

**ANNEXON**  
biosciences

**STOP** THE **START**

of classical  
complement-driven  
diseases

**ARCHER Trial Results in Geographic Atrophy**

**ASRS 2023**

**July 31, 2023**



# Forward-Looking Statements and Disclaimers

This presentation contains “forward-looking” statements about Annexon, Inc. and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts, including statements regarding topline data from the ARCHER Phase 2 trial and post-hoc analyses, our clinical and preclinical programs, timing and commencement of future nonclinical studies and clinical trials and research and development programs, timing of clinical results, strategic plans for our business and product candidates, including additional indications which we may pursue, our financial position, runway and anticipated milestones, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “focus,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

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Comparisons to third-party studies are provided for illustrative purposes only. Differences exist between trial designs, study sites, subject populations and applicable products or candidates, and caution should be exercised when comparing outcomes across studies.

# Agenda: ARCHER Results at ASRS Conference Call

	TOPIC	SPEAKER
➤ 4:30 - 4:35 PM ET	Opening Remarks	<b>Douglas Love</b> Chief Executive Officer
➤ 4:35 - 4:40 PM	Anti-C1q: A Distinct Neuroprotective Mechanism	<b>Ted Yednock, Ph.D.</b> EVP & Chief Innovation Officer
➤ 4:40 - 4:45 PM	ARCHER Trial Overview & Demographics	<b>Donald S. Fong, M.D., M.P.H</b> VP, Head of Ophthalmology
➤ 4:45 - 5:05 PM	ARCHER Phase 2 Results of ANX007 for Geographic Atrophy	<b>Jeffrey S. Heier, M.D.</b> Ophthalmic Consultants of Boston and an investigator in ARCHER
➤ 5:05 - 5:30 PM	Closing Remarks and Q&A	<b>Douglas Love</b>

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**A bold mission to free the body,  
brain and eye from complement-  
mediated disease**



# Annexon Overview: Pursuing Our Mission & Significant Value

## PIONEERING CLASSICAL COMPLEMENT PLATFORM in Autoimmunity, Neurodegeneration & Ophthalmology

- ANNX stopping classical complement where it starts on diseased tissue to treat complement-mediated diseases
- Differentiated approach now clinically demonstrated – functional benefit in GBS, HD and GA
- Opportunity to impact millions of patients and drive significant value

Achieving  
Our Mission  
with Four  
Flagship  
Programs



Guillain-Barré  
Syndrome (GBS)



Huntington's  
Disease (HD)



Geographic  
Atrophy (GA)



Orally Administered  
Small Molecule

# Multiple Catalysts Expected in 2H 2023 into Mid-2024

2H2023

2024



GA - Regulatory feedback to determine next steps



GBS - Complete Ph3 enrollment



GBS - Pivotal data in 1H'24



LN - Phase 1b signal-finding data



ALS - Phase 2a signal-finding data



HD - Initiate Ph 2/3 in 2023 with funding for full program development



ANX1502

- Healthy volunteer SAD/MAD
- Initiate CAD POC trial



Autoimmune



Neurodegeneration



Ophthalmology



Orally Administered Small Molecule

# ANX007: A Novel Neuroprotective Agent Demonstrating Benefit in Vision in ARCHER Trial

- **C1q inhibition: distinct neuroprotective MOA**
- **Consistent demonstration of visual function benefits**
  - Highly statistically significant on visual acuity endpoint
  - Dose and time dependent
  - Consistent across multiple prespecified measures of BCVA (10, 15, 20 letter loss)
  - Benefit in foveal and non-foveal patients
  - Benefit in additional prespecified measures of visual function (LLVA, LLVD)
  - Benefit observed in fellow eye analysis
- **Lesion growth not significantly slowed through 12 months, but may increase w/longer treatment**
- **Generally well tolerated; no CNV increase in treated vs. sham; no reported cases of vasculitis**

**Planning for regulatory discussions and Phase 3**

# Anti-C1q Mechanism of Action

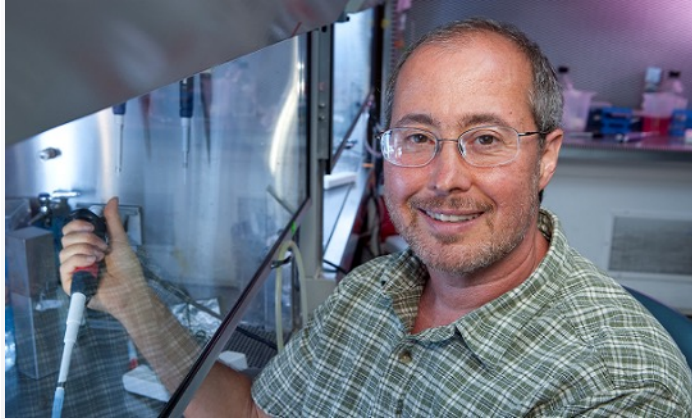
**Ted Yednock, Ph.D.**  
EVP & Chief Innovation Officer





# Classical Complement-Mediated Neurodegeneration Extensively Researched in Ophthalmic and Neurological Diseases

Functional clinical benefit previously demonstrated in Huntington's disease and ALS, and now in GA



**Ben Barres, M.D., Ph.D.**  
Discoverer of C1q Technology  
Scientific Co-Founder, Annexon

## Anti-C1q protective in several models, including:

- Geographic atrophy (photoreceptor damage)
- Glaucoma
- Retinal ischemia
- Huntington's disease
- Amyotrophic lateral sclerosis
- Alzheimer's disease
- Frontotemporal dementia
- Spinal muscular atrophy
- Traumatic brain injury

## ANTI-C1q PROTECTS AGAINST SYNAPSE LOSS AND NEURODEGENERATION

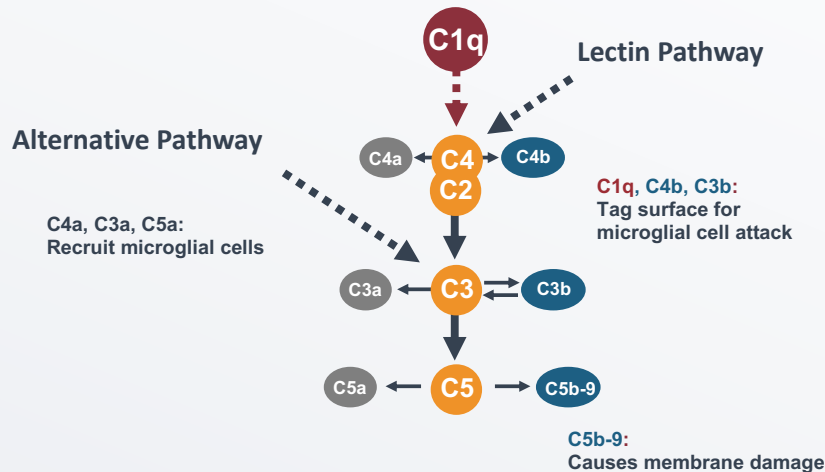
- Discovered by Annexon co-founder, Ben Barres, spawning an entire field and validated in multiple labs<sup>1</sup>
- Synapse loss correlates with functional decline<sup>2</sup>
- Synapse loss precedes neuronal loss<sup>3</sup>

<sup>1</sup>Stevens, et al., 2007 DOI 10.1016/j.cell.2007.10.036; Schafer et al., 2012 DOI 10.1016/j.neuron.2012.03.026; Hong, et al., 2016 doi: 10.1126/science.aad8373; Lui et al., 2016 doi.org/10.1016/j.cell.2016.04.001; <sup>2</sup>Davies et al., 1987 *J Neurological Sci* 78:151; Terry, et al., 1991 *Ann Neurol* 30:572; <sup>3</sup>Yoshiyama et al., 2007 DOI 10.1016/j.neuron.2007.01.010

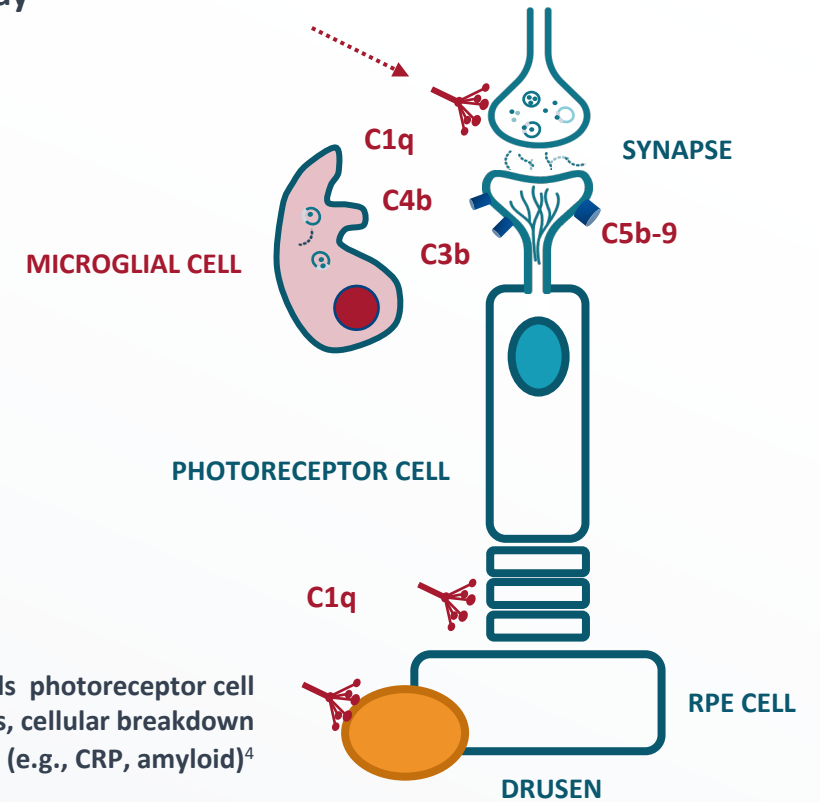
# Anti-C1q: A Distinct Neuroprotective Mechanism

