

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) September 10, 2026

EyePoint, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-51122
(Commission File Number)

26-2774444
(IRS Employer
Identification No.)

480 Pleasant Street
Watertown, Massachusetts
(Address of Principal Executive Offices)

02472
(Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 926-5000

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	EYPT	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On September 10, 2026, EyePoint, Inc. posted an updated investor presentation on its website at www.eyepoint.bio. A copy of the presentation is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Investor Presentation of EyePoint, Inc. dated September 10, 2026
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EYEPOINT, INC.

Date: September 10, 2026

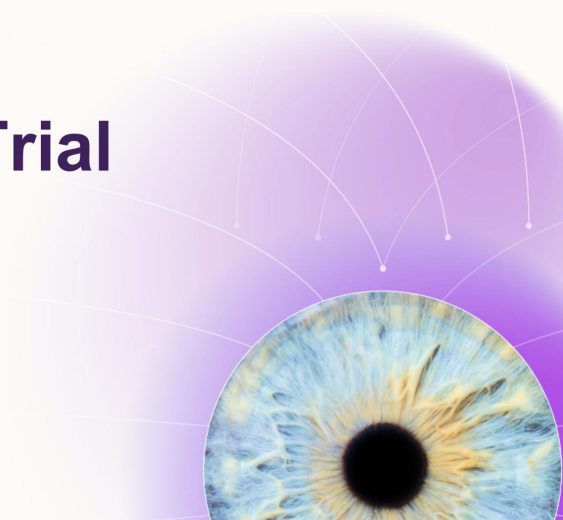
By: /s/ George O. Elston
George O. Elston
Executive Vice President and Chief Financial Officer



LUGANO Phase 3 Clinical Trial DURAVYU in Wet AMD

Expanded Results & Analyses | September 2026

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Legal Disclaimers

Various statements made in this presentation are forward-looking, within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect, plan or believe may occur in the future, are forward-looking statements, including but not limited to statements regarding: our expectations regarding our clinical development and regulatory plans, including the submission of a potential FDA New Drug Application for DURAVYU™ for the potential treatment of wet AMD in the first half of 2027; our confidence in DURAVYU as a potential treatment for wet AMD; our belief that DURAVYU is well positioned to be a potentially practice-changing product and potentially the first-to-market among all investigational sustained release treatments for the two largest retinal disease markets, wet AMD and DME; our belief that DURAVYU is the only TKI in development for DME; our belief that DURAVYU's potential real-world application in multiple retinal disease indications and established trial designs position DURAVYU for clinical and commercial success; our belief that DURAVYU brings a potential new multi-mechanism of action and treatment paradigm for retinal diseases beyond existing anti-VEGF large molecule ligand blocking therapies; our expectations regarding the timing of the availability and release of wet AMD and DME clinical data, including the reporting of LUCIA data in the fourth quarter of 2026 and topline results for Phase 3 COMO and CAPRI clinical trials in diabetic macular edema in the fourth quarter of 2027; our analysis of the LUGANO dataset, with subgroup analyses and interpretations that increase our confidence in the LUCIA trial and the FDA approval pathway; the size of the total addressable market for wet AMD and DME; our belief that DURAVYU has the potential to maintain patients with active disease with no supplemental anti-VEGF therapy for six months or longer; our expectations that if approved, physicians would incorporate DURAVYU into existing treatment approaches for a broad range of wet AMD patients; and other statements regarding the Company's future plans, objectives, strategies and beliefs, including the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause EyePoint's actual results to be materially different than those expressed in or implied by EyePoint's forward-looking statements. For EyePoint, these risks and uncertainties include the timing, progress and results of the Company's clinical development activities; uncertainties and delays relating to communications with the U.S. Food and Drug Administration and the ability to obtain regulatory approval from FDA for the commercialization of DURAVYU; unanticipated costs and expenses; the Company's cash and cash equivalents may not be sufficient to support its operating plan for as long as anticipated; the risk that results of clinical trials may not be predictive of future results, and interim and preliminary data are subject to further analysis and may change as more data becomes available; unexpected safety or efficacy data observed during clinical trials; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways for approval of the Company's product candidates; changes in the regulatory environment; disruptions at the FDA; changes in U.S. and international trade policies; changes in expected or existing competition; the success of current and future license agreements; our dependence on contract research organizations, and other outside vendors and service providers; product liability; the impact of general business and economic conditions; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; delays, interruptions or failures in the manufacture and supply of our product candidates, including due to unanticipated regulatory compliance issues or warning letters relating to the Company's manufacturing facilities; the availability of and the need for additional financing; our ability to obtain additional funding to support our clinical development programs; uncertainties regarding the FDA warning letter pertaining to the Company's Watertown, Massachusetts manufacturing facility; and other factors described in our filings with the Securities and Exchange Commission (SEC). More detailed information on these and additional factors that could affect our actual results are described in our filings with the SEC, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2025, as revised or supplemented by our Quarterly Reports on Form 10-Q and other documents filed with the SEC. We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. EyePoint undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.



Introduction



A Leader in Sustained Release Drug Delivery for Retinal Disease



DURAVYU™ - Phase 3 programs in two largest retinal disease markets wet AMD + DME (~\$15B¹ TAM)



Multiple potential catalysts over next 16 months:

- LUCIA Phase 3 data expected Q4 2026
- wAMD NDA filing targeted for 1H 2027
- DME topline data expected in Q4 2027



Veteran leadership with **decades of broad retina experience** across drug development, commercialization and manufacturing



Execution – Enrolled 4 Phase 3 trials in 7 months or less; commercial cGMP facility in place for US launch

1: Anti-VEGF sales, 2024 public financial statements
AMD, age-related macular degeneration; DME, diabetic macular edema; TAM, total addressable market

The DURAVYU™ Advantage: A Differentiated Program in Retina

- **CLINICAL PROGRAMS IN LARGE MARKETS**

Pivotal readouts in wet AMD in 2026 and DME in 2027

- **FAVORABLE SAFETY PROFILE**

Comprehensive safety database - favorable profile with **redosing**

- **CLINICALLY RELEVANT TRIAL DESIGN**

On-label SOC dosing as control

- **MULTI-MOA ADVANTAGE**

Potential mechanistic edge as only TKI combining VEGF receptor blockade + IL-6/JAK1 anti-inflammatory¹ + PDGF antifibrotic² benefit

- **PROVEN DELIVERY TECHNOLOGY**

DURASERT technology FDA approved in 4 products

DURAVYU™

vorolanib in bioerodible Durasert E™



Insert not drawn to scale and is enlarged for illustrative purposes.

Each insert:

94% drug / 6% matrix

1/5000th of vitreous volume

Drug release ≥ 6 months

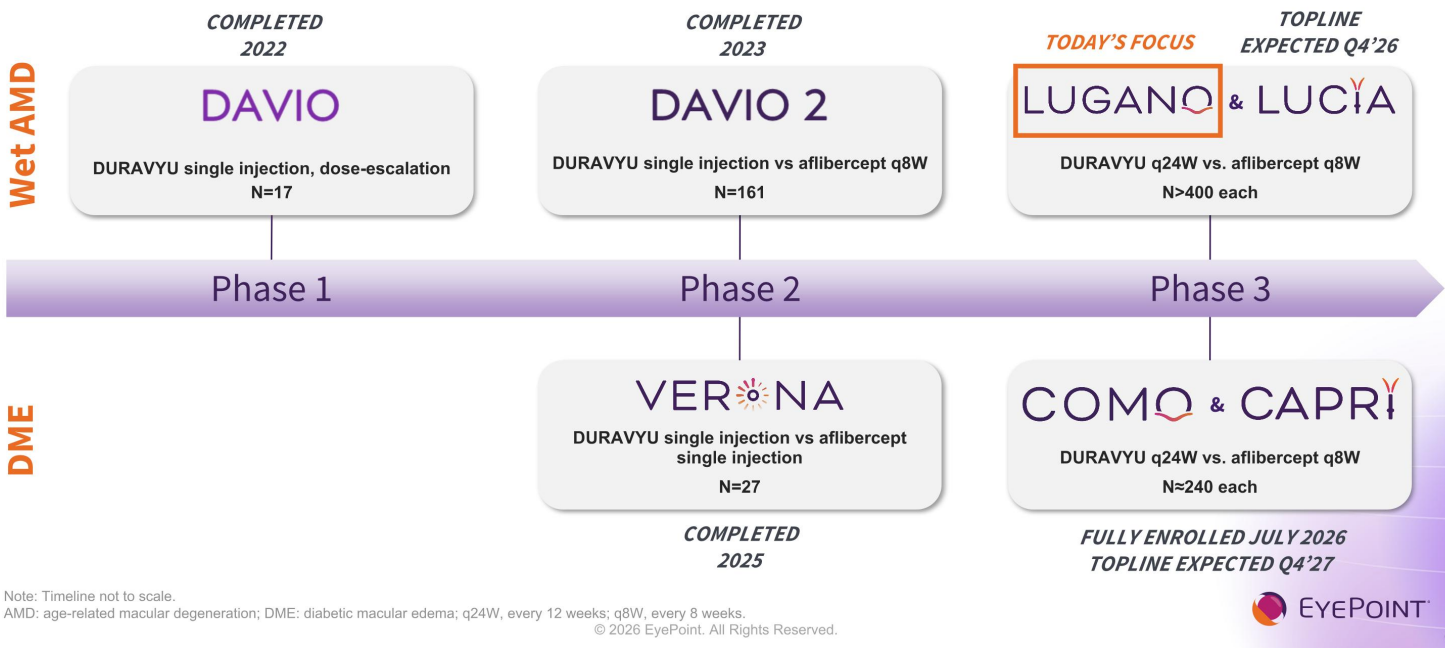
No PEG/PLGA

Room temperature storage

1. Data from preclinical studies. Following a single DURAVYU 900 µg dose in Dutch-Belted rabbits, vorolanib reached concentrations exceeding IC50 in the choroid and retina within hours of administration. 1. Wykoff CC, et al. J Vitreoretin Dis. 2024;8(5):577–86. 2. Eyecelerator @AAO 2025 presentation. TKI, tyrosine kinase inhibitor; AMD, age-related macular degeneration; DME, diabetic macular edema; NI, non-inferiority; MOA, mechanism of action; VEGF, vascular endothelial growth factor; AMD, age-related macular degeneration; DME, diabetic macular edema; SOC, standard of care; IL-6, interleukin 6; JAK, janus kinase; PDGF, platelet-derived growth factor; IVT, intravitreal; PEG, polyethylene glycol; PLGA, poly(lactic-co-glycolic acid).

