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

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Disclosures

- **Clare Bailey:** Receives honoraria from Alimera Sciences, Apellis, Bayer, and Roche; and has served on advisory boards for Apellis, Bayer, Boehringer Ingelheim, Janssen, and Roche
    - **CL:** Receives honoraria from Apellis, Bayer, Biogen, and Novartis. **VC:** Consulting fees from EyePoint; receives grants from Bayer, Novartis, Roche; and serves on advisory boards for Alcon, Apellis, Bayer, Boehringer Ingelheim, Novartis, and Roche. **PL:** Consultant for Aerie Pharmaceuticals, Allergan, Annexon, Apellis, Bausch + Lomb, Bayer, Biogen, Boehringer Ingelheim, Eyepoint Pharmaceuticals, Genentech, I-Care, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche. **HO:** Consultant for AbbVie, Bayer, Novartis, and Roche. **MK** and **TM**: Employees of Bayer AG. **HA**, **XZ**, and **ZH**: Employees of Bayer Consumer Care AG. **MRM**: Consulting fees from AbbVie, Allergan, Apellis, Aviceda Therapeutics, Bayer, Boehringer-Ingelheim, Dandelion, Eyepoint, Gensight, Isarna Therapeutics, Iveric Bio, Kubota, Lumithera, Novartis, Ocuterra, Oculis, Ocular Therapeutix, RetinAI, Roche, and Zeiss
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SPECTRUM: Global real-world study of aflibercept 8 mg

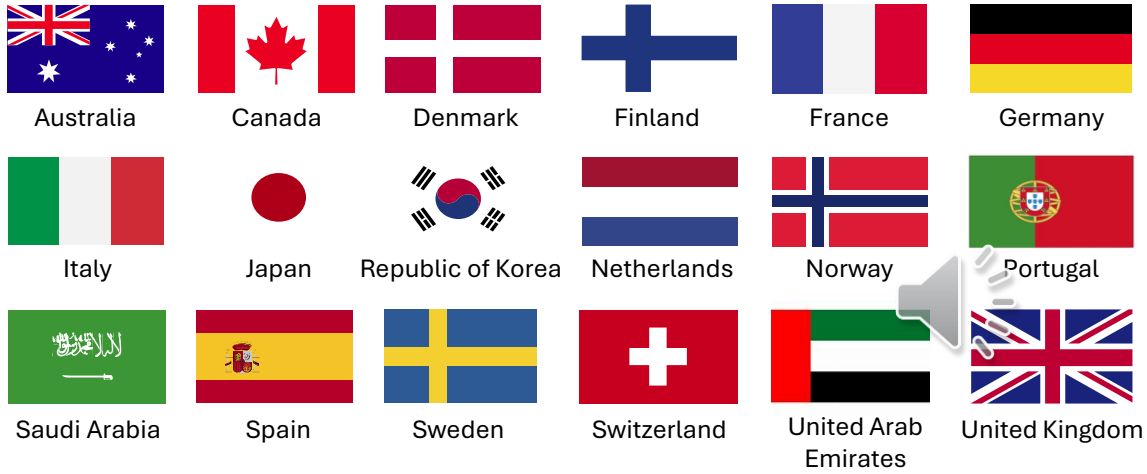
A **non-interventional country** and **global cohort** study planned in **18 countries**

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, **2149** patients enrolled



