Preservation of Vision by ANX007 in Geographic Atrophy: Clinical Results from the Phase 2 ARCHER Trial

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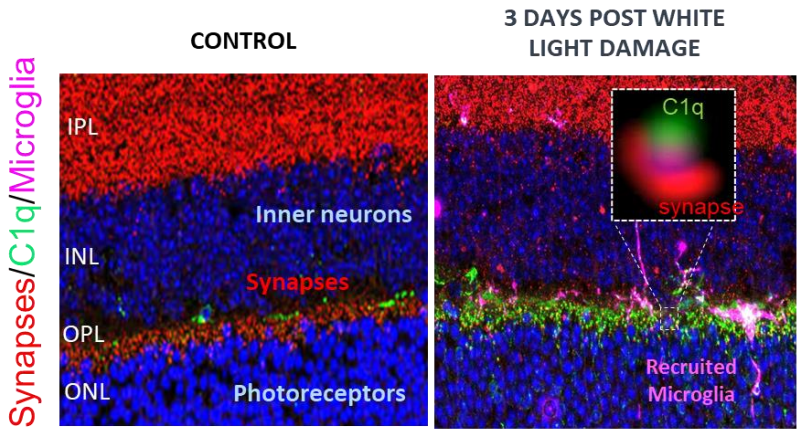
ANX007: C1q Inhibitor with Unique Neuroprotective Mechanism

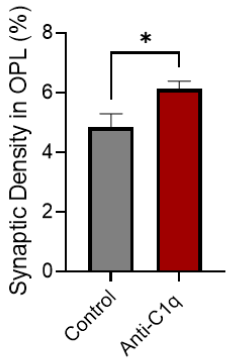
Protection from synapse loss & neurodegeneration in multiple animal models, including photoreceptor damage

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

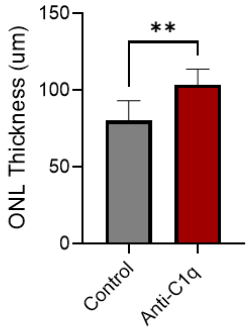


Anti-C1q Protected Photoreceptors and Function

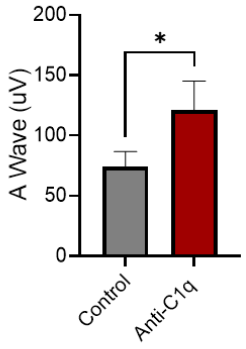
PROTECTED PHOTORECEPTOR SYNAPSES



PROTECTED PHOTORECEPTOR CELL BODIES



PROTECTED RETINAL FUNCTION



Phase II ARCHER Study: Safety and Efficacy of ANX007, non-pegylated IVT-administered Fab

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

Sham	ANX007	ANX007
monthly or every other month (n=89)	5mg monthly (EM) (n=89)	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)