Robust Evidence For DURAVYU with Established Regulatory Path

Follows non-inferiority pathway of five most recent FDA approvals in wet AMD





Phase 3 Wet AMD Program

LUGANO and LUCIA Pivotal Trials

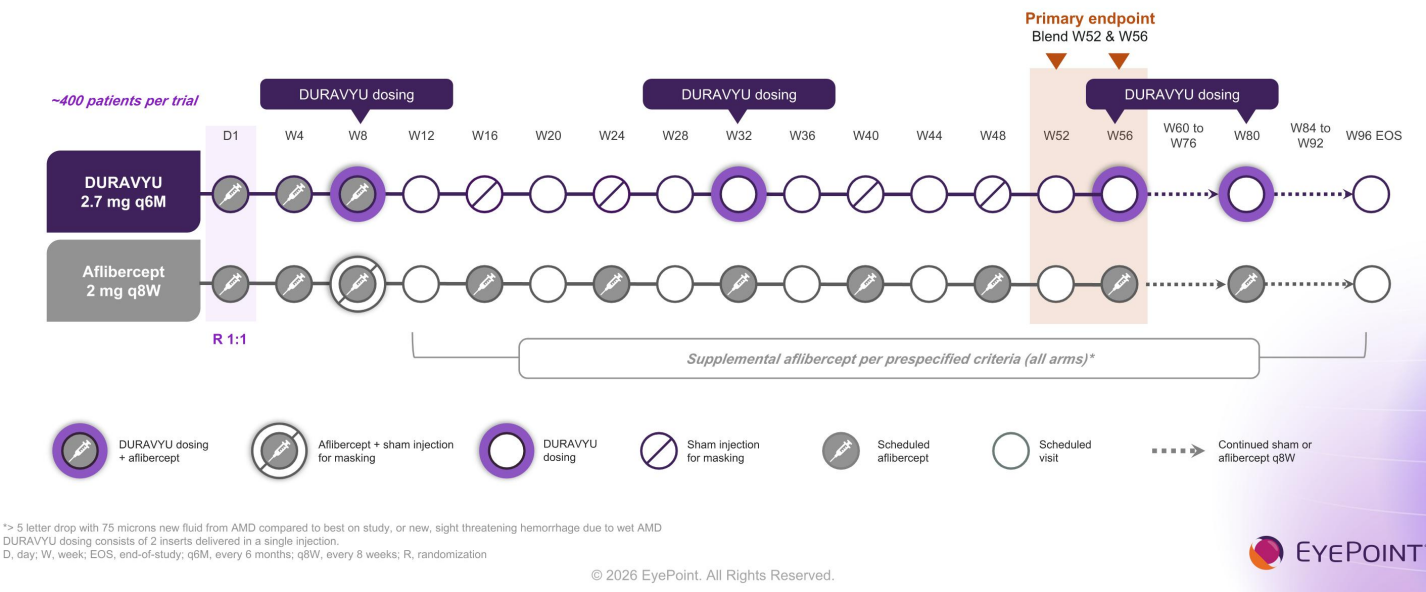
LUGANO & LUCIA Follow Established Non-Inferiority Regulatory Path in Wet AMD

Design	Endpoints
• Patients: 432 in LUGANO, 475 in LUCIA • Two arms (1:1) • DURAVYU 2.7mg • On-label aflibercept 2mg control given q8W • DURAVYU dosing every 6 months (q24W) • One year efficacy and safety endpoints for NDA submission	Primary Endpoint: • Non-inferior (NI) mean change in BCVA from Day 1 to Week 52 and Week 56 (blended) vs aflibercept control (NI margin of -4.5 letters) Key Secondary Endpoints: • Safety • Reduction in treatment burden (superiority vs on-label aflibercept) • Percent of eyes supplement-free • Anatomic stability

Program objective is to demonstrate DURAVYU, administered every six months, achieves similar visual outcomes to on-label aflibercept while reducing treatment burden

Pivotal Phase 3 Program Follows Established Non-Inferiority Regulatory Pathway

LUGANO & LUCIA





LUGANO Topline Results

LUGANO: DURAVYU Showed Clinically Meaningful Results to Support a Potential NDA Filing and Differentiated Profile

Visual Acuity

DURAVYU did not achieve statistical non-inferiority in full data set
DURAVYU **non-inferior** (nominal p-value=0.0096) excluding an asymmetric cohort
DURAVYU resulted in **visual gains**, on average

Treatment Burden

Superior reduction in treatment burden (nominal p-value <0.0001)

Supplement Free Rates

>50% controlled by DURAVYU alone with similar BCVA/CST vs. aflibercept
88% of DURAVYU eyes received 4 injections or fewer¹

Anatomy

Anatomic control **confirms potency and durability**

Safety

Continued **favorable safety profile** with *redosing*

Note: results through Week 56, unless specified.
1. After loading doses, 88% of DURAVYU eyes received 2 DURAVYU treatments and 2 or fewer supplemental injections up to Week 56.
NDA, New Drug Application; BCVA, best corrected visual acuity; CST, central subfield thickness.
Preliminary data – pending final analysis



LUGANO Topline Results

Baseline Characteristics

LUGANO Baseline Characteristics

	DURAVYU 2.7mg (n=211)	Aflibercept 2mg q8W (n=216)
Age (years), mean (SD)	77.5 (7.52)	77.0 (7.61)
≥ 65, n (%)	202 (95.7)	205 (94.9)
Female, n (%)	136 (64.5)	141 (65.3)
Treatment Naïve, n (%)	159 (75.4)	164 (75.9)
Previously Treated, n (%)	52 (24.6)	52 (24.1)
Annualized number of anti-VEGF for previously treated, mean (SD)	7.35 (2.21)	7.39 (2.01)

SD: standard deviation, n: number of patients
Preliminary data – pending final analysis

LUGANO Baseline Characteristics (Cont'd)

	DURAVYU 2.7mg (n=211)	Aflibercept 2mg q8W (n=216)
BCVA (ETDRS letters), mean (SD)	65.8 (8.95)	64.3 (10.35)
> 20/40 Snellen equivalent ¹ , n (%)	82 (38.9)	79 (36.6)
≤ 20/40 Snellen equivalent ¹ , n (%)	129 (61.1)	137 (63.4)
Central CST (um), mean (SD)	319.83 (71.429)	326.01 (71.906)
Total CNV Area by FA (mm²), mean (SD)	5.69 (4.44)	4.60 (3.86)
Medical History in Study Eye		
Dry AMD	24.6%	21.7%
Glaucoma ²	11.4%	5.9%

1. Snellen equivalent of 20/40 is 69 ETDRS letters.

2. Medical history of glaucoma includes preferred terms of "glaucoma", "borderline glaucoma", and "open angle glaucoma".

AMD: Age-related Macular Degeneration, SD: standard deviation, n: number of patients.

Preliminary data – pending final analysis

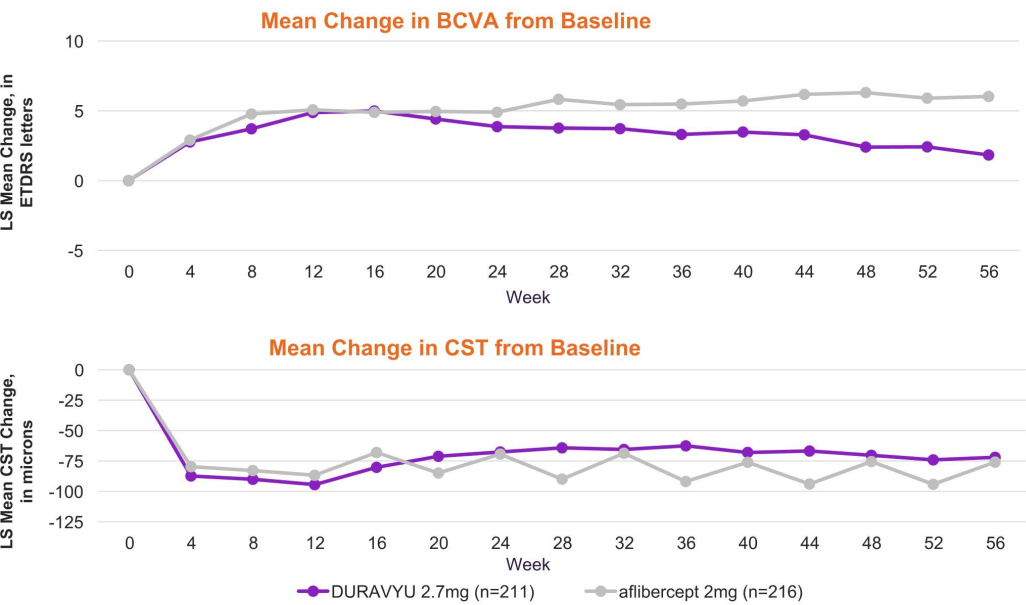
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LUGANO Topline Results

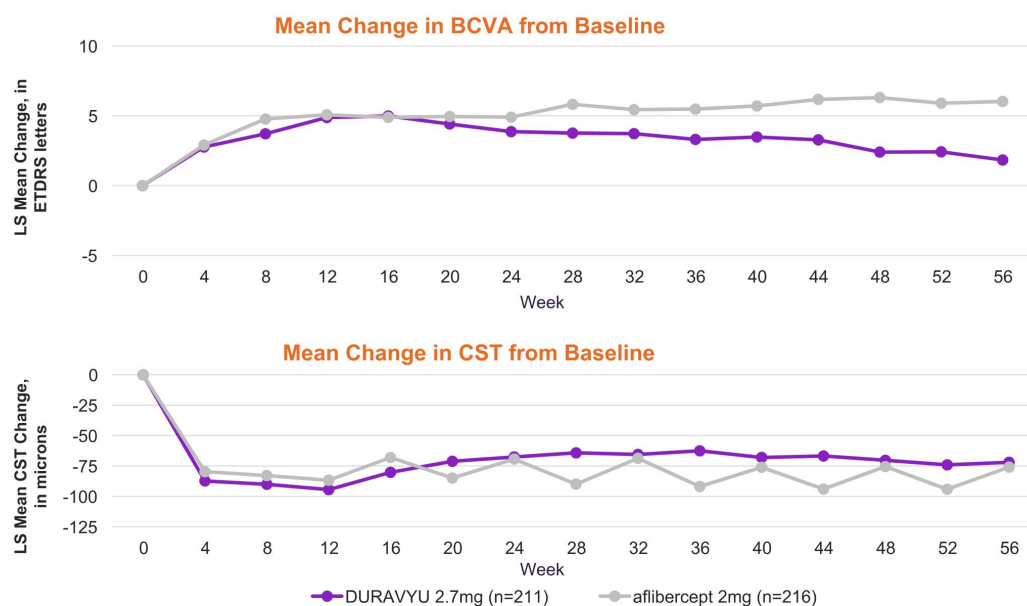
Visual Acuity

Primary Endpoint Not Achieved Despite Impressive Anatomic Control



*Blended week 52 and week 56 change vs. baseline by MMRM
BCVA, best-corrected visual acuity; ETDRS, early treatment diabetic retinopathy study; CST, central subfield thickness.
Preliminary data – pending final analysis