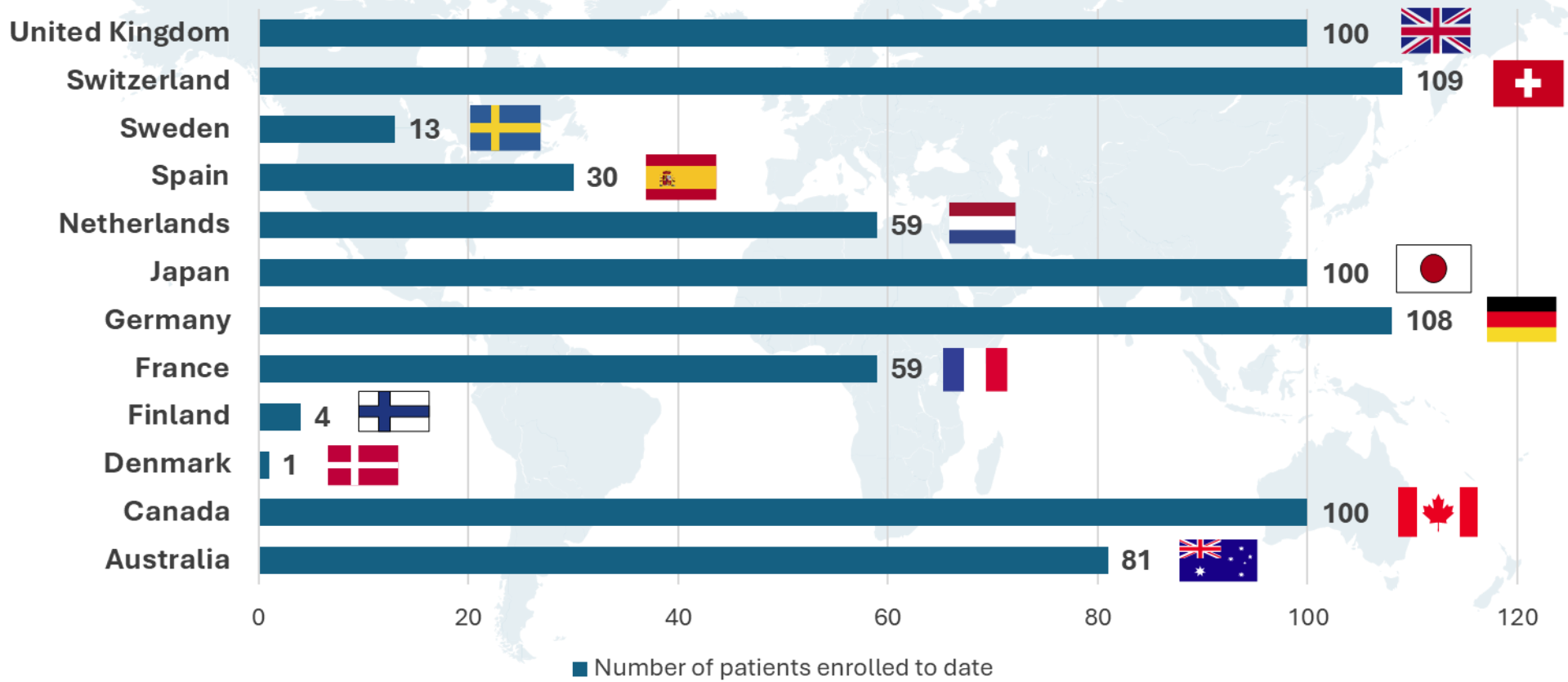
Secondary endpoints include:

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

Enrollment overview

To date, **764** out of **1110 (69%)** planned patients have been enrolled in the **previously treated nAMD** cohort



Enrollment overview

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

Baseline characteristics: Previously treated nAMD

Interim analysis of patients with a VA assessment at Week 8[a]

