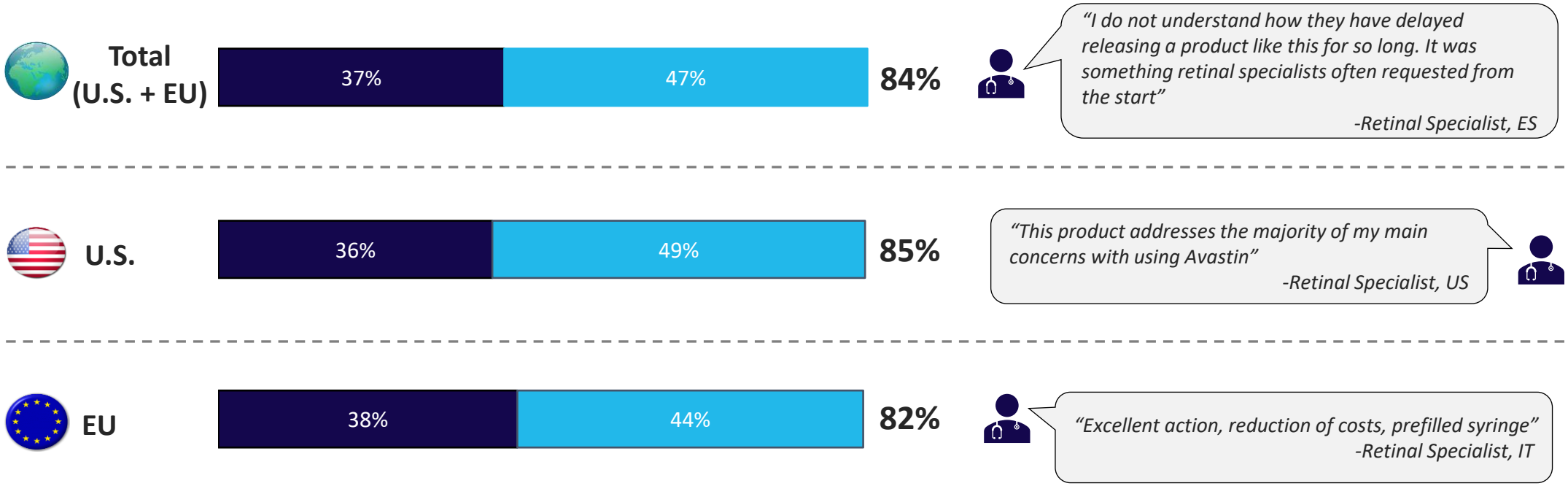
Opportunity to become first line “step-edit” drug of choice, if approved

Expand Outside U.S.

Penetrate EU5, Japan and developing markets where unapproved bevacizumab use has been restricted

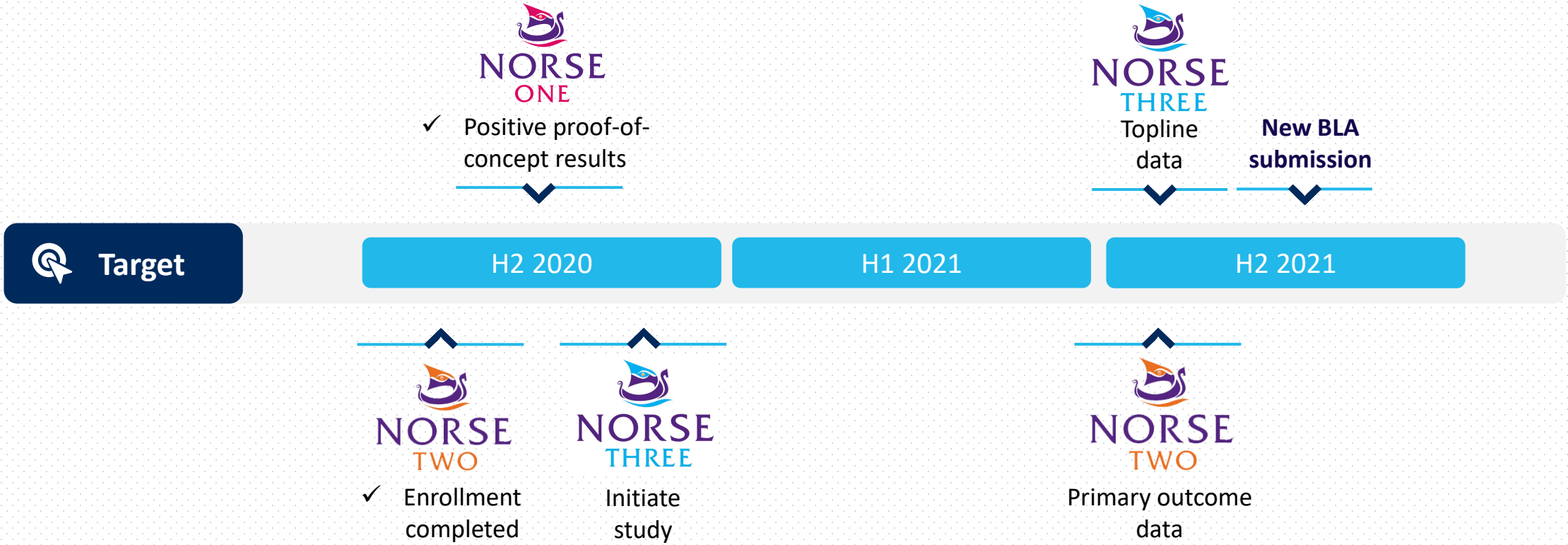
Physicians Want Approved Bevacizumab

>80% of retinal specialists express interest in an
FDA-approved 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"*

Upcoming Clinical and Regulatory Milestones



Company Highlights

- Lead product candidate ONS-5010 / LYTENAVA™ has potential to be first FDA-approved ophthalmic formulation of bevacizumab for use in multiple retinal indications
- Potential FDA Approval in 2022
- Targeting $9.1 Billion Anti-VEGF Market[1]
- Potential for 12 Years of Market Exclusivity
- Management Team with Extensive Clinical/Regulatory Ophthalmology & Drug Development Experience

1: GlobalData 2016