

SPECTRUM: Early global real-world results with aflibercept 8 mg in patients with treatment-naïve neovascular age-related macular degeneration

Hani Hasan,¹ Vasileios Konidakis,² Clemens Lange,^{3,4} Marion R. Munk,^{5,6,7} Paolo Lanzetta,^{8,9} Varun Chaudhary,¹⁰ Hassiba Oubraham,¹¹ Tobias Machewitz,¹² Helmut Allmeier,¹³ Xin Zhang,¹³ Clare Bailey,¹⁴
on behalf of the SPECTRUM study investigators

¹Newcastle Upon Tyne Hospitals NHS Foundation Trust, Newcastle Upon Tyne, UK; ²Department of Ophthalmology, University Hospitals of Leicester NHS Trust, Leicester, UK; ³Eye Center, Faculty of Medicine, Albert-Ludwig University Freiburg, Freiburg, Germany; ⁴Department of Ophthalmology, St Franziskus Hospital, Münster, Germany; ⁵Augenarzt Praxisgemeinschaft Gutblick AG, Pfäffikon, Switzerland; ⁶Department of Ophthalmology, University Hospital Bern, Switzerland; ⁷Northwestern University, Feinberg School of Medicine, Chicago, IL, USA; ⁸Department of Medicine–Ophthalmology, University of Udine, Udine, Italy; ⁹Instituto Europeo di Microchirurgia Oculare (IEMO), Udine, Italy; ¹⁰Hamilton Regional Eye Institute, St Joseph's Healthcare Hamilton, McMaster University, Hamilton, ON, Canada; ¹¹Centre OPHTA-45, Montargis, France; ¹²Bayer AG, Berlin, Germany; ¹³Bayer Consumer Care AG, Basel, Switzerland; ¹⁴Department of Ophthalmology, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK



Disclosures

- **Hani Hasan:** Speaker fees and travel grants from AbbVie, Bayer, and Roche
- **VK:** Receives honoraria from AbbVie, Bayer, Novartis, and Roche.
CL: Receives honoraria from Apellis, Bayer, Biogen, and Novartis.
MRM: Consulting fees from AbbVie, Allergan, Apellis, Aviceda Therapeutics, Bayer, Boehringer Ingelheim, Dandelion, EyePoint, Gensight, Iveric Bio, Isarna Therapeutics, Kubota, Lumithera, Novartis, Ocuterra, Oculis, Ocular Therapeutix, RetinAI, Roche, and Zeiss.
PL: Consultant for Aerie Pharmaceuticals, Allergan, Annexon, Apellis, Bausch + Lomb, Bayer, Biogen, Boehringer Ingelheim, EyePoint, Genentech, I-Care, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche. **VC:** Consulting fees from EyePoint; receives grants from Bayer, Novartis, and Roche; and serves on advisory boards for Alcon, Apellis, Bayer, Boehringer Ingelheim, Novartis, and Roche.
HO: Consultant for AbbVie, Bayer, Novartis, and Roche. **TM:** Employee of Bayer AG. **HA** and **XZ:** Employees of Bayer Consumer Care AG.
CB: Received honoraria from Alimera Sciences, Apellis, Bayer, and Roche; and has served on advisory boards for Apellis, Bayer, Boehringer Ingelheim, Janssen, and Roche
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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

Secondary endpoints include:

Change in **VA** and **CRT** from BL to Month 6



Number of **injections** and **visits**, and **safety** through Month 6



To date, **2896** patients enrolled



Australia



Canada



Denmark



Finland



France



Germany



Italy



Japan



Republic of Korea



The Netherlands



Norway



Portugal



Saudi Arabia



Spain



Sweden



Switzerland



United Arab
Emirates



United Kingdom

SPECTRUM inclusion criteria



Population

Aged ≥ 50 years

Aged ≥ 18 years with
type 1 or type 2
diabetes mellitus



Diagnosis

A diagnosis of nAMD

A diagnosis of DME



Treatment

Patients across all cohorts had to have been prescribed aflibercept 8 mg as part of routine clinical practice

