SPECTRUM: Early clinical experience from the first global real-world study of aflibercept 8 mg in patients with treatment-naïve neovascular age-related macular degeneration

Vasileios Konidaris,[1] Clemens Lange,[2,3] Marion R. Munk,[4,5,6] Paolo Lanzetta,[7,8] Varun Chaudhary,[9] Hassiba Oubraham,[10]

Tobias Machewitz,[11] Helmut Allmeier,[12] Xin Zhang,[12] Clare Bailey,[13] on behalf of the SPECTRUM study investigators

[1]Department of Ophthalmology, University Hospitals of Leicester NHS Trust, Leicester, UK;
[2]Eye Center, Faculty of Medicine, Albert-Ludwig University Freiburg, Freiburg, Germany; [3]Department of Ophthalmology, St Franziskus Hospital, Münster, Germany;
[4]Augenarzt Praxisgemeinschaft Gutblick AG, Pfäffikon, Switzerland; [5]Department of Ophthalmology, University Hospital Bern, Switzerland;
[6]Northwestern University, Feinberg School of Medicine, Chicago, IL, USA; [7]Department of Medicine–Ophthalmology, University of Udine, Udine, Italy;
[8]Instituto Europeo di Microchirurgia Oculare (IEMO), Udine, Italy; [9]Hamilton Regional Eye Institute, St Joseph's Healthcare Hamilton, McMaster University, Hamilton, ON, Canada; [10]Centre OPHTA-45, Montargis, France; [11]Bayer AG, Berlin, Germany; [12]Bayer Consumer Care AG, Basel, Switzerland;
[13]Department of Ophthalmology, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK

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SPECTRUM: Global real-world study of aflibercept 8 mg

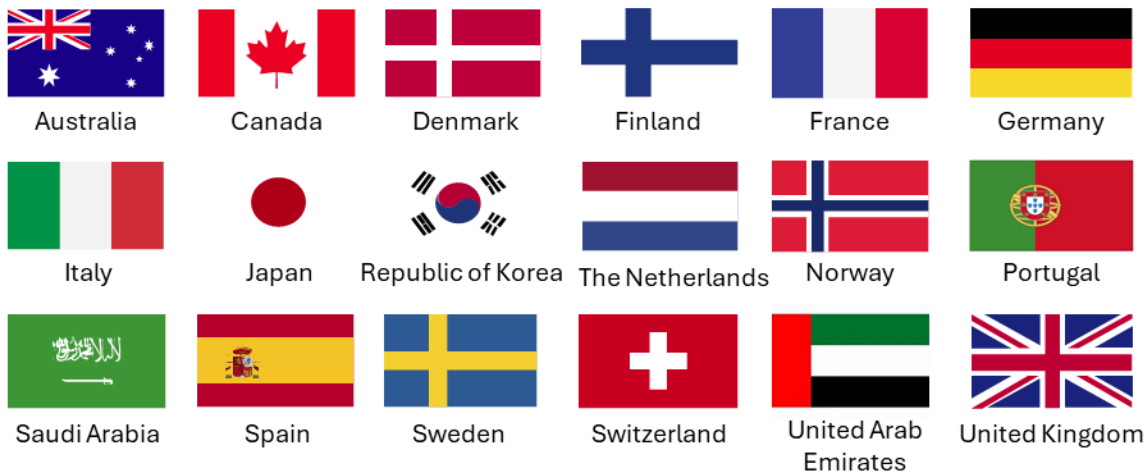
A **24-month, non-interventional country** and **global cohort** study planned in **18 countries**

2 indications, 4 patient cohorts

Treatment-naïve **nAMD** and previously treated **nAMD**
Treatment-naïve **DME** and previously treated **DME**

Primary endpoint: Change in **VA** from **BL to Month 12**

To date, **2308** patients enrolled



Secondary endpoints include:

- Change in **VA** and **CRT** from BL to Month 6
- Number of **injections** and **visits**, and **safety** through Month 6

BL, baseline; CRT, central retinal thickness; DME, diabetic macular edema; nAMD, neovascular age-related macular degeneration; VA, visual acuity.

SPECTRUM inclusion criteria

	Population	Diagnosis	Treatment
nAMD cohorts	Aged ≥50 years	A diagnosis of nAMD	Patients across all cohorts had to have been prescribed aflibercept 8 mg as part of routine clinical practice
DME cohorts	Aged ≥18 years with type 1 or type 2 diabetes mellitus	A diagnosis of DME	

All patients were categorized as being either:

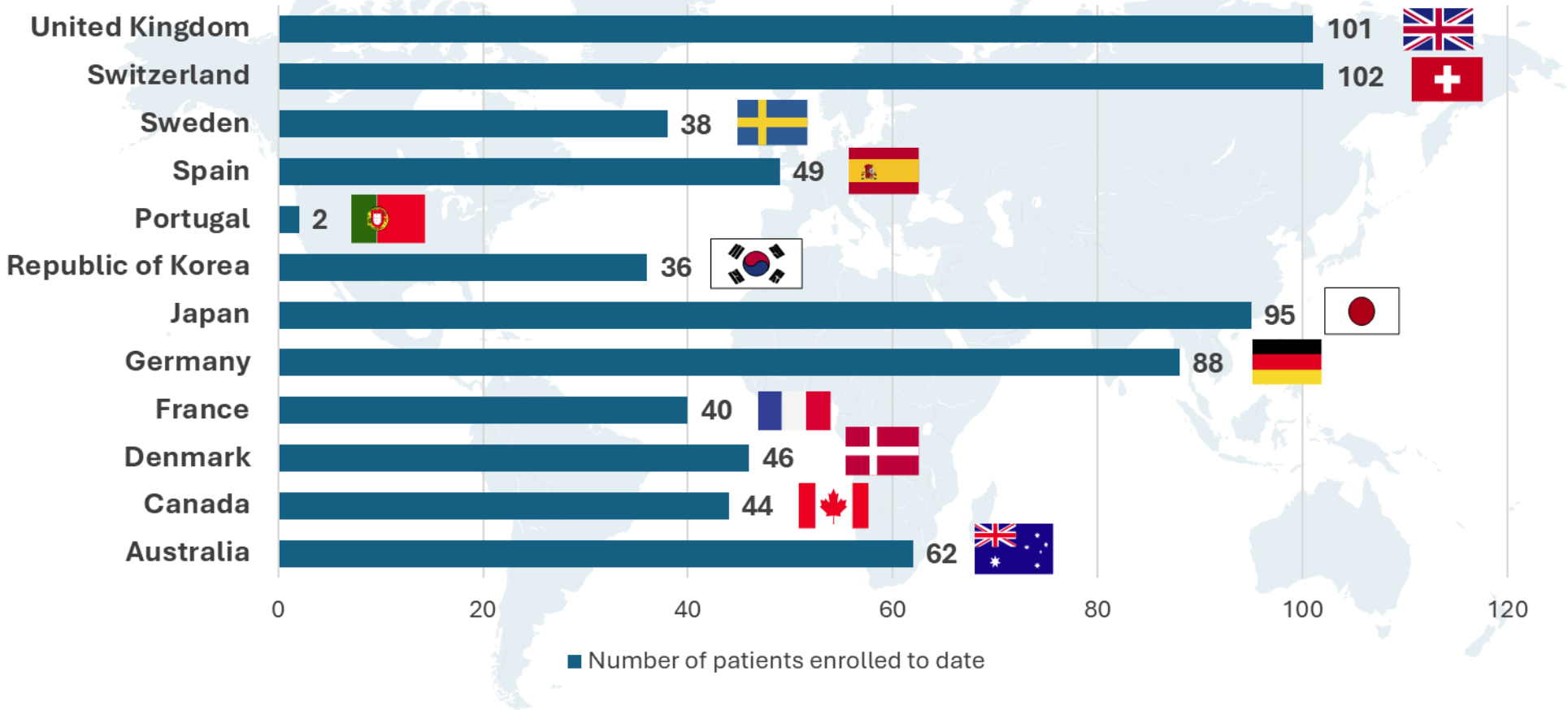
Treatment-naïve
Never been exposed to any medical treatment for nAMD/DME

