Efficacy and Safety of Aflibercept 8 mg in Previously Treated Patients with nAMD or DME: 24-week Results from the Phase 3b ELARA Trial

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DISCLOSURES

Diana V. Do is a consultant to Alcon, Apellis, AsclepiX, Bayer, Belite Bio, Boehringer Ingelheim, Eyepoint, Genentech, Kodiak Sciences, Kriya, Neurotech, Ocular Therapeutix, Regeneron Pharmaceuticals, Inc., and REGENXBIO; and has received research funding from Apellis, AsclepiX, Belite Bio, Boehringer Ingelheim, Genentech, Kriya, Neurotech, Ocular Therapeutix, Regeneron Pharmaceuticals, Inc., and REGENXBIO. Medical writing support was provided by Stephanie Agbu, PhD, of Regeneron Pharmaceuticals, Inc.

ELARA Study Design

Study eyes (N=1110) previously treated with ≥3 anti-VEGF injections within 5 months prior to study start in:

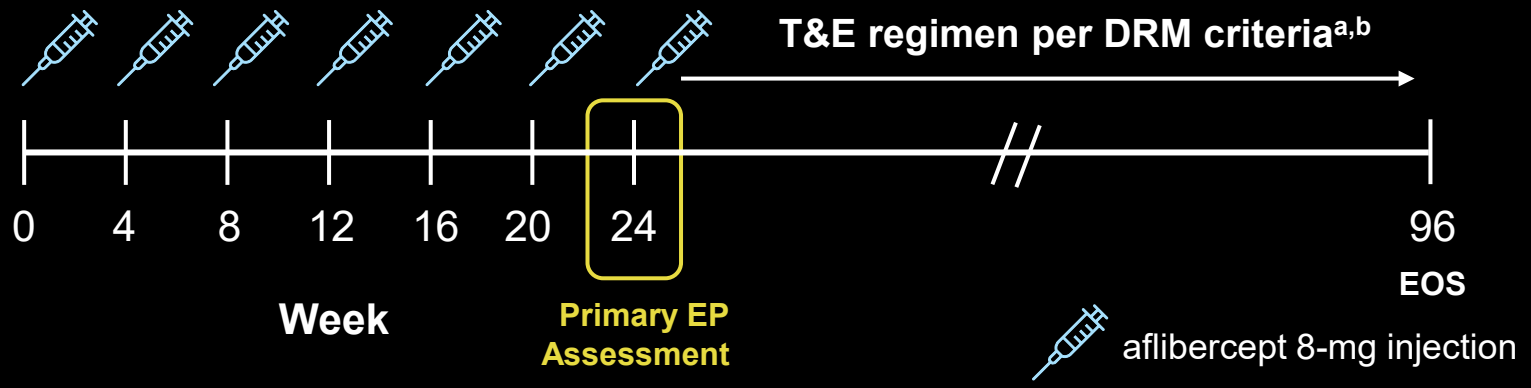
nAMD (n=622)

Patients aged ≥50 years with CNV lesions due to nAMD

DME (n=488)

Patients aged ≥18 years with center-involved DME

1110 patients enrolled across 53 US sites



[a]DRM-E: Interval Extension

- **nAMD**
  - No retinal fluid in central subfield **AND**
  - No new-onset foveal neovascularization or hemorrhage **AND**
  - No interval shortening within the prior 12 weeks
- **DME**
  - CST <300 µm (or <320 µm on Spectralis) **AND**
  - ≤10-µm increase from lowest previous CST value **AND**
  - No interval shortening within the prior 12 weeks
- Intervals are extended in **1-week or 2-week increments** based on response to treatment