C1q initiates classical complement cascade to drive photoreceptor synapse & cell loss and neuroinflammation

- C1q is a **key driver of neurodegeneration**<sup>1</sup>
- C1q anchors classical pathway activation on **photoreceptor cells to cause inflammation and loss**<sup>2</sup>
- **ANX007 inhibits C1q** and all damaging components of the classical pathway<sup>3</sup>



**C1q** binds stressed photoreceptor synapses and activates the classical pathway



In GA, **C1q** also binds photoreceptor cell outer segments, cellular breakdown products and drusen (e.g., CRP, amyloid)<sup>4</sup>

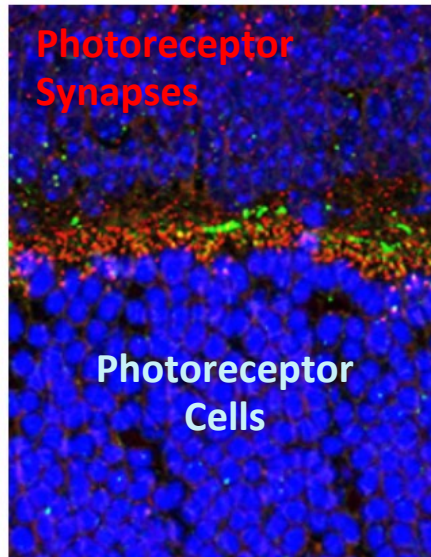
<sup>1</sup>Stevens, 2007, *Cell* **131**:1164; Howell, et al., 2011 *J Clin Invest.* **121**:1429; Schafer, et al., 2012 *Neuron* **74**: 691; Stephan et al., 2012 *Annu Rev Neurosci* **35**:369; Hong, et al., 2016 *Science.* **352**:712; Lui, et al., 2016 *Cell* **165**:921; Dejanovic, et al., 2018 *Neuron* **100**:1322; Vukojicic, et al., 2019, *Cell Rep.* **29**:3087; Williams, et al., 2016 *Mol Neurodegener* **11**:26; <sup>2</sup>Tassoni, et al., SFN 2022; Annexon data on file; Jiao, et al., 2018 *Mol Neurodegener* **13**:45; Katschke, 2018 *Sci Rep.* **8**:7348. <sup>3</sup>Lansita, et al., 2017 *International Journal of Toxicology*, **36**:449; <sup>4</sup>Yednock, et al., 2022 *Int J Retina Vitreous* **8**:79

# Anti-C1q Protected Photoreceptor Cells and Their Function in Models of Photoreceptor Damage

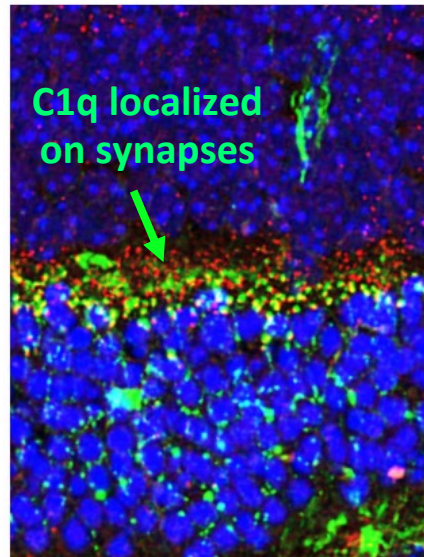


## C1q Deposition on Photoreceptor Cells and Synapses with Light-Induced Damage

CONTROL



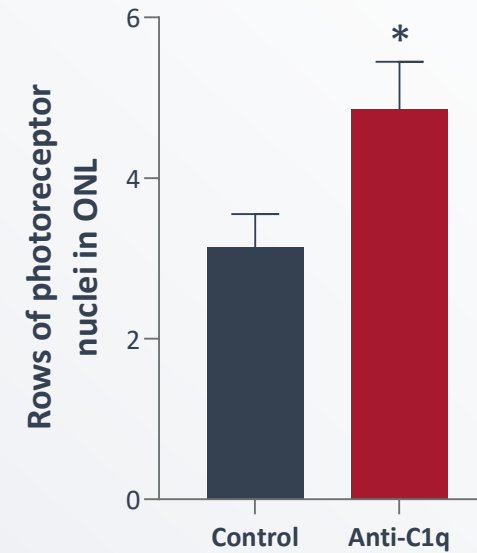
3 DAYS POST WHITE LIGHT DAMAGE



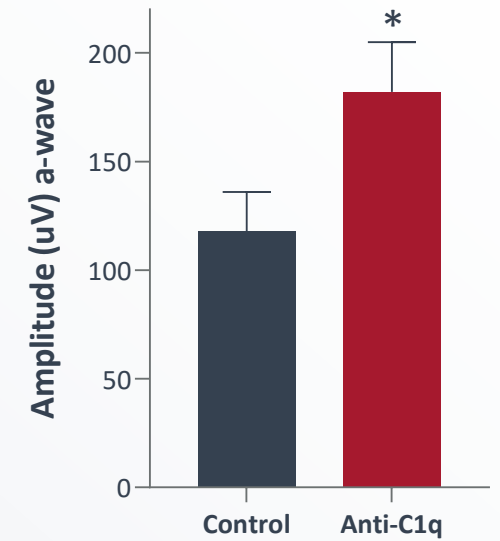
Annexon data on file

## Anti-C1q Protected Photoreceptors and Function

ANTI-C1Q PROTECTED PHOTORECEPTOR CELLS/RETINAL THICKNESS



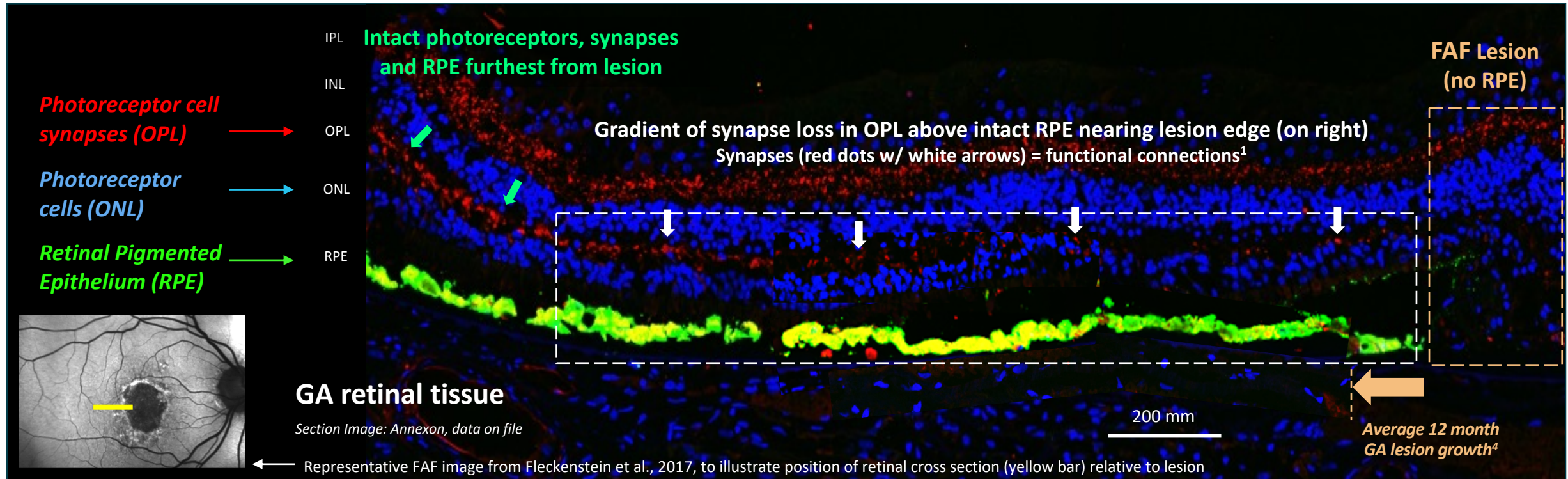
PROTECTED RETINAL FUNCTION



Jiao, et al., 2018 *Mol Neurodegener* 13(1):45

# Photoreceptor Cells, Synapses & Function Lost Prior to RPE in GA

- Photoreceptor cells and their synapses are lost over intact RPE (white box)
  - Decreasing gradient of **red-labeled synapses** (w/ white arrows) moving toward the lesion on right - loss of synapses is loss of function<sup>1</sup>
  - Also, decreasing gradient of **blue-labeled photoreceptor cells** toward lesion – photoreceptors are lost prior to RPE<sup>2</sup>
- FAF measures RPE loss/lesion growth, but not photoreceptor or synapse loss and correlates poorly w/ visual function<sup>3</sup>



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## ARCHER Trial Design

**Donald Fong, M.D., M.P.H.**  
VP, Head of Ophthalmology



# Geographic Atrophy (GA): Progressive and Life-altering Disease that Remains a Leading Cause of Blindness in Elderly People

- Advanced form of age-related macular degeneration (AMD)
- Chronic, progressive neurodegenerative disease of the eye with irreversible vision loss
- 1M people diagnosed in US; 5M people globally
- Diagnosis can be traumatic and impact the social and financial aspects of patients lives, including reading, daily activities and recognizing faces
- **No currently approved therapies have demonstrated preservation of visual function**
- **Urgent unmet need to protect against vision loss**