Previously treated
Received prior treatment, including other anti-VEGFs, up to prespecified timepoints before study start

Anti-VEGF, anti-vascular endothelial growth factor.

Enrollment overview

To date, **703** out of **1200 (59%)** planned patients have been enrolled in the **treatment-naïve nAMD** cohort (as of April 17, 2025)



SPECTRUM

Early outcomes in the first ~100 patients with treatment-naïve nAMD who had a visit and VA assessment at Week 4

Baseline characteristics: Treatment-naïve nAMD

Analysis of patients with a VA assessment at Week 4[a]

Total: 100 patients

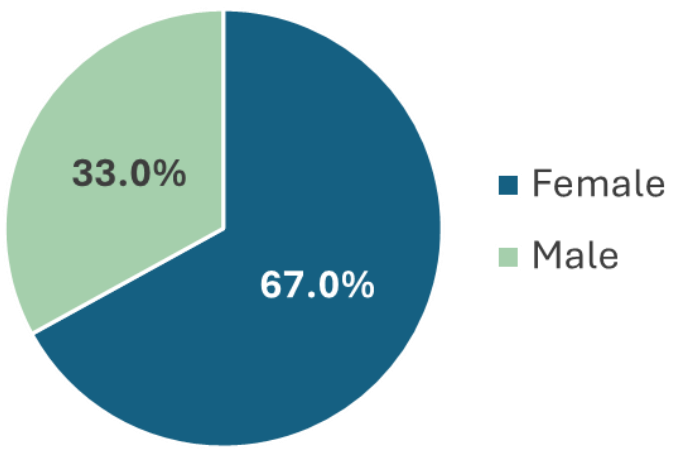
Mean age: 79.7 ± 6.6 years

Median (min, max) time from nAMD diagnosis: 0.1 (0.0, 21.9) months

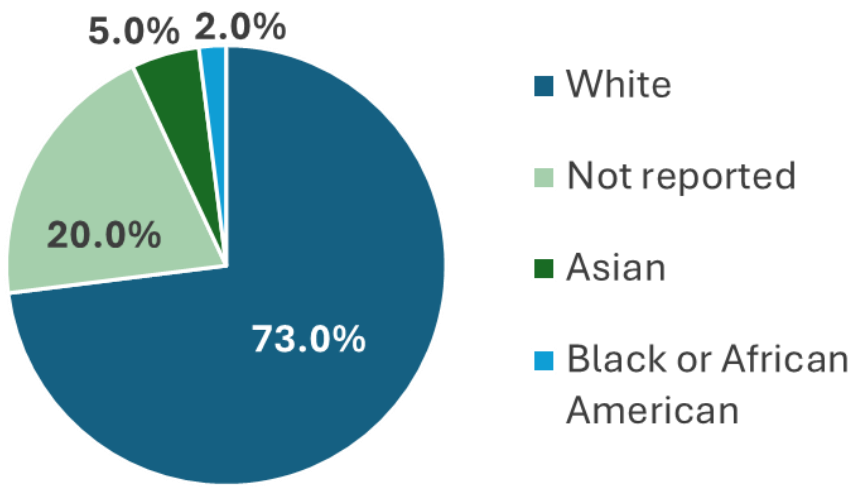
Mean baseline VA: 60.2 ± 17.4 ETDRS letters

Mean baseline CRT: 374 ± 124 µm

Sex



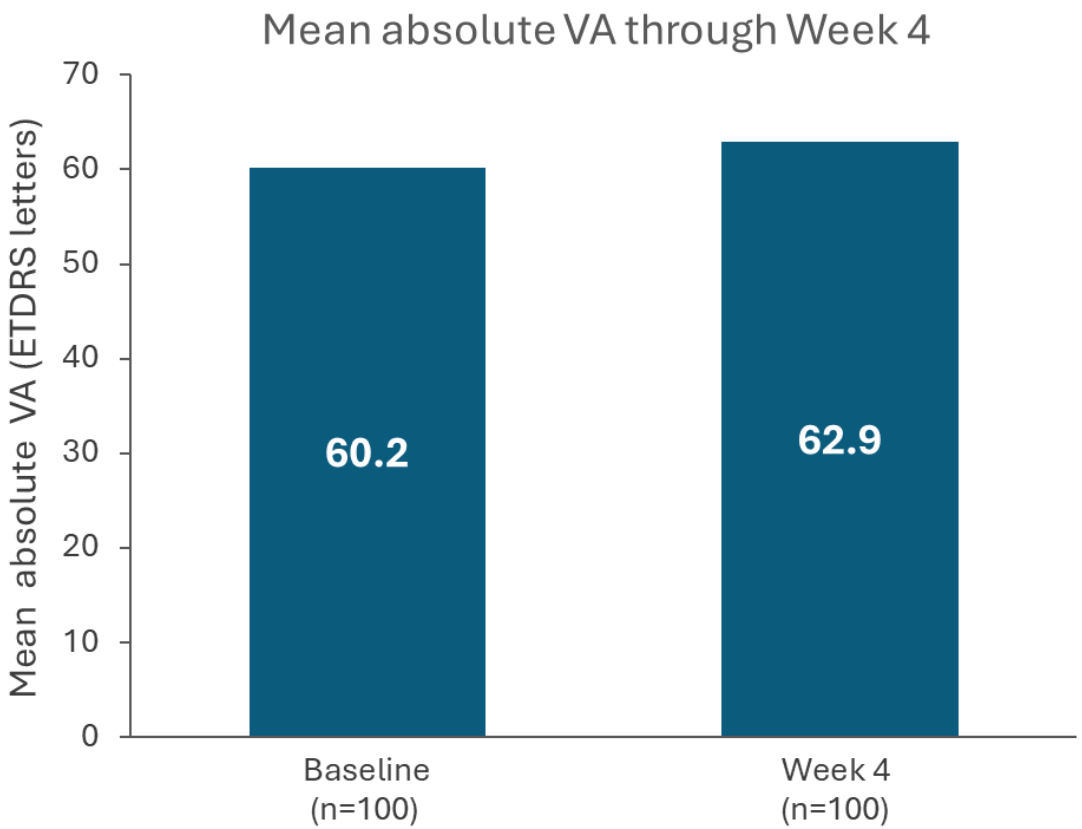
Race[b]

