OUTLOOK THERAPEUTICS

Corporate Presentation

September 2021

NASDAQ: OTLK

outlooktherapeutics.com

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OUTLOOK THERAPEUTICS

Enhancing the Standard of Care For Retinal Disorders

Investment Highlights

Positive Phase 3 Results Demonstrated with Lead Program, ONS-5010 (bevacizumab-vikg)[1], for Treatment of Wet AMD

U.S. FDA BLA submission targeted for calendar Q1 2022

Potential to be first U.S. FDA approved ophthalmic formulation of bevacizumab

Pre-commercialization activities underway to support potential launch

Targeting $13.1 Billion Global Ophthalmic Anti-VEGF Market[2]

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1. ONS-5010 / LYTENAVA™ (bevacizumab-vikg) is an investigational ophthalmic formulation of bevacizumab
2. Guidehouse Triangulation of Global Data, Market Scope and Investor Forecasts (2020)

Leadership Team: Global Ophthalmic Development and Commercial Launch Excellence

C. RUSSELL TRENARY III
President, CEO and Director

INNFOCUS · G&H ORTHODONTICS · AMO · Allergan

LAWRENCE KENYON
Chief Financial Officer and Director

ARNO THERAPEUTICS · TAMIR · PAR PHARMACEUTICAL

JEFF EVANSON
Chief Commercial Officer

NOVARTIS · Alcon · Medtronic · NAVIGANT

TERRY DAGNON
Chief Operating Officer

NOVARTIS · Johnson & Johnson · Alcon · DOHMEN

RANDY THURMAN
Executive Chairman of the Board

MARK HUMAYUN, MD, PhD
Medical Advisor

Goal of ONS-5010 (Bevacizumab-vikg) Program

Provide Physicians and Patients an Ophthalmic FDA Approved Alternative of a Drug Widely Used Off-Label

Deliver cGMP formulation to ensure essential drug strength, quality, and purity

Eliminate impurities and particulates from legacy re-packaging processes

Create a product offering with a differentiated delivery system to enhance physician ease of use

Provide an economically elegant anti-VEGF solution

Executing on Pathway Towards Potential FDA Approval in Wet AMD

U.S. BLA Submission Targeted Calendar Q1 2022

✓ **Positive Results**

NORSE ONE

Clinical Experience Trial

1st Registration Trial

✓ **Positive Top-line Data**

NORSE TWO

Pivotal Trial

2nd Registration Trial

✓ **Completed**

NORSE THREE

Open-Label Safety Study

Supports BLA Requirements

NORSE TWO

Pivotal Trial

2nd Registration Trial

Trial Highlights:

- Randomized masked controlled trial
- ONS-5010 (bevacizumab-vikg) vs LUCENTIS® (ranibizumab)
- 228 patients enrolled
- Trial conducted in the United States
- Trial arms included >95% treatment-naïve patients
- Safety & efficacy data support planned U.S. BLA submission in calendar Q1 2022