Primary Endpoint Not Achieved Despite Impressive Anatomic Control



Asymmetric Cohort

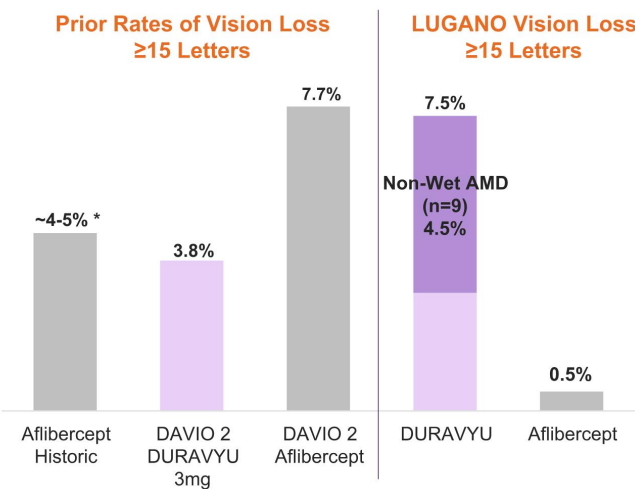
- 9 patients (of 211) lost ≥ 15 letters from non-wet AMD etiologies in DURAVYU arm, **driving the endpoint result**
- **Zero** patients (of 216) in aflibercept control arm lost ≥ 15 letters from non-wet AMD etiologies
- DURAVYU arm demonstrated strong anatomic control through Week 56

*Blended week 52 and week 56 change vs. baseline by MMRM
BCVA, best-corrected visual acuity; ETDRS, early treatment diabetic retinopathy study; CST, central subfield thickness.

Preliminary data – pending final analysis

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Patients with ≥15-Letter Vision Loss in LUGANO Aflibercept Arm Up to 10x Lower Than Prior Trials



Cause of Visual Loss in the 9 Patients:

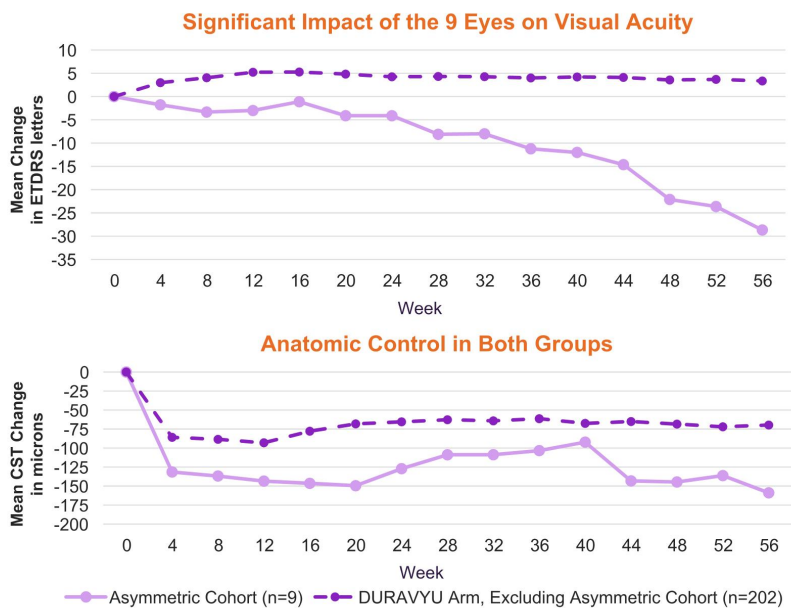
- Geographic atrophy (n=6)
- Glaucoma (n=2)
- Retinal detachment (n=1)
- 258 letters lost despite good anatomic control
- 6 received supplemental injections with no VA improvement

No eyes in the control arm had vision loss ≥15 letters due to non-AMD causes

No imbalance in vision loss 10-14 letters

Note: Main cause of vision loss was determined by multiple retina specialists reviewing study and reading center data (including OCT, FA/CFP, and FAF imaging).
* See slide 22.
OCT, optical coherence tomography; FA, fluorescein angiography; CFP, color fundus photography; FAF, fundus autofluorescence.
Preliminary data – pending final analysis

Profound Impact of the Asymmetric Cohort (9 Eyes) on VA Outcome

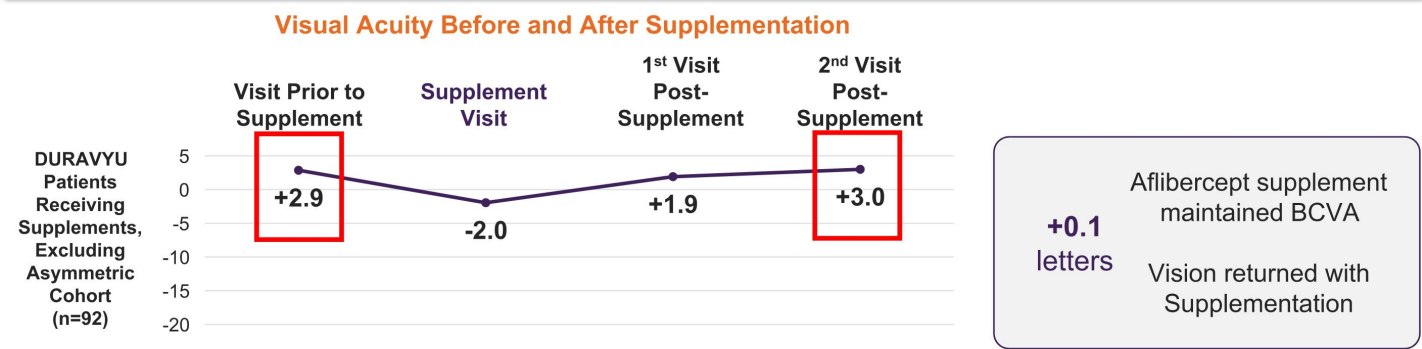


Asymmetric cohort - 9 patients (4%)

- Excluding the cohort, DURAVYU arm gained +3.5 letters
- Anatomic control maintained
- Anti-VEGF therapy did not affect vision loss, further suggesting these eyes lost vision from non-wet AMD etiologies

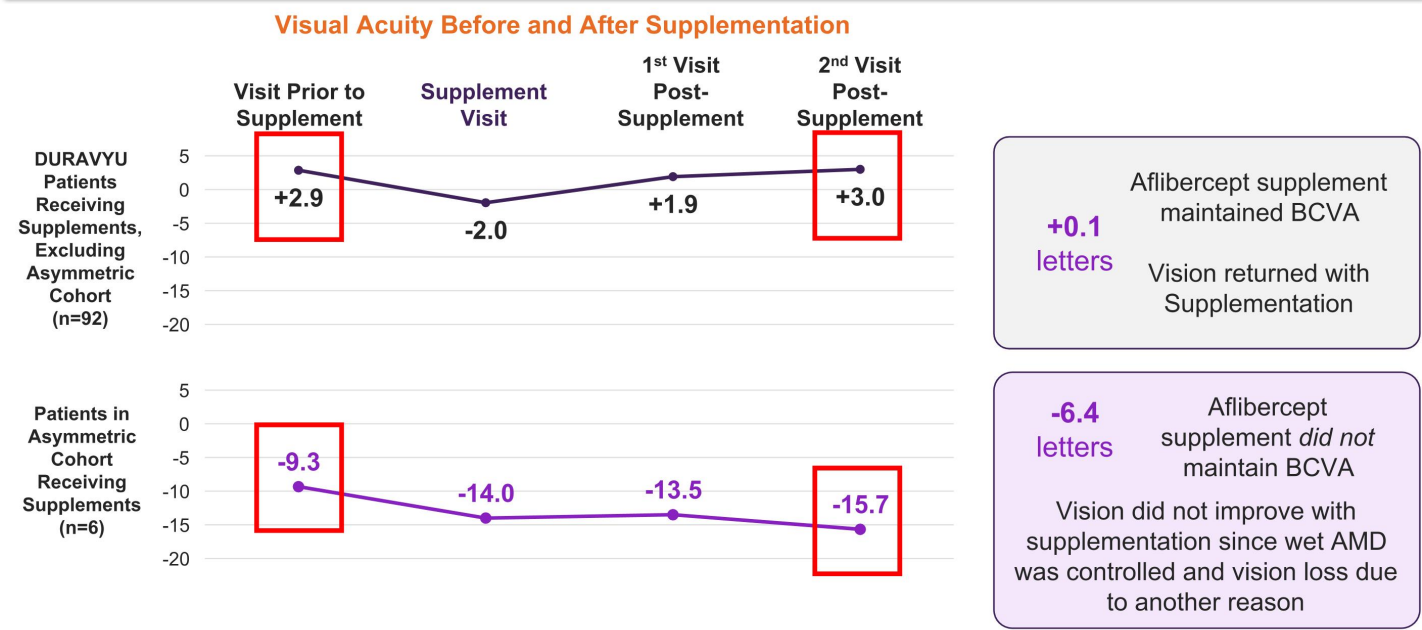
VA, visual acuity; ETDRS, early treatment diabetic retinopathy study; CST, central subfield thickness.
Preliminary data – pending final analysis © 2026 EyePoint. All Rights Reserved.