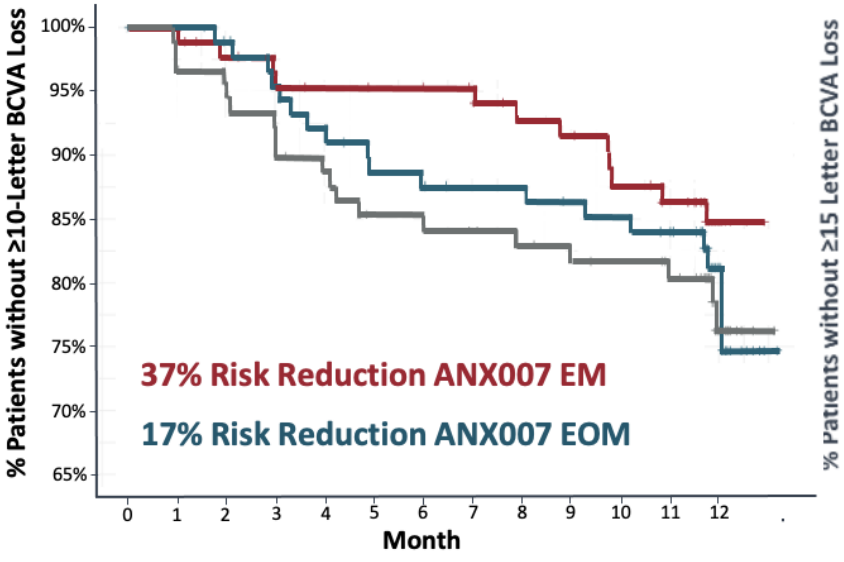
END OF STUDY
Month 18

Significant Protection from Vision Loss: BCVA 15- and 20-Letter Loss

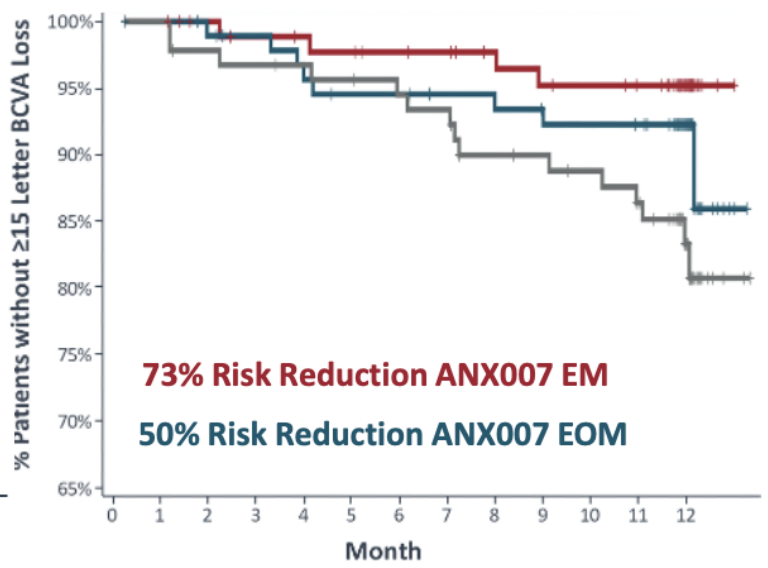
First demonstration of consistent, dose dependent preservation across multiple measures of visual acuity