nAMD
cohorts

DME
cohorts

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

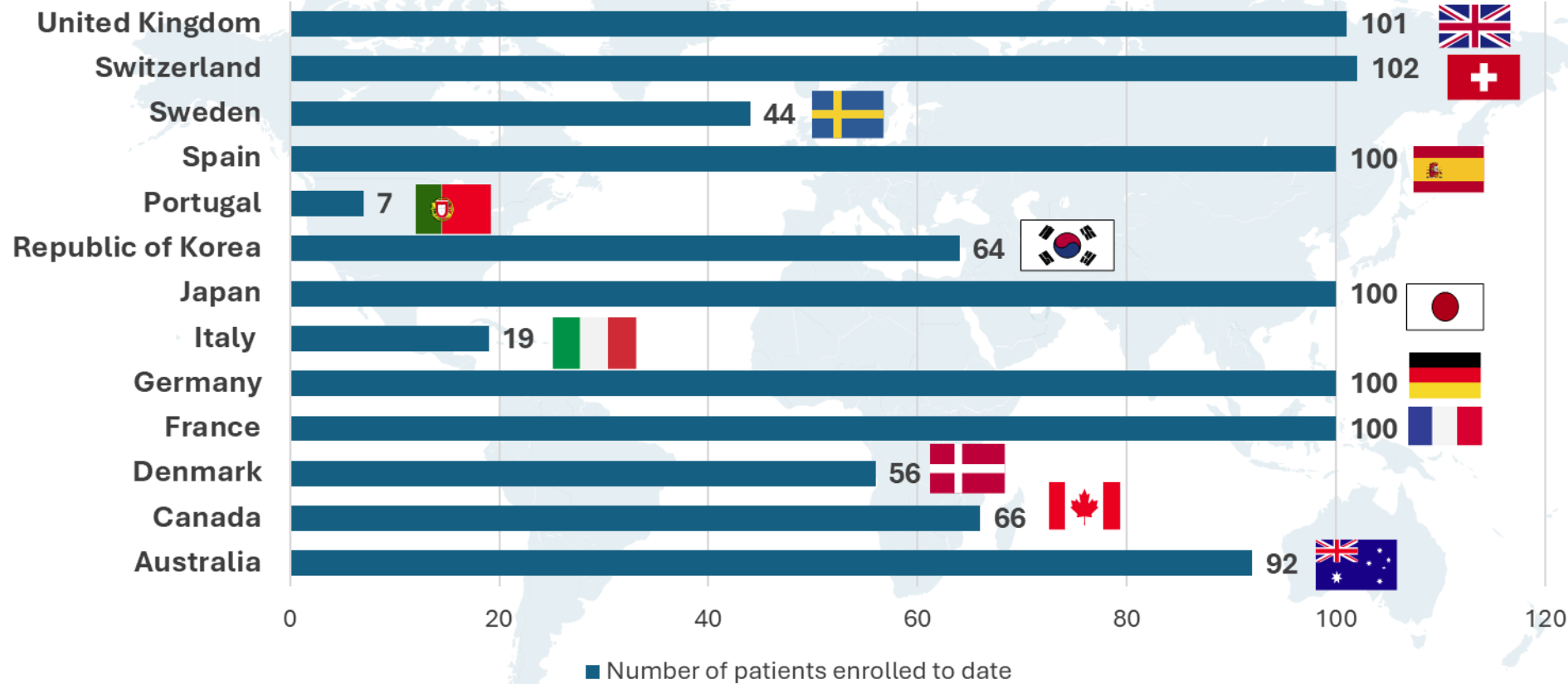




Enrollment overview



To date, **951** out of **1200 (79%)** planned patients have been enrolled in the **treatment-naïve nAMD** cohort (as of May 30, 2025)



**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

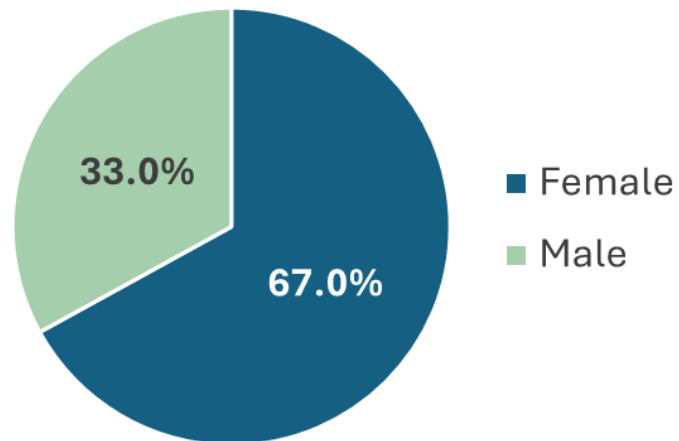
Mean age: 79.7 ± 6.6 years

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

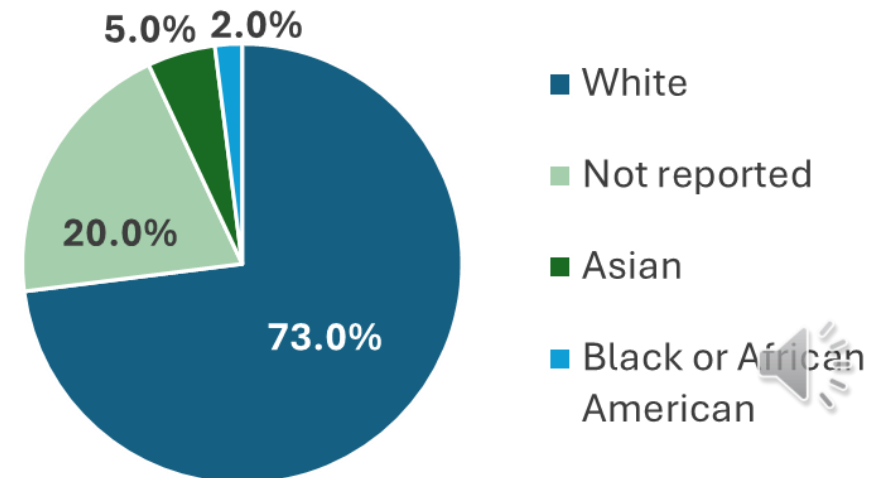
Mean baseline VA: 60.2 ± 17.4 ETDRS letters