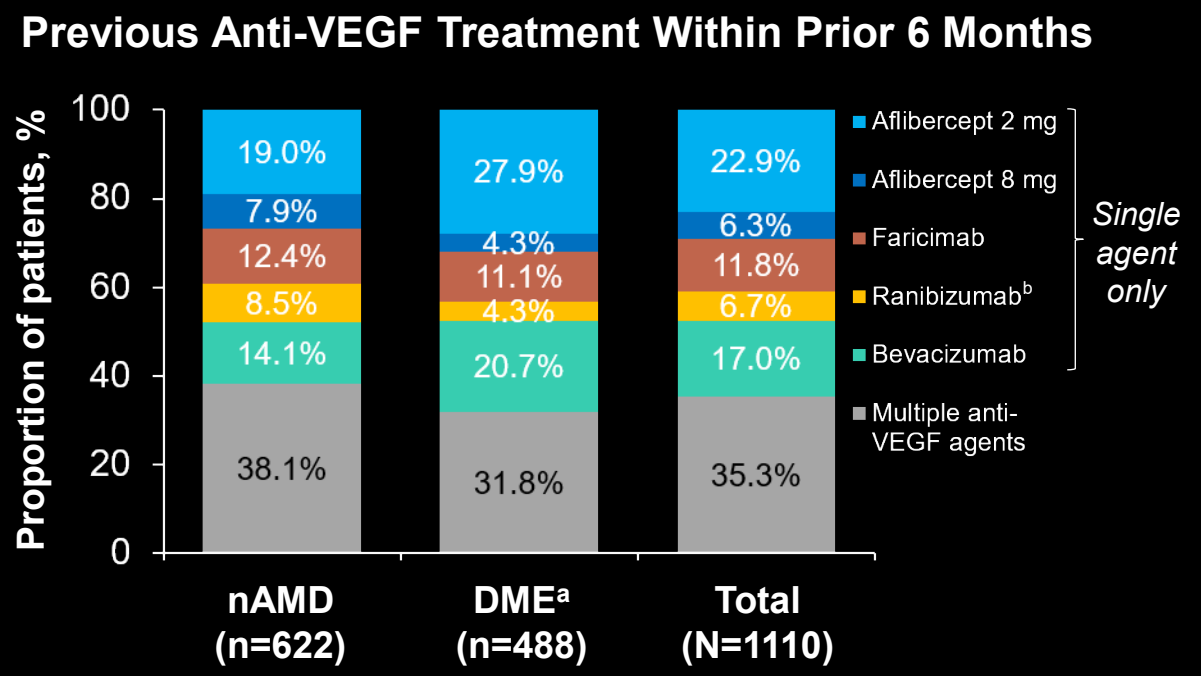
[b]DRM-S: Interval Shortening

- **nAMD**
  - Any new retinal fluid in central subfield **OR**
  - New-onset foveal neovascularization or hemorrhage **OR**
  - >5-letter loss in BCVA from best previous value
- **DME**
  - >25-µm increase in CST from previous visit **OR**
  - >10-letter loss in BCVA from best previous value
- Intervals are shortened in **1-week increments**
- The minimum interval is Q4

BCVA, best-corrected visual acuity; CNV, choroidal neovascularization; CST, central subfield thickness; DME, diabetic macular edema; DRM, dose regimen modification; EOS, end of study; EP, endpoint; nAMD, neovascular age-related macular degeneration; T&E, treat and extend; VEGF, vascular endothelial growth factor.

Baseline Characteristics and Previous Treatment Exposure

	nAMD (n=622)	DME (n=488)	Total (N=1110)
Age, mean (SD), years	77.1 (8.5)	62.8 (9.8)	70.8 (11.5)
Female, n (%)	360 (57.9)	203 (41.6)	563 (50.7)
Hispanic or Latino, n (%)	43 (6.9)	114 (23.4)	157 (14.1)
White, n (%)	589 (94.7)	387 (79.3)	976 (87.9)
History of hypertension, n (%)	459 (73.8)	397 (81.4)	856 (77.1)
BCVA, mean (SD), ETDRS letters	68.0 (15.3)	69.8 (13.4)	68.8 (14.5)
CST, mean (SD), µm	254.3 (66.0)	328.1 (104.0)	287.1 (92.5)



