



CORPORATE PRESENTATION

July 2020

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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



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



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 Market²

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

Leadership Team: Global Ophthalmic Development and Commercial Launch Excellence



LAWRENCE KENYON
President, CEO, CFO



JEFF EVANSON
Chief Commercial Officer



TERRY DAGNON
Chief Operating Officer



RANDY THURMAN
Executive Chairman of the Board



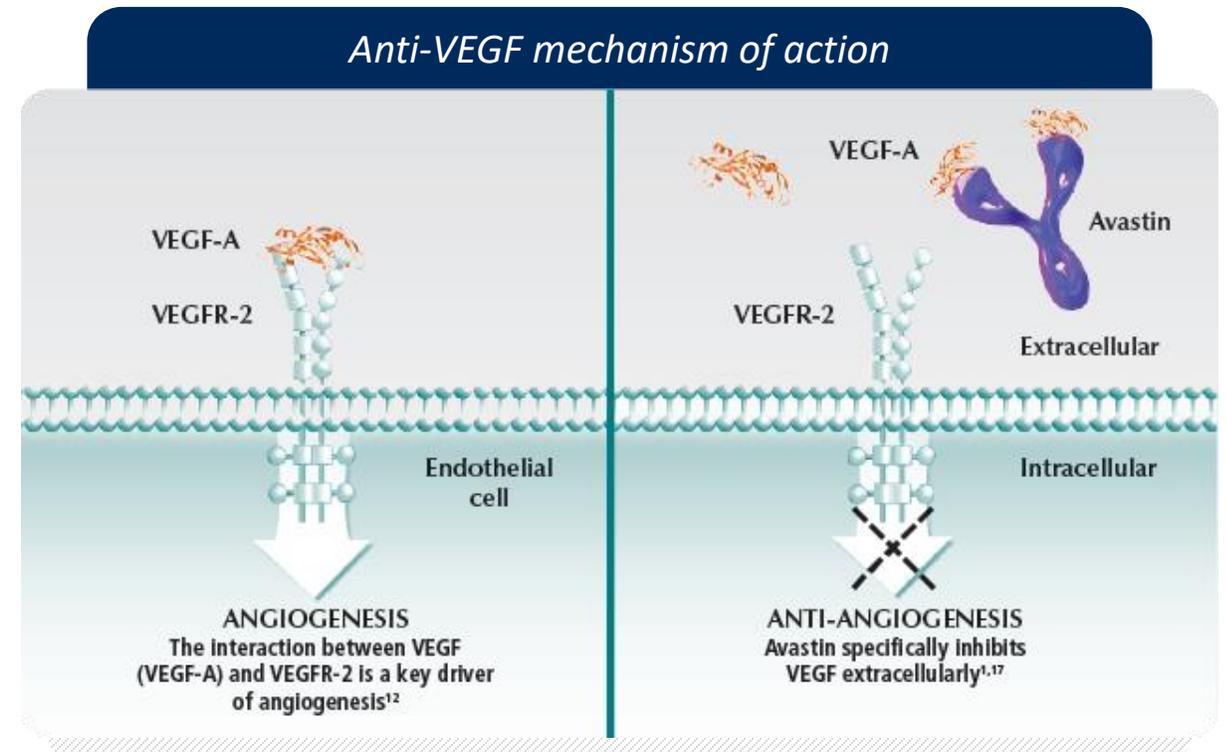
MARK HUMAYUN, MD PhD
Medical Advisor



Standard of Care in Wet AMD

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

- ❑ 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

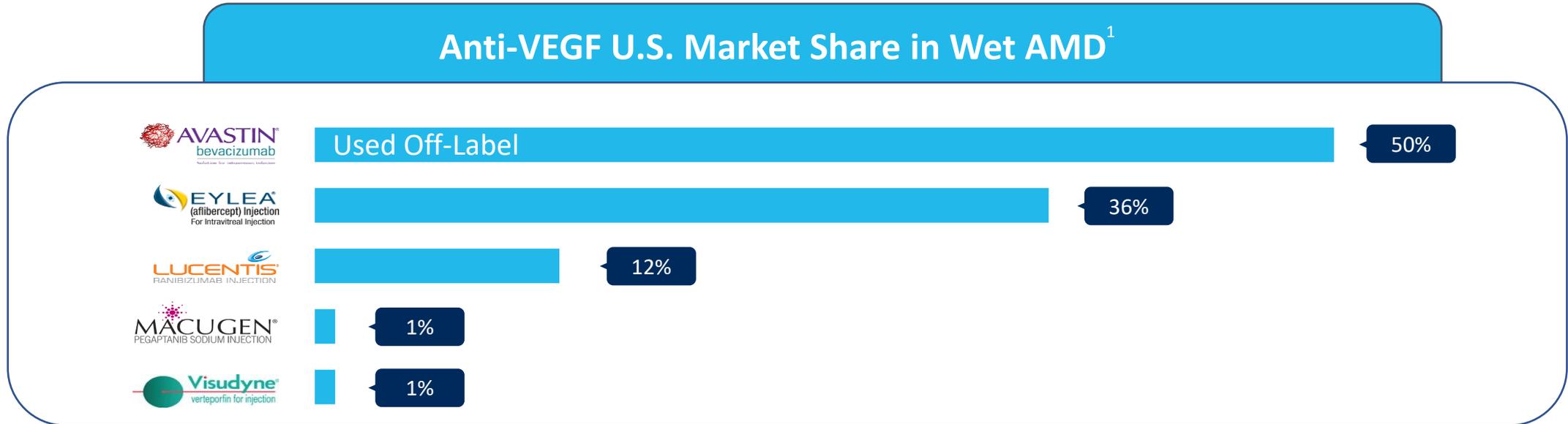
\$9.1 Billion Anti-VEGF Market¹

Does not include off-label 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