# ANX007: Differentiated Inhibitor of C1q and Classical Complement to Treat Geographic Atrophy

## ANX007

IVT administered antigen-binding fragment (Fab)

### KEY ATTRIBUTES

- ✓ **Design:** Modeled after established IVT administered Fab antibodies
- ✓ **Profile:** 50kD Fab antibody; low viscosity / non-pegylated; <10 pM potency formulated for intravitreal administration
- ✓ **Dosing:** 5 mg / 100 microliter. PK in patient aqueous humor supports monthly/every other month dosing
- ✓ **Specificity:** Full target engagement / inhibition of classical complement pathway observed; lectin and alternative pathway in place for immune and homeostatic functions<sup>1</sup>

<sup>1</sup>Sun, et al., 2023 Ophthal Sci 3(2):100290

# ARCHER: Phase 2 Trial of C1q Inhibitor ANX007 in GA Patients

Randomized, double-masked  
Included **foveal and non-foveal** lesions  
**Stratified for lesion location and lesion size**  
12 months (n=270)

**Sham monthly or every other month**  
(n=89)

**ANX007 5mg monthly (EM)**  
(n=89)

**ANX007 5mg every other month (EOM)**  
(n=92)

## PRIMARY BIOMARKER ENDPOINT

Change in GA lesion area as assessed by fundus autofluorescence at Month 12

## PRESPECIFIED SECONDARY FUNCTIONAL ENDPOINTS

Best Corrected Visual Acuity (BCVA)  
Low Luminance Visual Acuity (LLVA) & Deficit (LLVD)

Off-treatment  
(6 months)

**END OF STUDY**  
Month 18



# Patient Demographics and Study Eye Characteristics Generally Well-Balanced Across Groups

CHARACTERISTIC	SHAM POOLED (N=89)	ANX007 EM (N=89)	ANX007 EOM (N=92)
Age, mean (SD)	79.8 (7.49)	79.7 (8.64)	80.5 (8.53)
Female, n (%)	59 (66.3%)	47 (52.8%)	60 (65.2%)
Caucasian, n (%)	87 (97.8%)	87 (97.8%)	89 (96.7%)
<b>Mean BCVA, mean (SD)</b>	<b>58.5 (16.2)</b>	<b>58.8 (17.2)</b>	<b>58.3 (15.0)</b>
Foveal Lesion	49.4%	57.3%	53.3%
GA Lesion Size (mm <sup>2</sup> ), mean (SD)	7.28 (3.99)	7.28 (3.96)	7.53 (4.10)
GA Lesion < 7.5 mm <sup>2</sup>	61.8%	58.4%	57.6%
Fellow Eye CNV	22.5%	24.7%	17.4%
Multifocality, n (%)	65 (73.0%)	61 (68.5%)	67 (72.8%)

# Discontinuations Consistent with Previous GA Studies

	SHAM (N=89)	EM (N=89)	EOM (N=92)
<b>Discontinued treatment</b>	<b>10 (11.2%)</b>	<b>13 (14.6%)</b>	<b>11 (12.0%)</b>
Withdrawal by subject			
Unrelated health issues	2	1	2
Moved / travel / time	1	2	2
Personal reasons / no reason given	2	3	2
Other	1	2	---
Death	2	2	3
Lost to follow-up	1	2	2
Physician decision	1	1	---

# BCVA: Widely Accepted Functional Endpoint of Visual Acuity

BCVA 15 letter change or Mean BCVA change used in sham-controlled pivotal trials

## BEST CORRECTED VISUAL ACUITY (BCVA)

### 15 Letter Loss

20/60 to 20/120 vision



PRODUCT	PRIMARY ENDPOINT MEASURE
<b>Wet AMD</b>	
Lucentis	Trial 1 & 2: BCVA $\geq$ 15 letter Trial 3 & 4: mean BCVA change
Eylea	BCVA $\geq$ 15 letter
Vabysma	Mean BCVA change
<b>DME</b>	
Lucentis	BCVA $\geq$ 15 letter
Eylea	Mean BCVA change
Vabysma	Mean BCVA change
Iluvien	BCVA $\geq$ 15 letter
<b>Retinal Vascular Occlusion (BRVO/CRVO)</b>	
Lucentis	BCVA $\geq$ 15 letter
Eylea	BCVA $\geq$ 15 letter
Ozurdex	BCVA $\geq$ 15 letter

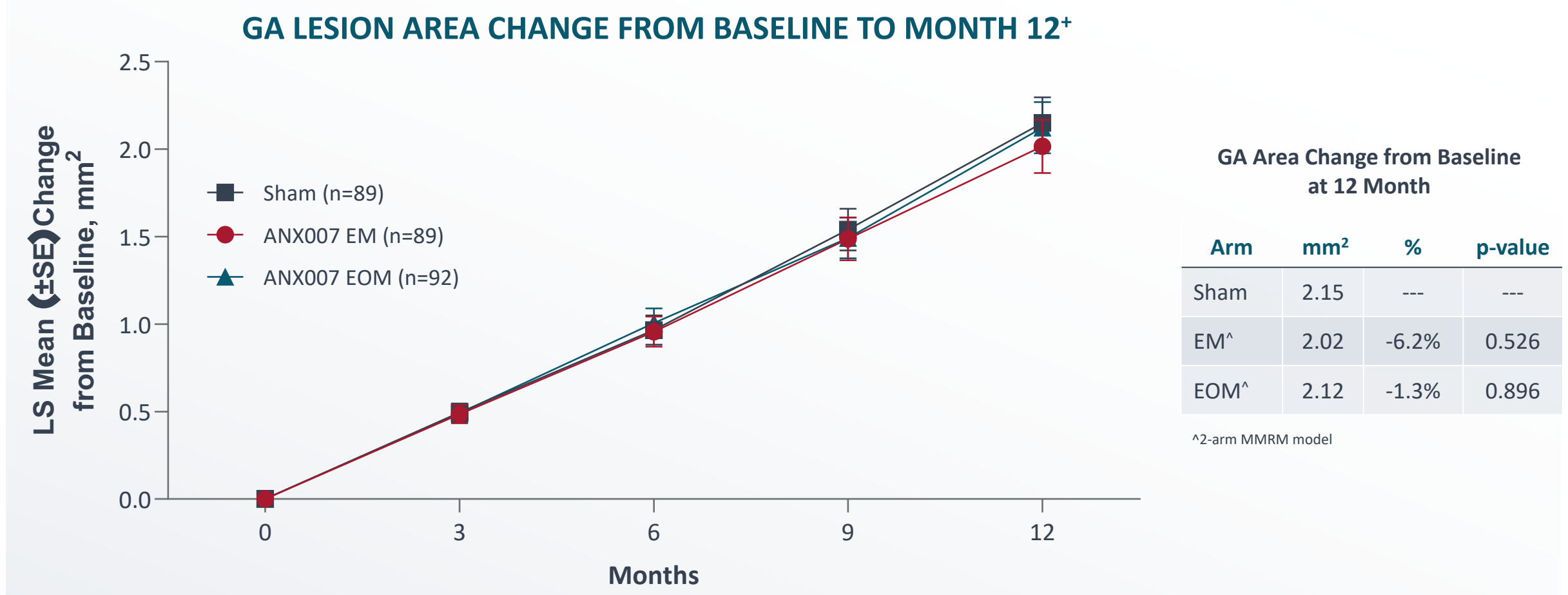
## ARCHER Trial Results

**Jeffrey S. Heier, M.D.**

Director of the Retina Service and Retina Research, Ophthalmic Consultants of Boston, and an investigator in ARCHER