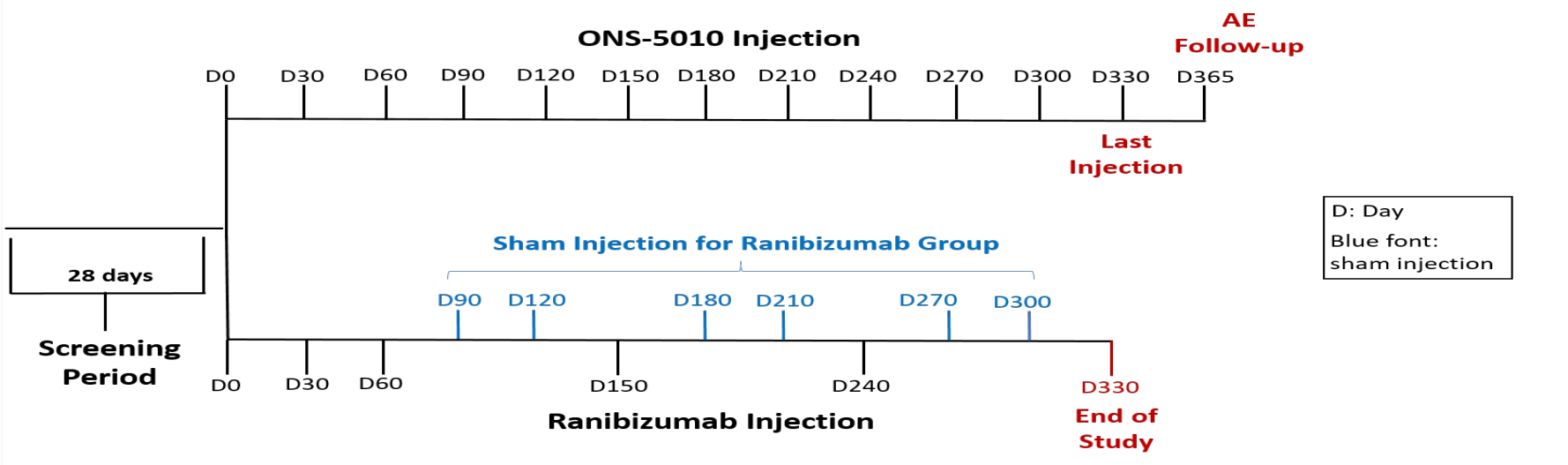
NORSE TWO Pivotal Trial Design

Randomized masked controlled trial with 228 subjects

ONS-5010 (bevacizumab-vikg) administered monthly X 12

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

Primary endpoint difference in proportion of subjects gaining 15 letters of BCVA at Day 330



NORSE TWO: Positive Efficacy Data

Unprecedented 41% ONS-5010 with 3-Line Gainers[1]

Statistically Significant Difference Across Both Primary and Key Secondary Endpoints

	ONS-5010 (bevacizumab-vikg)	LUCENTIS® (ranibizumab)	p-value
Primary Endpoint: Difference in subjects who gained at least 15 letters in the best corrected visual acuity (BCVA) at 11 months[2]			
Intent-to-Treat (ITT) Primary Dataset	**41%**	**23%**	**p = 0.0052**
Secondary Per-Protocol (PP) Dataset	**41%**	**24%**	**p = 0.04**
Key Secondary Endpoint: Mean change in the BVCA through 11 months[2]			
Intent-to-Treat (ITT) Primary Dataset	**11.2 letters**	**5.8 letters**	**p = 0.0043**
Secondary Per-Protocol (PP) Dataset	**11.1 letters**	**7.0 letters**	**p = 0.05**

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1. When considering adequate and well-controlled registration studies
2. Participants in the trial were treated for 12 months

NORSE TWO Safety Results:

Consistent with Previously Reported Results from NORSE ONE and NORSE THREE

In All Three Studies Only One Subject has Reported Ocular Inflammation

Characteristic	Statistic	ONS-5010 (Masked Data) (N=113)	Ranibizumab (N=115)	Overall (Masked Data) (N=228)
At Least 1 TEAE	n (%)	83 (73.5)	88 (76.5)	171 (75.0)
At Least 1 Related TEAE	n (%)	6 (5.3)	2 (1.7)	8 (3.5)
Maximum Severity				
CTCAE Grade 1 Mild	n (%)	46 (40.7)	45 (39.1)	91 (39.9)
CTCAE Grade 2 Moderate	n (%)	23 (20.4)	30 (26.1)	53 (23.2)
CTCAE Grade 3 Severe	n (%)	11 (9.7)	9 (7.8)	20 (8.8)
CTCAE Grade 4 Life-threatening	n (%)	0	2 (1.7)	2 (0.9)
CTCAE Grade 5 Death	n (%)	3 (2.7)	2 (1.7)	5 (2.2)
At Least 1 Ocular TEAE	n (%)	55 (48.7)	60 (52.2)	115 (50.4)
At Least 1 Ocular TEAE in Study Eye	n (%)	47 (41.6)	47 (40.9)	94 (41.2)
At Least 1 Non-Ocular TEAE	n (%)	55 (48.7)	57 (49.6)	112 (49.1)
At Least 1 >= Grade 3 Related TEAE	n (%)	2 (1.8)	1 (0.9)	3 (1.3)
At Least 1 Serious TEAE	n (%)	14 (12.4)	16 (13.9)	30 (13.2)
At Least 1 Related Serious TEAE	n (%)	2 (1.8)	1 (0.9)	2 (0.9)
At Least 1 TEAE Leading to Study Withdrawal	n (%)	2 (1.8)	4 (3.5)	6 (2.6)