Total: 104 patients

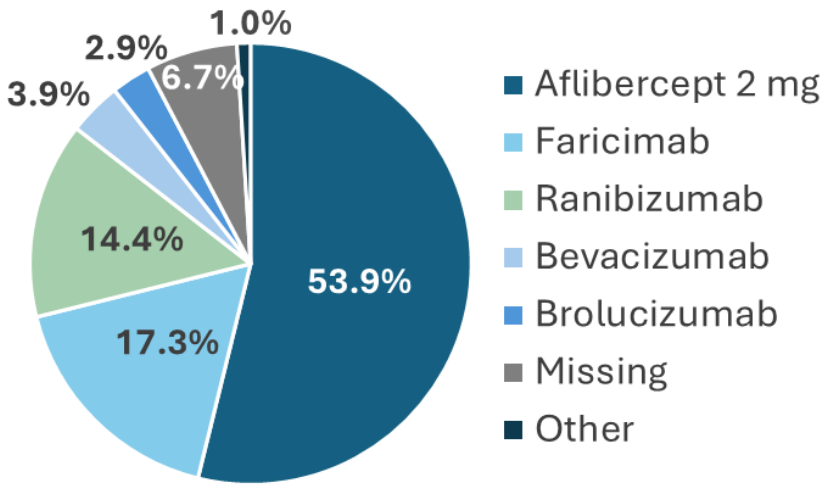
Mean age: 79.5 ± 7.3 years

Median (min, max) time from nAMD diagnosis: 36.9 (1.4, 178.9) months

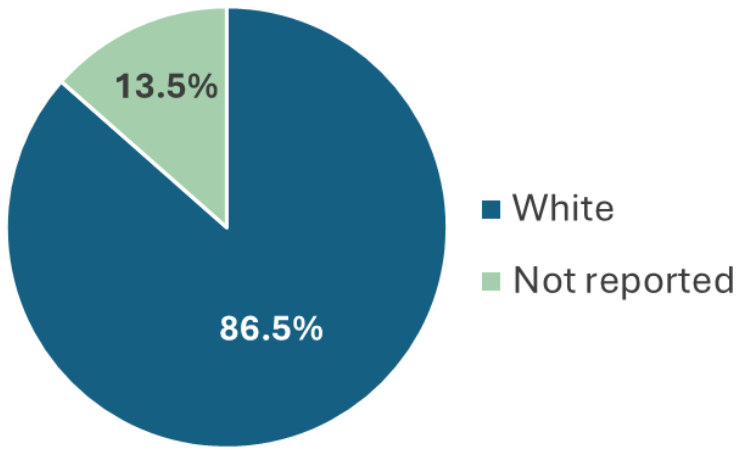
Mean baseline VA: 61.6 ± 19.4 ETDRS letters

Mean baseline CRT: 316 ± 102 µm

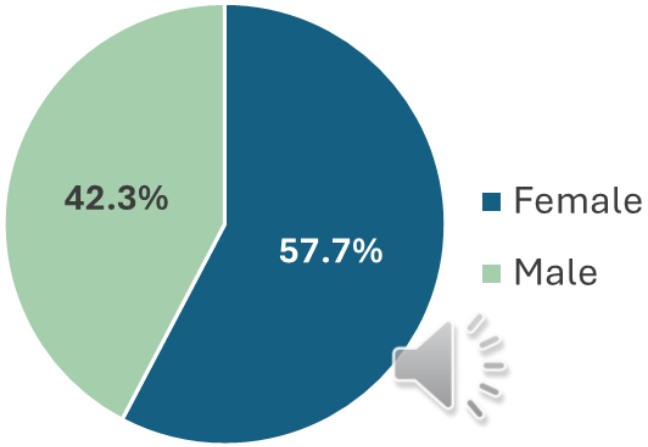
Previous nAMD medication



Race[b]