Mean baseline CRT: 374 ± 124 µm

Sex



Race^b



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

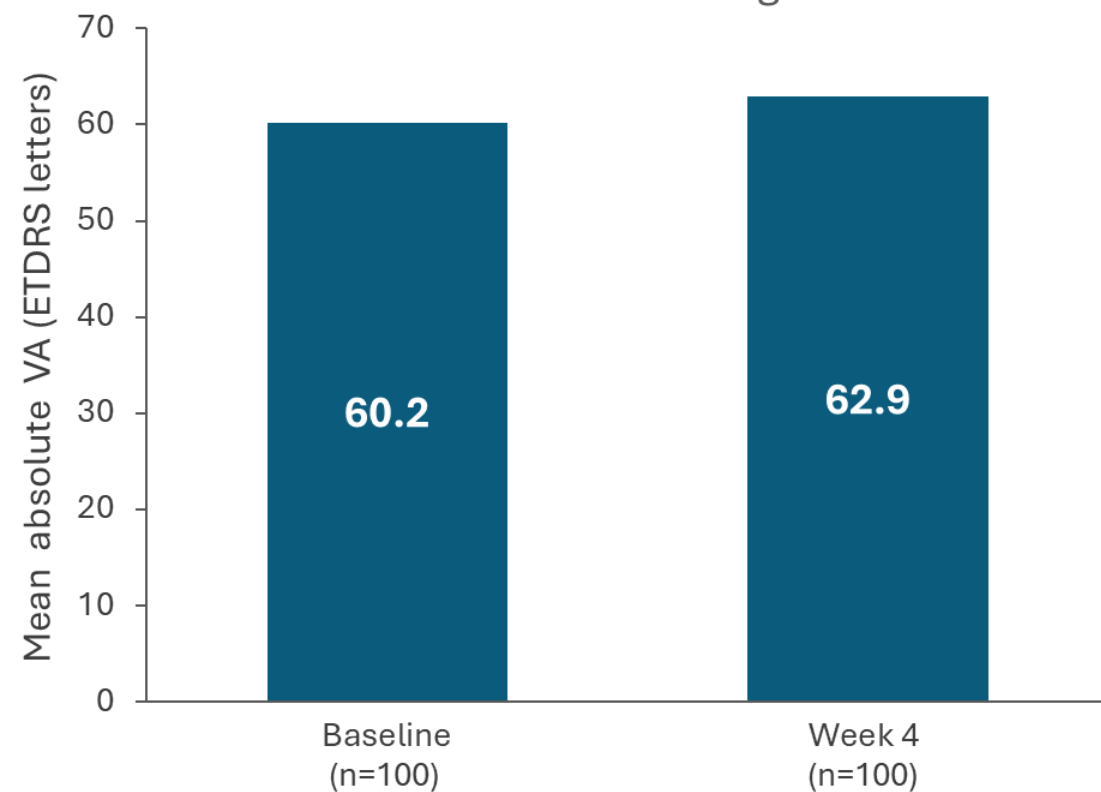
^aData are mean ± SD unless otherwise indicated. ^bData on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the UK only.

ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; Max, maximum; Min, minimum; SD, standard deviation; UK, United Kingdom.