NORSE TWO Safety Results: Consistent with Previously Reported Results from NORSE ONE and NORSE THREE - Frequency and Incidence of Ocular Study Eye Adverse Events > 1%

In All Three Studies Only One Subject has Reported Ocular Inflammation

MedDRA System Organ Class MedDRA Preferred Term		Statistic	Ranibizumab (N=115)	ONS-5010 (Masked Data) [1] (N=113)	Overall (Masked Data) [1] (N=228)
At Least 1 Ocular TEAE in Study Eye		n (%)	47 (40.9)	47 (41.6)	94 (41.2)
Cataract		n (%)	1 (0.9)	2 (1.8)	3 (1.3)
Cataract nuclear		n (%)	0	3 (2.7)	3 (1.3)
Conjunctival hemorrhage		n (%)	3 (2.6)	10 (8.8)	13 (5.7)
Conjunctival hyperaemia		n (%)	2 (1.7)	0	2 (0.9)
Corneal abrasion		n (%)	1 (0.9)	4 (3.5)	5 (2.2)
Dermatochalasis		n (%)	2 (1.7)	2 (1.8)	4 (1.8)
Dry eye		n (%)	5 (4.3)	2 (1.8)	7 (3.1)
Eye irritation		n (%)	0	2 (1.8)	2 (0.9)
Eye pain		n (%)	2 (1.7)	1 (0.9)	3 (1.3)
Hordeolum		n (%)	2 (1.7)	0	2 (0.9)
Metamorphopsia		n (%)	3 (2.6)	1 (0.9)	4 (1.8)
Neovascular age-related macular degeneration		n (%)	3 (2.6)	0	3 (1.3)
Posterior capsule opacification		n (%)	2 (1.7)	1 (0.9)	3 (1.3)
Punctate keratitis		n (%)	2 (1.7)	3 (2.7)	5 (2.2)

Frequency and Incidence of Ocular Study Eye Adverse Events ≥ 1%

(continued)

MedDRA System Organ Class MedDRA Preferred Term		Statistic	Ranibizumab (N=115)	ONS-5010 (Masked Data) [1] (N=113)	Overall (Masked Data) [1] (N=228)
Retinal degeneration		n (%)	2 (1.7)	1 (0.9)	3 (1.3)
Retinal haemorrhage		n (%)	6 (5.2)	2 (1.8)	8 (3.5)
Retinal oedema		n (%)	2 (1.7)	0	2 (0.9)
Subretinal fibrosis		n (%)	2 (1.7)	2 (1.8)	4 (1.8)
Subretinal fluid		n (%)	3 (2.6)	2 (1.8)	5 (2.2)
Vision blurred		n (%)	0	2 (1.8)	2 (0.9)
Visual acuity reduced		n (%)	14 (12.2)	2 (1.8)	16 (7.0)
Vitreous detachment		n (%)	2 (1.7)	3 (2.7)	5 (2.2)
Vitreous floaters		n (%)	1 (0.9)	4 (3.5)	5 (2.2)
Vitreous haemorrhage		n (%)	1 (0.9)	2 (1.8)	3 (1.3)
Conjunctivitis		n (%)	0	1 (0.9)	1 (0.4)
Procedural pain		n (%)	2 (1.7)	0	2 (0.9)
Intraocular pressure increased		n (%)	1 (0.9)	7 (6.2)	8 (3.5)

NORSE ONE and NORSE THREE Results

NORSE ONE — Completed Clinical Experience Trial

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

Trial Highlights:

- Desired proportion of 3-line visual acuity gainers achieved
- Desired mean gain in visual acuity achieved
- Zero ocular inflammation observed
- Safety was comparable to published bevacizumab studies, such as CATT

NORSE THREE — Open-Label Safety Study

Positive safety profile reinforces previously reported safety data for ONS-5010 (bevacizumab-vikg)

Trial Highlights:

- Provided adequate number of patient exposure required for BLA submission
- No unexpected safety trends
- Zero cases of ocular inflammation, a concern that has emerged for other anti-VEGF therapies to treat retinal conditions