Persistent BCVA Vision Loss Through Month 12#

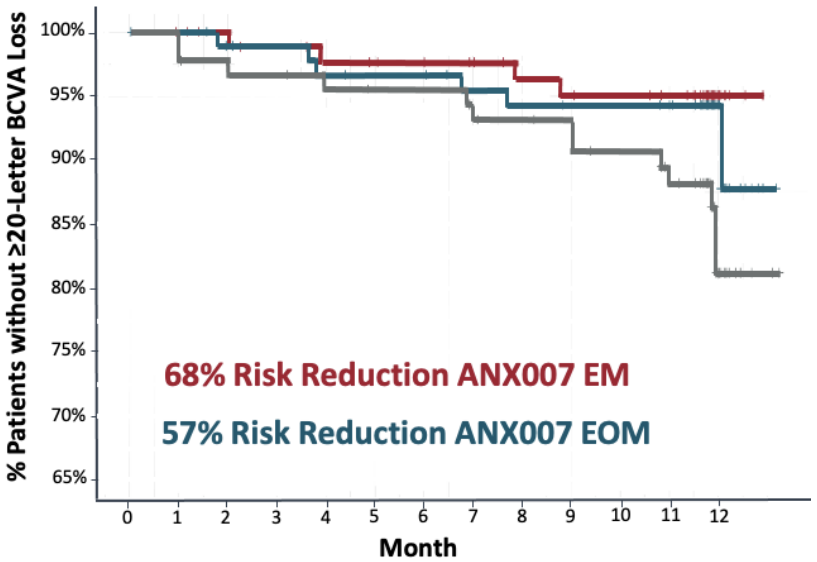
≥10-LETTER LOSS



≥15-LETTER LOSS



≥20-LETTER LOSS



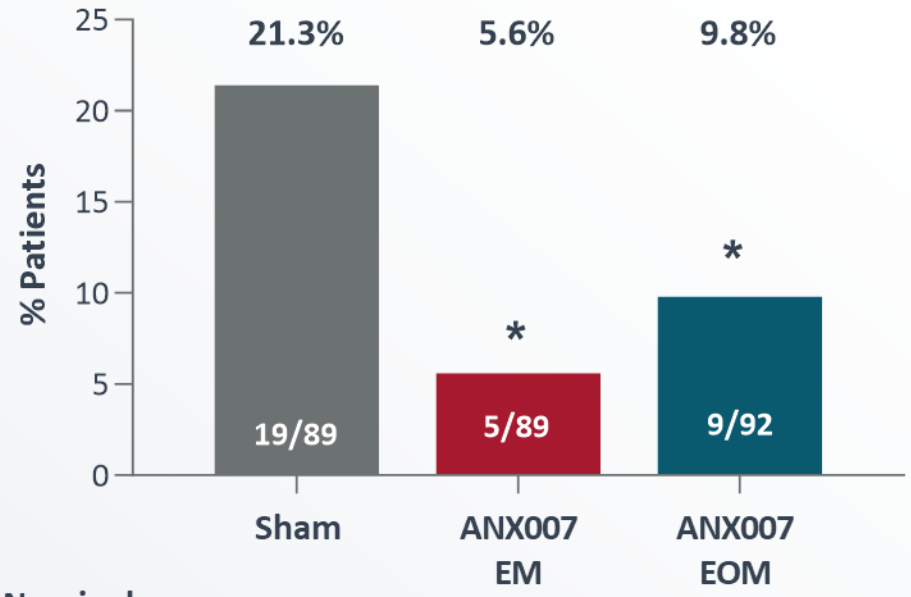
Nominal p-value vs sham^	≥10-LETTER LOSS EM	≥10-LETTER LOSS EOM	≥15-LETTER LOSS EM	≥15-LETTER LOSS EOM	≥20-LETTER LOSS EM	≥20-LETTER LOSS EOM
	0.1952	0.6015	0.0098*	0.0788	0.0330*	0.0841

#Persistent for two consecutive visits through month 12; month 12 confirmed at month 15 visit
^Nominal p-value from a Chi-square test in ITT population
* P < 0.05

Consistent, Significant Protection from Vision Loss: BCVA and LLVA

First demonstration of consistent, dose dependent preservation across multiple measures of visual acuity

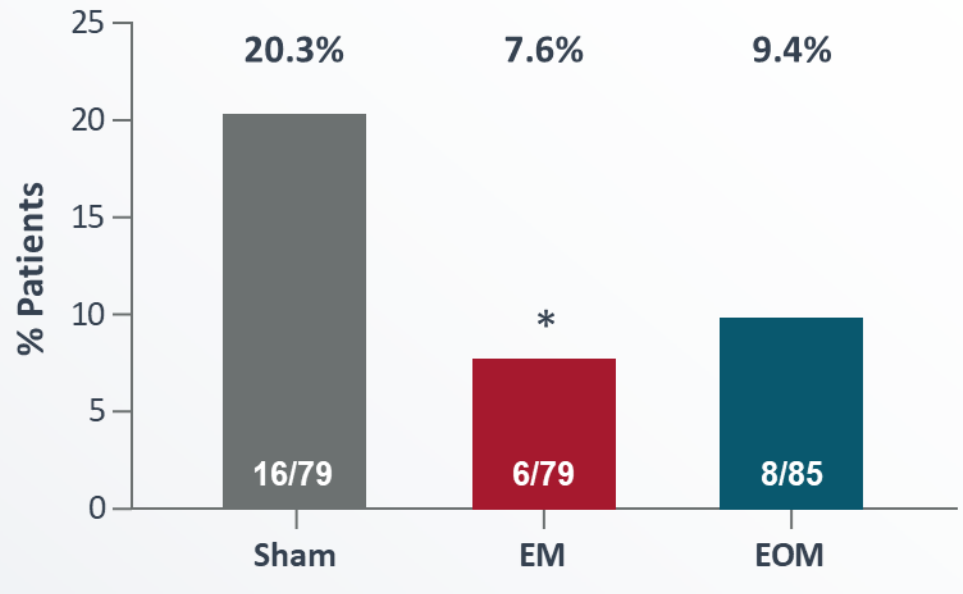
PATIENTS WITH PERSISTENT BCVA ≥15-LETTER LOSS THROUGH MONTH 12#



Nominal p-value vs sham^	---	0.0021	0.032

#Persistent for two consecutive visits through month 12 or at last study visit
^Nominal p-value from a Chi-square test in ITT population: * Nominal $p < 0.05$
Final data