Supplementation Worked as Expected in Overall Population – Asymmetric Cohort Did Not Respond to Aflibercept Supplementation



Note: 3/9 patients in asymmetric cohort did not receive supplement.
Preliminary data – pending final analysis

Supplementation Worked as Expected in Overall Population – Asymmetric Cohort Did Not Respond to Aflibercept Supplementation



Note: 3/9 patients in asymmetric cohort did not receive supplement.
Preliminary data – pending final analysis

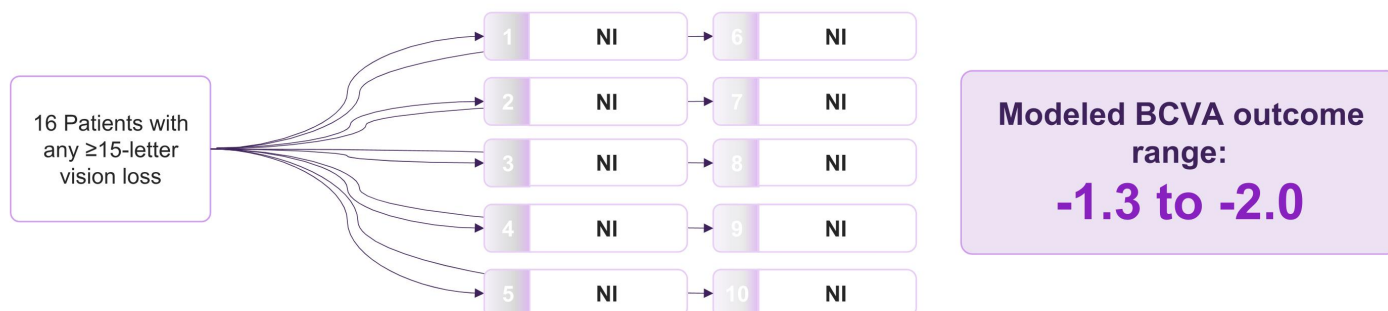
% of ≥15 Letter Vision Loss in Aflibercept Control Arm Significantly Lower than Any Prior Wet AMD Trial

Aflibercept 2mg (Q8W) Arm				
Trial	Phase	N	Timepoint	Patients with ≥15 Letter Loss* (%)
VIEW 1	3	301	Week 52	4.9% ^a
VIEW 2	3	306	Week 52	4.4% ^a
HAWK	3	360	Week 48	5.5% ^b
HARRIER	3	369	Week 48	4.8% ^b
TENAYA	3	300	Week 40-48, avg	5.9% ^c
LUCERNE	3	291	Week 40-48, avg	2.7% ^d
PULSAR	3	335	Week 48	3.3% ^e
DAVIO 2	2	54	Week 56	7.7% ^f
LUGANO	3	216	Week 52/56, avg	0.5% ^f

*Loss of letters from baseline
a. Heier et al. Ophthalmology 2012 (VIEW 1/2), Bayer VIEW combined analysis; b. CADTH Beovu Clinical Review (NBK565336), HAWK/HARRIER wk48. c. ClinicalTrials.gov TENAYA Posted Results (NCT03823287). Accessed Aug. 15, 2026. d. ClinicalTrials.gov LUCERNE Posted Results (NCT03823300). Accessed Aug. 15, 2026. e. Center for Drug Evaluation and Research Statistical Review, BLA 761355Orig1s000. f. EyePoint internal data
Preliminary data – pending final analysis

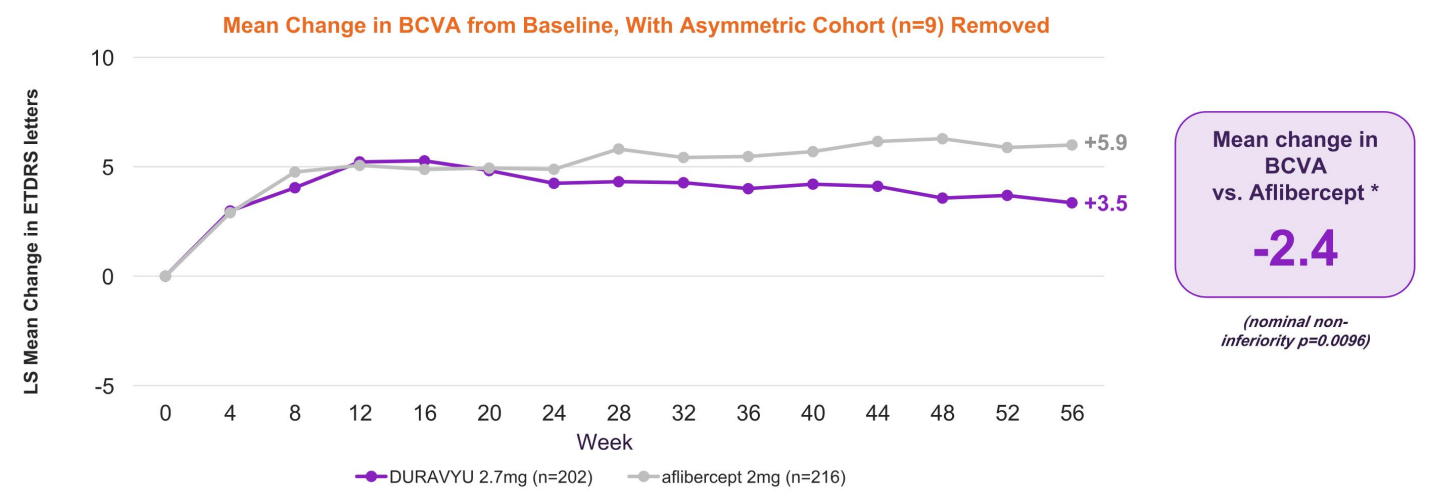
DURAVYU Achieved NI Across 10 / 10 Modeled Randomization Scenarios

Random reassignment of the 16 LUGANO patients with any ≥ 15 -letter vision loss resulted in DURAVYU non-inferiority in every simulation:



Modeling demonstrates impact of control arm overperformance and supports potential regression-to-the-mean for LUCIA

Ad Hoc Analysis Excluding Asymmetric Cohort (9 of 211): Non-Inferiority in BCVA Change from Baseline Was Achieved

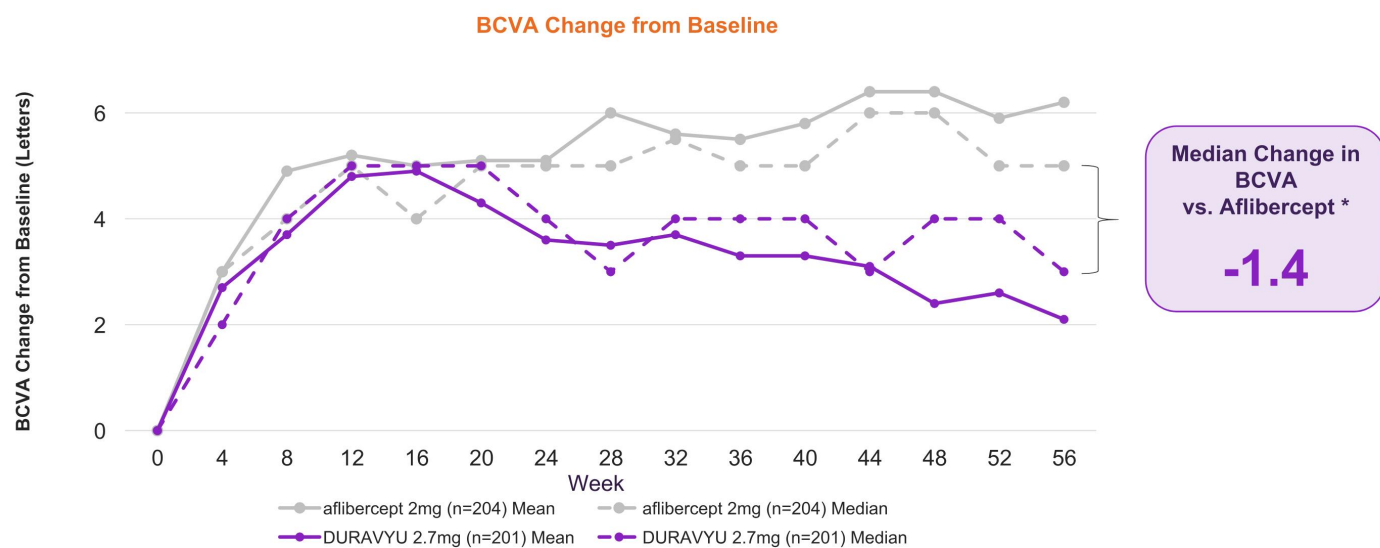


DURAVYU demonstrated non-inferiority mean change in BCVA vs. on-label aflibercept control excluding the asymmetric cohort

*Blended week 52 and week 56 change vs. baseline by MMRM
BCVA, best-corrected visual acuity; ETDRS, early treatment diabetic retinopathy study; MMRM, mixed model repeated measures.
Preliminary data – pending final analysis

Median Analysis Demonstrates Non-Inferiority

Median Regression Reduces Influence of Vision Outliers



Note: Median Regression is more robust than MMRM/ANCOVA to extremes. Analysis performed on all patients with available Week 52 or Week 56 BCVA.

* Blended week 52 and week 56 Median change vs. baseline.

BCVA, best-corrected visual acuity; MMRM, mixed model repeated measures; ANCOVA, analysis of covariance.

Preliminary data – pending final analysis

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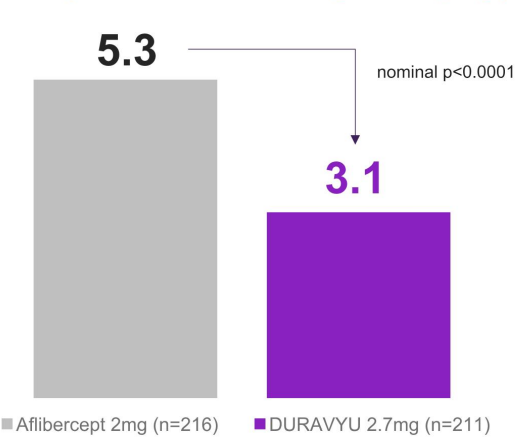


LUGANO Topline Results

Reduction in Treatment Burden & Supplement-Free Rates

DURAVYU Achieved Superiority In Treatment Burden Reduction vs. On-Label Aflibercept Up to Week 56

Total Injections* After Loading Doses (Avg.)