U.S. Law & FDA Regulations for Compounding & Repackaging

- The Food Drug and Cosmetic Act (FD&CA) and Drug Quality and Security Act of 2013 define what is legal for 503A and 503B Compounding Pharmacies.[1]
  - ***Once a drug or biologic is FDA approved and commercially available compounding is no longer authorized.***[2,3,4,5]
    - 503A Compounding pharmacies are regulated by federal regulations and state laws and can only compound or repackage for individual prescriptions in limited quantities and cannot distribute across state lines for > 5% of business.
    - 503B Compounding Pharmacies / Outsourcing facilities must comply with CGMP regulations, are inspected by FDA and must adhere to reporting requirements.
    - Neither 503A nor 503B pharmacies can compound or repackage commercially available drugs unless they appear on the official FDA drug shortage list.
- "***Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality." – FDA***[6]
- "The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product." – FDA[6]
- "Such a practice would create significant public health risks because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared under substandard manufacturing conditions." – FDA[6]
- ***"Under the statutory scheme, only very rarely should a compounded drug product that is essentially a copy of a commercially available drug product be offered to a patient." – FDA***[6]

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1. Food Drug and Cosmetic Act 503A snd 503B & Drug Quality and Security Act of 2013; 2. Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities; Guidance for Industry; DHHS, FDA; January 2017; 3. Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application Guidance for Industry; DHHS, FDA; January 2018; 4. Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; DHHS, FDA; Draft Guidance: January 2020; 5. Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry; DHHS, FDA: January 2018; 6. Source: Compounding Laws and Policies | FDA www.fda.gov

Compounded Drug Compared to FDA Approved

Ophthalmic Solution Requirement	Off-Label Compounded Repackaged IV Solution	FDA Approved Ophthalmic Solution for Intravitreal Injection
Sterile USP <71>[1]	?	Yes
FDA Approved Ophthalmic Package consistent with USP <771>[1]	No	Yes
FDA Reviewed Stability Data supporting shelf life[2,3]	No	Yes
Particulates per USP <789> for Ophthalmic Solutions[1]	?	Yes
pH FDA approved and consistent with USP <771>[1,2,3]	No	Yes
Potency FDA Approved specifications for shelf life[2,3]	No	Yes
Osmolarity specification for ophthalmic solution[2,3]	No	Yes
Bacterial Endotoxins USP <85>[1]	?	Yes
GMP[2,3]	?	Yes

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1: USP general Chapter <771> OPHTHALMIC PRODUCTS—QUALITY TESTS USP40-NF35, second supplement, June 1, 2017; 2: Aldrich, Dale S., Bach, Cynthia M., Brown, William, Chambers, Wiley, Fleitman, Jeffrey, Hunt, Desmond, Marques, Margareth R. C., Mille, Yana, Mitra, Ashim K., Platzer, Stacey M., Tice, Tom, Tin, George W.; Ophthalmic Preparations USP STIMULI TO THE REVISION PROCESS Vol. 39(5) [Sept.–Oct. 2013]; 3: Missel PJ, Lang JC, Rodeheaver DP, Jani R, Chowhan MA, Chastain J, Dagnon T. Design and evaluation of ophthalmic pharmaceutical products. In: Florence, AT, Siepmann J. Modern Pharmaceutics—Applications and Advances. New York: Informa; 2009:101–189.

Bevacizumab Solution Injection Options

- **Off label** - IV Solutions Given via IV Administration
  Does Not Meet Requirements for FDA Approved Ophthalmic Dosage Form
  - Bascom Palmer (Dr. Rosenfeld) initially employed bevacizumab intravenously as a therapy for wet age-related macular degeneration and showed it was successful, however it was concluded intravitreal injection should be investigated[1]
- **Off label – Not FDA Approved** - Compounded Repackaged IV Solution for Intravitreal Injection
  Does Not Meet Requirements for FDA Approved Ophthalmic Dosage Form
  - The National Eye Institute conducted the landmark CATT clinical trial under an FDA IND with FDA oversight on a single manufacturing/repackaging process
  - Subsequent to the CATT Trial, many Compounding Pharmacies have supplied compounded repackaged AVASTIN with a long history of ocular safety issues, recalls, FDA Warning letters, with peer reviewed publications demonstrating a concerning lack of potency and other concerns[2,3]
- **Investigational Ophthalmic Solution** - Dosage Form
  FDA oversight under FDA IND
  - ONS-5010 bevacizumab-vikg an investigational ophthalmic solution has been investigated in NORSE ONE, NORSE TWO and NORSE THREE under an FDA IND and a new BLA is planned to be submitted in Q1/2022. Clinical trials and manufacturing has been conducted under an IND and FDA oversight