LLVA ≥15-LETTER LOSS THROUGH MONTH 12#

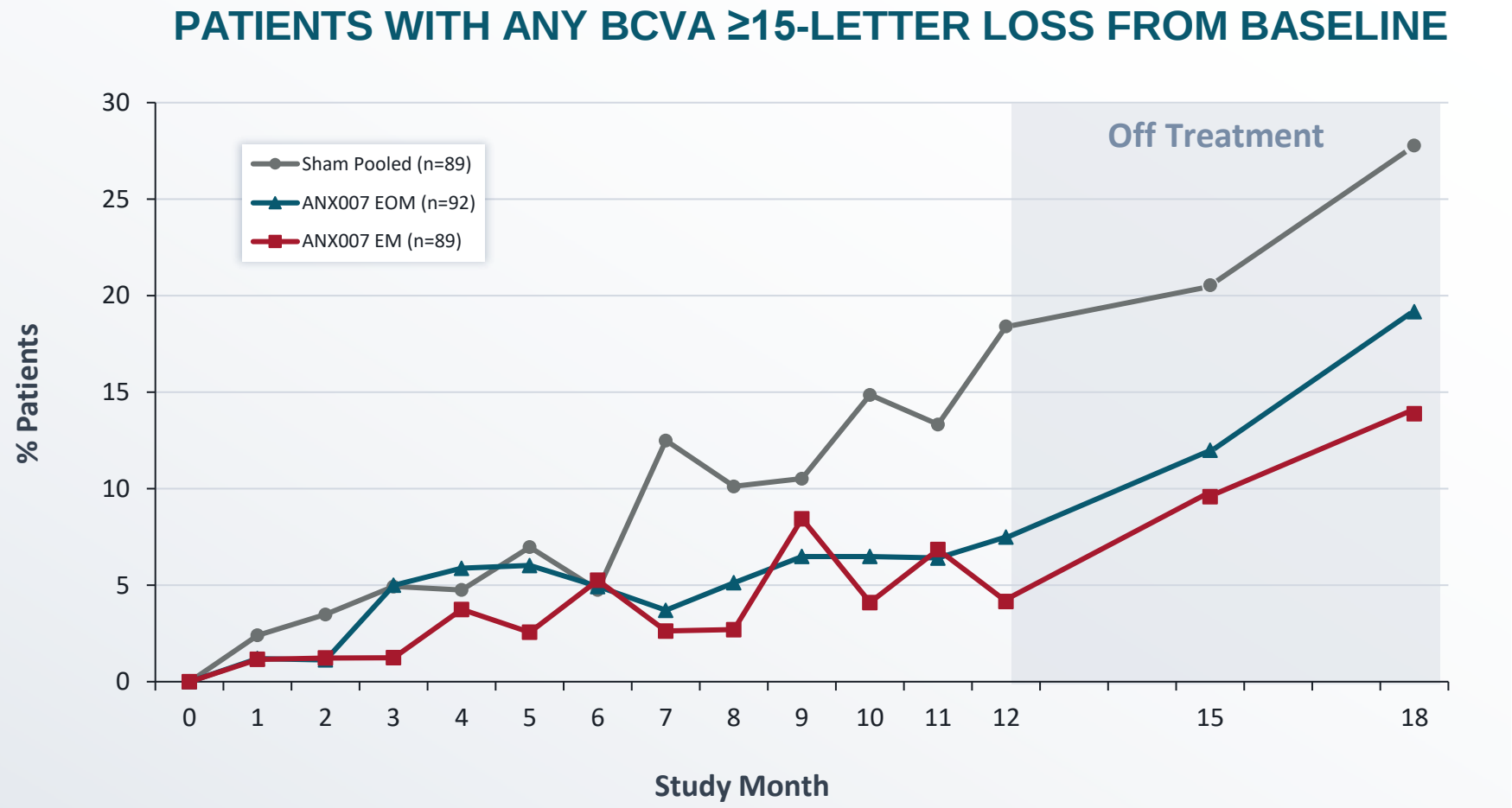


Nominal p-value vs Sham^	--	0.022	0.050

#Patients with single LLVA ≥15-letter loss event and at least one post-baseline LLVA measurement
^Nominal p-value from a Chi-square test
Final data