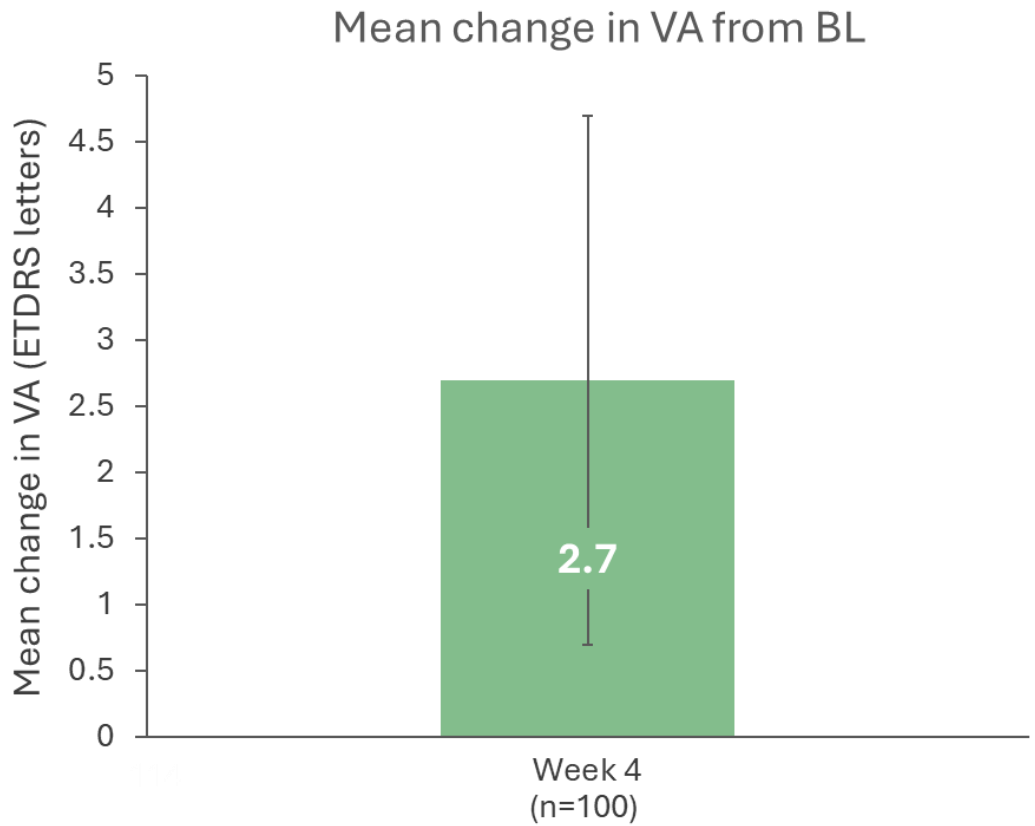


FAS. Percentages may not add up to 100 due to rounding.

[a]Data are mean ± SD unless otherwise indicated. [b]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the UK only.
ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; Max, maximum; Min, minimum; SD, standard deviation; UK, United Kingdom.