Sex

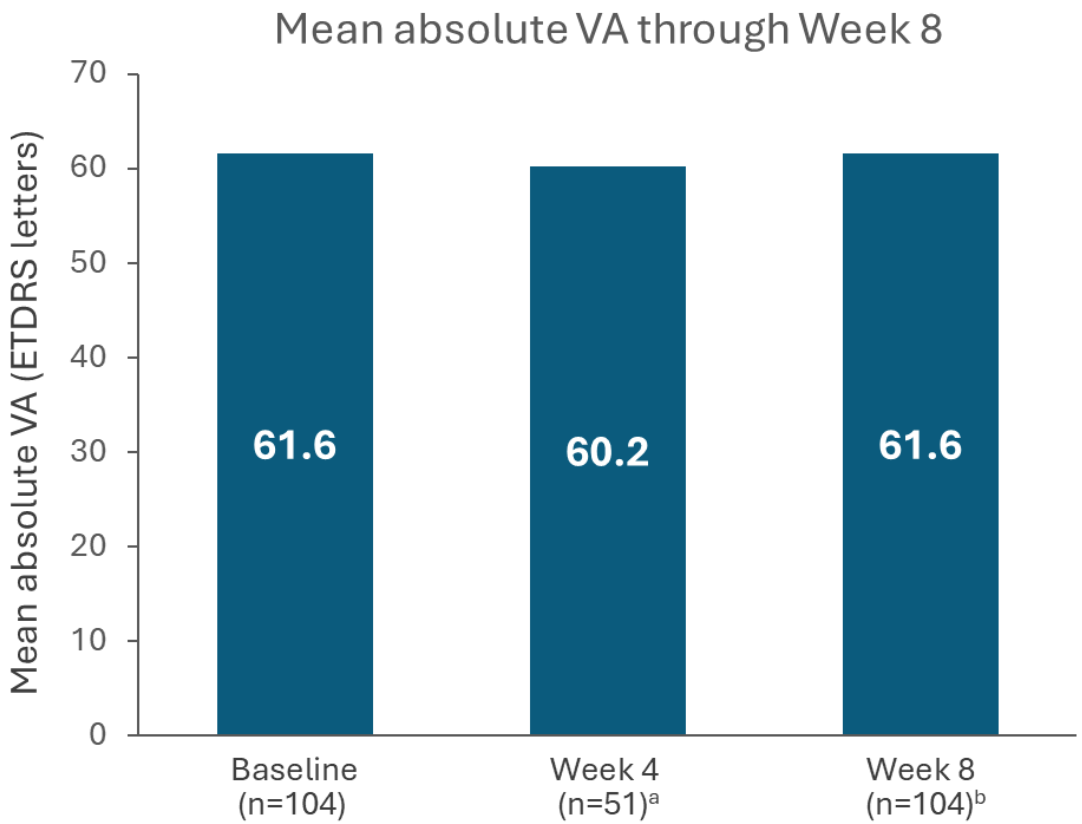


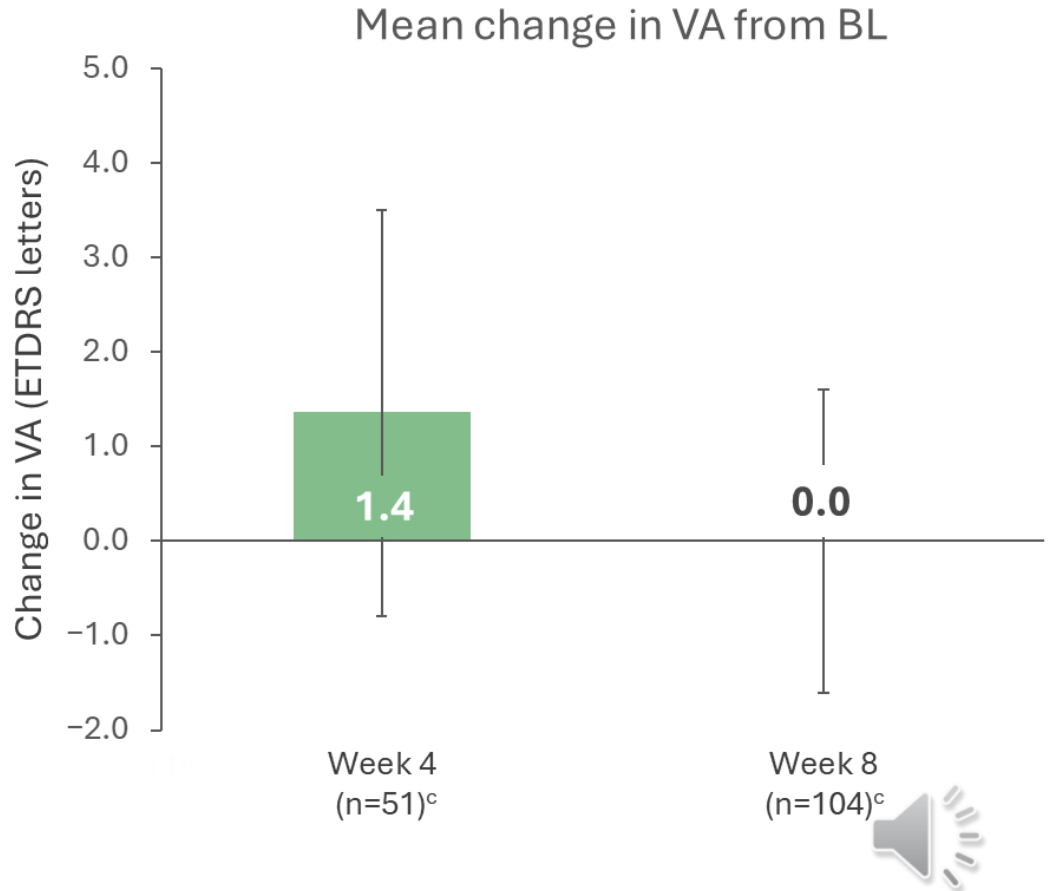
FAS. Percentages may not add up to 100 due to rounding.