42%

Treatment Burden Reduction achieving superiority to on-label aflibercept (maximum 60%)

1.1

Average Supplements in DURAVYU patients¹

2

Fewer Injections on average, in DURAVYU patients vs. on-label aflibercept

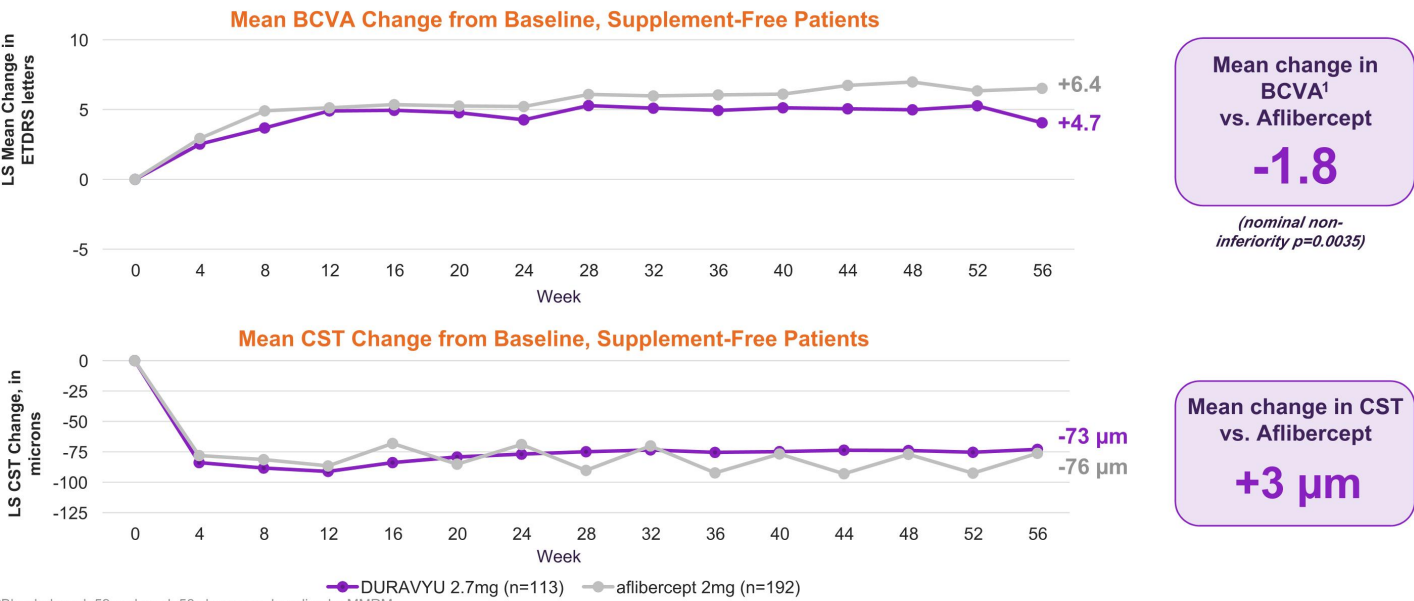
1. 1.1 average supplemental injection annualized
*Participants who discontinued treatment or study early without any Week 8 or later injections of study drug were not included.
For DURAVYU group: the number of injections includes the DURAVYU injections at Week 8 and Week 32, and all supplemental injections after Week 8 through Week 56. For aflibercept group: the number of injections includes all aflibercept and supplemental injections after Week 8 through Week 56. Scheduled aflibercept injections from Day 1 through Week 8 were excluded. Week 56 study treatment injection was excluded from this analysis.
Preliminary data – pending final analysis

Supplement-Free Rates Demonstrate DURAVYU’s Potency and Durability

Over half of eyes were controlled by DURAVYU alone up to Week 56

	DURAVYU 2.7mg	
	Up to Week 32	Up to Week 56
Supplement-Free Patients	76%	54%
Patients with 0 or 1 Supplement	96%	79%
Patients with 2 or fewer Supplements	99%	88%

DURAVYU was Non-Inferior to On-Label Aflibercept Control In Supplement-Free Subgroup (n=113, 54%)



*Blended week 52 and week 56 change vs. baseline by MMRM
1. This analysis includes 3 patients who experienced ≥ 15 -letter vision loss not due to wet AMD. The mean change in BCVA would have been -1.1 excluding the 3.
BCVA, best-corrected visual acuity; ETDRS, early treatment diabetic retinopathy study; CST, central subfield thickness; MMRM, mixed model repeated measures.
Preliminary data – pending final analysis



LUGANO Topline Results

Safety Data

AE Profile Confirms DURAVYU's Favorable Safety Profile With Repeat Dosing

- **No cases of:**
 - Insert migration into the anterior chamber
 - Anterior chamber opacities
 - Free-floating particles
 - Retinal vasculitis (occlusive or non-occlusive)
 - Severe intraocular inflammation
- AEs of particular interest – all **<1%** in both arms:
 - Retinal detachment
 - Intraocular inflammation
 - Endophthalmitis
- All cases of floaters were mild or moderate with no required treatment or impact on vision
- Low patient discontinuation rate of 6% through Week 56 in each arm
 - No study or treatment discontinuations were related to DURAVYU

AE Profile Confirms DURAVYU’s Favorable Safety Profile With Repeat Dosing

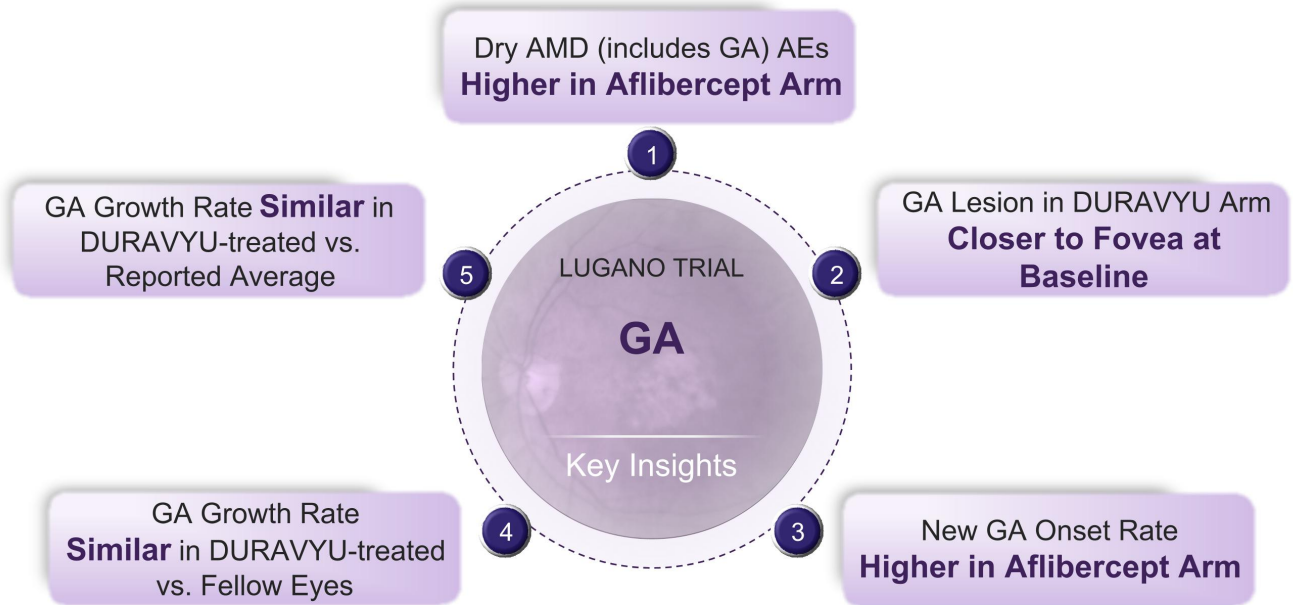
Subjects with Ocular AEs in Study Eye ≥2% through Week 56	DURAVYU 2.7mg (n=211)	Aflibercept 2mg (n=221)
Conjunctival haemorrhage	11.4%	5.0%
Vitreous floaters	9.0%	3.6%
Neovascular age-related macular degeneration	7.1%	1.4%
Retinal haemorrhage	4.7%	1.8%
Vitreous detachment	4.7%	4.1%
Cataract	4.3%	5.4%
Dry eye	4.3%	6.3%
Posterior capsule opacification	4.3%	2.3%
Intraocular pressure increased	3.8%	3.2%
Visual acuity reduced	3.8%	5.4%
Retinal oedema	2.8%	0.9%
Visual impairment	2.4%	0.0%
Dry age-related macular degeneration	2.4%	3.2%
Eye pain	2.4%	0.9%
Subretinal fluid	2.4%	1.4%



LUGANO – Evaluation of Geographic Atrophy (GA) Across Cohorts

**LUGANO Data Supports Assessment that DURAVYU
Did Not Influence GA Onset or Progression**

LUGANO Data Supports Assessment That DURAVYU Did Not Influence GA Onset or Progression



Note: TKI mechanism of action, preclinical data, and Phase 2 Davio 2 also supportive of DURAVYU. Calculations determined by masked reading center.
GA, geographic atrophy; TKI, tyrosine kinase inhibitor; AE, adverse event.
Preliminary data – pending final analysis

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Phase 2 DAVIO 2: Fewer ≥15-Letter Vision Losses with DURAVYU; No GA Observed

At Week 56	DURAVYU 2mg (47)	DURAVYU 3 mg (52)	Aflibercept 2mg q8W (52)
15 letter losers	4.3 %	3.8%	7.7 %
15 letter losers from GA	0	0	1
15 letter losers from glaucoma	0	0	0
AE of GA at study end	0	0	1

DAVIO 2 ≥15-letter vision loss consistent with other clinical trials

No observed GA supports assessment that DURAVYU does not cause GA

GA, geographic atrophy; AE, adverse event.
Preliminary data – pending final analysis