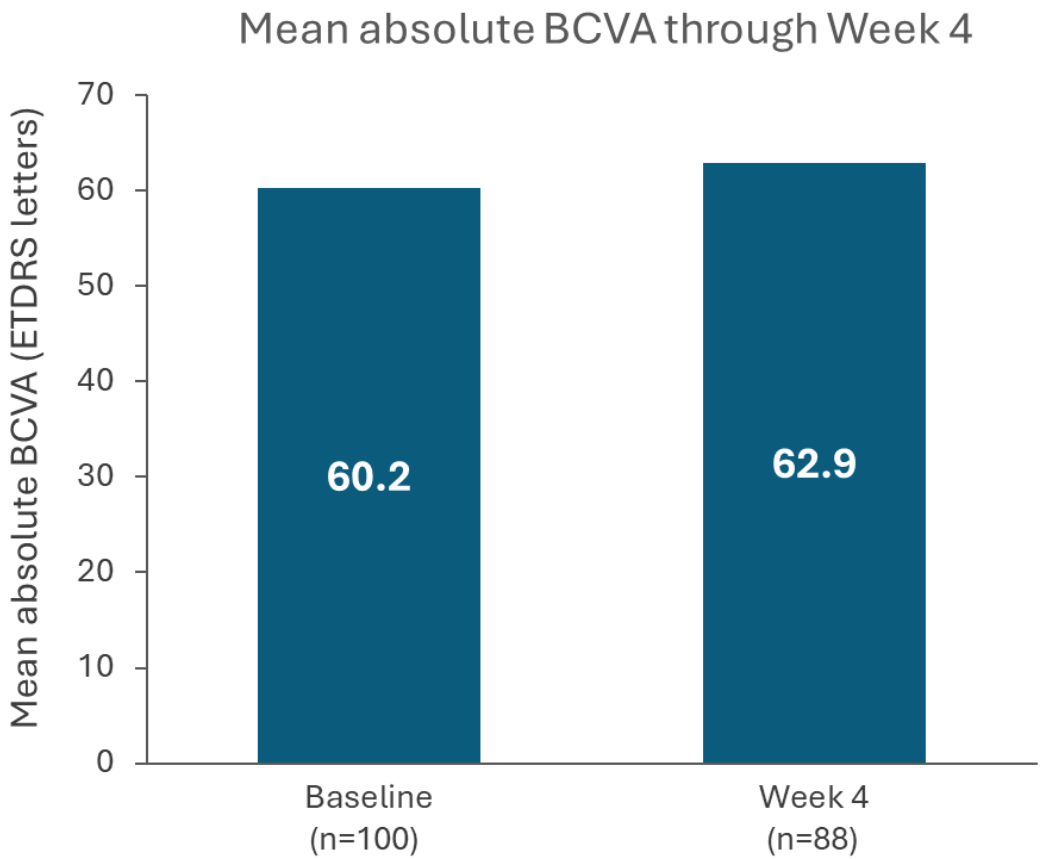
Key endpoint: VA through Week 4

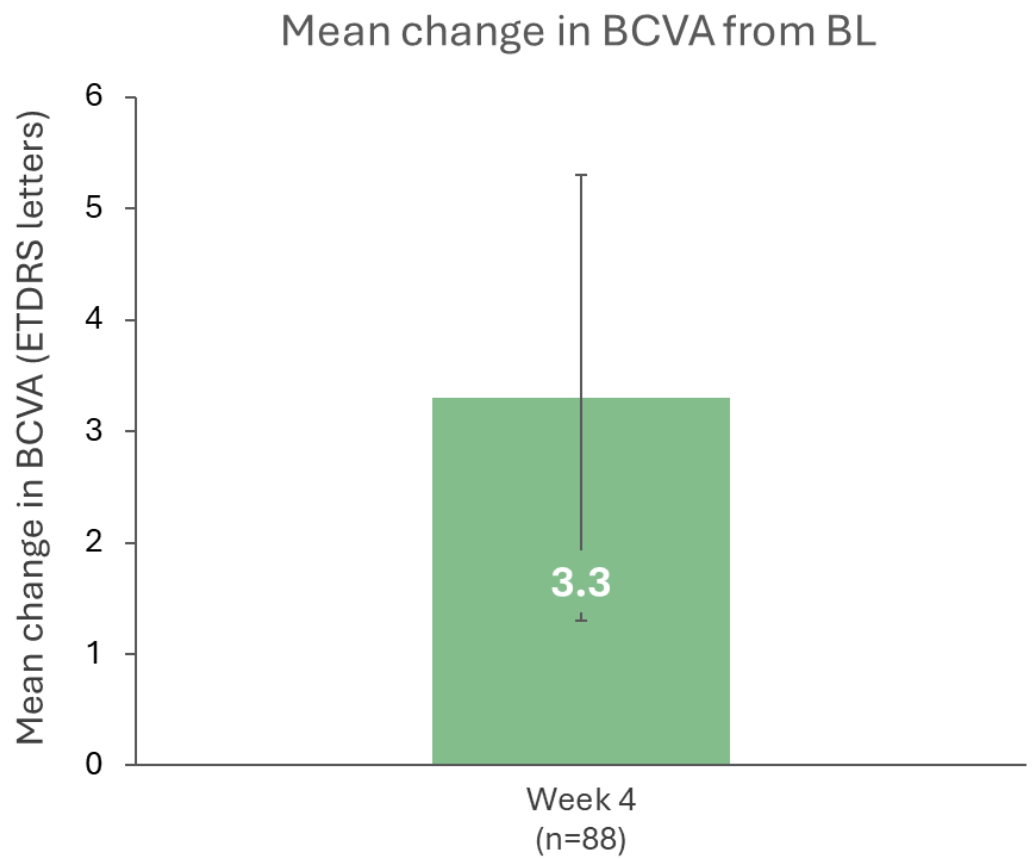




FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI. This analysis was based on patients with a VA assessment at Week 4. Mean change was calculated in 100 patients with a VA assessment at baseline and Week 4. CI, confidence interval; OC, observed cases.

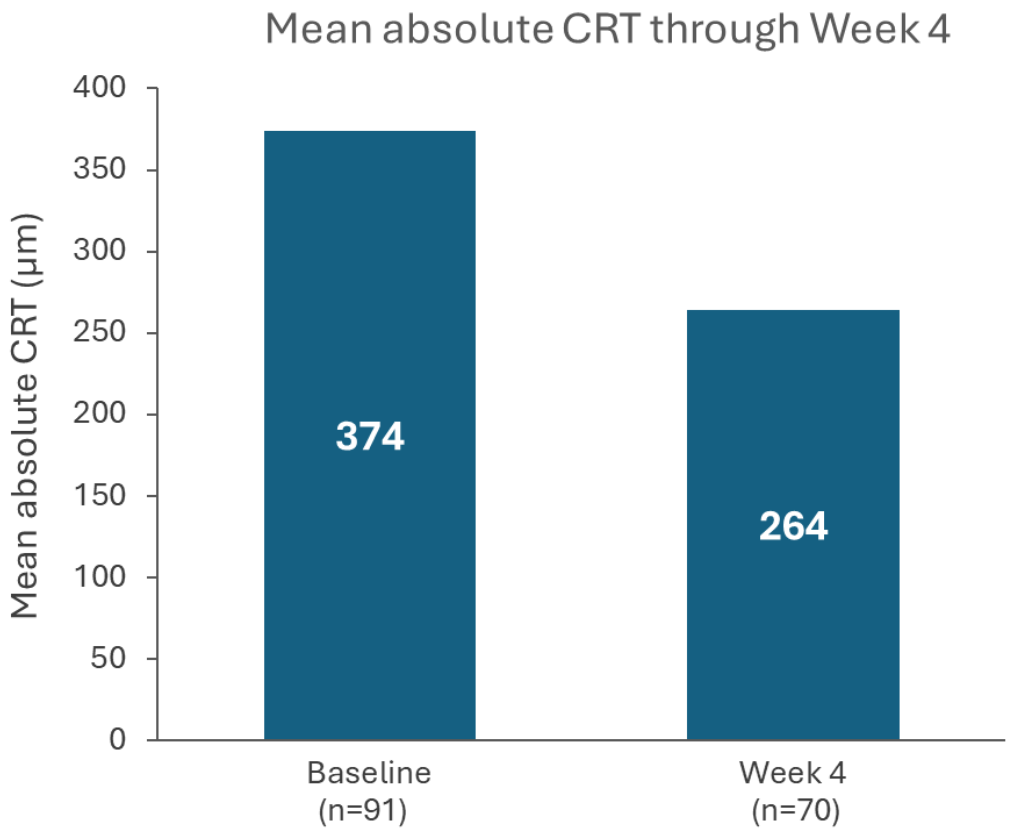
Sensitivity analysis: BCVA through Week 4