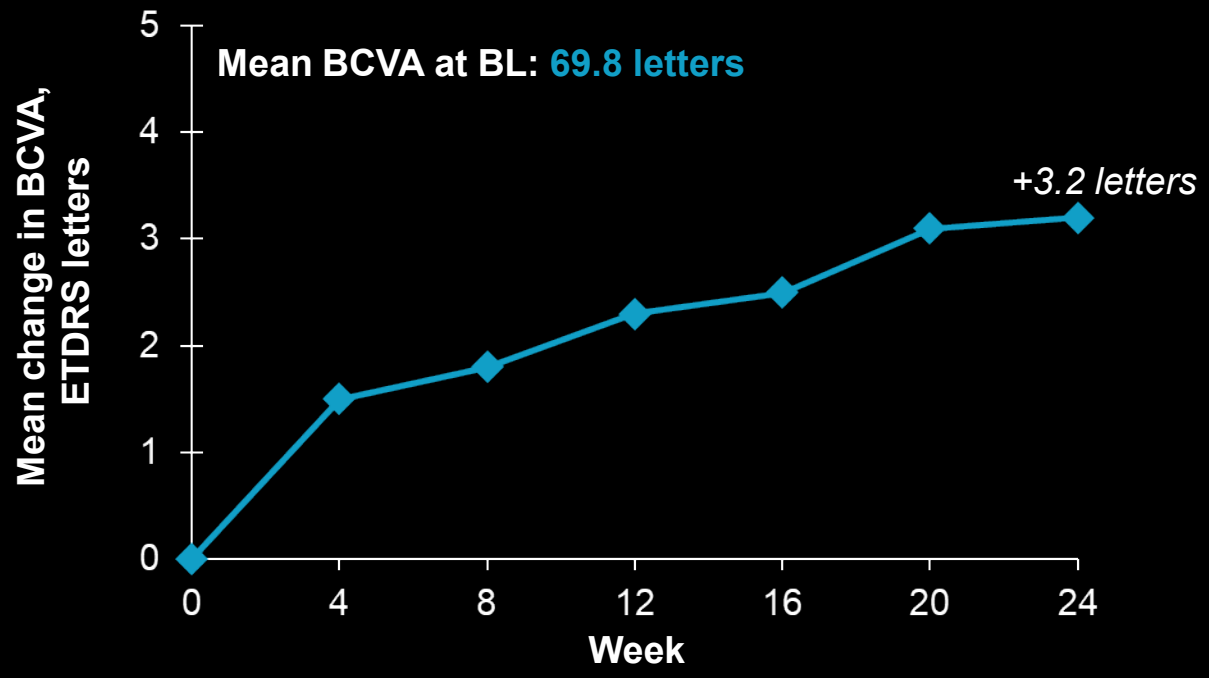
- Most patients (nAMD: 63.2%; DME: 75.8%) received 3-4 anti-VEGF injections in the study eye in the 6 months before trial start

SAF.
ETDRS, Early Treatment Diabetic Retinopathy Study; SAF, safety analysis set.
[a]Data for 1 patient in the DME cohort were missing.
[b]Ranibizumab or ranibizumab biosimilar (ranibizumab-eqrn or ranibizumab-nuna).

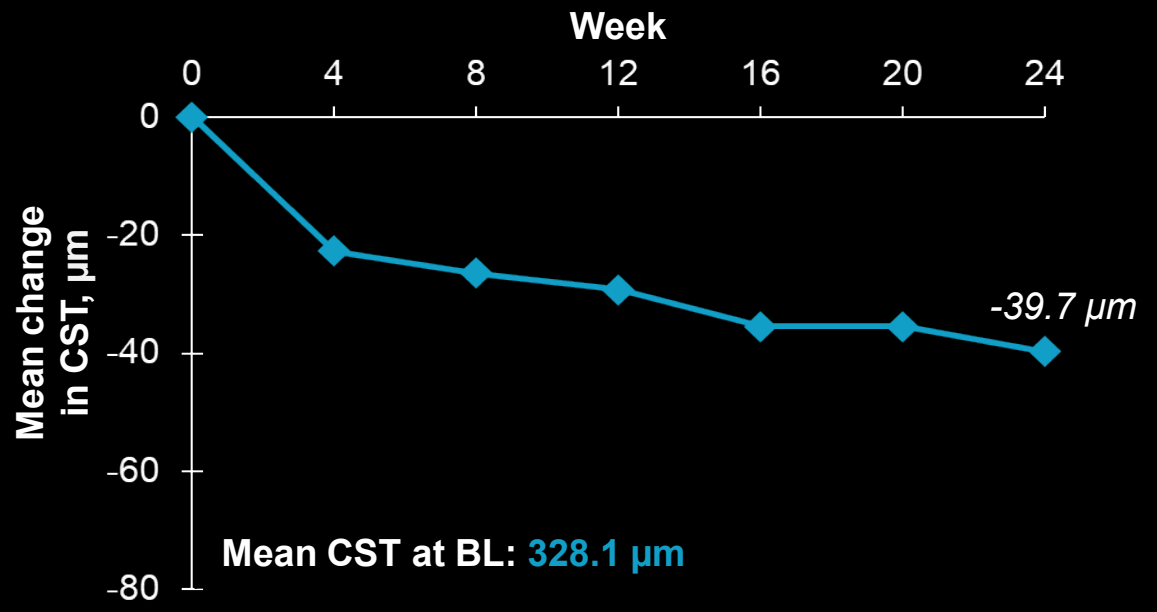
Mean Change in BCVA and CST Through Week 24 in Patients With nAMD or DME