BCVA ≥15-Letter Loss Accelerated After Cessation of Treatment

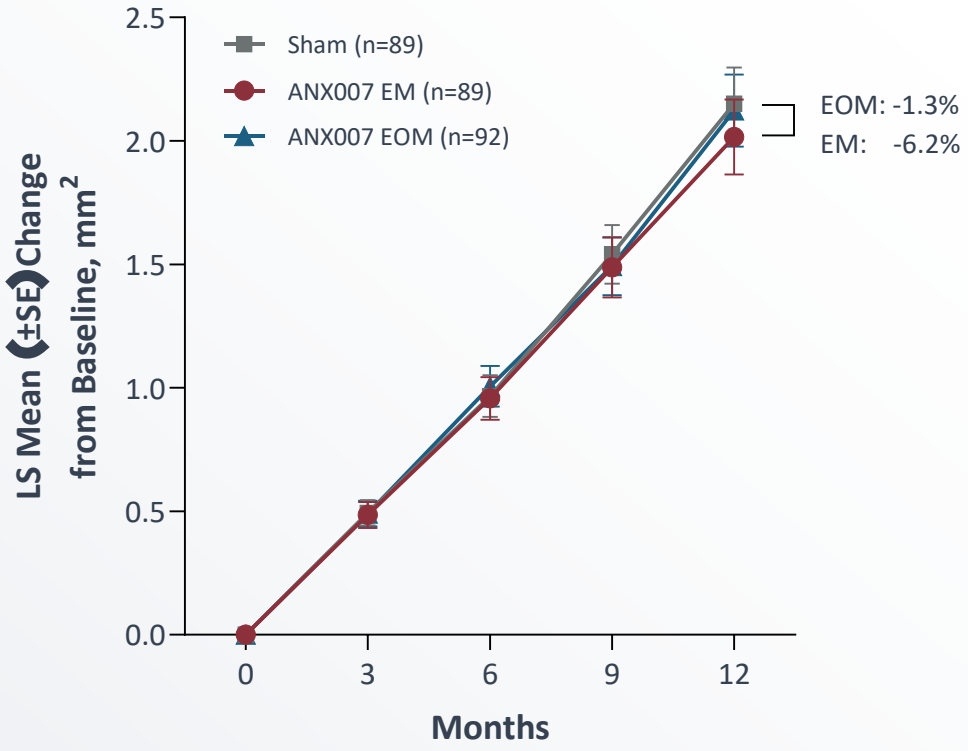
Consistent with true on-treatment drug effect and disease-modifying mechanism of action



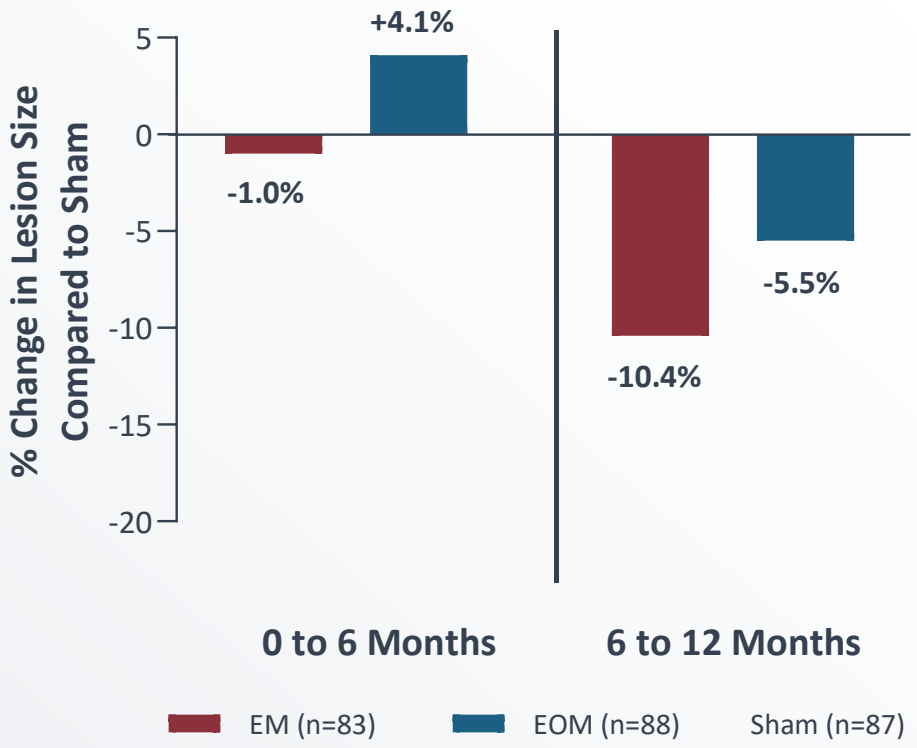
- Low frequency (<0.6% per month) of single BCVA ≥15-letter losses in EM- and EOM-treated groups during 12-month treatment period
- While benefit was maintained after treatment cessation the rate of BCVA≥15 LL increased to parallel that of sham (>1.6% per month)