1: Moshfeghi AA, Rosenfeld PJ, Puliafito CA, et al. Systemic Bevacizumab (Avastin) for Neovascular Age-Related Macular Degeneration. Ophthalmology 2006;113:2002. 2: JAMA Ophthalmol. 2015 Jan;133(1):32-9. doi: 10.1001/jamaophthalmol.2014.3591; 3: 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

The Unmet Medical Need Due To Repackaged and Off-Label Use of Bevacizumab

Variability in Potency[1]

JAMA Ophthalmology

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

Safety and Sterility Adverse Events[2]

Warning Letter FDA

- 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

Syringe Adverse Events[3]

ASRS American Society of Retina Specialists

- 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

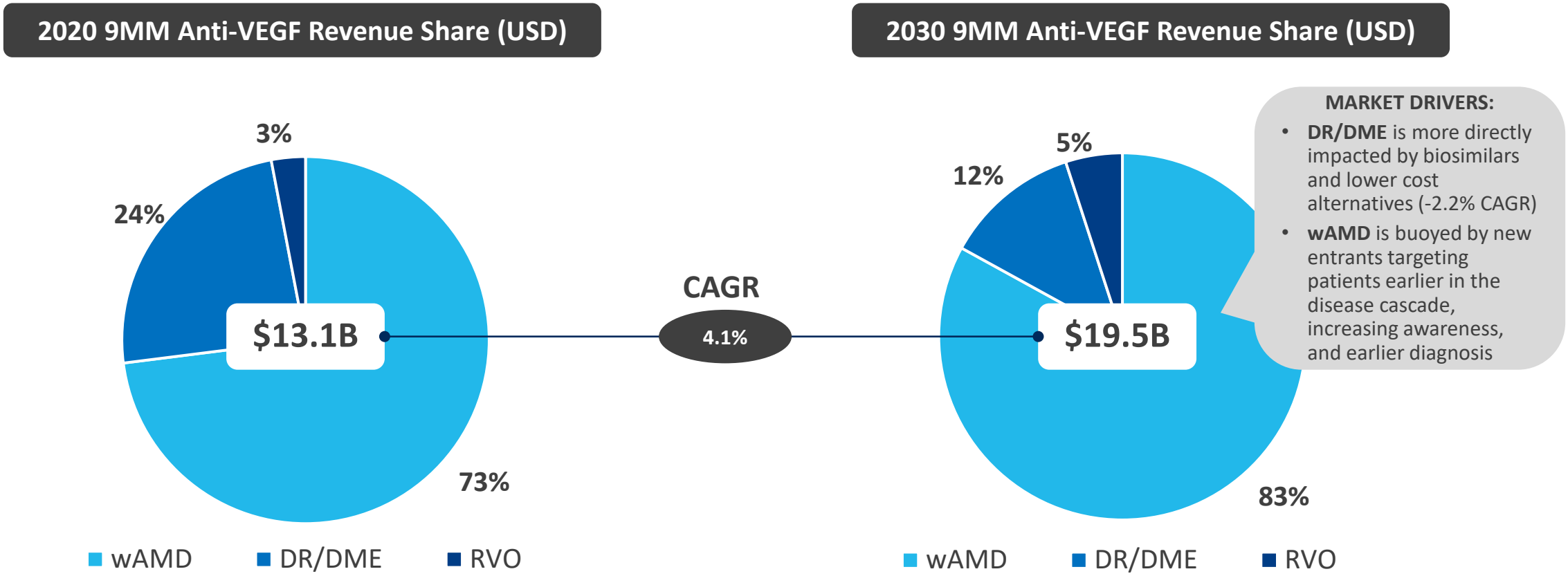
Not Held to FDA Ophthalmic Quality Standards When Repackaged