# ANX007 Did Not Significantly Reduce Lesion Area, a Surrogate Biomarker of Functional Change in GA



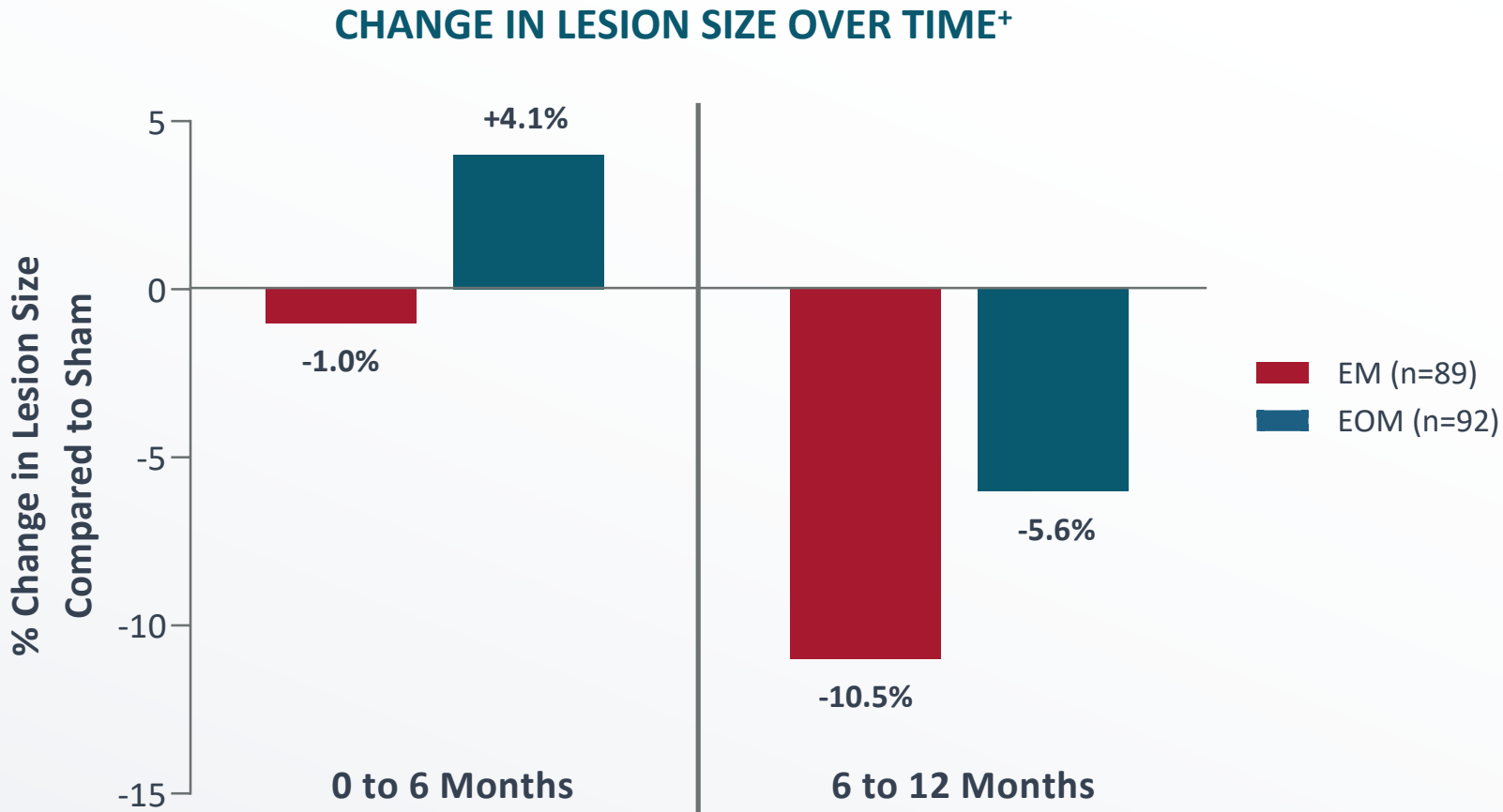
**GA Area Change from Baseline at 12 Month**

Arm	mm <sup>2</sup>	%	p-value
Sham	2.15	---	---
EM <sup>^</sup>	2.02	-6.2%	0.526
EOM <sup>^</sup>	2.12	-1.3%	0.896

<sup>^</sup>2-arm MMRM model

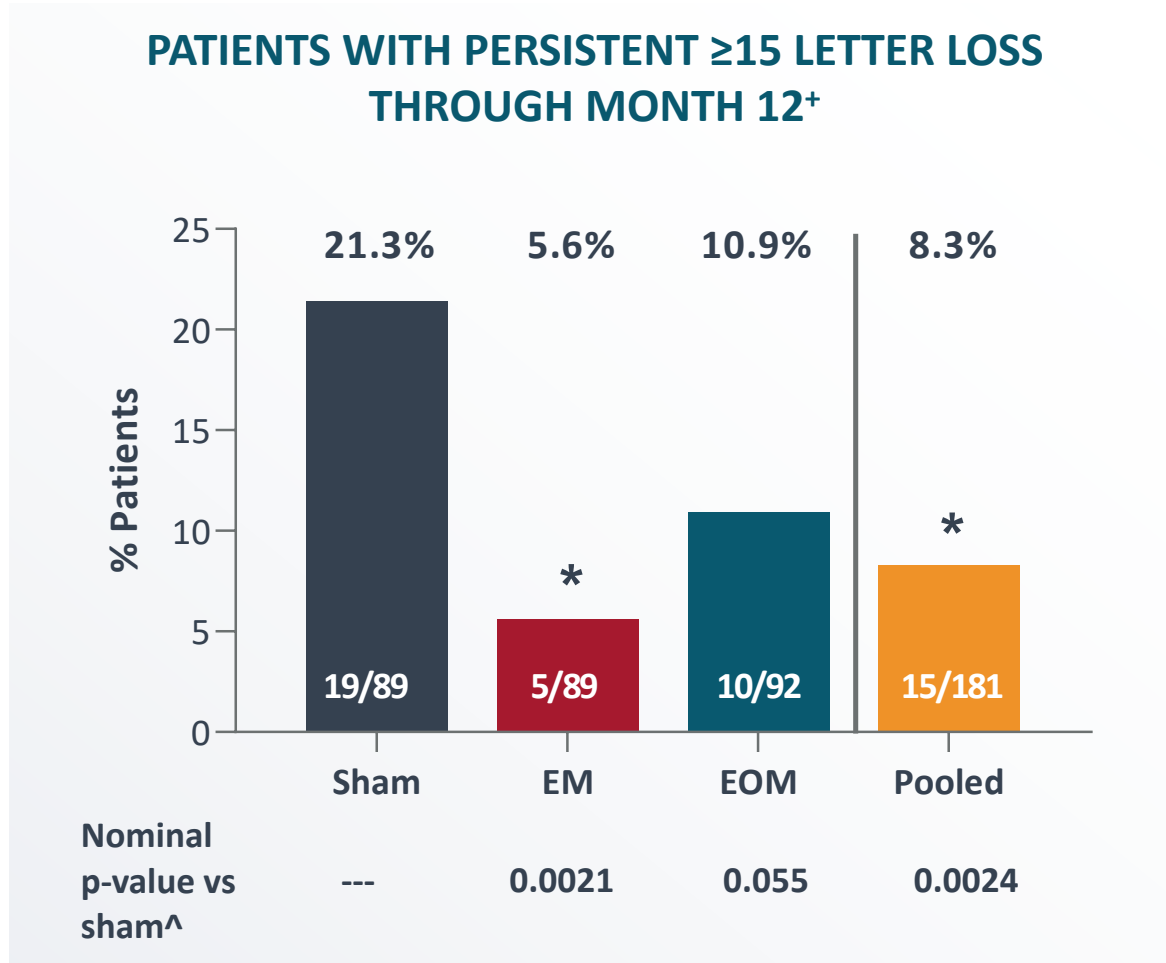
\*The least-square (LS) mean, its standard error (SE), and p-value are based on a mixed-effect model for repeated measures (MMRM) adjusting for baseline lesion location, lesion focality, baseline GA lesion, and the baseline GA lesion by visit interaction.

# ANX007 Effect on Lesion Size May Increase with Longer Treatment



<sup>†</sup>The least-square (LS) mean and its standard error (SE) are based on a mixed-effect model for repeated measures (MMRM) adjusting for baseline lesion location, lesion focality, baseline GA lesion, and the baseline GA lesion by visit interaction.

# Prespecified Secondary Endpoint (BCVA): ANX007 Demonstrated Significant, Dose-Dependent Protection From Vision Loss



- Dose-dependent response
- 15 letter loss clinically meaningful
- Widely accepted endpoint

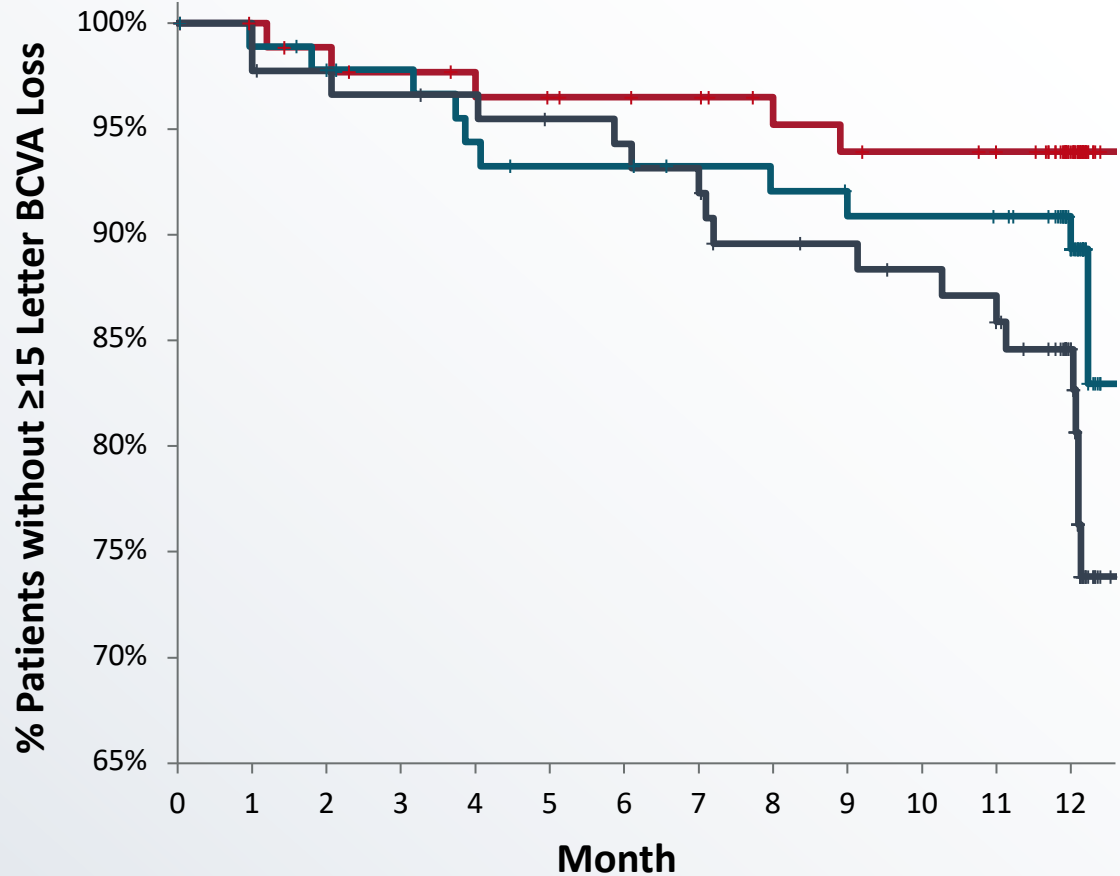
<sup>\*</sup>Persistent for two consecutive visits through month 12 or at last visit