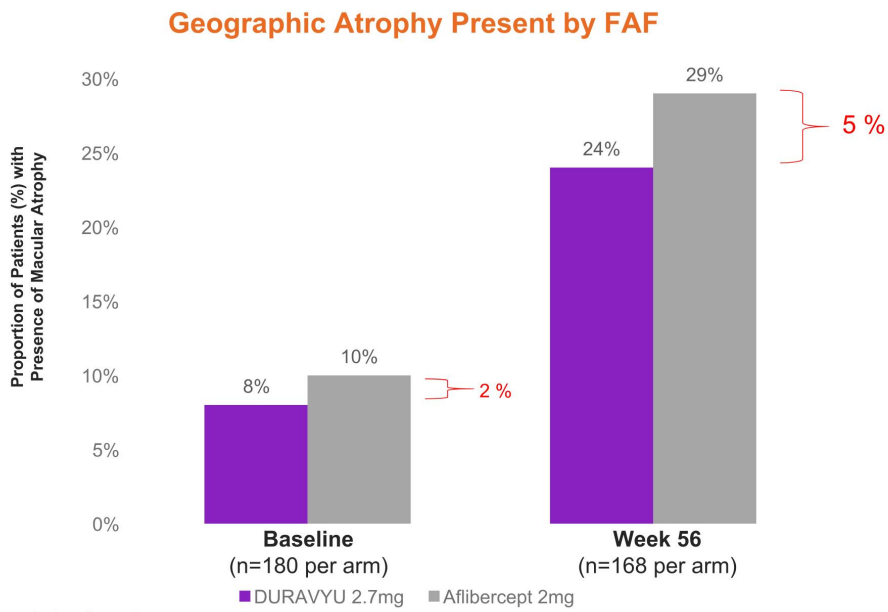
LUGANO: AEs Due to Dry AMD and GA Were Similar – Slightly Higher with Aflibercept

Select Ocular AEs in Study Eye	DURAVYU 2.7mg (N=211)	Aflibercept 2mg (N=221)
Cataract	4.3%	5.4%
Intraocular pressure increased	3.8%	3.2%
Intraocular inflammation (IOI)	0.5%	0.5%
Dry age-related macular degeneration	2.4%	3.2%
Geographic Atrophy ¹	2.4%	2.7%
Dry age-related macular degeneration ¹	0	0.5%
Retinal Detachment	0.5%	0.5%
Vision loss in patient with retinal detachment ²	-40 letters	+1 letter

Numerically higher rate of onset of GA in aflibercept control

1. Lower-level term (LLT) presented in AE table. LLT or geographic atrophy and dry age-related macular degeneration are part of the preferred term of dry age-related macular degeneration.
2. Patient in DURAVYU arm required surgery after retinal detachment and experienced cataract progression and development of epiretinal membrane that led to vision loss. Patient in aflibercept arm was pseudophakic.
AE, adverse event; AMD, age-related macular degeneration; GA, geographic atrophy.
Preliminary data – pending final analysis

LUGANO: Onset of New GA Was Greater in Aflibercept Arm



Note: GA progression determined by masked, independent reading center FAF, fundus autofluorescence.
Preliminary data – pending final analysis

LUGANO: GA Growth Rate Progression Consistent Between Treated and Fellow Eye and Slower than Historical Published Average

GA growth rate published average of ~2.0 mm²/year ¹

	DURAVYU Treated Eyes (n=211)	Untreated Fellow Eye (n=211)
Number of eyes w GA at the start of the study	n=14	n=25
Growth rate in mm ² per independent reading center ²	1.7 mm ²	1.6 mm ²

1. Holz F, et al. JAMA Ophthalmology, 2018. Khanani A, et al., Lancet, 2023. Heier J, et al., Lancet, 2023. Fleckenstein M, et al., Ophthalmology, 2018.
2. Fleckenstein M., Ophthalmology & Visual Science, 2010.
GA, geographic atrophy.

Preliminary data – pending final analysis

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LUGANO: GA Location at Baseline Was Closer to Fovea in DURAVYU Arm Compared to Aflibercept Arm

In DURAVYU eyes, GA started meaningfully closer to fovea at baseline compared to control, therefore at higher risk of losing vision

Distance from fovea	DURAVYU 2.7mg (N=14)	Aflibercept 2mg (N=17)
At baseline	825 microns	1009 microns
Change from Baseline	-236 microns	-254 microns

Progression towards fovea was similar between groups

Note: These patients met criteria for enrollment, as exclusion criteria regarding GA involved presence of atrophy in the center subfield at baseline.
GA, geographic atrophy.

Preliminary data – pending final analysis

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LUGANO: DURAVYU Arm Had Meaningfully Lower Rate of Fibrosis Progression Versus On-Label Aflibercept

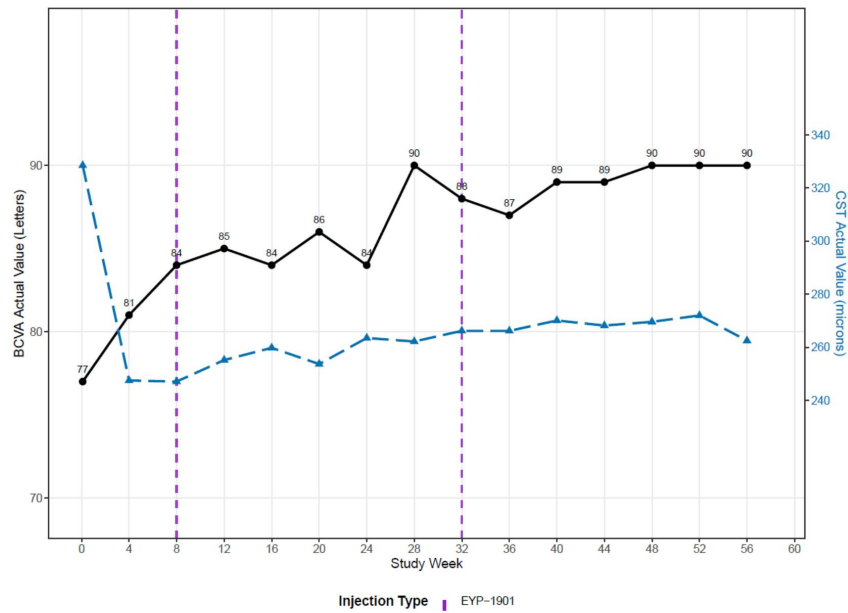
No increase in subretinal fibrosis
in the DURAVYU arm compared to the aflibercept arm

Proportion of Patients with Subretinal Fibrosis Present	DURAVYU 2.7mg	Aflibercept 2mg
Baseline	2.8% (6 of 211)	1.4% (3 of 216)
Week 56	4.1% (8 of 193)	4.1% (8 of 197)
Progression of Fibrosis from Baseline	+ 46%	+ 193%



Representative Case Studies

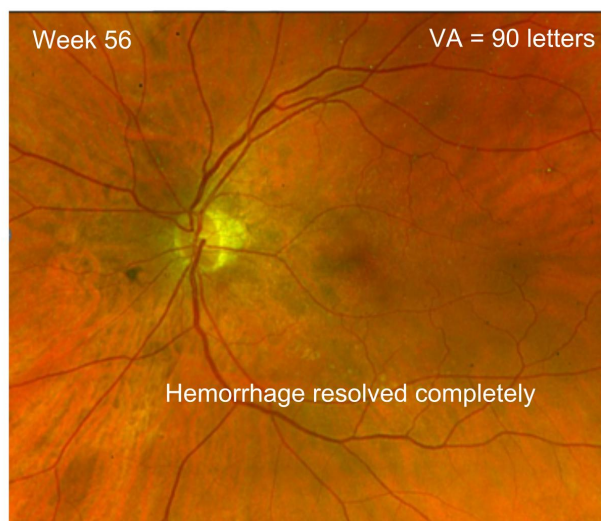
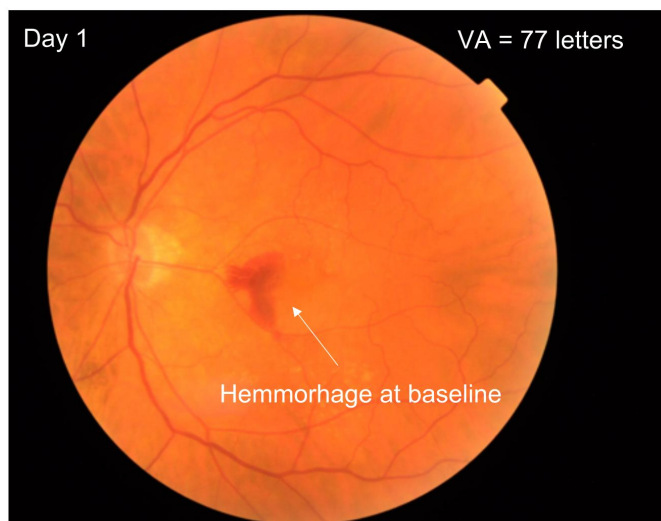
Case 1: DURAVYU 2.7 mg Supplement-free Patient with a 13 Letter VA Gain



VA, visual acuity; AE, adverse event; SAE, severe adverse event.
Preliminary data – pending final analysis

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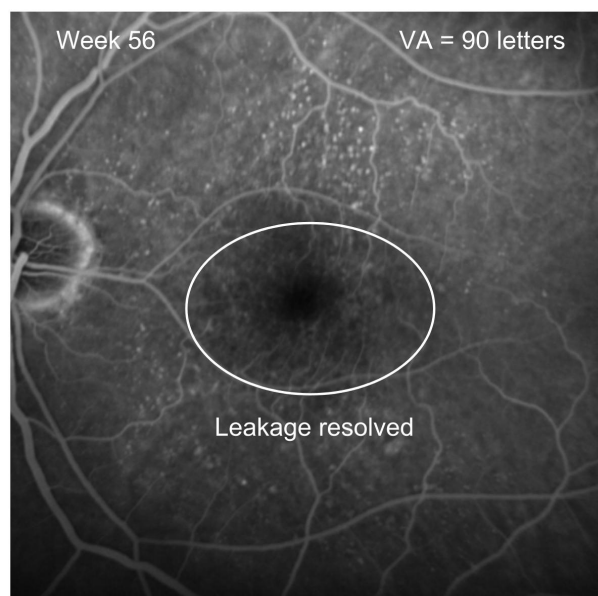
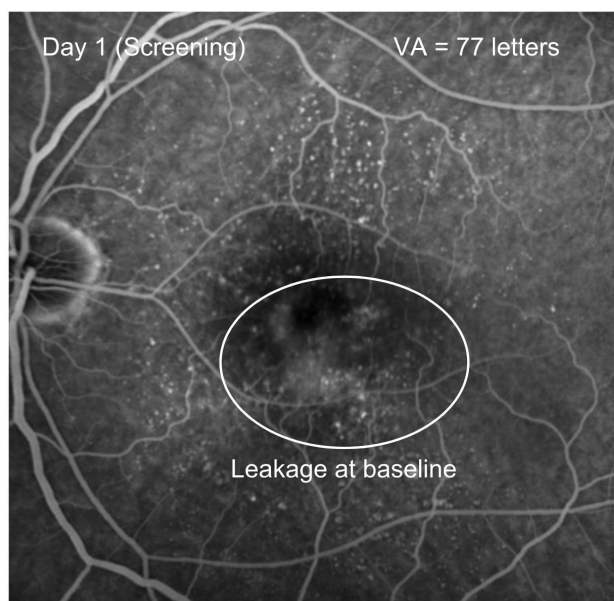
Case 1: DURAVYU 2.7 mg Supplement-free Patient with a 13 Letter VA Gain