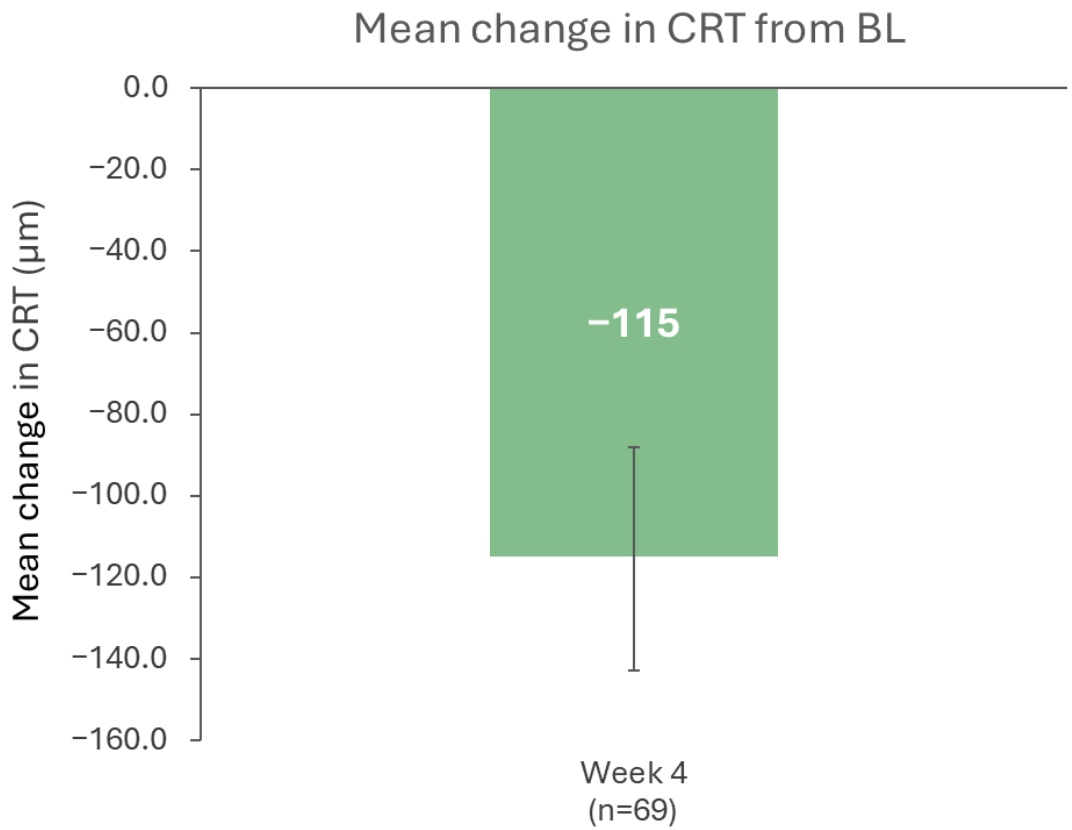




FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI. This analysis was based on patients with a BCVA assessment at Week 4. Mean change was calculated in 88 patients with a BCVA assessment at baseline and Week 4. BCVA, best-corrected visual acuity.

CRT through Week 4





FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI. Mean change was calculated in 69 patients with a CRT assessment at baseline and Week 4.

Safety overview: Adverse events

	Total (N=100)
Ocular TEAEs in the study eye, n (%)	3 (3.0)
Non-ocular TEAEs, n (%)	1 (1.0)

No serious ocular or non-ocular TEAEs were reported

SAF. Percentages may not add up to 100 due to rounding.
SAF, safety analysis set; TEAE, treatment-emergent adverse event.

SPECTRUM

Early outcomes in the first ~100 patients with previously treated nAMD who had a visit and VA assessment at Week 8

Baseline characteristics: Treatment-naïve nAMD

Analysis of patients with a VA assessment at Week 8[a]