<sup>^</sup>Nominal p-value from a Chi-square test in ITT population

\* Nominal  $P < 0.05$

# Significant, Time-Dependent Protection From $\geq 15$ Letter Vision Loss with ANX007 Monthly Treatment

$\geq 15$  LETTER BCVA LOSS AT 2 CONSECUTIVE VISITS THROUGH MONTH 12 OR LAST VISIT



**EM (n=89)**

**72% Risk Reduction ANX007 EM**

HR (CI) = 0.28 (0.11 to 0.76)  
p = 0.006

**EOM (n=92)**

**48% Risk Reduction ANX007 EOM**

HR (CI) = 0.52 (0.24 to 1.13)  
p = 0.064

**Sham (n=89)**

**Sensitivity analysis confirmed treatment effect:**

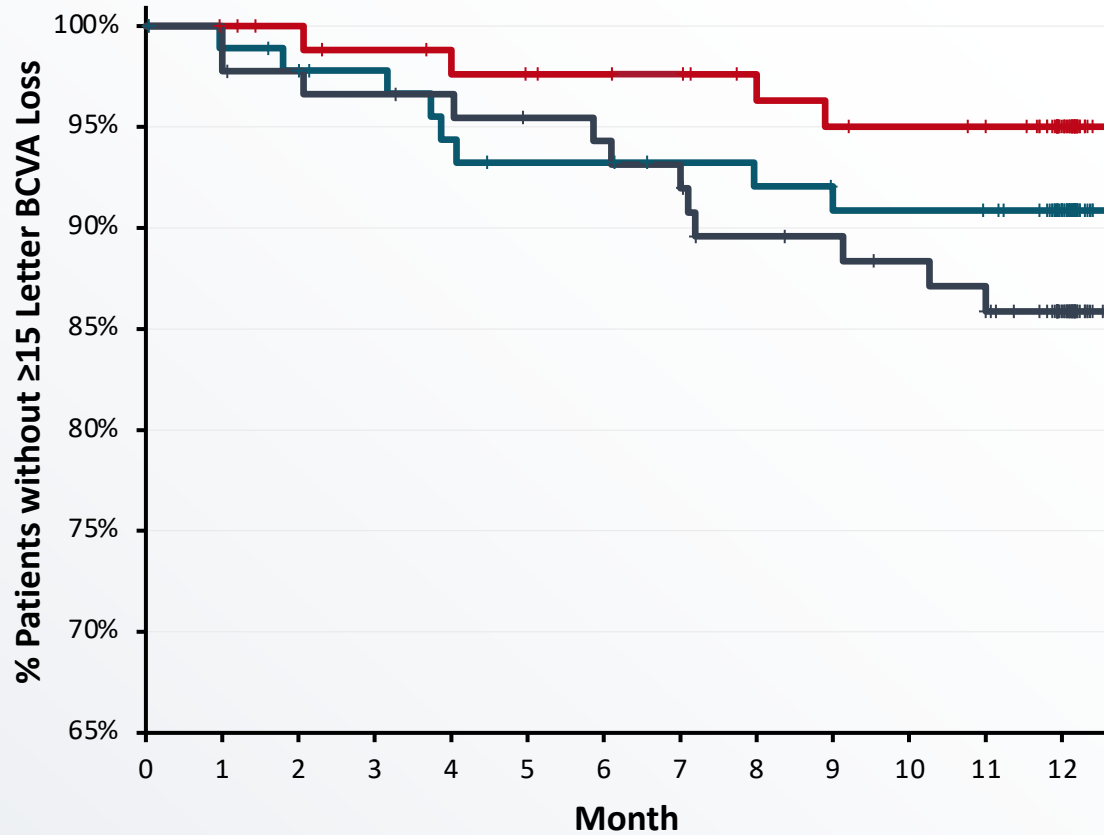
Significant 66% reduction in risk in EM group when excluding patients with vision loss only at month 12



# Significant, Time Dependent Risk Reduction for BCVA $\geq 15$ Letter Loss Maintained for EM Group in More Sensitive Analysis

NEW  
ANALYSIS

**$\geq 15$  LETTER BCVA LOSS AT 2 CONSECUTIVE VISITS THROUGH MONTH 12**



**EM (n=89)**

**66% Risk Reduction ANX007 EM**

HR (CI) = 0.34 (0.11 to 1.05); p = 0.047

**EOM (n=92)**

**35% Risk Reduction ANX007 EOM**

HR (CI) = 0.65 (0.27 to 1.59); p = 0.297

**Sham (n=89)**

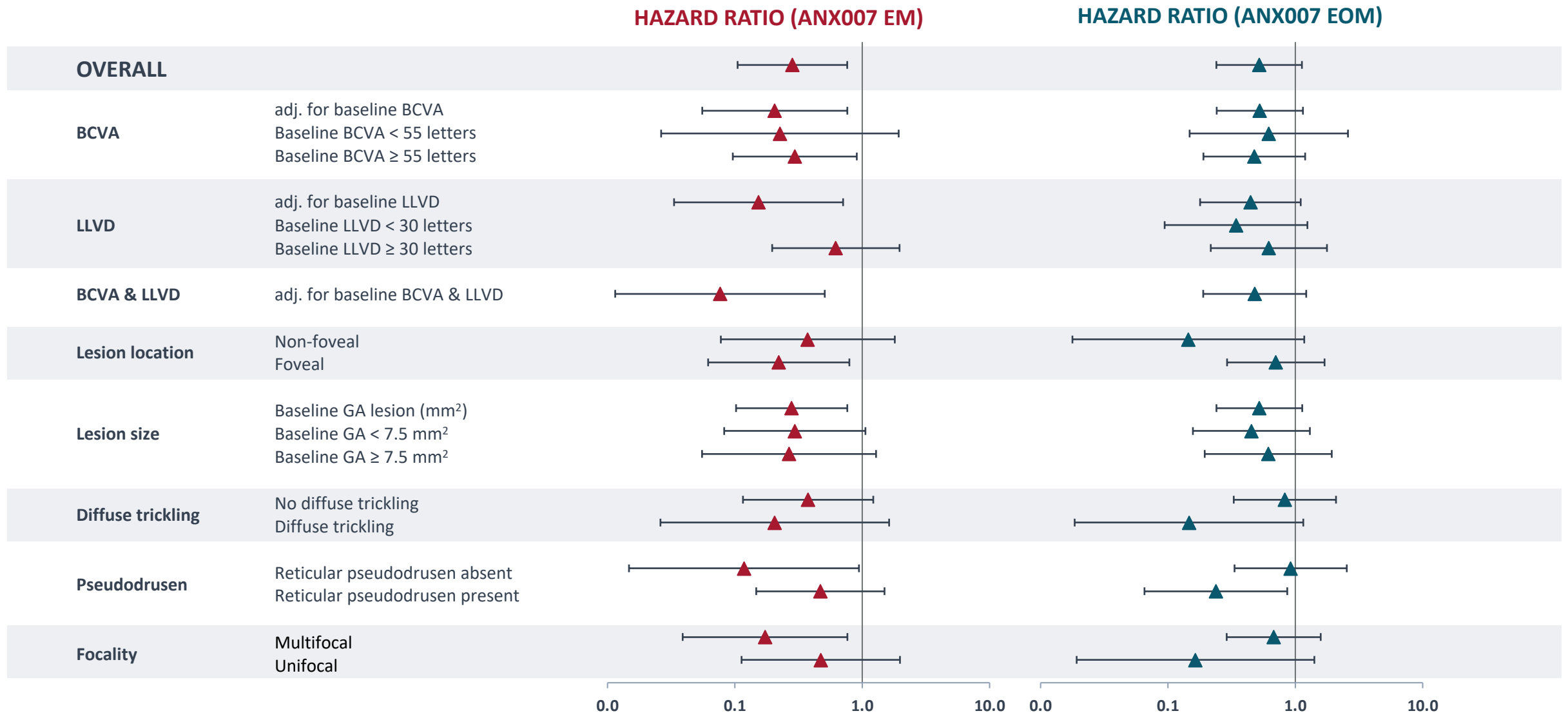
**Loss of  $\geq 15$  Letter BCVA in sham consistent with lampalizumab trials<sup>1</sup>**

HR, hazard ratio.  
Nominal log-rank test (versus Sham) p-values are presented

<sup>1</sup>Chakravarthy U et al. Visual Functional Loss in Geographic Atrophy (GA): Learnings from Lampalizumab Trial Data. Macula Society 2023 Annual Meeting, Feb 2023. Miami FL