VA, visual acuity.
Preliminary data – pending final analysis

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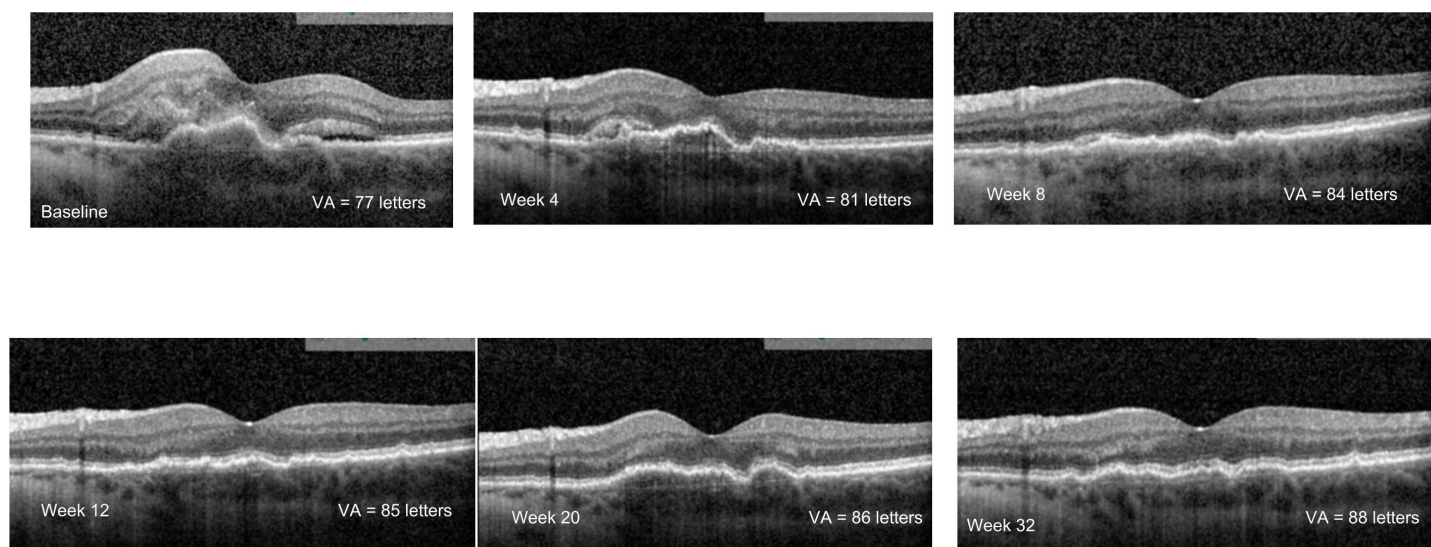
Case 1: DURAVYU 2.7 mg Supplement-free Patient with a 13 Letter VA Gain



VA, visual acuity.
Preliminary data – pending final analysis

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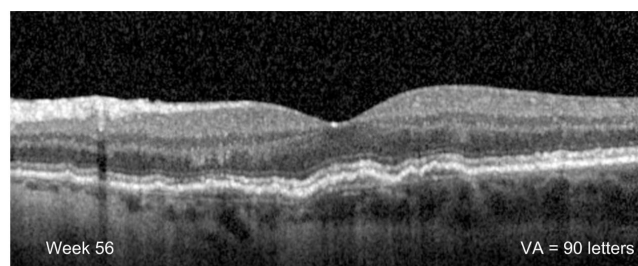
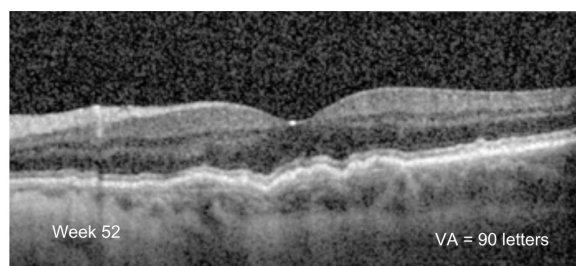
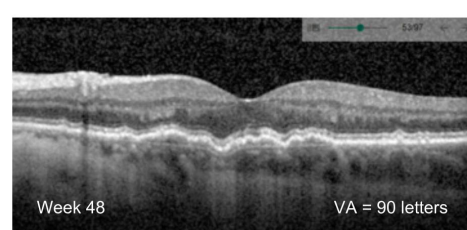
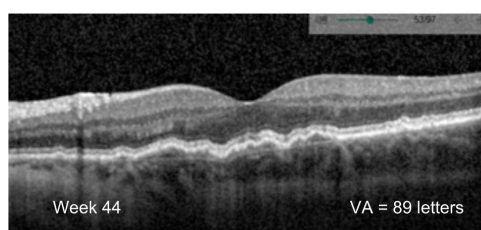
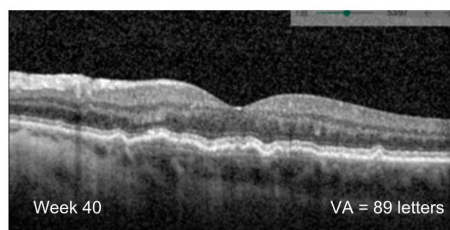
Case 1: DURAVYU 2.7 mg Supplement-free Patient with a 13 Letter VA Gain Well-Controlled Through Week 56



VA, visual acuity.
Preliminary data – pending final analysis

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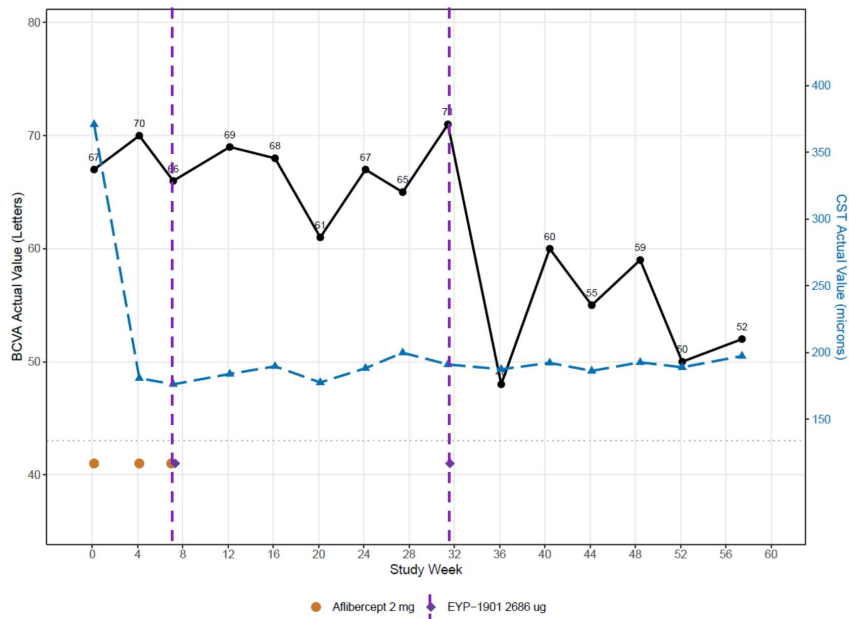
Case 1: DURAVYU 2.7 mg Supplement-free Patient with a 13 Letter VA Gain Well-Controlled Through Week 56



VA, visual acuity.
Preliminary data – pending final analysis

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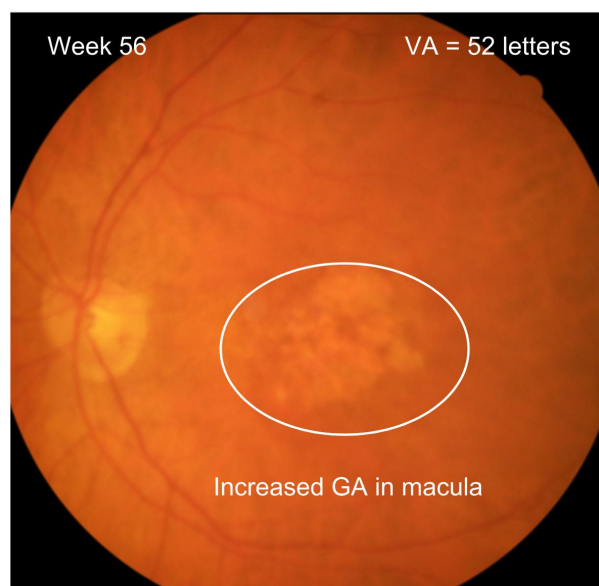
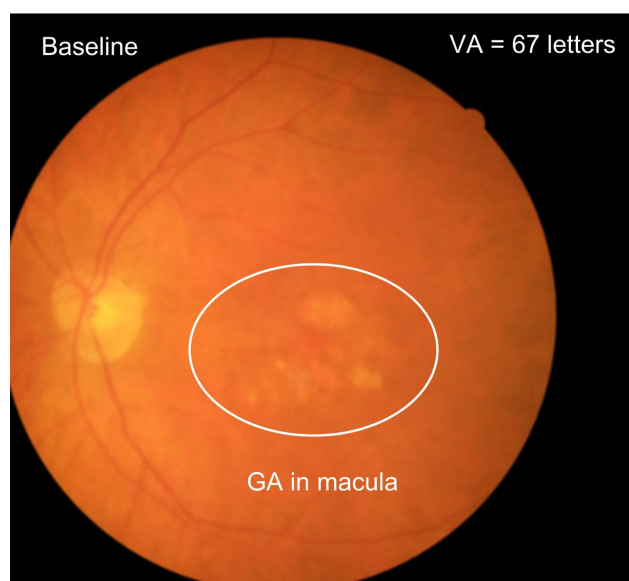
Case 2: DURAVYU 2.7 mg Supplement-free Pt with GA (VA Loss 15 Letters)