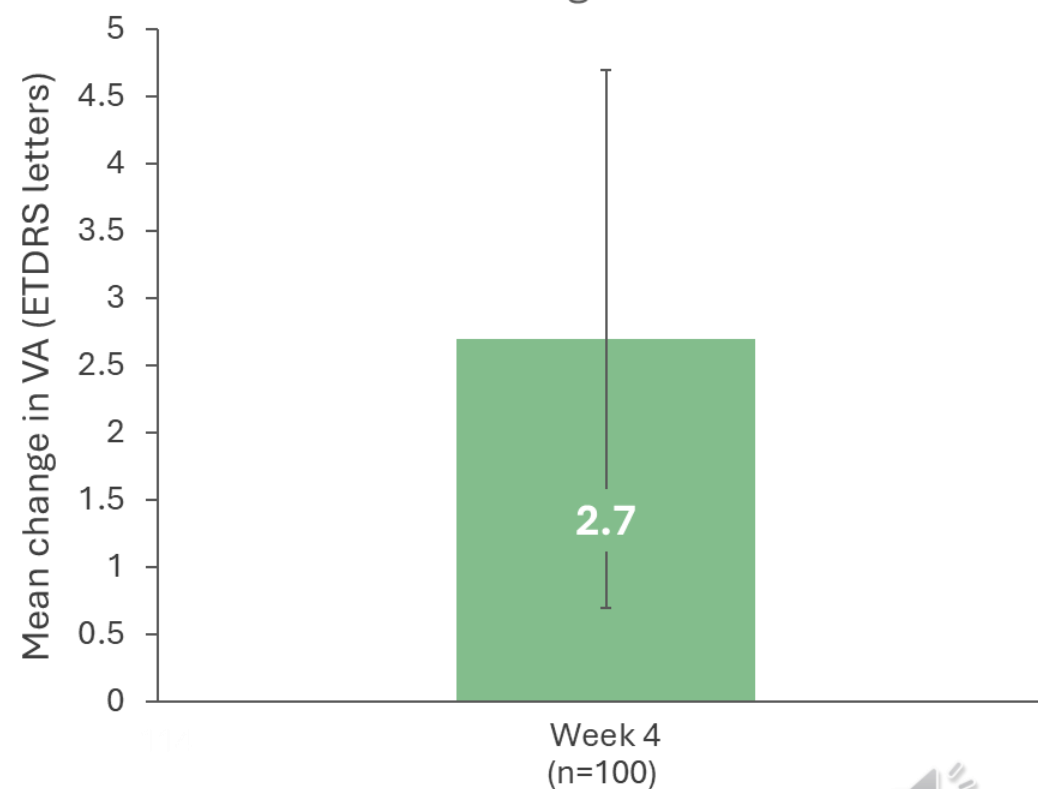


Key endpoint: VA through Week 4

Mean absolute VA through Week 4



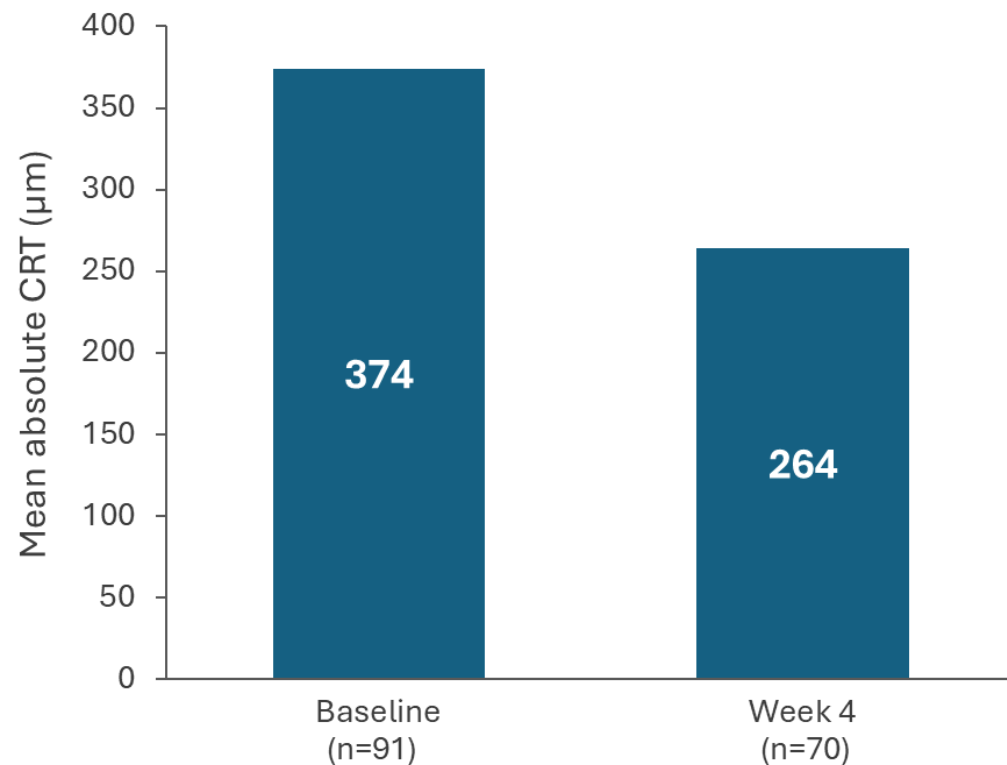
Mean change in VA from BL



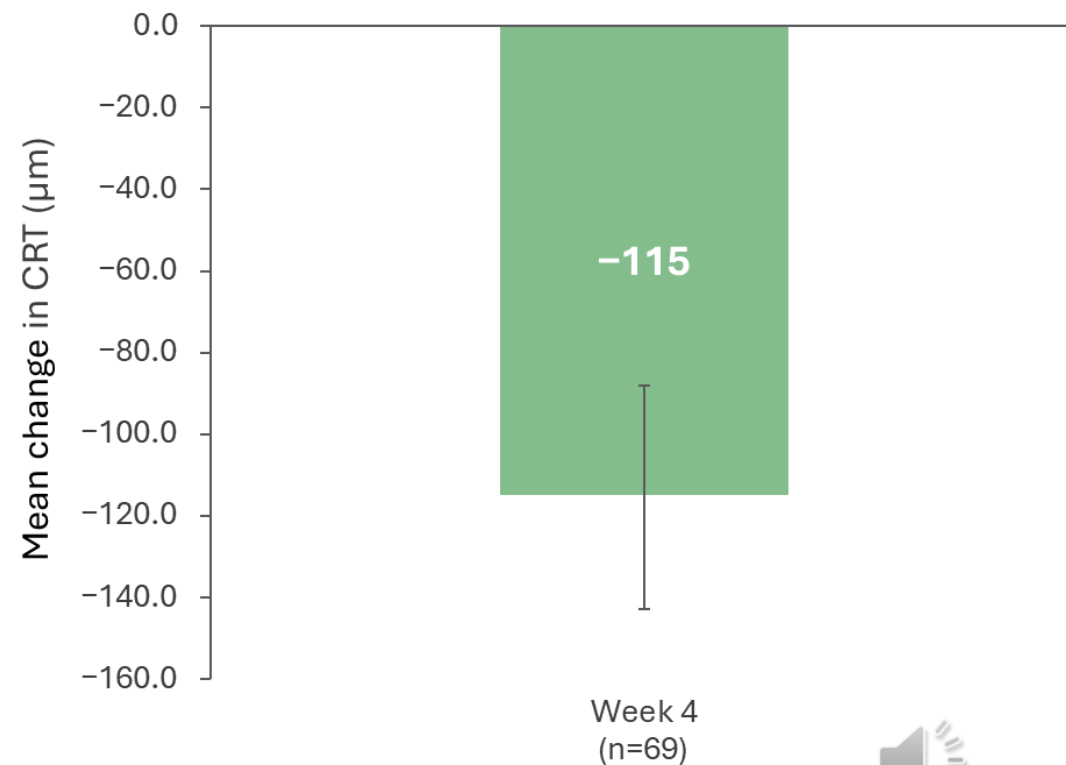
FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI.
CI, confidence interval; OC, observed cases.