ANX007 Did Not Significantly Reduce RPE Loss Across Full Retina, but Effects Increased Over Time

RPE LOSS FROM BASELINE TO MONTH 12#



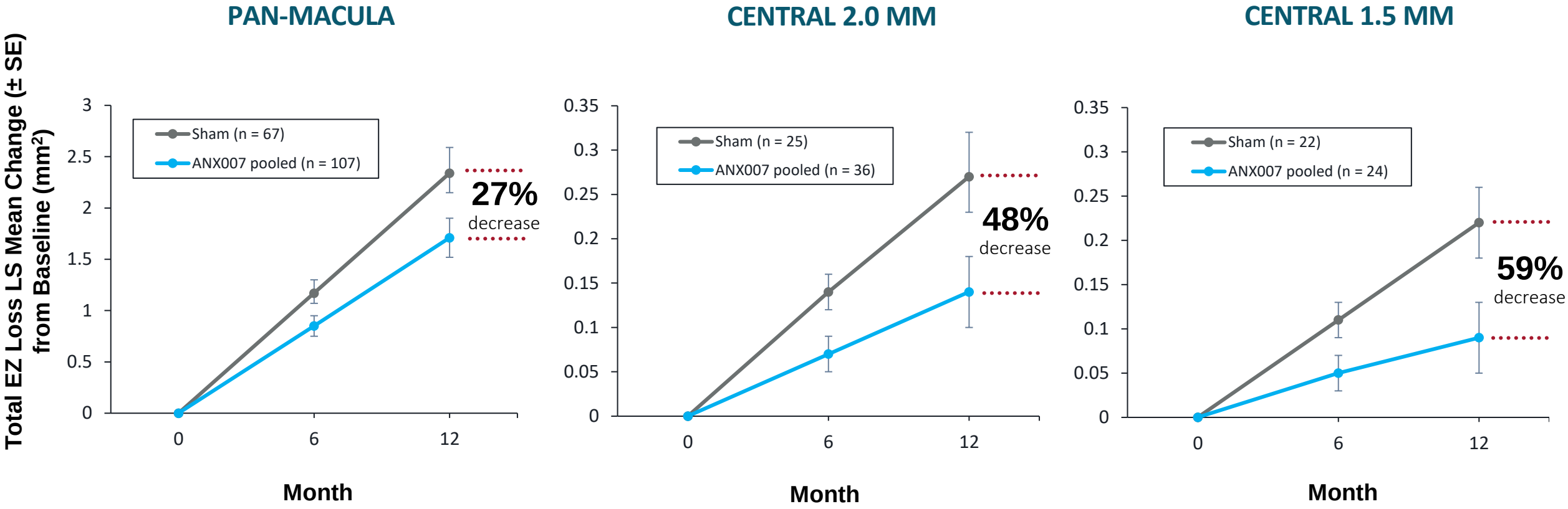
CHANGE IN RPE LOSS OVER TIME#



#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.

Significant Photoreceptor Protection Through 12 Months

More robust protection with ANX007 in central fovea, area best associated with vision, compared to pan-macula



^Nominal p-values from a linear mixed model for repeated measures model (slope) analysis;
Heidelberg Spectralis OCT population with baseline OCT data, excludes patients with >98% atrophy/attenuation at baseline

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^ (1.1%)
Retinal Vasculitis – No Cases Reported			
Intraocular Inflammation+	0	2 (2.2%)	1 (1.1%)
Ischemic Optic Neuropathy+ - No Cases Reported			

^Isolated cilioretinal artery occlusion; no vasculitis confirmed by DSMC and reading center
+Not AESI, included because of current interest

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

ANX007: A Novel Neuroprotective Agent Demonstrating Vision Protection Supported by Structure Protection Now in Phase 3

Blocking C1q for neuroprotection, prevented synapse loss and protected photoreceptors from elimination in animal models

ANX007, an anti-C1q Fab antibody administered IVT, **consistently protected against the loss of visual acuity** in the Phase 2 ARCHER study

Visual function benefit **supported by presumptive protection of photoreceptors,** responsible for visual function

ANX007 treatment was **generally well-tolerated;** no CNV increase; no reported cases of vasculitis

Global, regulatory-aligned Phase 3 program initiated July 2024