Total: 114 patients

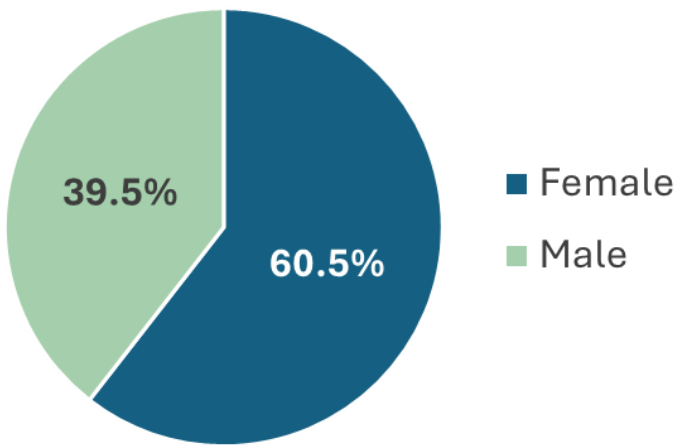
Mean age: 80.8 ± 7.1 years

Median (min, max) time from nAMD diagnosis: 0.2 (0.0, 21.9) months

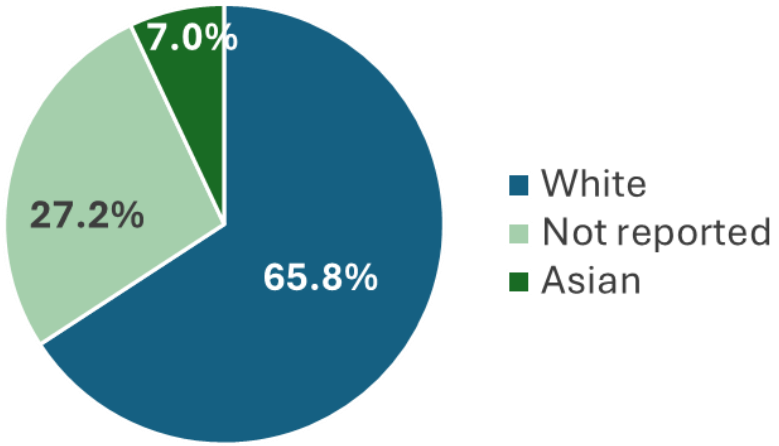
Baseline VA: 60.1 ± 17.4 ETDRS letters

Baseline CRT: 358 ± 110 µm

Sex



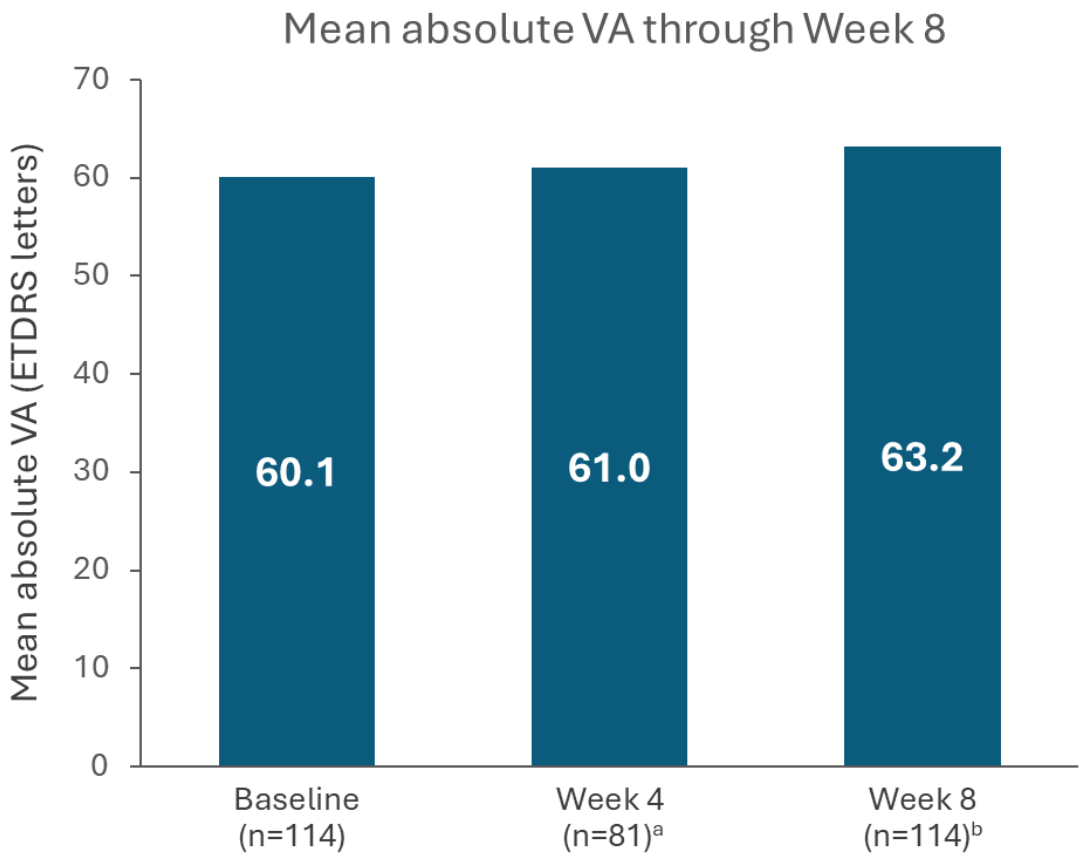
Race[b]

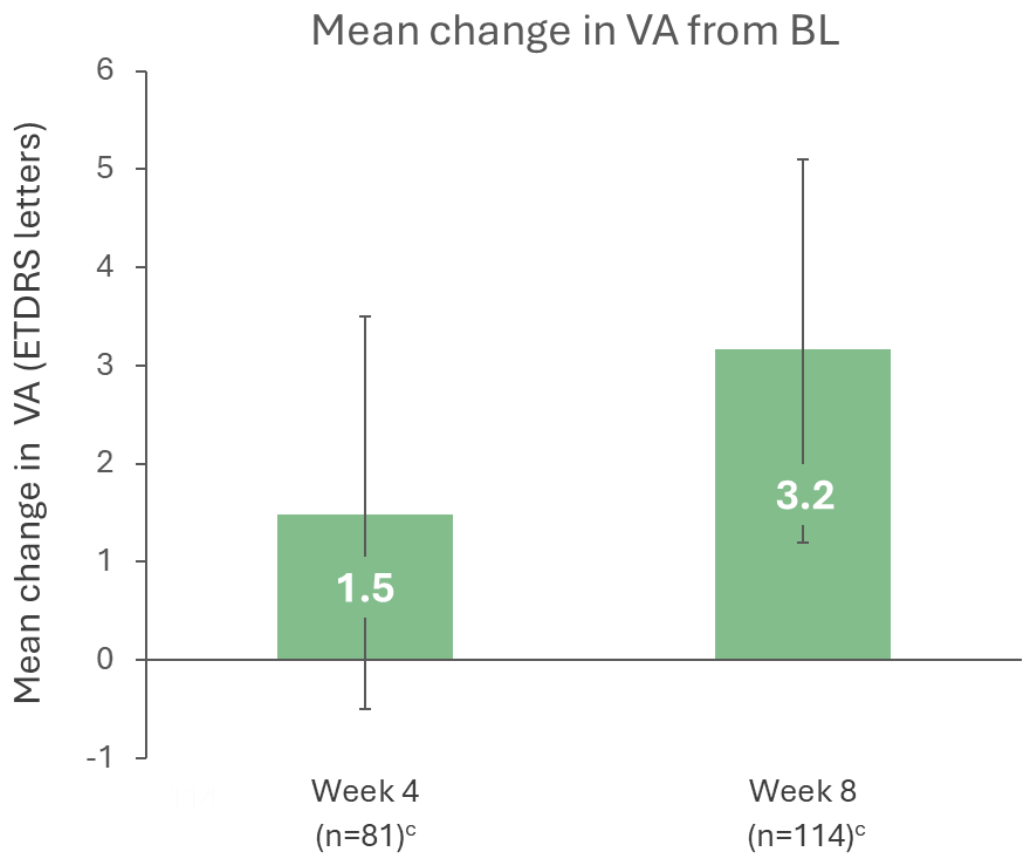


FAS. Percentages may not add up to 100 due to rounding.

[a]Data are mean ± SD unless otherwise indicated. [b]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the UK only.