400 mg/16 mL, single-use vial;
100 mg/4 mL, single-use vial

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

Targeting Large and Growing Ophthalmic Markets

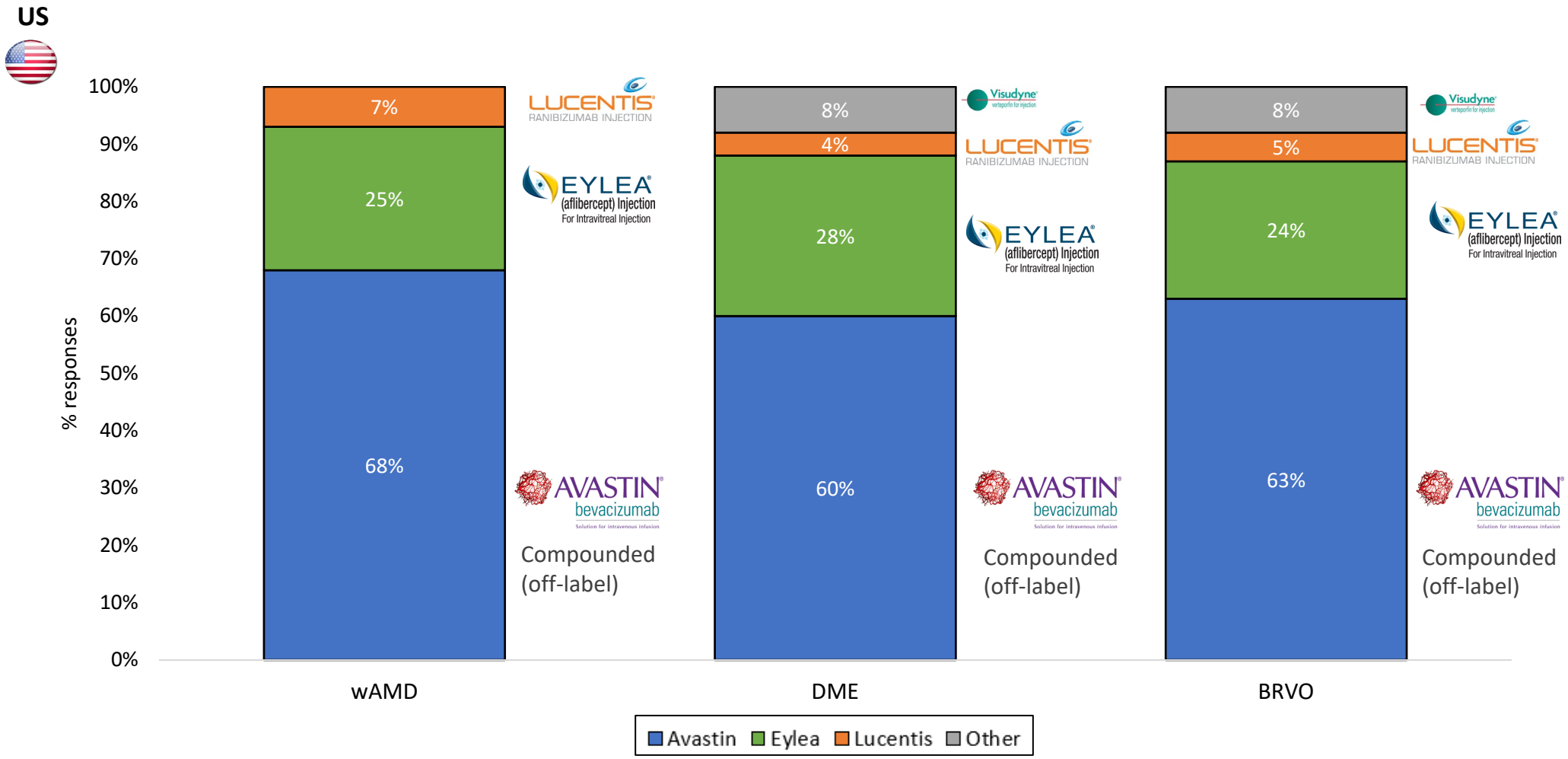
ONS-5010, if approved, will be a significant therapy in the retinal anti-VEGF market, currently estimated to be in excess of $13.1 billion worldwide



Sources: Guidehouse Triangulation of Global Data, Market Scope and Investor Forecasts (2020)
AMD = Age-Related Macular Degeneration; DME = Diabetic Macular Edema ; BRVO = Branch Retinal Vein Occlusion

New Patient Starts (US)

If Approved, ONS-5010 could have direct access to up to 60-68% of new patient starts