Off-Label Bevacizumab Represents 50% of Wet AMD Market

Anti-VEGF U.S. Market Share in Wet AMD¹



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

Off-Label Bevacizumab Presents Safety Issues

Off-label ophthalmic bevacizumab injections can vary significantly when repackaged by compounding pharmacies, affecting quality, safety and access

Variability in Potency¹

- 81% of samples had lower protein concentrations than required
- Samples had statistically significant variations in protein concentration among samples

Safety and Sterility Adverse Events²

- Unvalidated hold times in syringes not designed to be primary packages
- Patients have lost eyesight due to infections
- Multiple bevacizumab recalls due to unsterile compounding practices

Syringe Malfunctioning³

- 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

JAMA Ophthalmology



Warning Letter



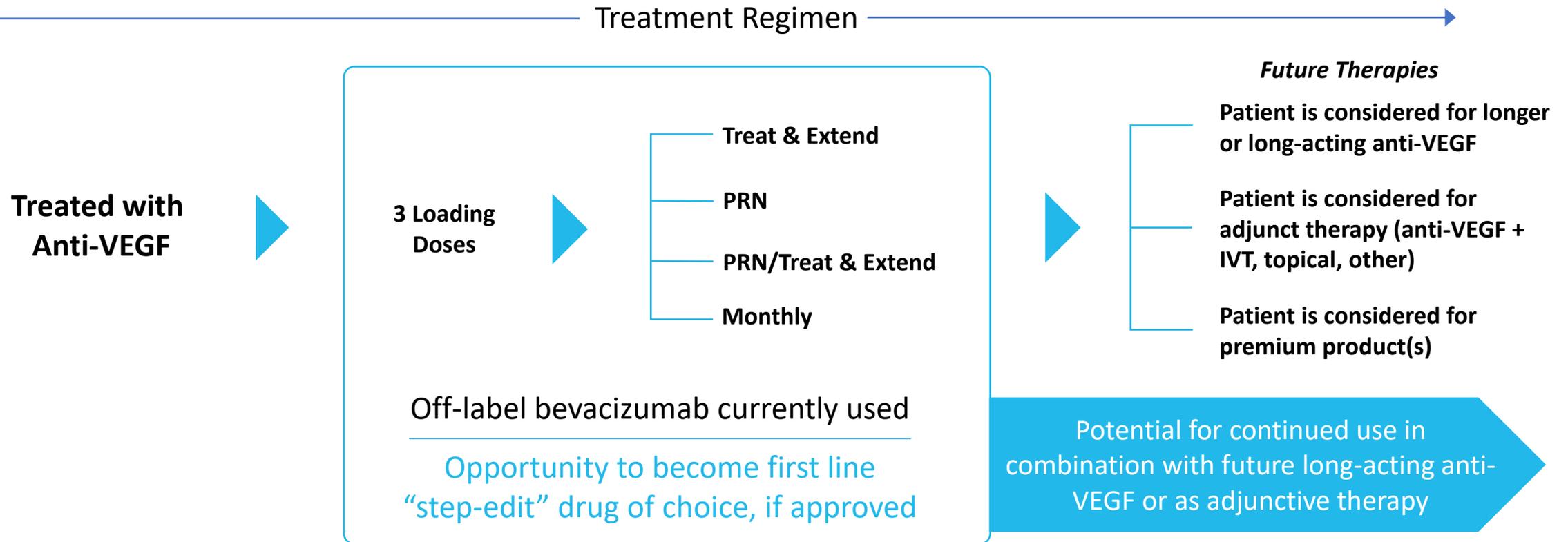
Step-Edit Therapy Provides Market Opportunity