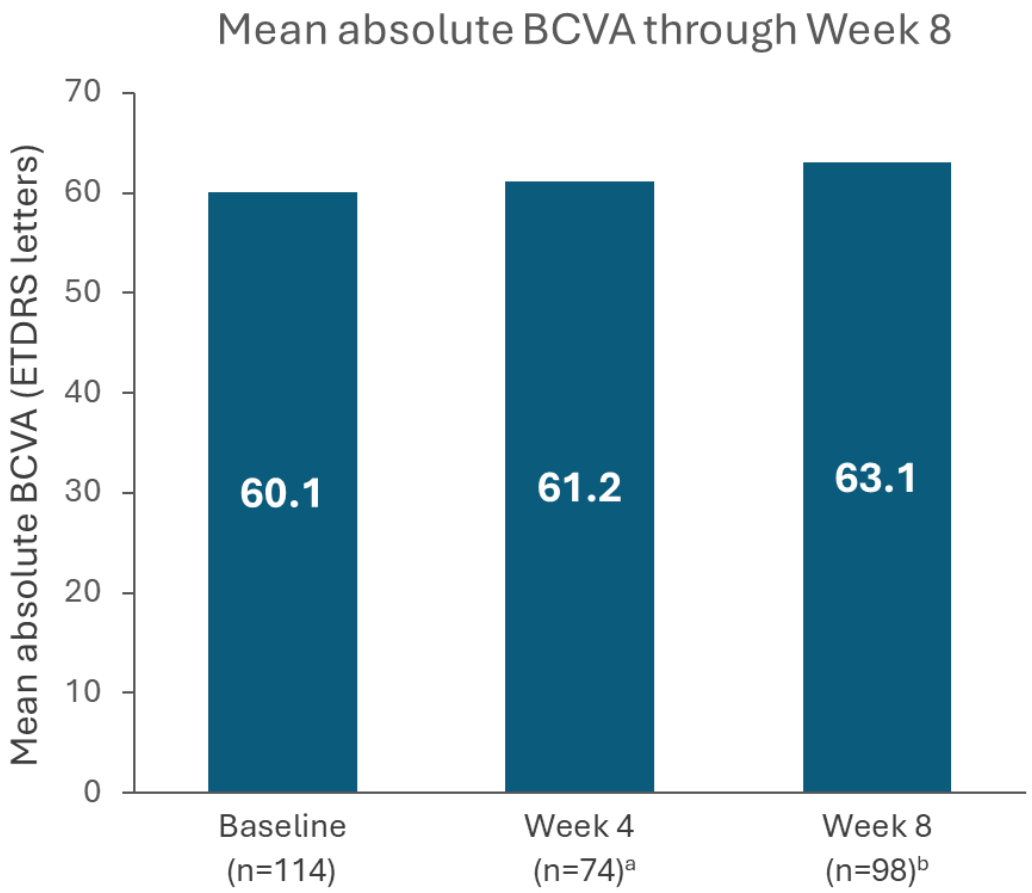
Key endpoint: VA through Week 8

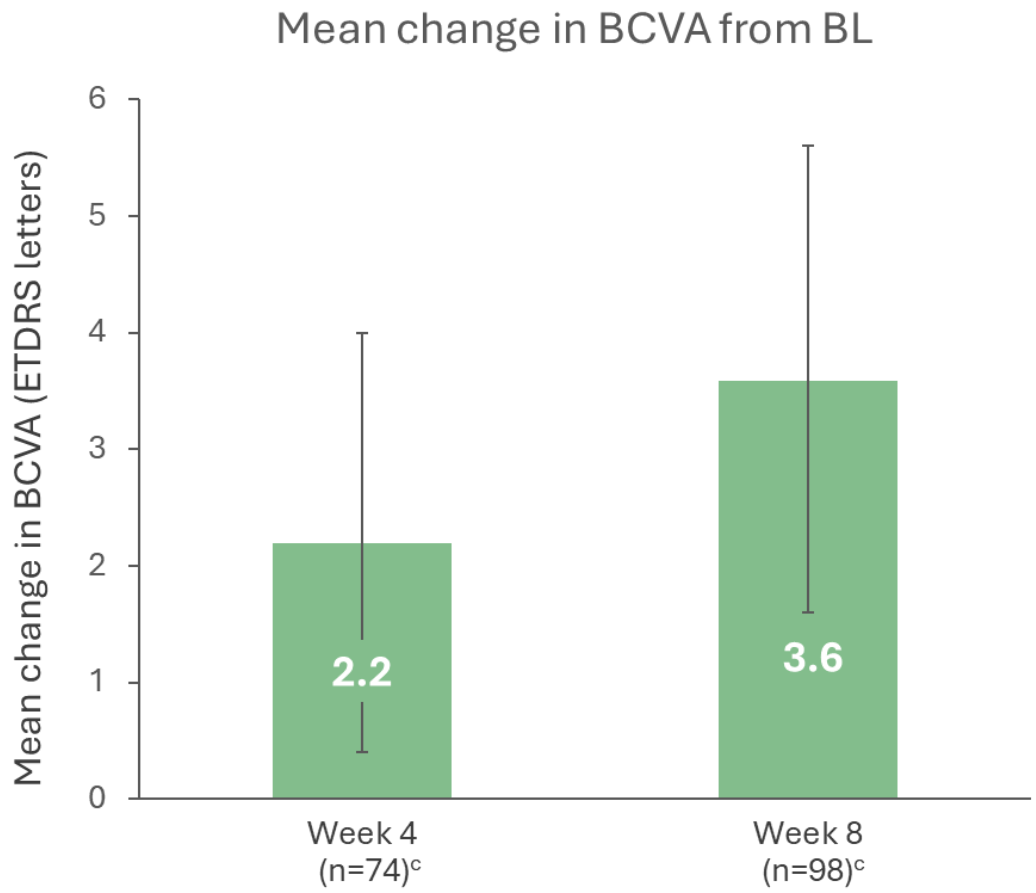




FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI. This analysis was based on patients with a VA assessment at Week 8. [a]Patients with a VA assessment at BL and Week 4. [b]Patients with a VA assessment at BL and Week 8. [c]Mean VA change at Week 4 and Week 8 from BL was calculated in 81 and 114 patients with a VA assessment at Week 4 and Week 8, respectively.