# ANX007 Protection from Vision Loss Consistent Across Baseline Characteristics

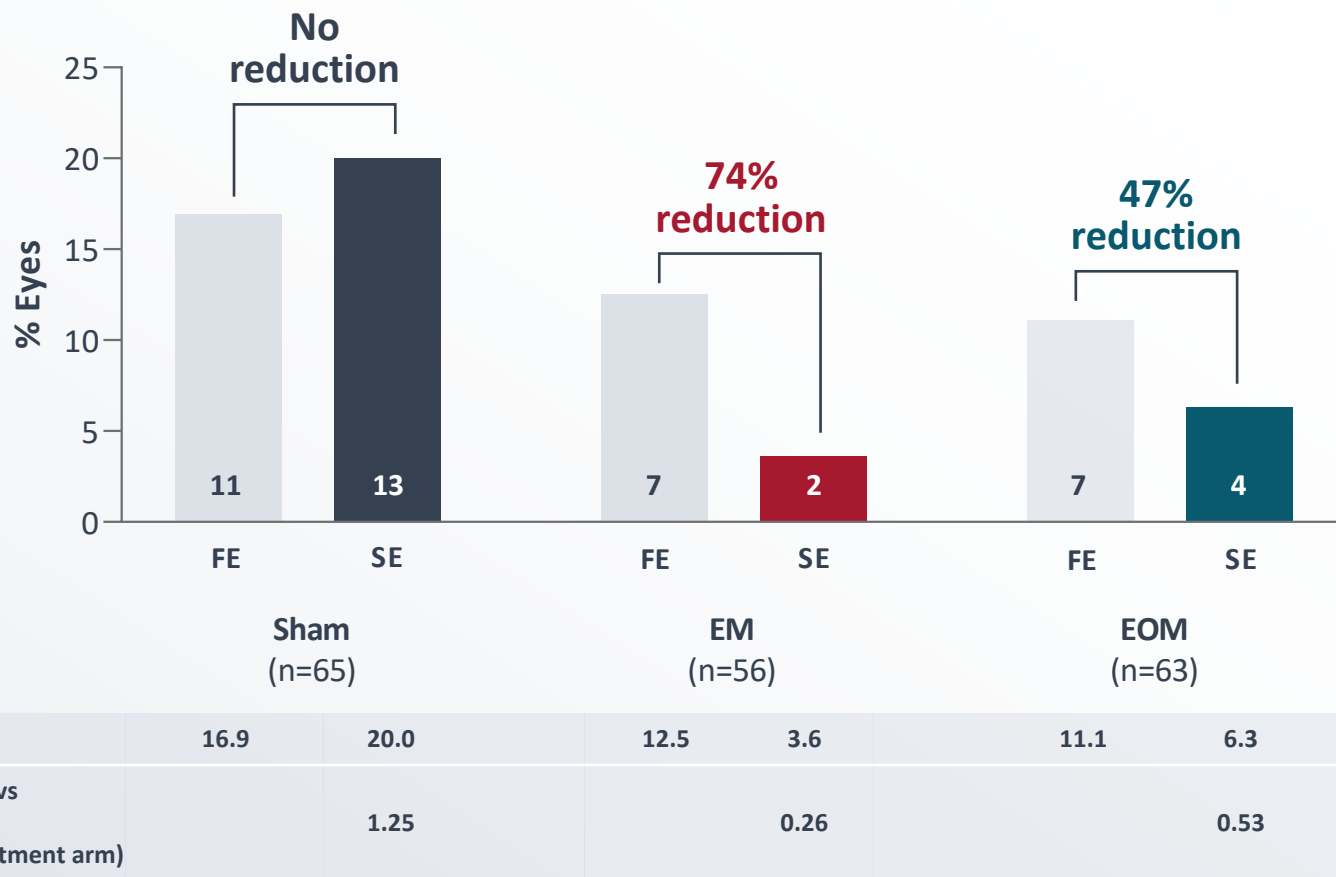
NEW ANALYSIS



\*persistent for two consecutive visits through month 12 or at last visit; Hazard ratios are from Cox regressions accounting for event time and censorship  
 NOTE: Hazard ratio not estimated for ANX007 EM vs Sham with baseline LLVD < 30 due to zero (0) event in ANX007 EM group for the subgroup.

# Protection From Vision Loss Supported by Fellow Eye Analysis

EYES WITH ≥15 LETTER BCVA LOSS AT MONTH 12 IN ALL PATIENTS WITH BILATERAL GA



- Sham: No reduction in BCVA vision loss study vs. fellow eye
- Dose dependent protection from vision loss in ANX007 treated study eyes relative to fellow eyes
  - EM: 74% reduction in 15 letter loss
  - EOM: 47% reduction in 15 letter loss

BCVA, best-corrected visual acuity; CI, confidence interval; OR, odds ratio; EM, every month; EOM, every other month; Pooled: EM+EOM; FE, fellow eye; SE, study eye  
All patients with bilateral GA were included due to small sample size

# Consistent Protection from Vision Loss with BCVA $\geq 10$ and $\geq 20$ Letter Assessments

NEW ANALYSIS

## Persistent BCVA Vision Loss Through Month 12+



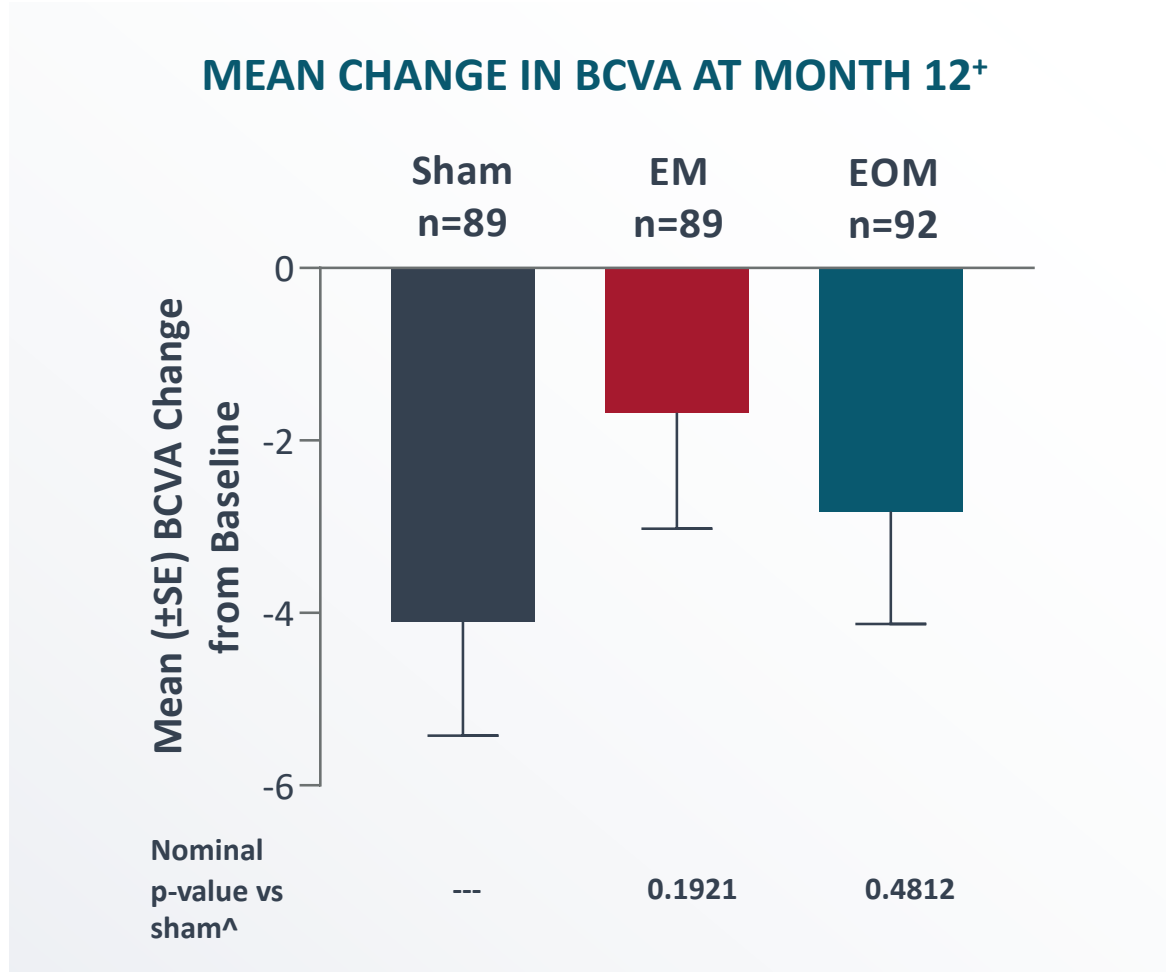
<sup>^</sup>Persistent for two consecutive visits through month 12 or at last visit

<sup>^</sup>Nominal p-value from a Chi-square test in ITT population

\* P < 0.05

# Mean Change in BCVA at Month 12 Further Supports Consistent Protection From Vision Loss with ANX007 Treatment

NEW  
ANALYSIS



- Trend for dose-dependent response in ANX007 treated groups
- BCVA loss in sham through 12 months consistent with previous GA trials<sup>1,2,3,4</sup>

<sup>+</sup>Mean, standard error (SE), and p-value based on MMRM adjusting for baseline lesion location, lesion focality, baseline GA lesion, and the baseline GA lesion by visit interaction.