ELARA

Mean change in BCVA



Mean change in CST



	Proportion of patients with ≥5-letter gain at Week 24	Mean number of injections through Week 24
DME (n=488)	36.8%	5.8

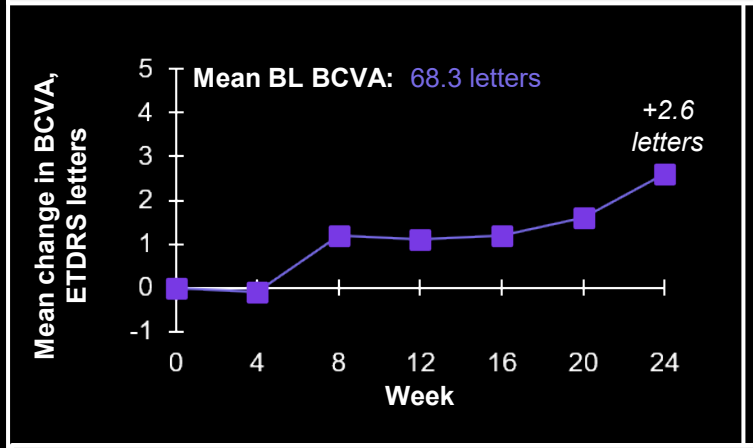
SAF, observed cases.
BL, baseline.

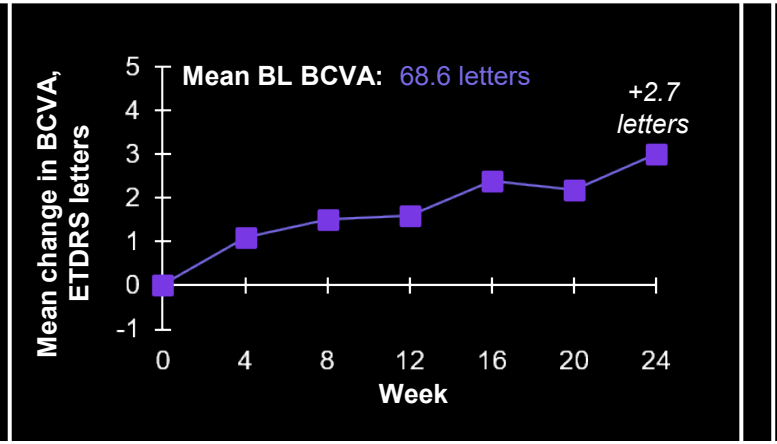
Improvement in BCVA and CST Through Week 24 in Patients with nAMD by Prior Anti-VEGF Therapy[a]

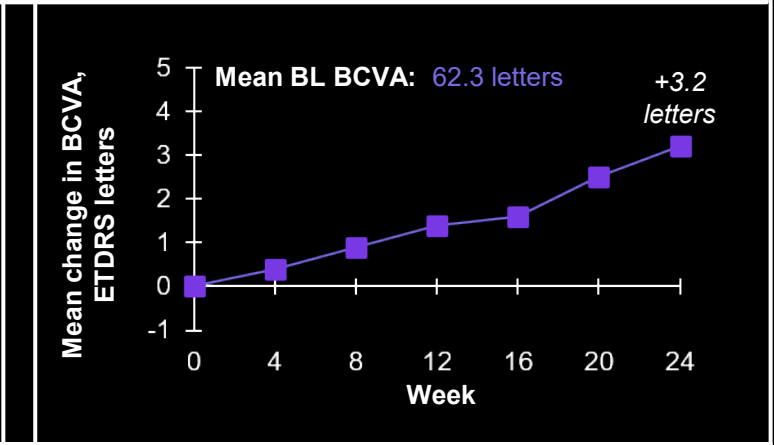
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Aflibercept 2 mg[a] (n=118)	Faricimab[a] (n=77)	Bevacizumab[a] (n=88)