CRT through Week 4

Mean absolute CRT through Week 4



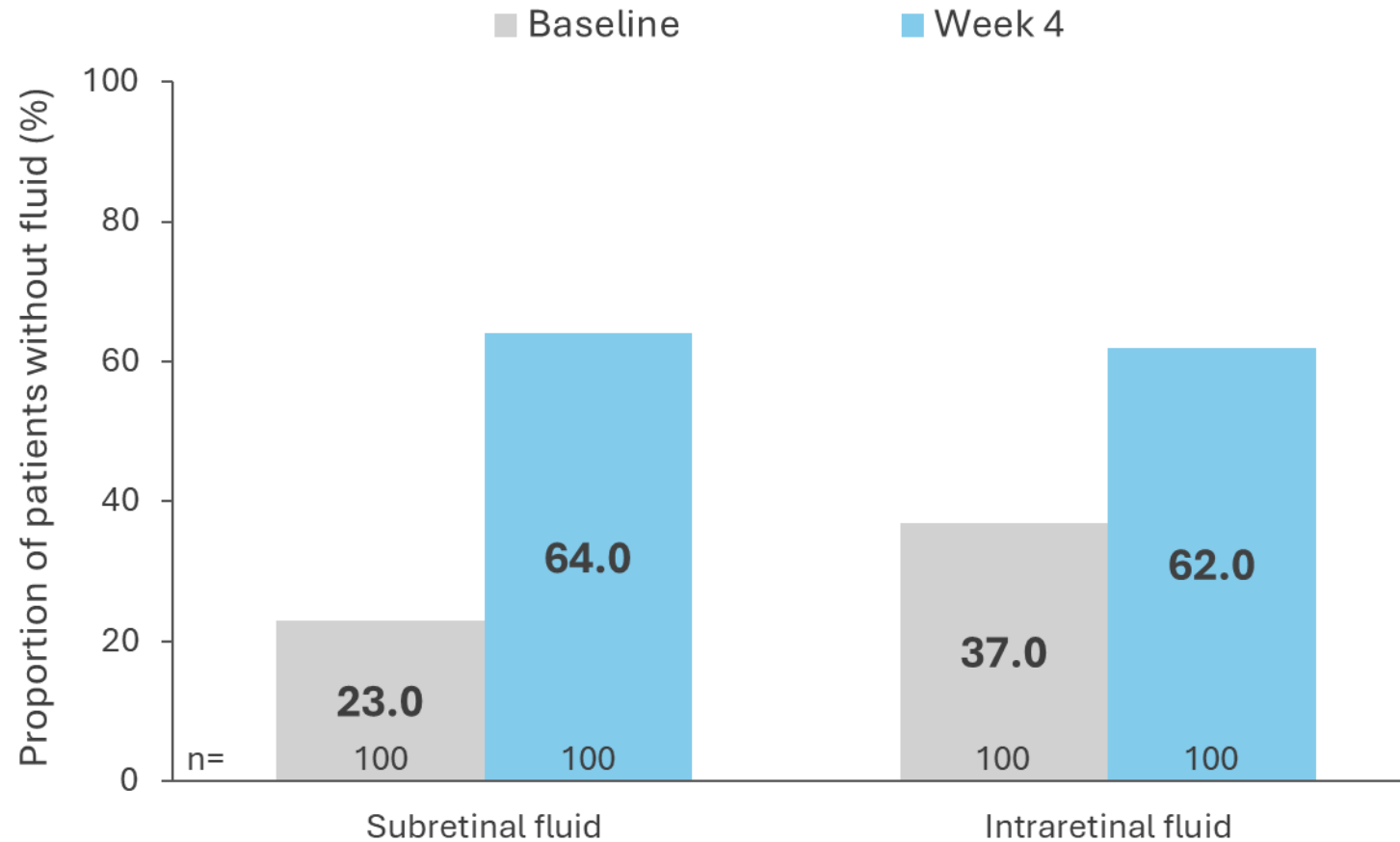
Mean change in CRT from BL



FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI.



Proportion of patients without fluid through Week 4



FAS, OC. Values have been rounded to the nearest decimal point.

Based on instructions on the case report form, fluid data were collected during a macular assessment (6 mm) per investigator discretion.



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



Data are from the SAF.

SAF, safety analysis set; TEAE, treatment-emergent adverse event.

**Early outcomes in the first ~100 patients
with treatment-naïve 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

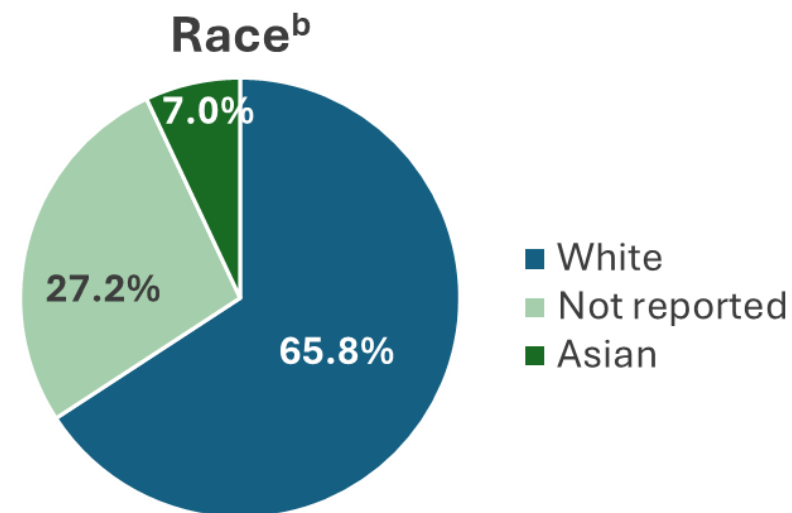
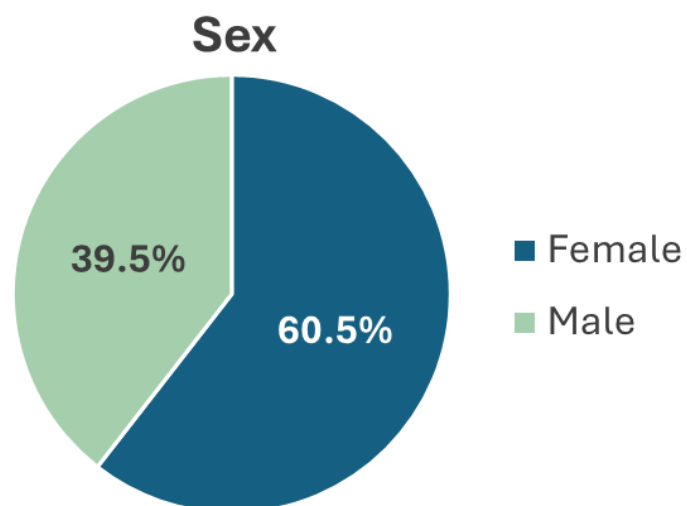
Total: 114 patients