The screenshot shows the CMS.gov Newsroom page. At the top left is the CMS.gov logo and the text 'Centers for Medicare & Medicaid Services'. Below this is a dark blue navigation bar with 'Newsroom' in white, and 'Press Kit', 'Data', 'Contact', and 'Blog' in white text. The main content area has a yellow 'Fact sheet' tag. The article title is 'Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs'. Below the title is the date 'Aug 07, 2018' and a list of tags: 'Leadership, Medicare Part C, Medicare Parts A & B, Prescription drugs'. There are social media share icons for Facebook, Twitter, LinkedIn, and Email. The article text begins with '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 off-label use of bevacizumab for Medicare patients before covering more expensive, approved premium therapies (effective January 1, 2020)¹

Regulatory Strategy Aligned with FDA

New Biologics License Application (BLA) submission in wet AMD expected Q3 2021



- PHS 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



ONS-5010-001:
Safety and efficacy study
Data expected: August 2020



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



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



Two ongoing studies in wet AMD



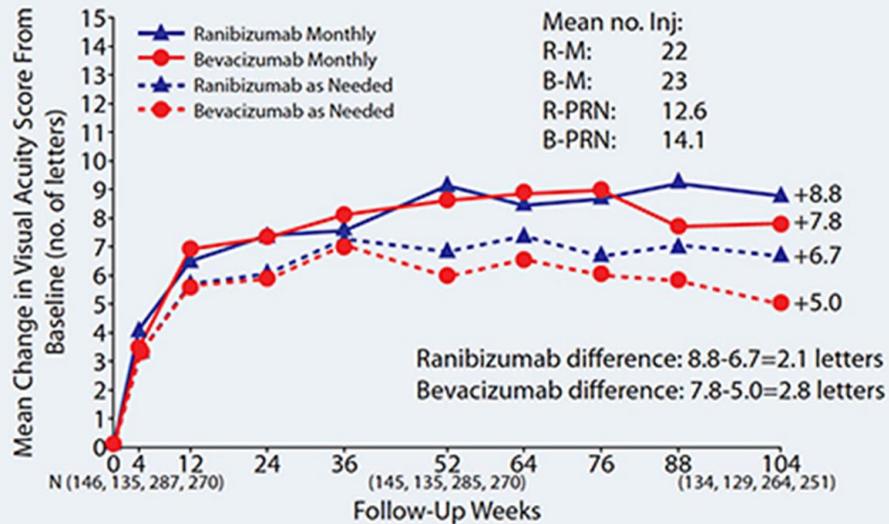
Safety & efficacy data from ongoing studies expected to support planned new U.S. BLA filing in 2021