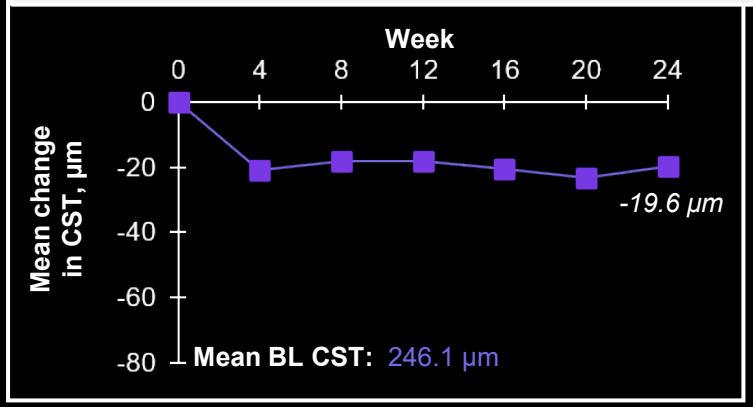
Mean Change in BCVA

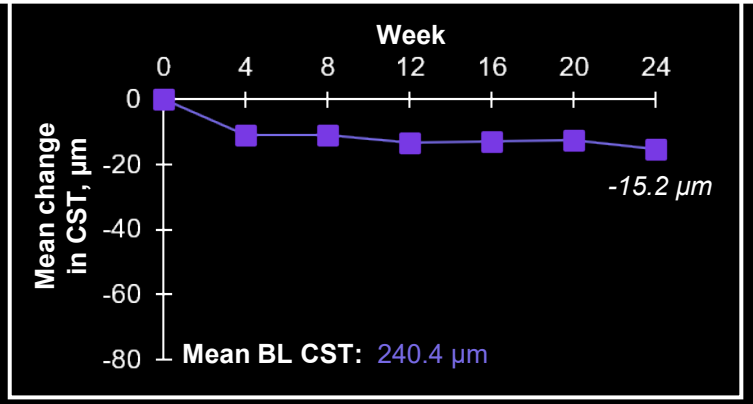


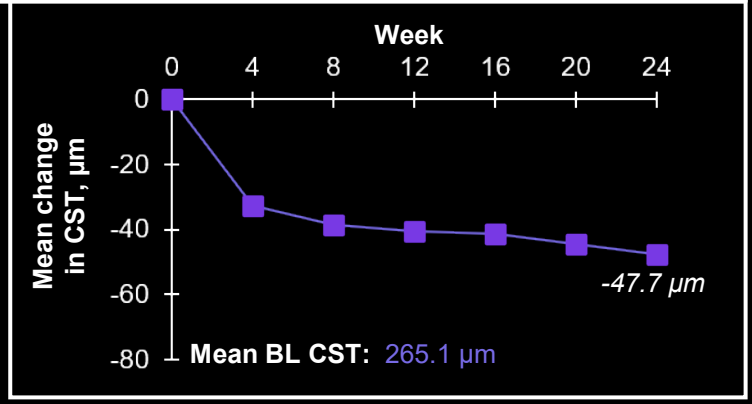




Mean Change in CST







SAF, observed cases.

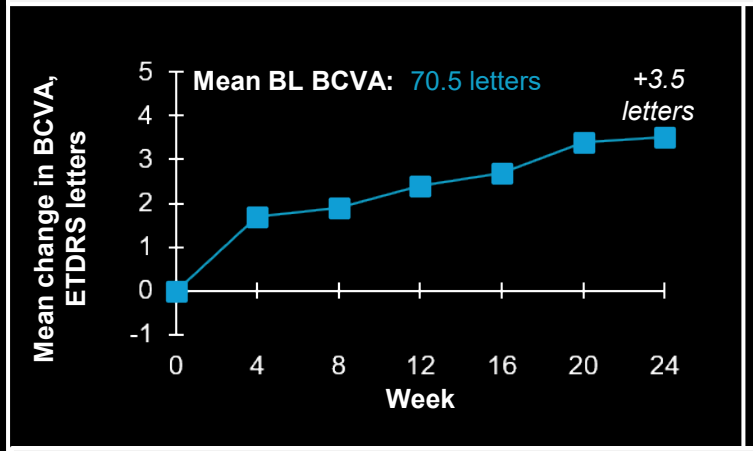
[a]Patients received only aflibercept 2 mg, faricimab, or bevacizumab in the 6 months prior to trial start.