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

ONS-5010 Ophthalmic Bevacizumab Target Product Profile

ONS-5010 (bevacizumab-vikg)	
Patient Population	• Patients diagnosed with **wet AMD, DME, or BRVO**
Description	• Anti-VEGF **bevacizumab designed for ophthalmic indications** wet AMD, DME, and BRVO
Dosing and Administration	• Supplied either as **pre-filled ophthalmic syringe for intravitreal 1.25 mg injection** administered once monthly, **or as a glass vial**
Efficacy, Safety, and AEs	• Demonstrated efficacy and safety in NORSE TWO trial • Comparable to data from the National Eye Institute (NEI) Comparison of Age-Related Macular Degeneration Treatments Trials (CATT) Study as equivalent to LUCENTIS®

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Anti-VEGF - Anti–vascular endothelial growth factor therapy ; AMD – Age-related macular degeneration; DME – Diabetic macular edema; BRVO – Branch retinal vein occlusion; CATT – National Eye Institute, Comparison of Age-related Macular Degeneration Treatments Trials, 2011

ONS-5010 Ophthalmic Bevacizumab Potential Value Proposition

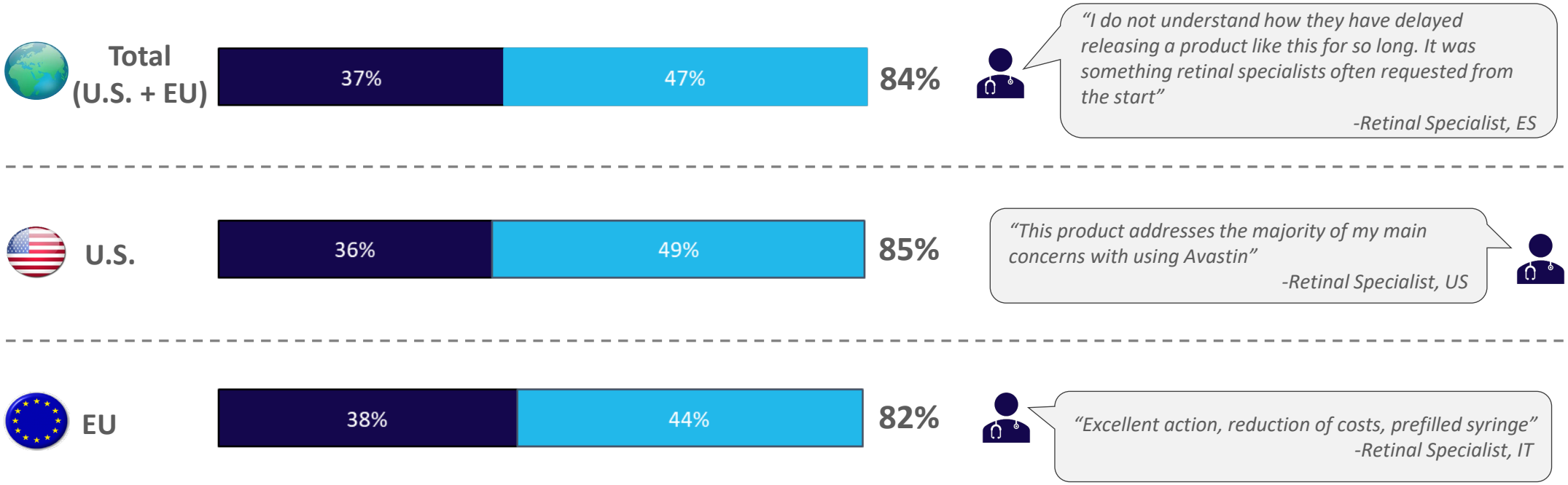
ONS-5010 (bevacizumab-vikg)

Potential Value Proposition

- Potential FDA approved bevacizumab for the treatment of wet AMD
- **Addresses compounding pharmacy quality control issues** causing potential AEs, product shortages, and liability risks associated with off-label repackaged IV Avastin®
  - Ensures cGMP quality and delivery system designed for retinal disorders
- Addresses issue of AAO requesting that CMS modify Avastin® reimbursement rates to **protect physicians from financial risk**
- Ability for **bilateral administration with malpractice insurance coverage**
- **Priced to allow a cost-effective FDA approved option for first-line**

Do Physicians Want an Ophthalmic Approved Bevacizumab?