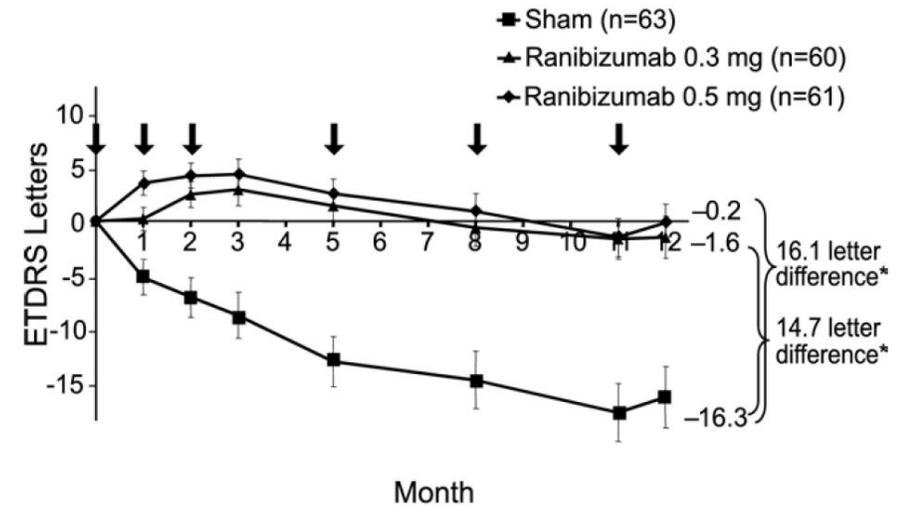
SPA agreements reached with FDA for planned DME and BRVO registration clinical studies

Bevacizumab Demonstrated to be Equivalent to LUCENTIS® in CATT Trial

CATT Study Results¹



LUCENTIS® PIER Study²



Outlook Bevacizumab Demonstrated PK Biosimilarity to Avastin®

Phase 1 PK Study

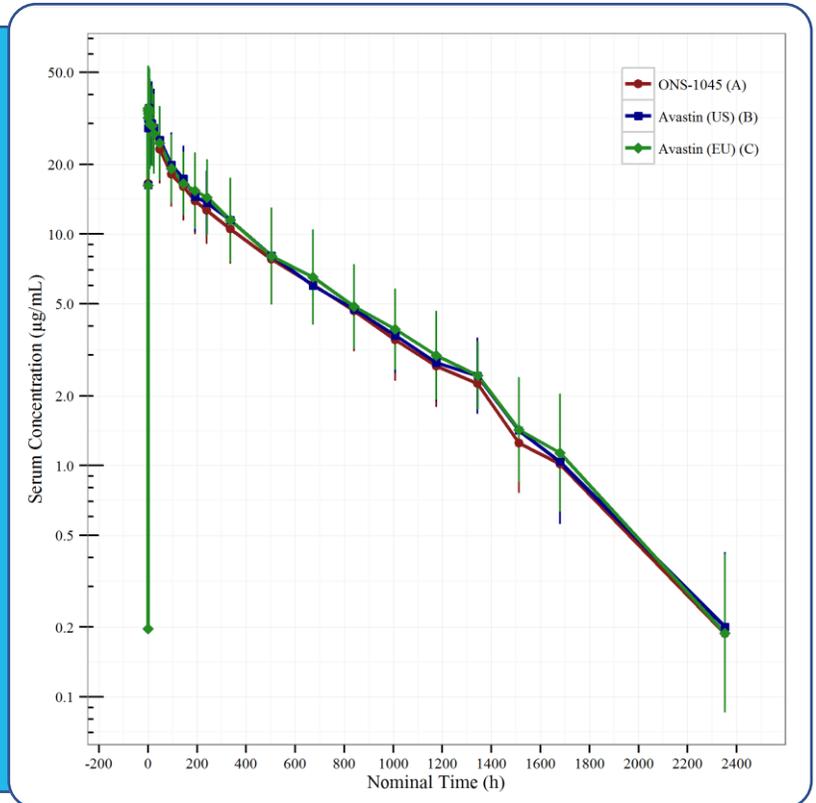
OTLK IV bevacizumab vs. U.S. and EU Avastin®