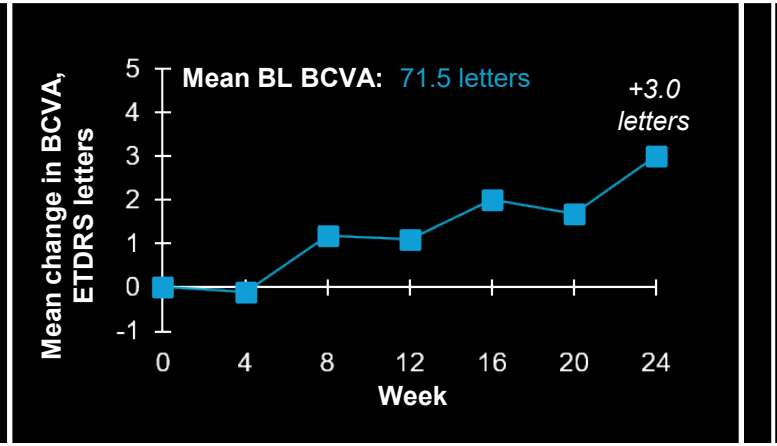
Improvement in BCVA and CST Through Week 24 in Patients with DME by Prior Anti-VEGF Therapy[a]

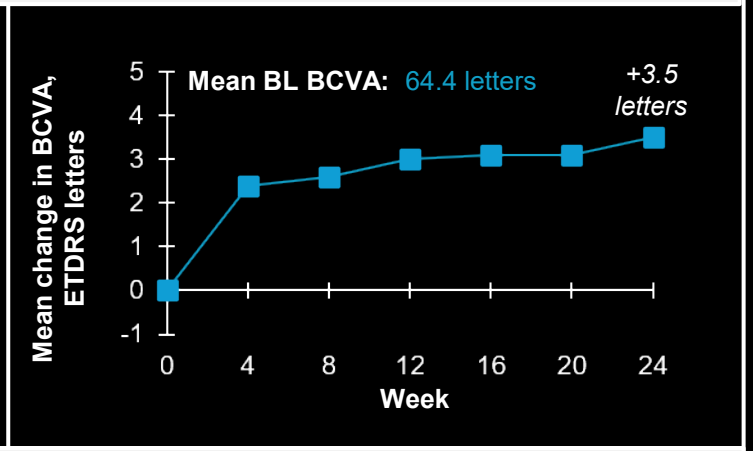
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Aflibercept 2 mg[a] (n=136)	Faricimab[a] (n=54)	Bevacizumab[a] (n=101)