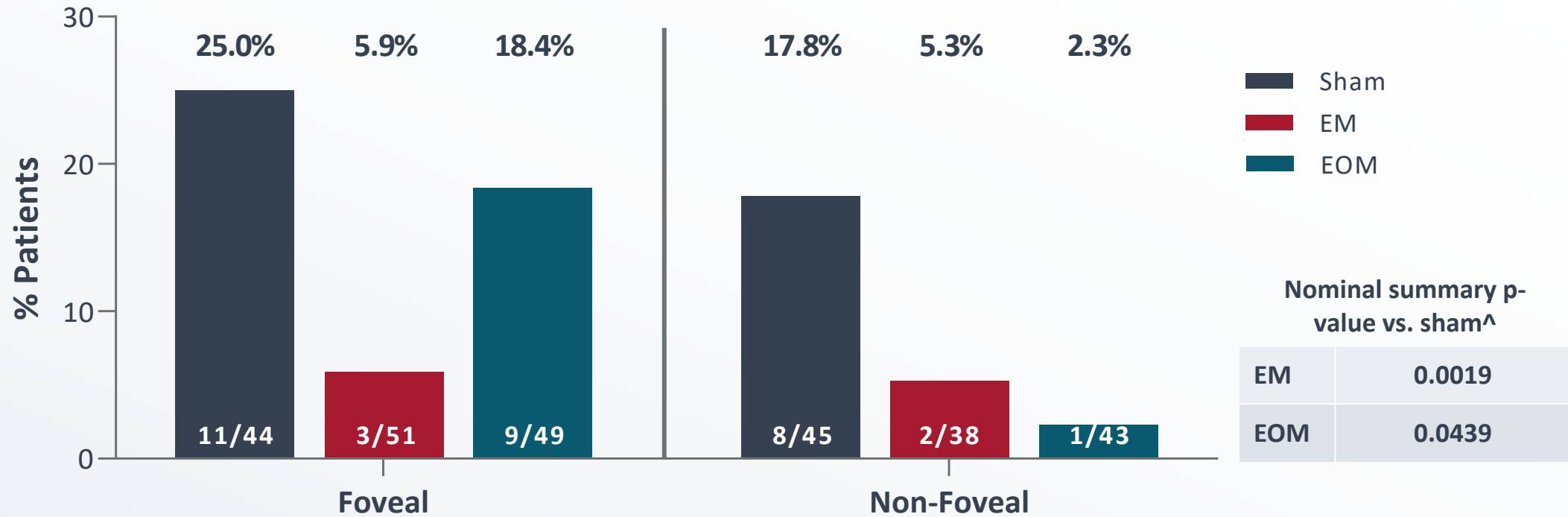
<sup>^</sup>Nominal p-value from MMRM adjusting for baseline lesion location, lesion focality, baseline GA lesion, and the baseline GA lesion by visit interaction in ITT population

<sup>1</sup>Liao et al (2020) *Ophthalmology* 127: 186-195; <sup>2</sup>Holtz et al (2018) *JAMA Ophthalmology* 136:666-677;

<sup>3</sup>Jaffee et al (2021) *Ophthalmology* 128:576-586; <sup>4</sup>Heier et al, *Retina Society* 2022

# ANX007 BCVA Subgroup Analysis: Protection from Vision Loss in Foveal and Non-Foveal Patients

PATIENTS WITH PERSISTENT  $\geq 15$  LETTER LOSS THROUGH MONTH 12<sup>+</sup>



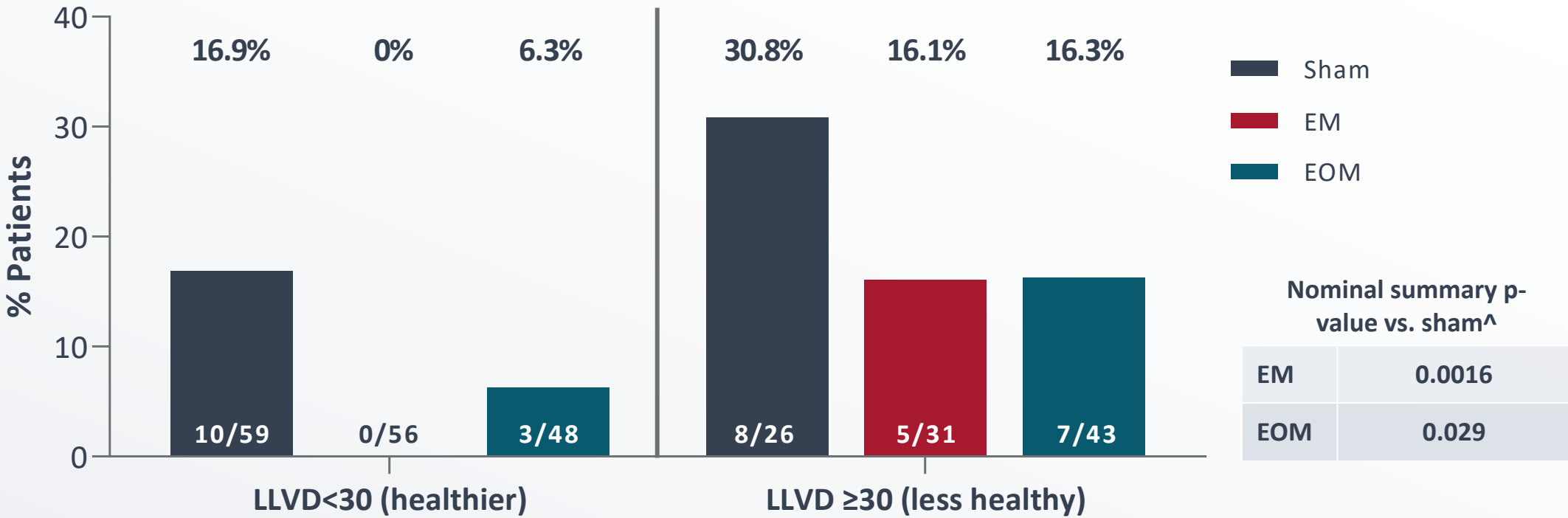
<sup>+</sup>Persistent for two consecutive visits at any time through month 12 or at last visit

<sup>^</sup>Nominal p-value from a Cochran Mantel-Haenszel test (General Association) in ITT population

# BCVA by Retinal Health Status: ANX007 Protected From Vision Loss Across Patient Subgroups – Healthier and Less Healthy Eyes

Potential to treat early in disease

PATIENTS WITH ≥15 LETTER VISION LOSS THROUGH MONTH 12+



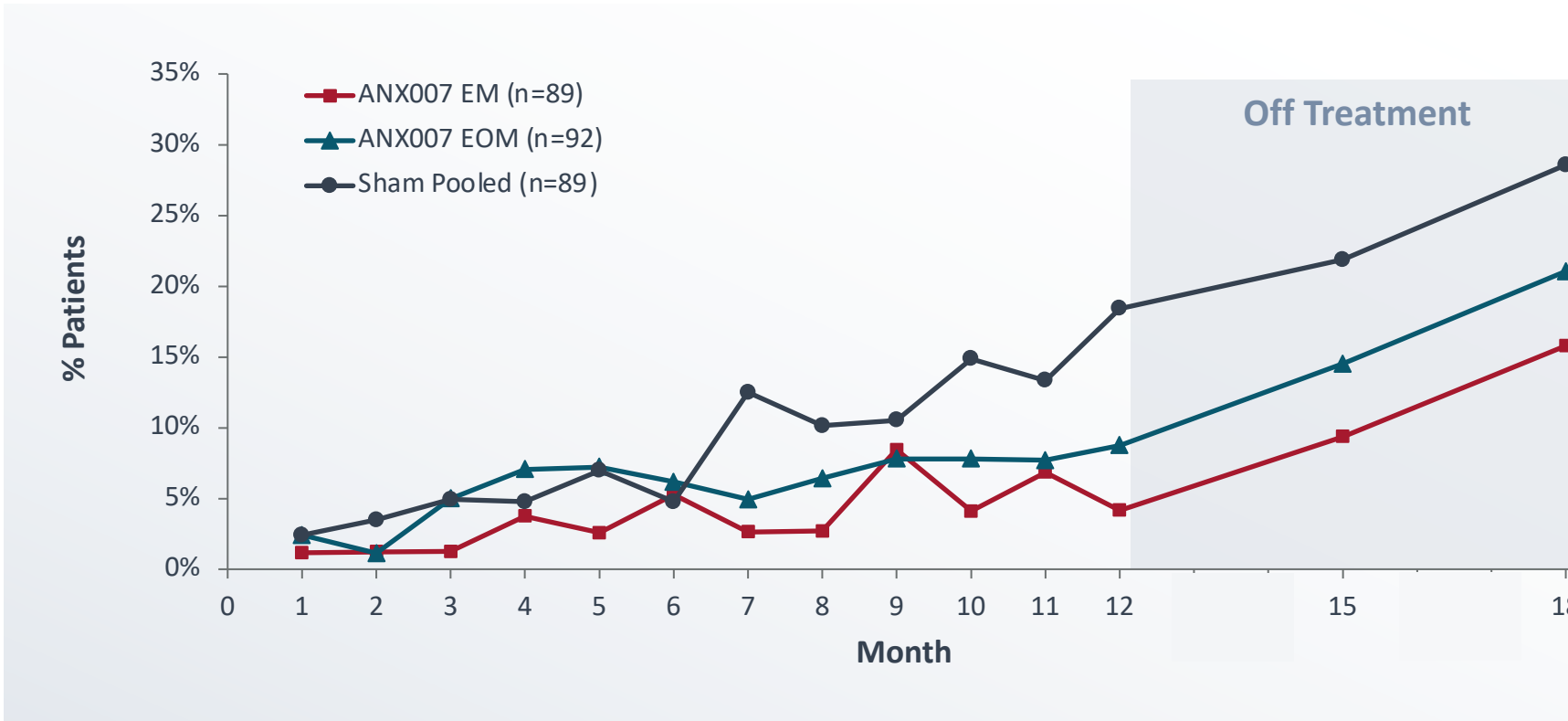
\*Persistent for two consecutive visits at any time through month 12 or at last visit  
<sup>^</sup>Nominal, from a Cochran-Mantel-Haenszel test (General Association) in ITT population

# Preliminary: BCVA $\geq 15$ Letter Loss Accelerated After ANX007 Discontinuation, Supporting Significant On-Treatment Effect