GA, geographic atrophy; VA, visual acuity; AE, adverse event; SAE, severe adverse event.
Preliminary data – pending final analysis

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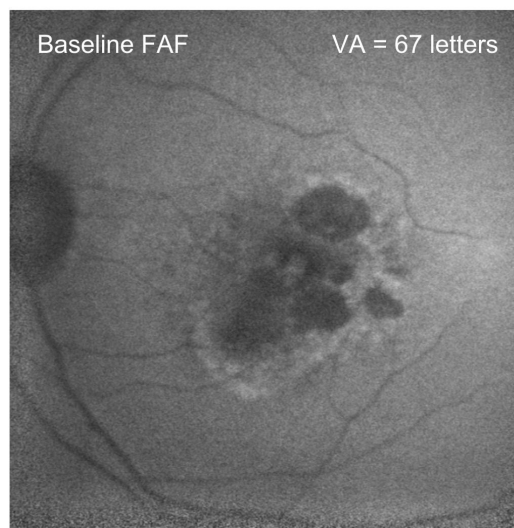
Case 2: DURAVYU 2.7 mg Supplement-free Pt with GA (VA Loss 15 Letters)



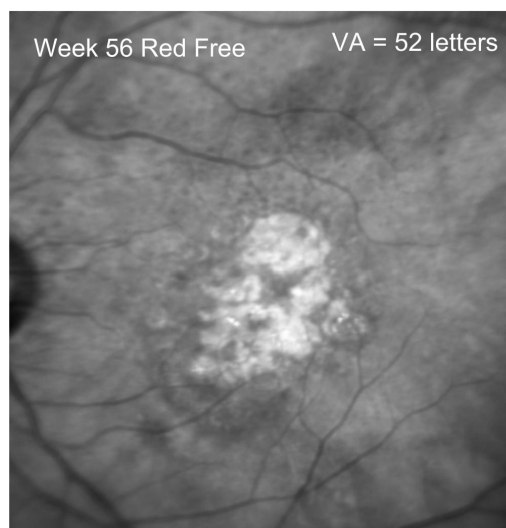
GA, geographic atrophy; VA, visual acuity.
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Case 2: DURAVYU 2.7 mg Supplement-free Pt with GA (VA Loss 15 Letters)



GA Area = 1.55 mm²

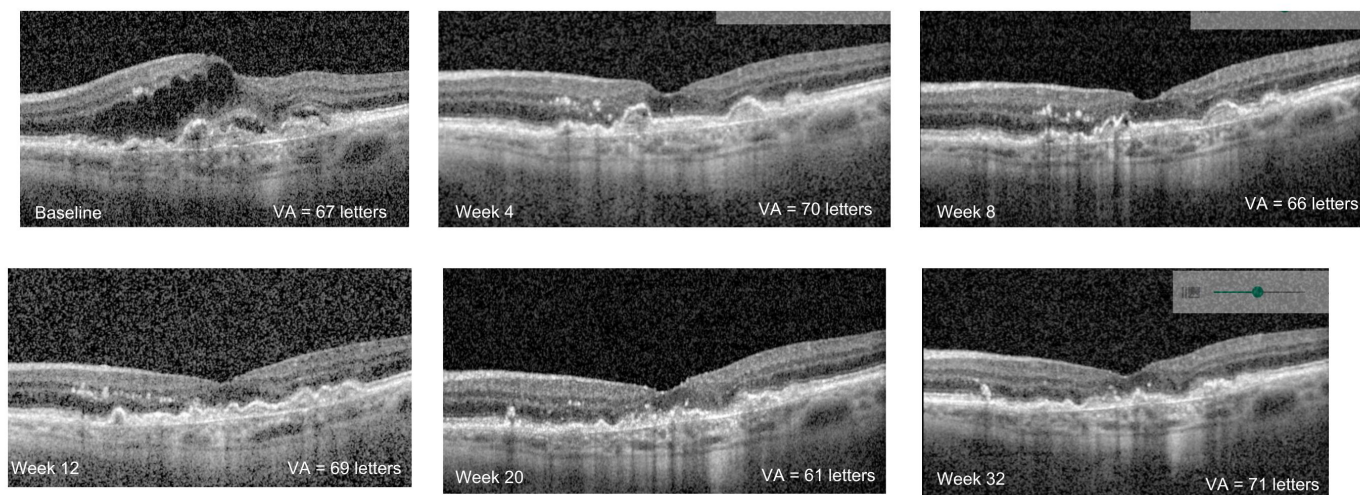


GA Area = 1.85 mm²
Growth rate = 0.30 mm²

Note: Reading center measurements.
GA, geographic atrophy; VA, visual acuity.
Preliminary data – pending final analysis

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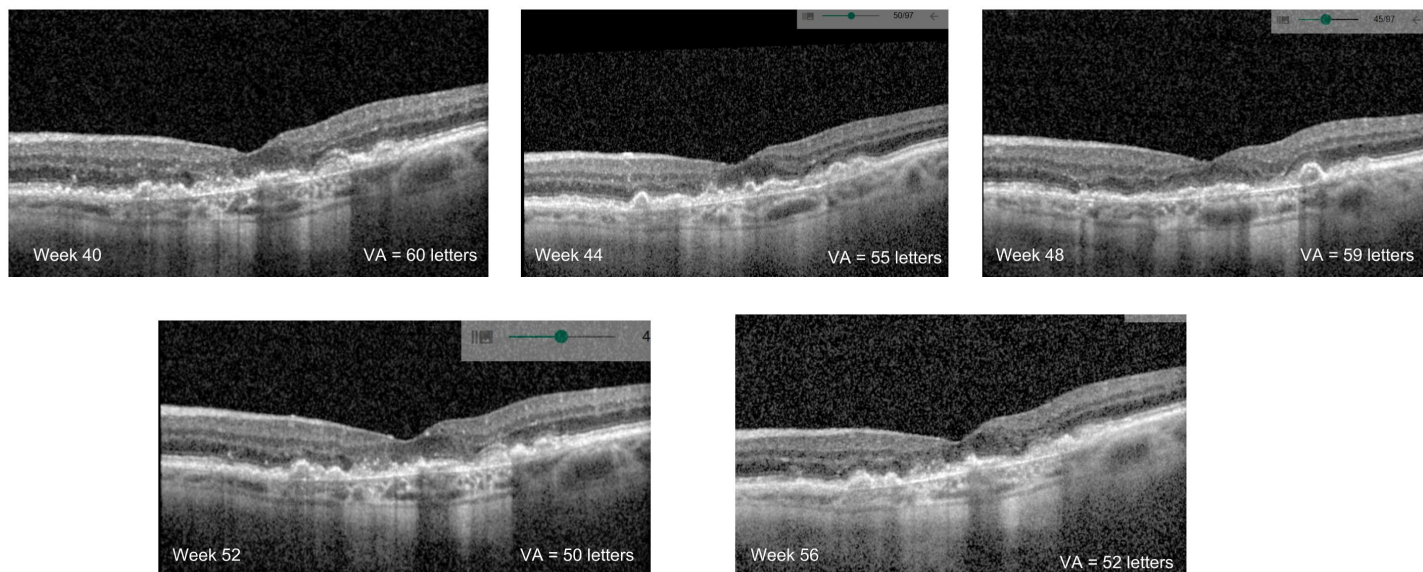
Case 2: DURAVYU 2.7 mg Supplement-free Pt with GA (VA Loss 15 Letters)



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Case 2: DURAVYU 2.7 mg Supplement-free Pt with GA (VA Loss 15 Letters)



GA, geographic atrophy; VA, visual acuity.
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Conclusions & Next Steps

LUGANO: Clinically Meaningful Results, Commercially Impactful Opportunity

PRIMARY ENDPOINT:

 Non-inferior (NI)

DURAVYU was non-inferior (nominal $p=0.0096$) excluding the asymmetric cohort, who experienced vision loss (≥ 15 letters) **unrelated to wet AMD**

>50% of eyes controlled by DURAVYU alone

SECONDARY ENDPOINTS:

-  Safety
-  Reduction in treatment burden (superiority vs on-label aflibercept)
-  Percent of eyes supplement-free
-  Anatomic stability

Favorable safety profile with redosing

42% reduction -superior to SOC (nominal $p<0.0001$)

79% received zero or 1 supplement

Only **4 microns difference** confirms potency

 **LUGANO supportive for NDA submission, pending positive LUCIA results**

AMD, age-related macular degeneration; NDA, New Drug Application.
Preliminary data – pending final analysis

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Key Takeaways from LUGANO Trial

1	Clinically relevant Phase 3 results against SOC on-label comparator
2	Only sustained-delivery TKI with Phase 3 repeat-dose safety
3	Topline result driven by imbalance of ≥ 15 -letter losses in control arm, despite DURAVYU activity
4	Regression-to-the-mean potential supports confidence in LUCIA

Totality of data supports DURAVYU differentiated profile in wet AMD

Strategy for NDA Filing in H1 2027, Provided Positive LUCIA Results

1	Pre-NDA meeting in Q4 2026 based on totality of data
2	Multiple precedents for NDA approval in ophthalmology following mixed results across two well-controlled Phase 3 trials
3	Strong secondary endpoints of safety, treatment burden reduction, and anatomic control
4	Clinically sound rationale for LUGANO ad hoc analyses

Upcoming DURAVYU Milestones Through 2027

1	LUCIA	- Includes learnings from LUGANO for the LUCIA analysis plan, ahead of topline results - Report topline data from the Phase 3 LUCIA wet AMD trial	Q4 2026
2	Wet AMD NDA	- Engage FDA to discuss Wet AMD data package - Submit comprehensive Phase 3 data package (LUGANO & LUCIA) to FDA	Q4 2026 H1 2027
3	DME Program	Report topline data simultaneously for both pivotal DME trials, COMO and CAPRI	Q4 2027

LUGANO Phase 3 Clinical Trial

DURAVYU in Wet AMD

Expanded Results & Analyses | September 2026

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