Retina2026

ARCHER II, a Phase 3, randomized clinical trial of Vonaprument (ANX007) in patients with dry AMD and GA: Study design and rationale

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Financial Disclosures

4D Molecular Therapeutics	Research Funding, Steering Committee
AbbVie	Consultant
Adverum Biotechnologies	Research Funding, Advisor
Alkeus	Advisor
Alcon	Advisor
ANI Pharmaceuticals	Advisor
Annexon Biosciences	Research Funding, Advisor
Apellis Pharmaceuticals	Speaker, Advisor
Astellas Pharma	Speaker, Advisor, Consultant
Bayer AG	Advisor
Coherus Biosciences	Advisor
CorEvitas	Advisor, Consultant
EyePoint Pharmaceuticals	Advisor, Consultant
Kodiak Sciences	Research Funding
Genentech	Consultant, Advisor
Heidelberg Engineering	Speaker
Ocular Therapeutix	Advisor, Research Funding, Steering Committee
Opthea	Advisor
Regeneron Pharmaceuticals	Consultant, Advisor, Speaker, Steering Committee
Topcon	Consultant

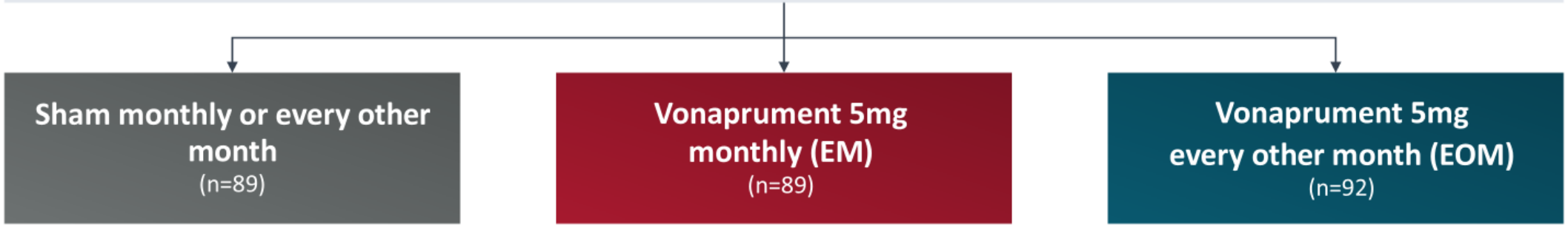
All relevant relationships have been mitigated

Key Take-Away Points:

- The Phase 3 ARCHER II program is now fully enrolled with a path to global registration
- ARCHER II is the only global pivotal program with vision preservation as the primary endpoint
- Learnings from the Phase 2 ARCHER study informed the ARCHER II design
  - As in ARCHER, eyes with foveal and non-foveal lesions are included
  - Eyes with <45 ETDRS letters at baseline are excluded
- Vonaprument (ANX007) has the potential to be the first pharmacologic treatment to preserve vision in patients with dry AMD with GA

ARCHER: Phase 2 Trial Of The C1q Inhibitor ANX007 (vonaprument) in Patients with Dry AMD and GA

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



PRIMARY ENDPOINT

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

PRESPECIFIED FUNCTIONAL ANALYSES

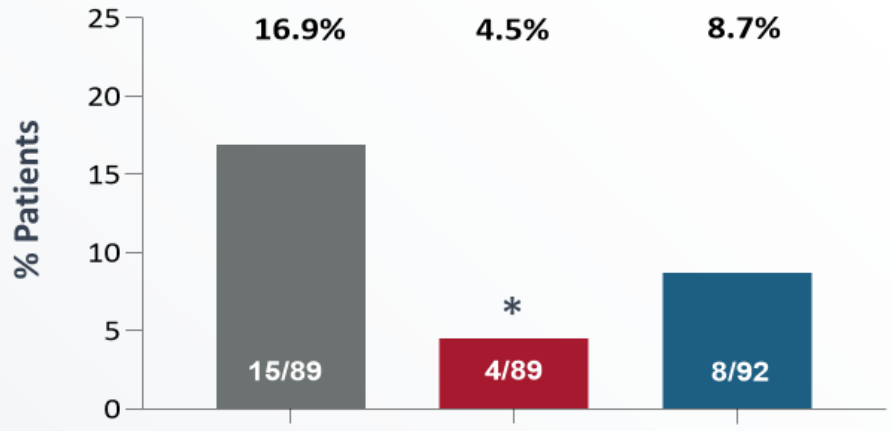
Best Corrected Visual Acuity (BCVA)
Low Luminance Visual Acuity (LLVA) & Deficit (LLVD)

Off-treatment
(6 months)