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



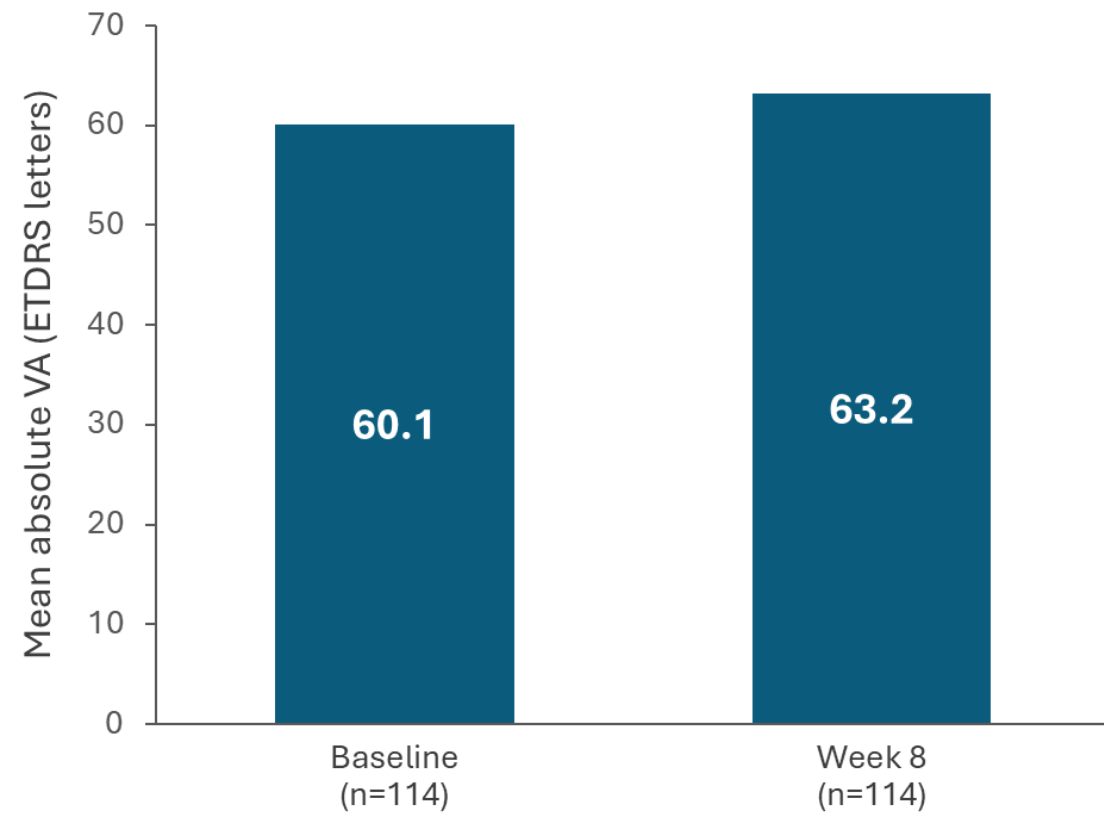
FAS. Percentages may not add up to 100 due to rounding.

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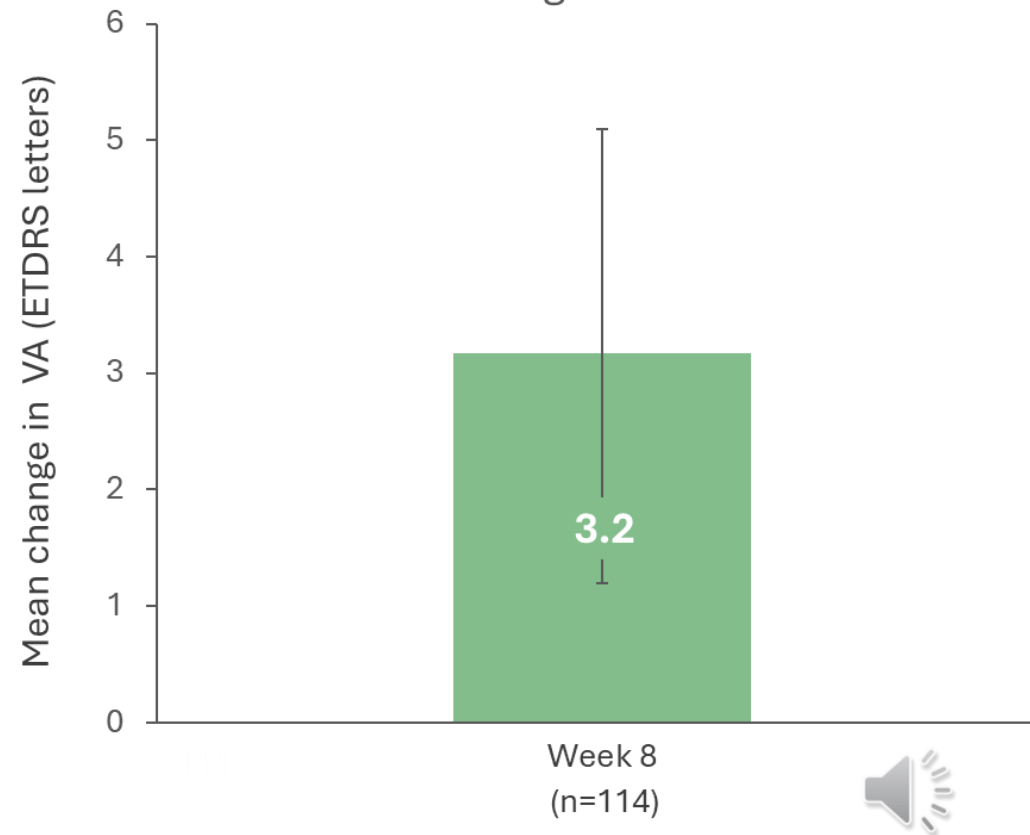