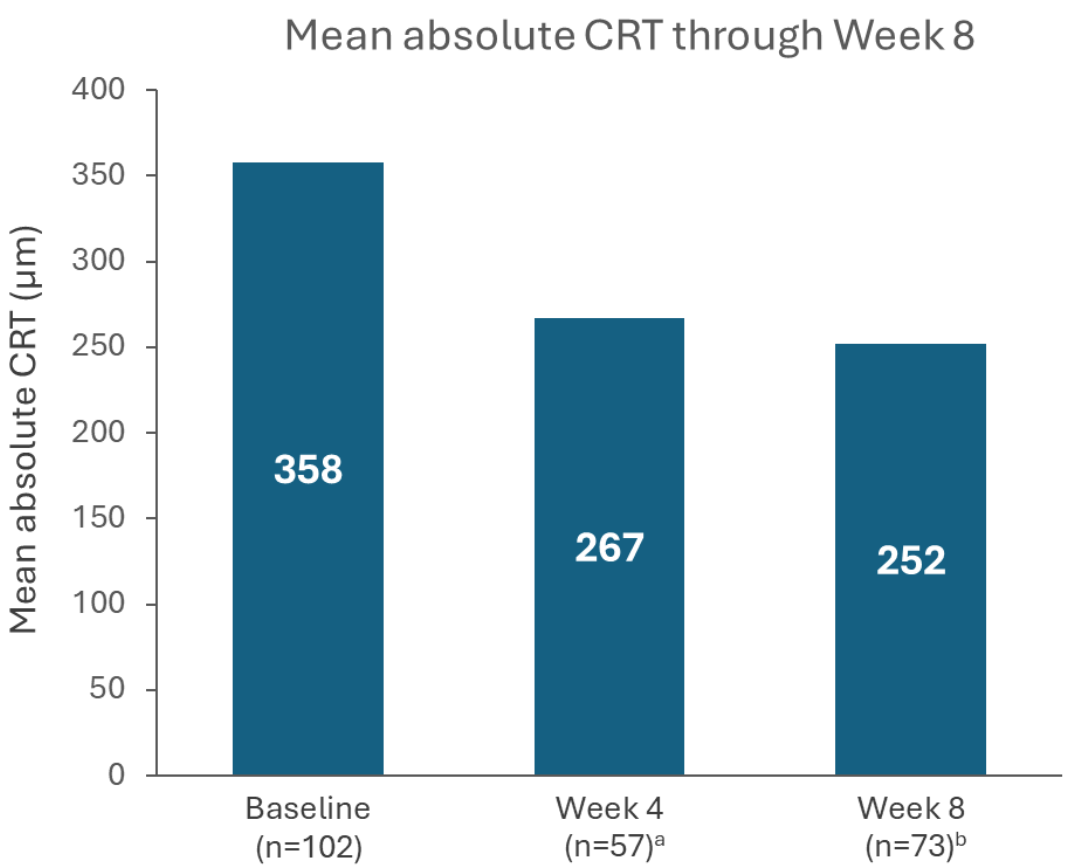
Sensitivity analysis: BCVA through Week 8

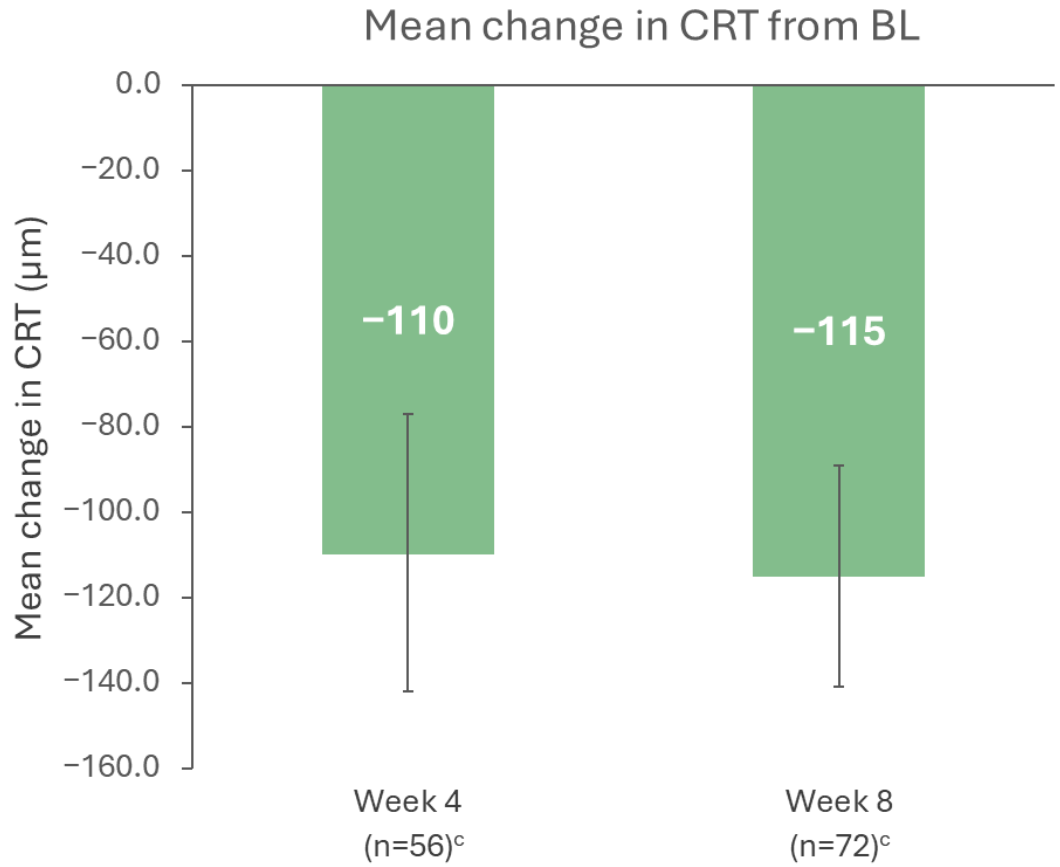




FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI. This analysis was based on patients with a BCVA assessment at Week 8. [a]Patients with a BCVA assessment at BL and Week 4. [b]Patients with a BCVA assessment at BL and Week 8. [c]Mean BCVA change at Week 4 and Week 8 from BL was calculated in 74 and 98 patients with a BCVA assessment at Week 4 and Week 8, respectively.

CRT through Week 8





FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI. [a]Patients with a CRT assessment at BL and Week 4. [b]Patients with a CRT assessment at BL and Week 8. [c]Mean CRT change at Week 4 and Week 8 from BL was calculated in 56 and 72 patients with a CRT assessment at Week 4 and Week 8, respectively.

Safety overview: Adverse events

	Total (N=114)
Ocular TEAEs in the study eye, n (%)	3 (2.6)
Non-ocular TEAEs, n (%)	5 (4.4)

No serious ocular or non-ocular TEAEs were reported

SAF. Percentages may not add up to 100 due to rounding.

Early findings from SPECTRUM support the real-world effectiveness and safety of aflibercept 8 mg in the treatment of treatment-naïve nAMD

More than **2000** patients enrolled in SPECTRUM across **17 countries** to date

More than **700** patients enrolled in the **treatment-naive nAMD cohort** across **12 countries** to date

Early clinical outcomes at Week 4/Week 8

- Improved VA through Week 4 and Week 8 (+2.7 and +3.2 ETDRS letters, respectively), improved BCVA, and reduced CRT

Safety outcomes at Week 4/Week 8

- No new safety signals identified
- No cases of IOI or serious ocular TEAEs

As the **first global real-world study of aflibercept 8 mg**, early findings from SPECTRUM will help **inform clinical management** of treatment-naïve nAMD in patients receiving aflibercept 8 mg

Month 6 data will be presented in **2025,** with Month 12 and Month 24 analyses on track

IOI, intraocular inflammation.