END OF STUDY
Month 18

Fewer Vonaprument-Treated Eyes Experienced BCVA ≥15-Letter Loss Compared to Sham

PROPORTION OF PATIENTS WITH CONFIRMED BCVA ≥15-LETTER LOSS AT TWO CONSECUTIVE VISITS THROUGH MONTH 12*

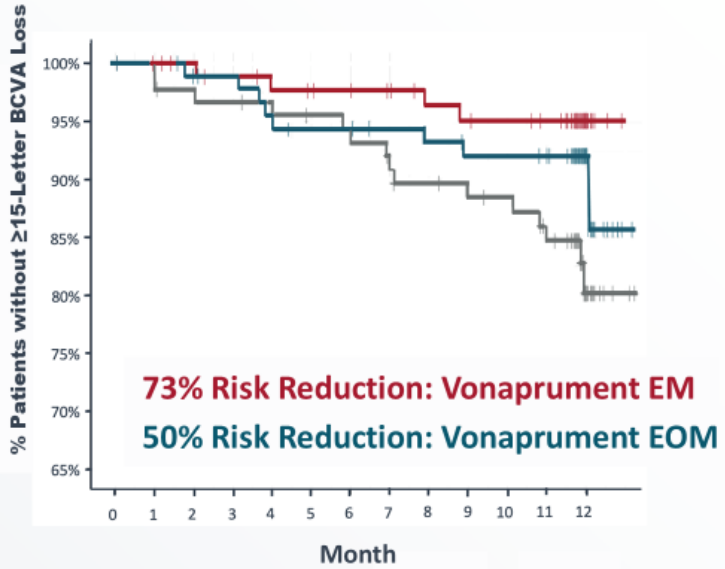


Nominal p-value vs Pooled Sham^	---	Vonaprument EM 0.0076	Vonaprument EOM 0.0994

*BCVA ≥15-Letter Loss at Month 12 was confirmed at the subsequent visit (Month 15). In ARCHER, visits were monthly through Month 12 and then at Months 15 & 18

^Nominal p-value from a Chi-square test in ITT population: *Nominal p < 0.05

PROBABILITY OF CONFIRMED## BCVA ≥15-LETTER LOSS THROUGH MONTH 12



Nominal p-value vs sham^	EM	EOM
	0.0119*	0.1098

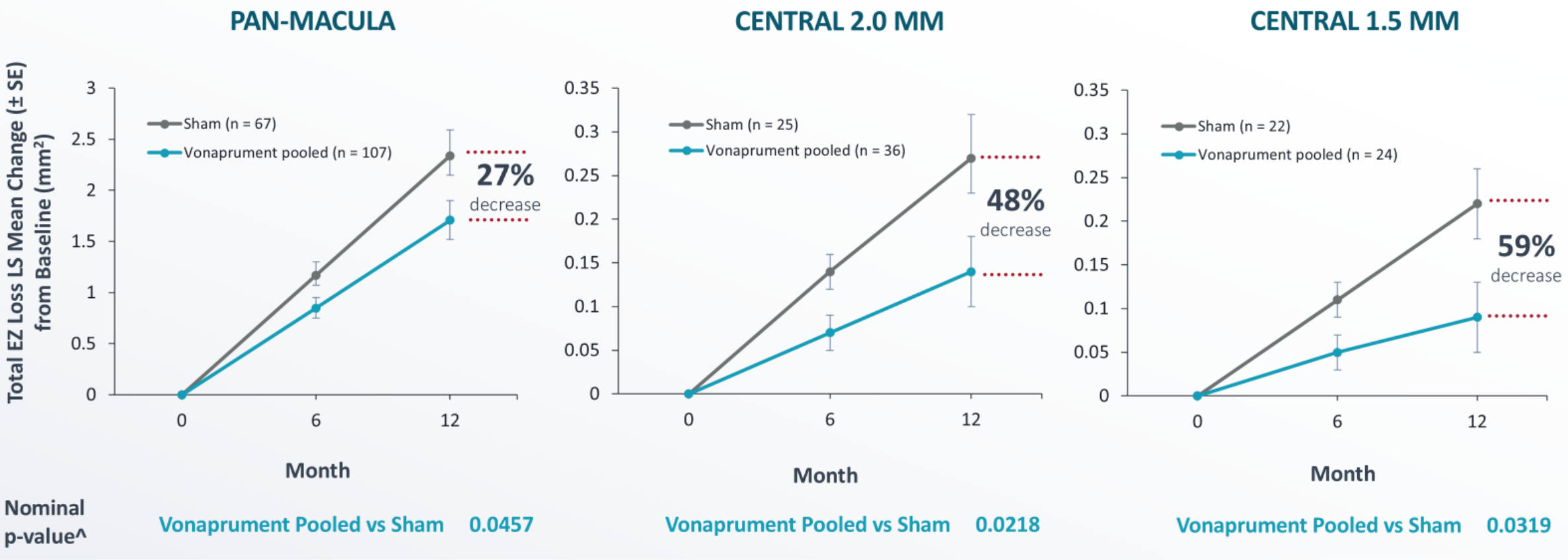
##Confirmed for two consecutive visits through month 12; month 12 confirmed at month 15 visit

^Nominal p-value from a Chi-square test in ITT population

* P < 0.05

Numerically Greater Photoreceptor Protection in Central Macula with Vonaprument

Comparison of Vonaprument effect on Ellipsoid Zone (EZ) across macula and in central subdomains through 12 months