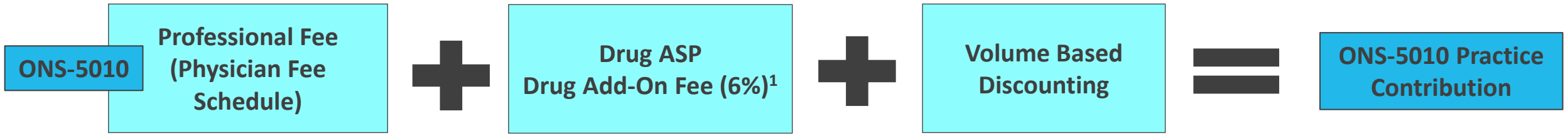
>80% of retinal specialists express interest/high interest in an FDA-approved ophthalmic bevacizumab to treat wet AMD, DME and BRVO



Source: Navigant Quantitative Survey (n=152), 2019, **Respondents who have interest or high interest in ONS-5010**
*Other survey options not shown were "neutral, not likely to use, and not interested at all"

Compelling and Predictable Physician Economics Compared to Unapproved Compounded Bevacizumab

Per Injection Revenue (unilateral)



- In contrast, ASRS has identified that compounded off-label bevacizumab is not adequately reimbursed at the national level
- Costs of compounding have continued to rise due to increased efforts to meet UPS 789 criteria. Physicians have shared that there is reduced margin for physicians choosing to compound bevacizumab due to these changes
- Additionally, several large compounding pharmacies have either moved away from compounding (AMEX) or have had to issue recalls and product safety bulletins
- **ONS-5010 can directly address this economic and quality dilemma for physicians and patients alike**

1. ASP+6% continues through sequestration

Manufacturing and Regulatory Progress Towards Commercialization

Manufacturing

Best-in-class cGMP manufacturing partners

Pre-Filled Syringes

Supply agreement for a best-in-class pre-filled ophthalmic syringe

Regulatory

Achieved clinical requirements agreed upon with the FDA

Commercial Planning Activities Underway

If ONS-5010 (bevacizumab-vikg) is FDA approved and has a cost-effective profile, Outlook Therapeutics expects ONS-5010 to be widely adopted by payors and clinicians worldwide and to become the first-line drug of choice for payor-mandated “step-edit” in the United States for retinal indications

Physician and Patient Outreach

Aligning Key Opinion Leaders

Payor Community Engagement

Company Summary

- **Positive Phase 3 results demonstrated with lead program, ONS-5010 (bevacizumab-vikg), for treatment of wet AMD**
  - **Preparing U.S. FDA BLA submission targeted for calendar Q1 2022**
    - **Potential for first FDA approved ophthalmic formulation of bevacizumab**
  - **Targeting $13.1 billion global ophthalmic anti-VEGF market[1]**
- **Management team with proven ophthalmic commercial launch expertise**

1. Guidehouse Triangulation of Global Data, Market Scope and Investor Forecasts (2020)

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Thank You!

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Appendix

AAO Addressing Compounding Pharmacy Concerns

AAO is monitoring Avastin shortages and pricing

Issues continue to be reported with compounded bevacizumab:

- Change in syringe type to comply with USP 789 standards for particulate matter in ophthalmic solutions (i.e. eliminating silicone oil droplets in insulin syringes)

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

- Continuity of source and quality
- Uniformity of product
- Supply chain integrity
- FDA approved delivery vehicle/syringe

AMERICAN ACADEMY OF OPHTHALMOLOGY®

Email from AAO dated May 30 , 2019

Academy Communication

The Facts About the Avastin Shortage

The Academy continues to seek new information on the ongoing Avastin shortages that are affecting the drug's supply nationwide. Today, we're sharing with you the latest information and a comprehensive document to explain this issue and actions the Academy is taking.

Avastin is a critically important treatment option for ophthalmology patients facing sight threatening diseases, including AMD, macular edema, neovascular glaucoma and others. It is the most commonly administered intravitreal drug worldwide and therefore any disruption to its availability has a major impact on patients.

The basics:

- A shortage of Avastin has affected access to the drug and prices.
- The shortage is related to a change in syringe type to comply with Food and Drug Administration guidance and with USP 789 standards for particulate matter in ophthalmic solutions.
- Suppliers are providing the Academy with updates on supplies and prices.
- The Academy has asked CMS to modify Avastin reimbursement rates to protect physicians from financial risk.

Get the latest details below on the impact of the shortage, and visit the AAO.org Avastin Shortages and Reimbursements page for our comprehensive report on this issue. We will update that page regularly with new information.