Randomized, IV double-masked, single dose study

Met primary and secondary endpoints

- Biosimilar PK
- Low immunogenicity

Mean (\pm SD)
bevacizumab serum
concentration - log
scale





NORSE ONE

First Registration Study

Phase 3 Clinical Program



Enrollment Completed



Topline Data Expected August 2020



Study Highlights:

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

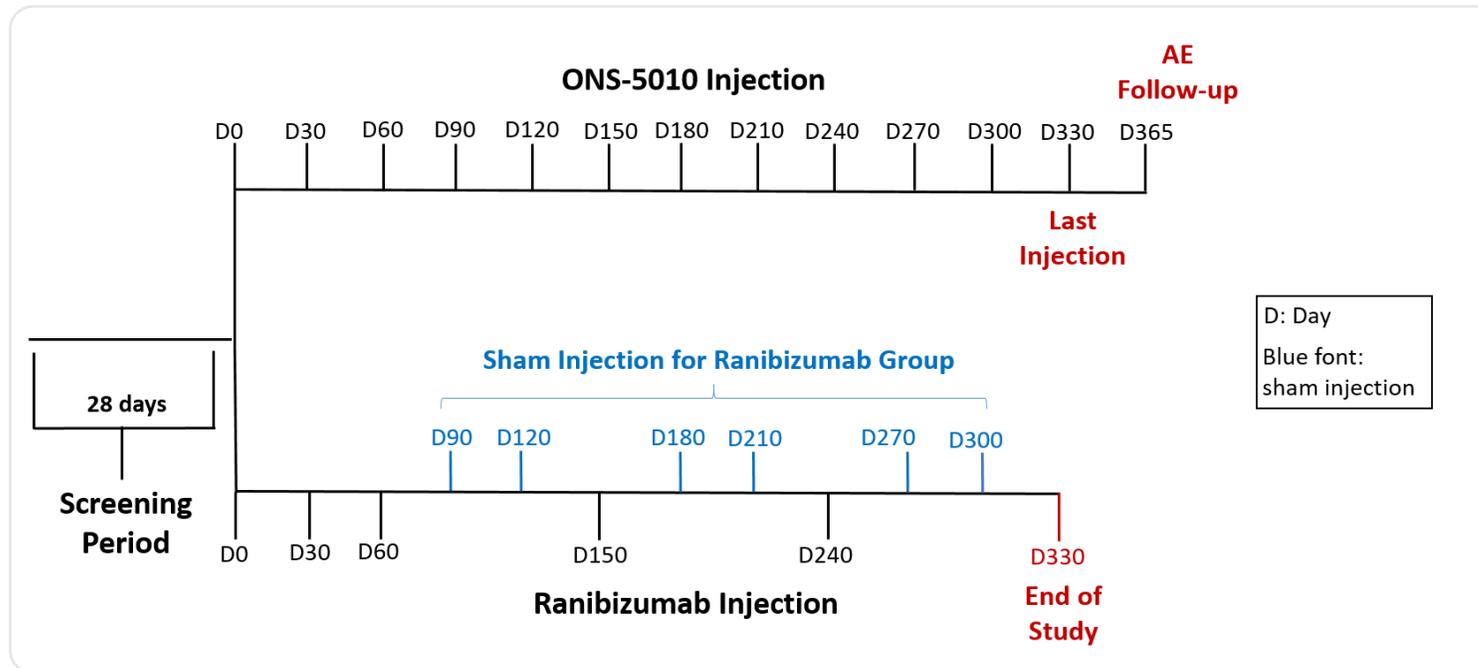
Study Design

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



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



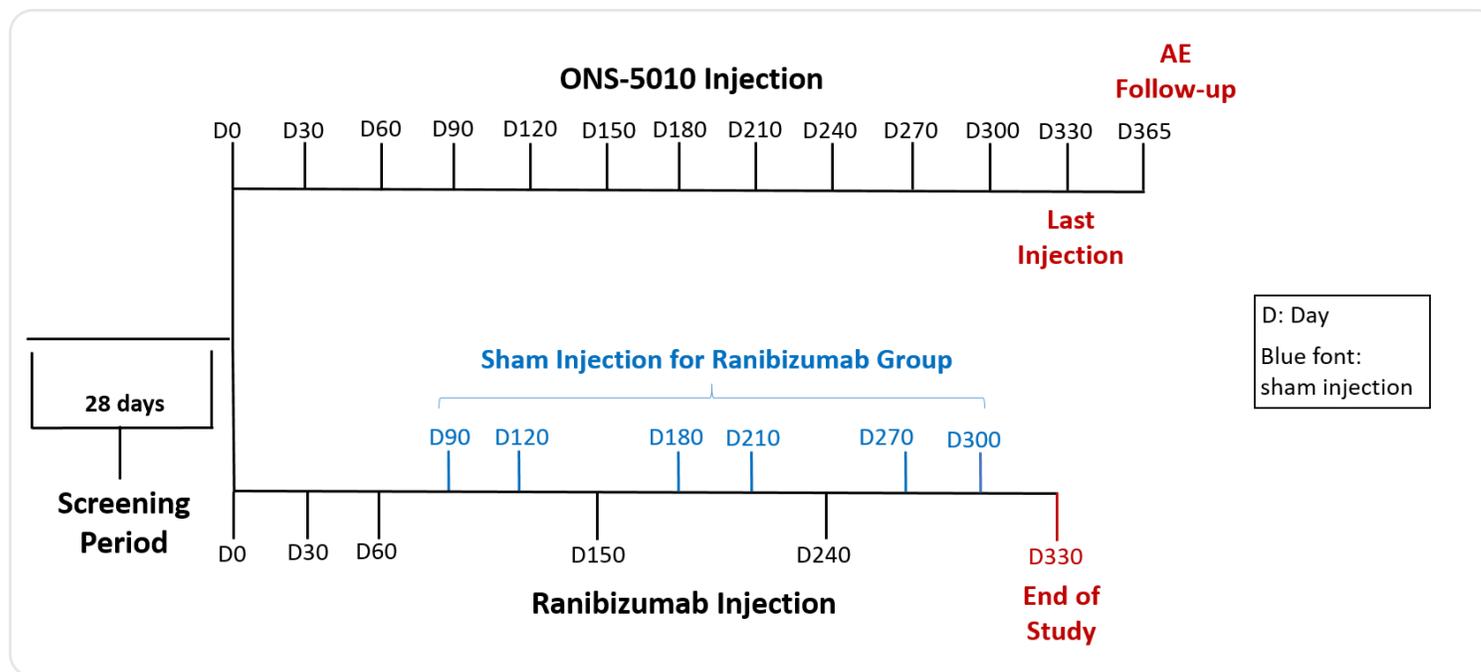
Study Design

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 on-label 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