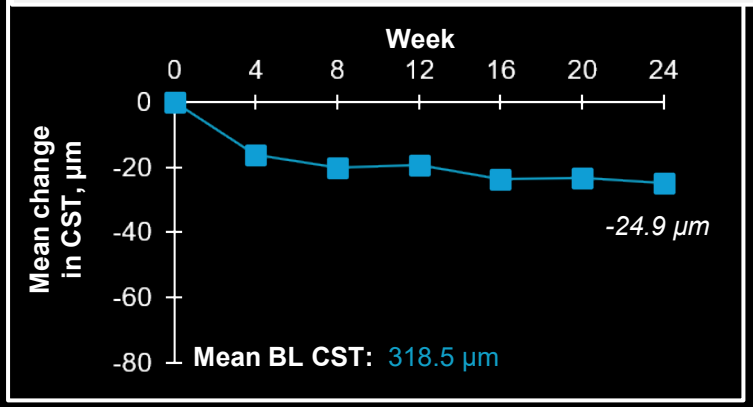
Mean Change in BCVA

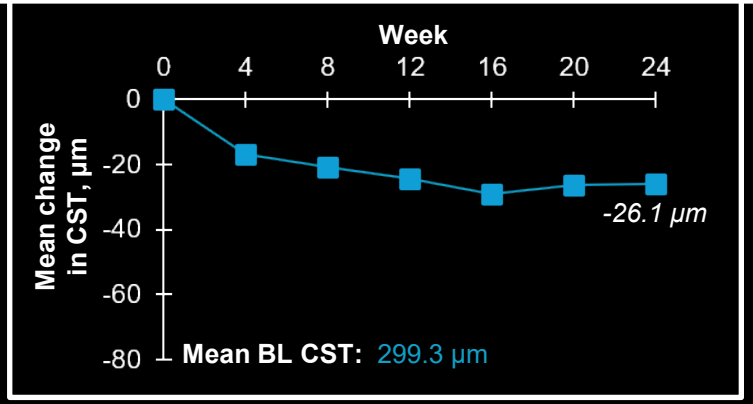


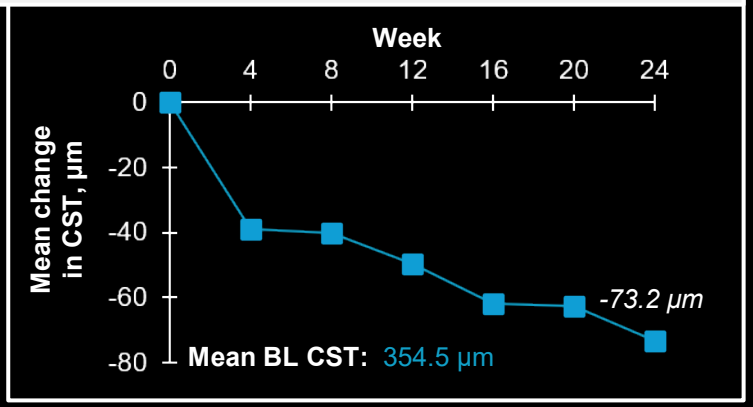




Mean Change in CST







SAF, observed cases.

[a]Patients received only aflibercept 2 mg, faricimab, or bevacizumab in the 6 months prior to trial start.

Ocular and Non-ocular Safety Through Week 24

	nAMD (n=622)	DME (n=488)	Total (N=1110)
Patients with ≥1 ocular TEAE, n (%)[a]	106 (17.0)	109 (22.3)	215 (19.4)
Patients with ≥1 serious ocular TEAE, n (%)[a]	1 (0.2)	4 (0.8)	5 (0.5)
Endophthalmitis	0	3 (0.6)	3 (0.3)
Retinal detachment	1 (0.2)	0	1 (<0.1)
Vasculitis	0	1 (0.2)	1 (<0.1)
Patients with ≥1 IOI TEAE, n (%)[a]	6 (1.0)	5 (1.0)	11 (1.0)
Patients with ≥1 serious non-ocular TEAE, n (%)	31 (5.0)	35 (7.2)	66 (5.9)
Patients with ≥1 hypertension-related TEAE, n (%)	22 (3.5)	14 (2.9)	36 (3.2)
Death, n (%)[b]	2 (0.3)	4 (0.8)	6 (0.5)

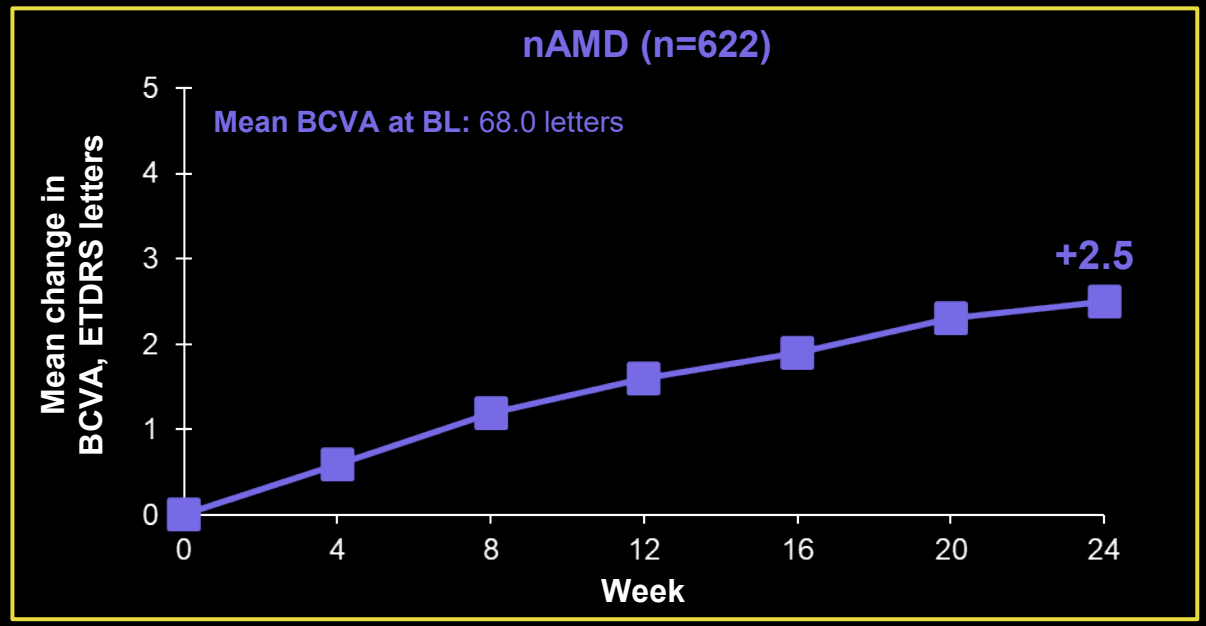
- In the study eye, no clinically relevant change in pre-dose IOP was observed in all patients over time