NEW ANALYSIS

BCVA  $\geq 15$  letter loss at each time point; completers to date for month 15 and 18 visits

% PATIENTS WITH  $\geq 15$  LETTER LOSS FROM BASELINE IN BCVA



RATE OF INCREASE IN BCVA 15-LETTER LOSS EVENTS (Monthly, %)

	On-treatment	Off-treatment
Sham	1.36	1.70
EM	0.54	1.94
EOM	0.84	2.05

ELIGIBLE PATIENTS COMPLETING OFF-TREATMENT FOLLOW UP

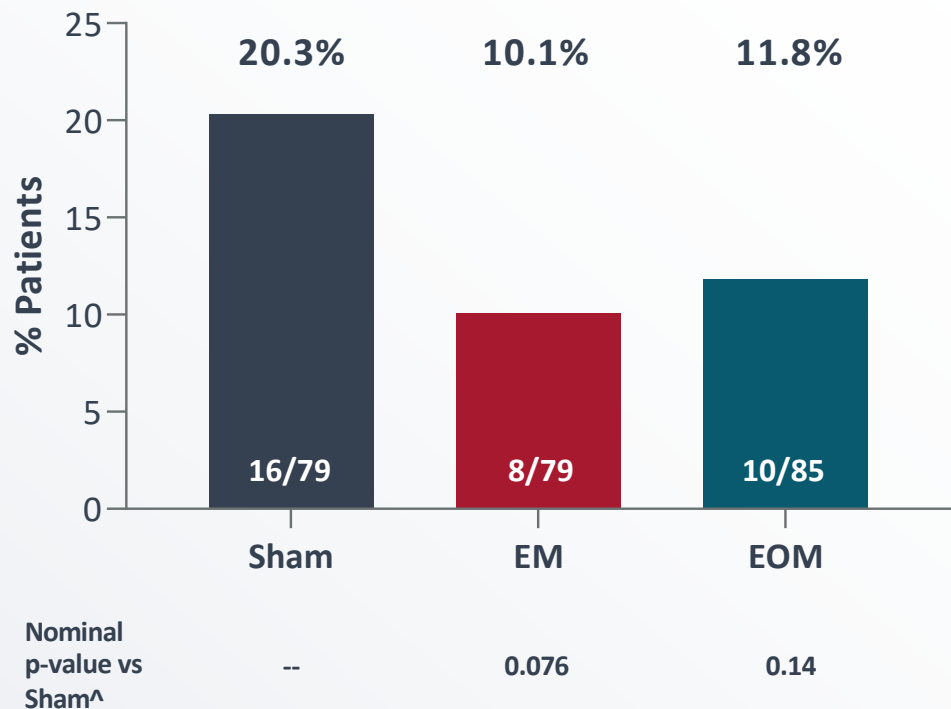
15 months: ~83%  
18 months: ~49%

BCVA, best-corrected visual acuity; CI, confidence interval; EM, every month; EOM, every other month  
BCVA assessments conducted monthly during treatment period and quarterly during off-treatment period in all study arms

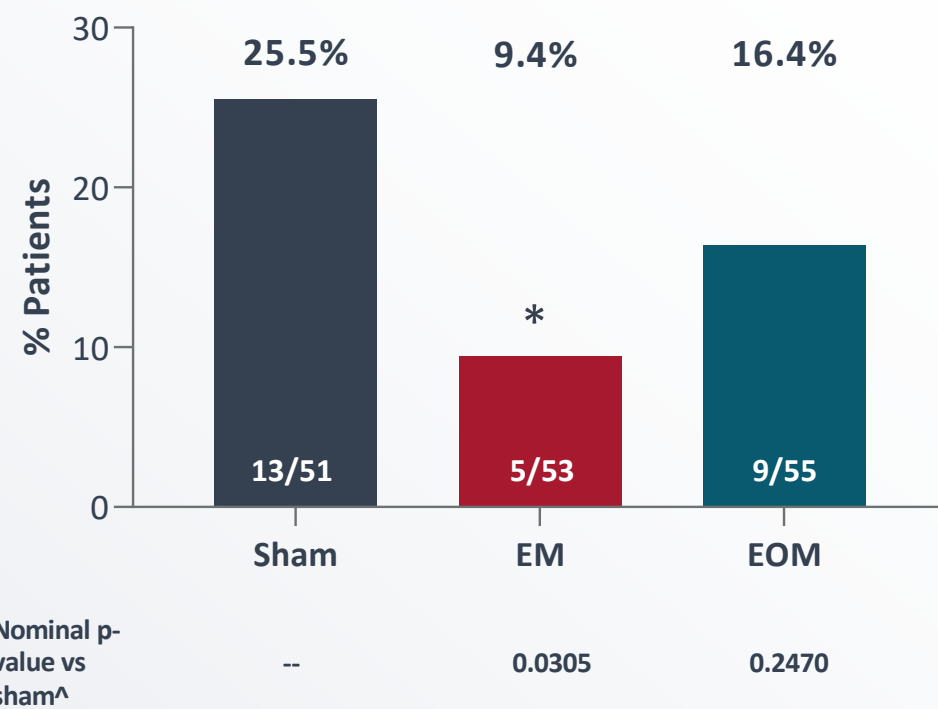


# Prespecified Secondary Analyses: ANX007 Provided Consistent Protection from Vision Loss on Additional Measures—LLVA & LLVD

## LLVA ≥15 LETTER LOSS THROUGH MONTH 12<sup>+</sup>



## LLVD ≥15 LETTER WORSENING THROUGH MONTH 12<sup>+</sup>



<sup>+</sup>Patients with at least one post baseline LLVA measurement

<sup>^</sup>Nominal p-value from a Chi-square test

<sup>+</sup>in subjects with BCVA ≥55

<sup>^</sup>Nominal p-value from a Chi Square test

\*p<0.05

# ANX007 Generally Well-Tolerated

ADVERSE EVENTS OF SPECIAL INTEREST n (%)	SHAM (N=89)	ANX007 EM (N=89)	ANX007 EOM (N=92)
Choroidal Neovascularization	3 (3.4%)	4 (4.5%)	4 (4.3%)
Endophthalmitis	0	1 (1.1%)	2 (2.2%)
Retinal Vascular Occlusion	0	0	1 <sup>^</sup> (1.1%)
Retinal Vasculitis	0	0	0
Intraocular Inflammation <sup>+</sup>	0	2 (2.2%)	1 (1.1%)
Ischemic Optic Neuropathy <sup>+</sup>	0	0	0

## INTRAOCULAR INFLAMMATION DETAILS\* n

### Iritis – 1

Resolved with topical steroids in 2 days  
No Vasculitis

### Vitritis – 1

Resolved with topical steroids in 9 days  
No Vasculitis

### Vitreous Debris – 1

KP on endothelium, prior treatment with topical steroids  
No Vasculitis

\*Event Verbatim term listed

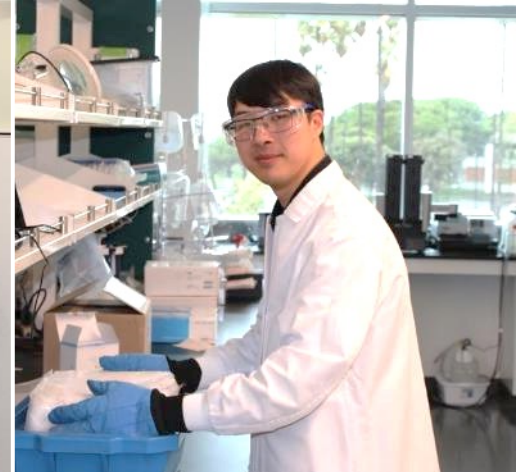
<sup>^</sup>Isolated cilioretinal artery occlusion; no vasculitis confirmed by DSMC and reading center

<sup>+</sup>Not AESI, included because of current interest

# ANX007: A Novel Neuroprotective Agent Demonstrating Benefit in Vision in ARCHER Trial

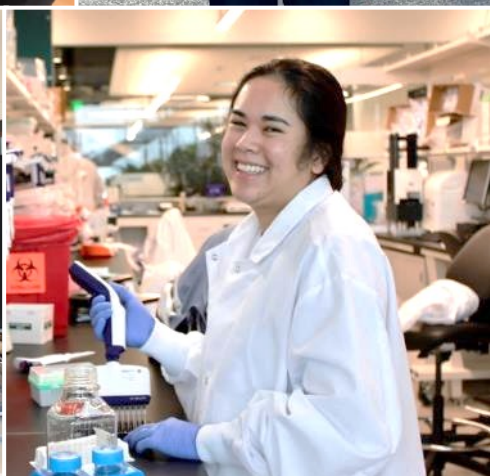
- **C1q inhibition: distinct neuroprotective MOA**
- **Consistent demonstration of visual function benefits**
  - Highly statistically significant on visual acuity endpoint
  - Dose and time dependent
  - Consistent across multiple prespecified measures of BCVA (10, 15, 20 letter loss)
  - Benefit in foveal and non-foveal patients
  - Benefit in additional prespecified measures of visual function (LLVA, LLVD)
  - Benefit observed in fellow eye analysis
- **Lesion growth not significantly slowed through 12 months, but may increase w/longer treatment**
- **Generally well tolerated; no CNV increase in treated vs. sham; no reported cases of vasculitis**

**Planning for regulatory discussions and Phase 3**



To the patients, families, caregivers, physicians and medical teams who participated in our trial, we are eternally grateful for your support and contributions!

To our employees, collaborators and advisors, thank you for your Warrior Spirit and All For One commitment!



# ANNEXON

biosciences

## Q&A