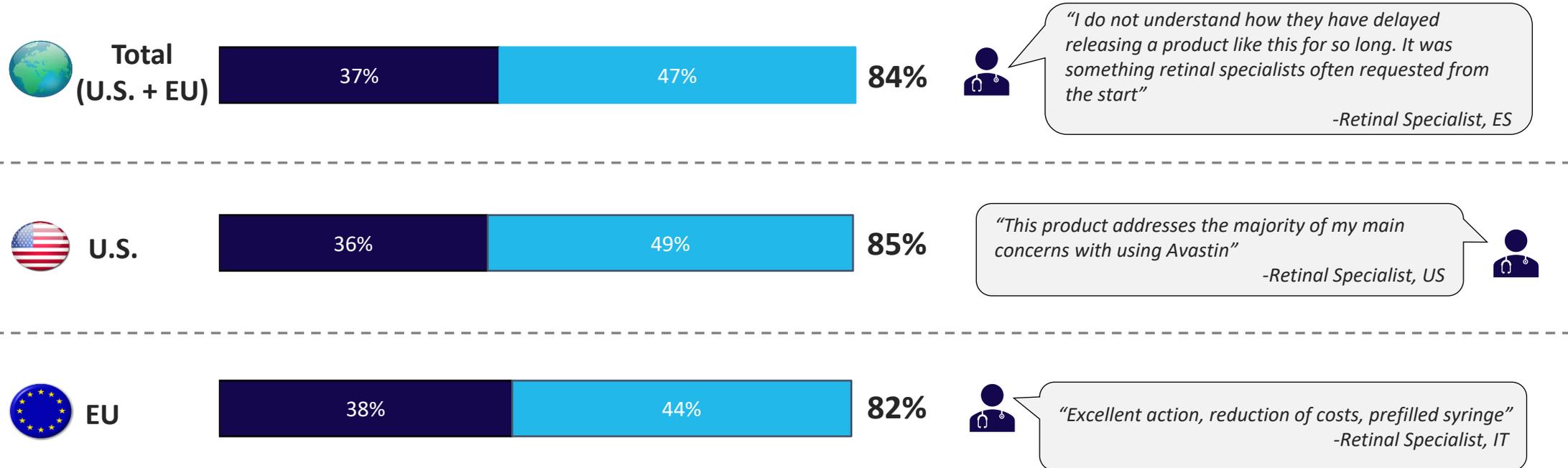


Expand Outside U.S.

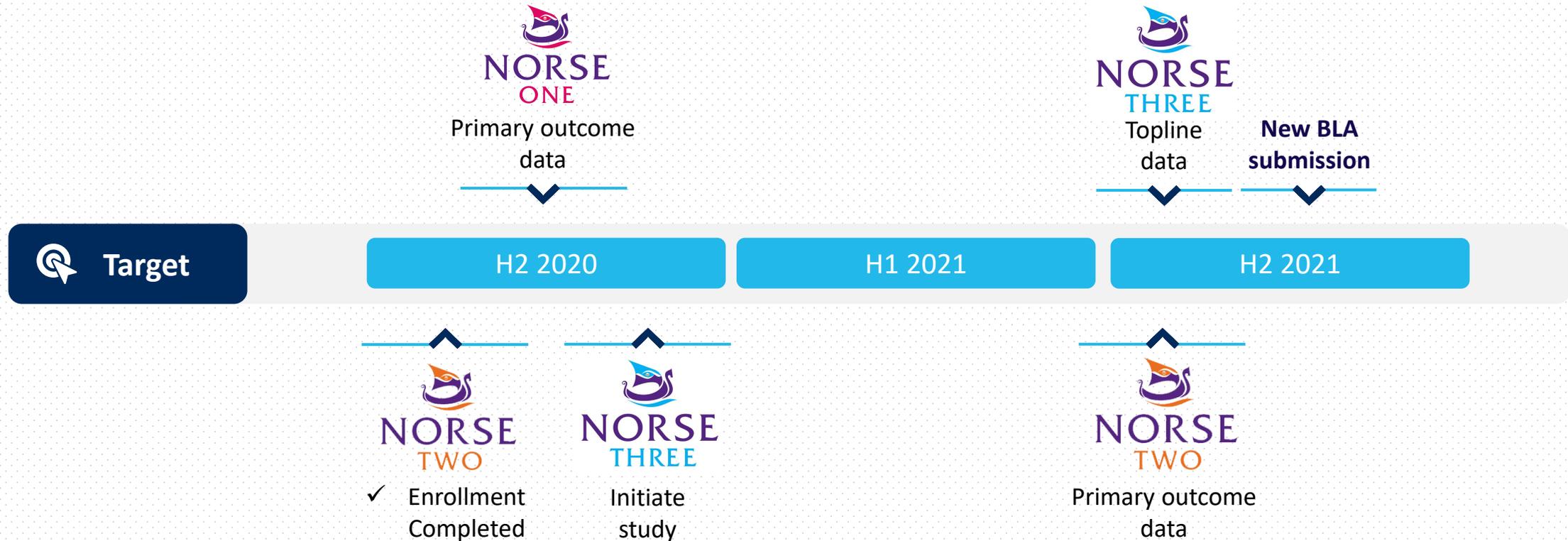
Penetrate EU5, Japan and developing markets where off-label bevacizumab use has been restricted

Physicians Want On-Label Bevacizumab

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



Upcoming Clinical and Regulatory Milestones





Company Highlights

- Lead product candidate ONS-5010 / LYTENATM 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 Market¹
- Potential for 12 Years of Market Exclusivity
- Management team with extensive clinical/regulatory ophthalmology & drug development experience