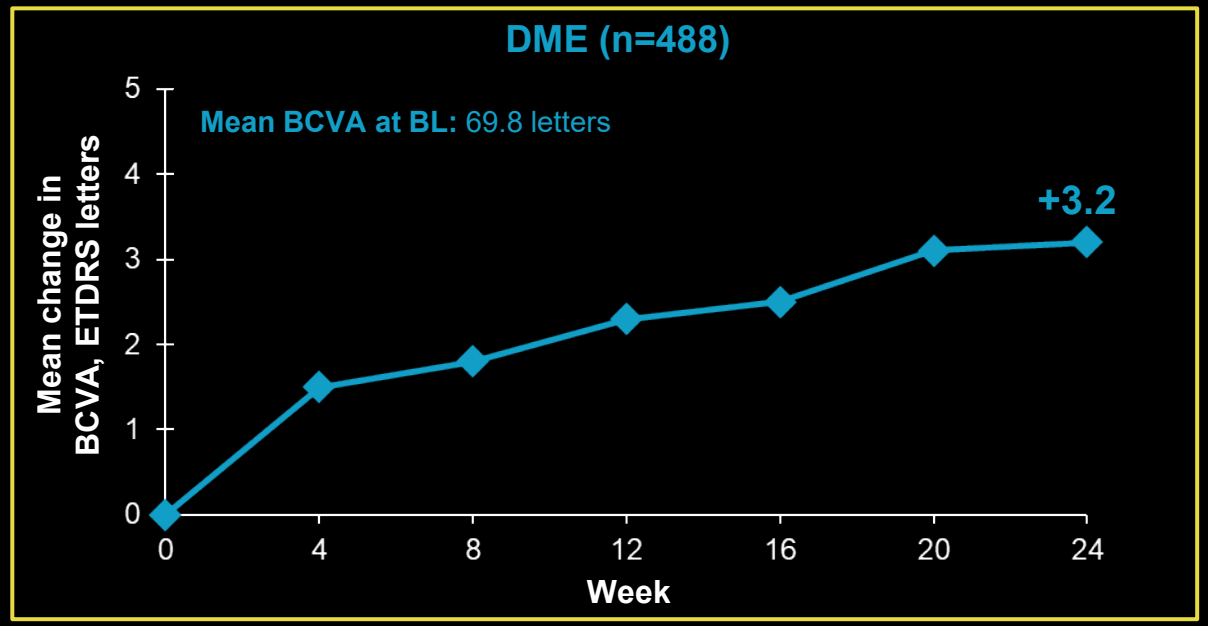
SAF.
IOI, intraocular inflammation; IOP, intraocular pressure; TEAE, treatment-emergent adverse event.
[a]In the study eye.
[b]All events.

ELARA Summary of Week 24 Results

- Aflibercept 8 mg every 4 weeks achieved meaningful functional and anatomic improvements at Week 24 in patients who previously received frequent anti-VEGF injections for nAMD or DME
  - Overall, comparable visual and anatomic improvements were observed in patients with nAMD or DME who were previously treated with aflibercept 2 mg, faricimab, or bevacizumab
- The safety profile of monthly dosing with aflibercept 8 mg through Week 24 was consistent with the established safety profile of aflibercept 2 mg and 8 mg

Mean Change in BCVA Through Week 24





SAF, observed cases.