^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

ARCHER: Key Safety Data

ADVERSE EVENTS OF SPECIAL INTEREST n (%)	SHAM (N=89)	VONAPRUMENT EM (N=89)	VONAPRUMENT 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	0	0	0
Intraocular Inflammation+	0	2 (2.2%)	1 (1.1%)
Ischemic Optic Neuropathy+	0	0	0

^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

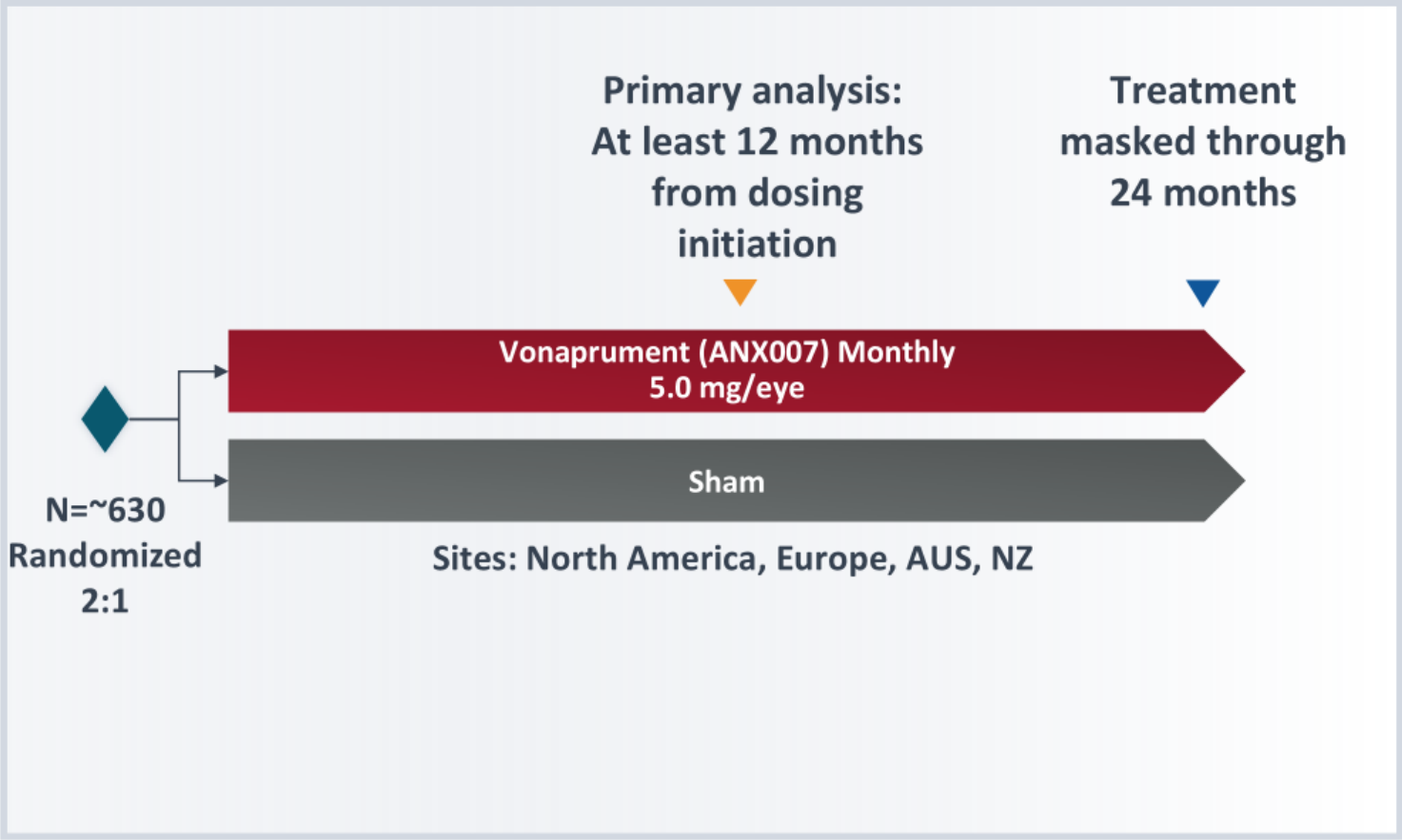
Vitreous Debris – 1
KP on endothelium, prior treatment with topical steroids
No Vasculitis

*Event Verbatim term listed

ARCHER II Phase 3 Program – Now Fully Enrolled

POPULATION FOR ARCHER II: Similar to ARCHER population, including foveal and non-foveal lesions and enriched for BCVA to exclude those with <45 ETDRS letters at baseline

PRIME designation from EMA



PRIMARY ENDPOINT

Persistent* BCVA ≥15-letter loss through primary analysis timepoint

** ≥15-letter loss confirmed at two consecutive visits*

SECONDARY ENDPOINTS

Safety, LLVA, EZ integrity