Key endpoint: VA through Week 8

Mean absolute VA through Week 8

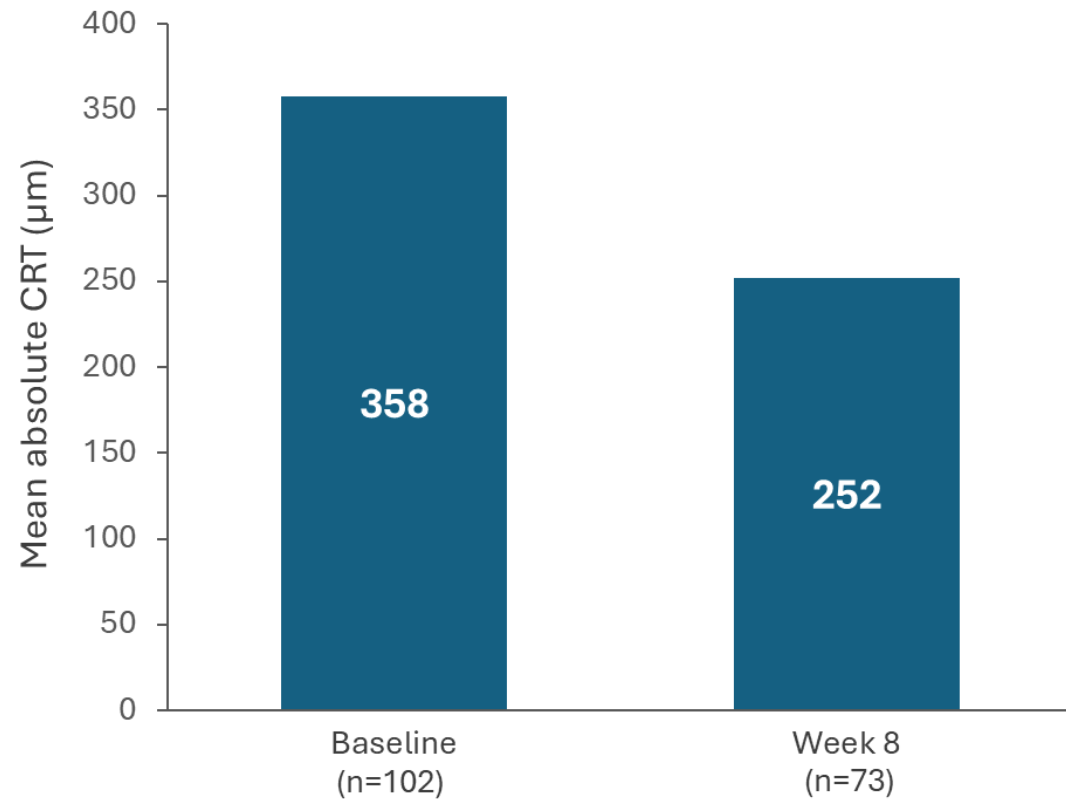


Mean change in VA from BL

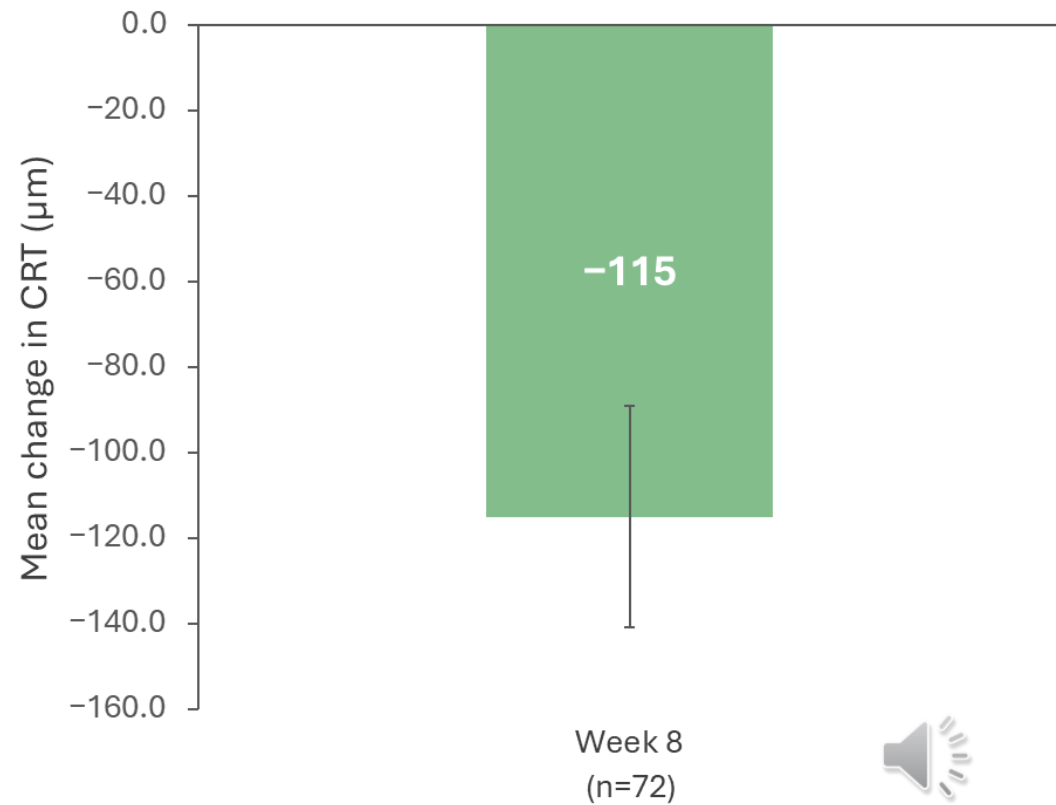


CRT through Week 8

Mean absolute CRT through Week 8



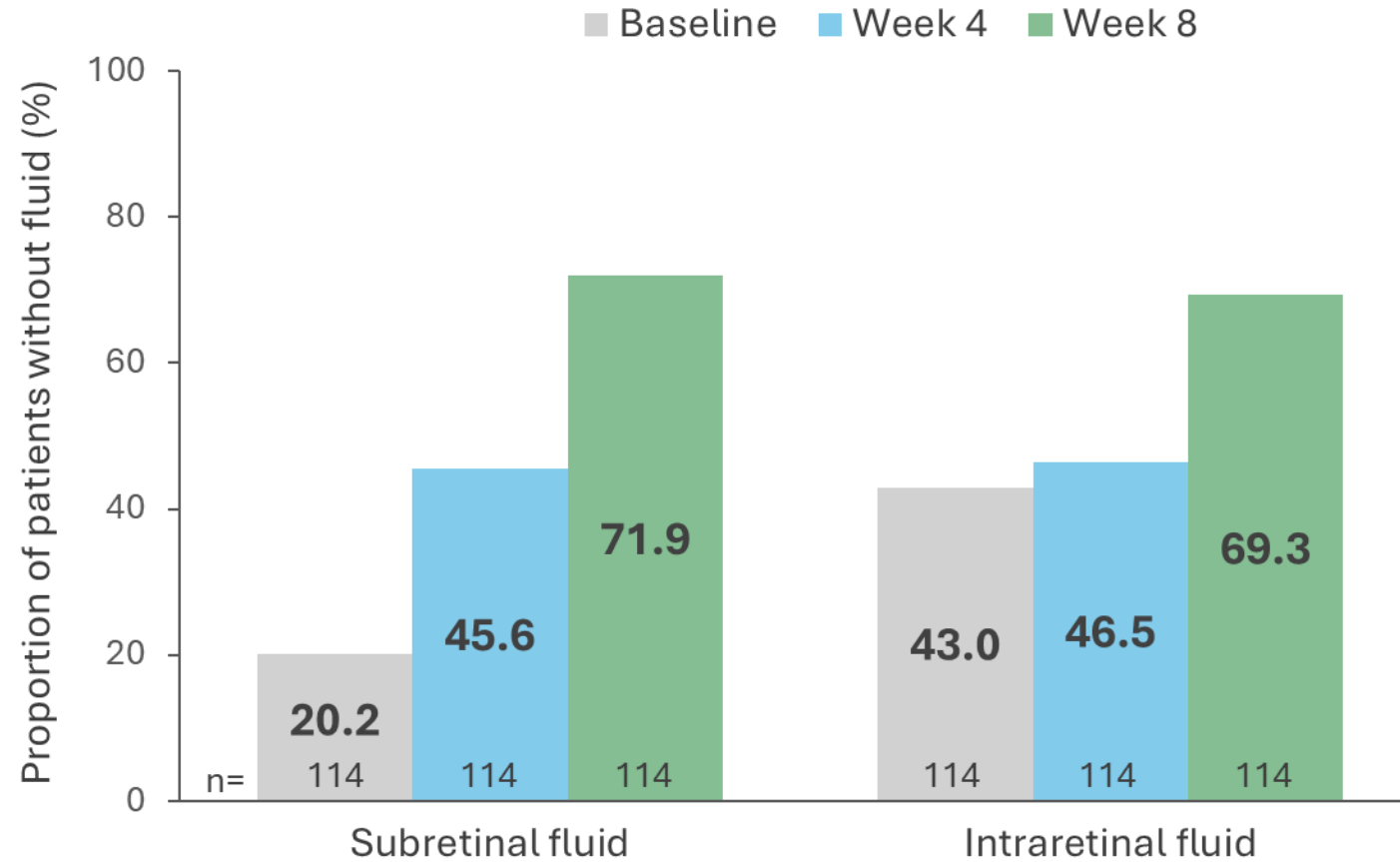
Mean change in CRT from BL



FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI.



Proportion of patients without fluid through Week 8



FAS, OC. Values have been rounded to the nearest decimal point.

Based on instructions in the case report form, fluid data were collected during a macular assessment (6 mm) per investigator discretion.



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



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



More than **2800** patients enrolled in SPECTRUM across **17 countries** to date



More than **900** patients enrolled in the **treatment-naïve nAMD cohort** across **13 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) 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