[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.

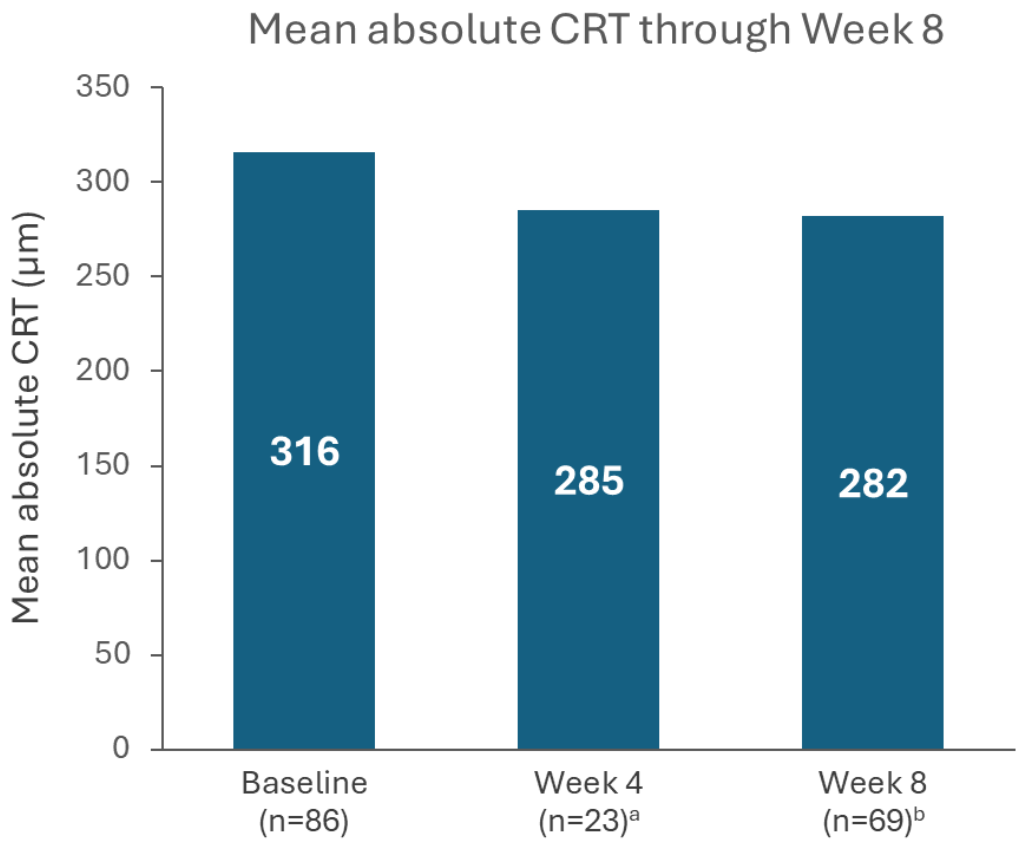
VA through Week 8

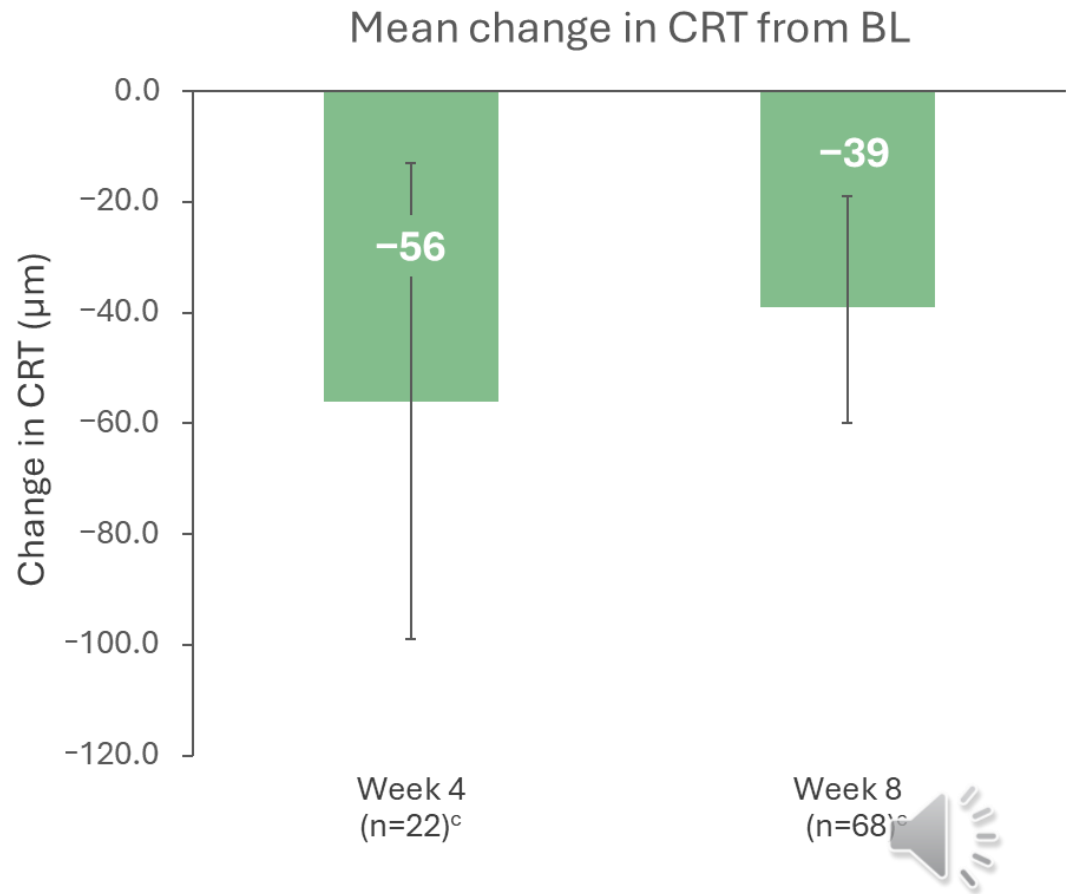




FAS, OC. Values have been rounded to the nearest decimal point. [a]Patients with a VA assessment at BL and Week 4. [b]Patients with a VA assessment at BL and Week 8. [c]Mean VA change at Week 4 and Week 8 from BL was calculated in patients with a VA assessment at Week 4 and Week 8, respectively; error bars are 95% CI. CI, confidence intervals; OC, observed cases.

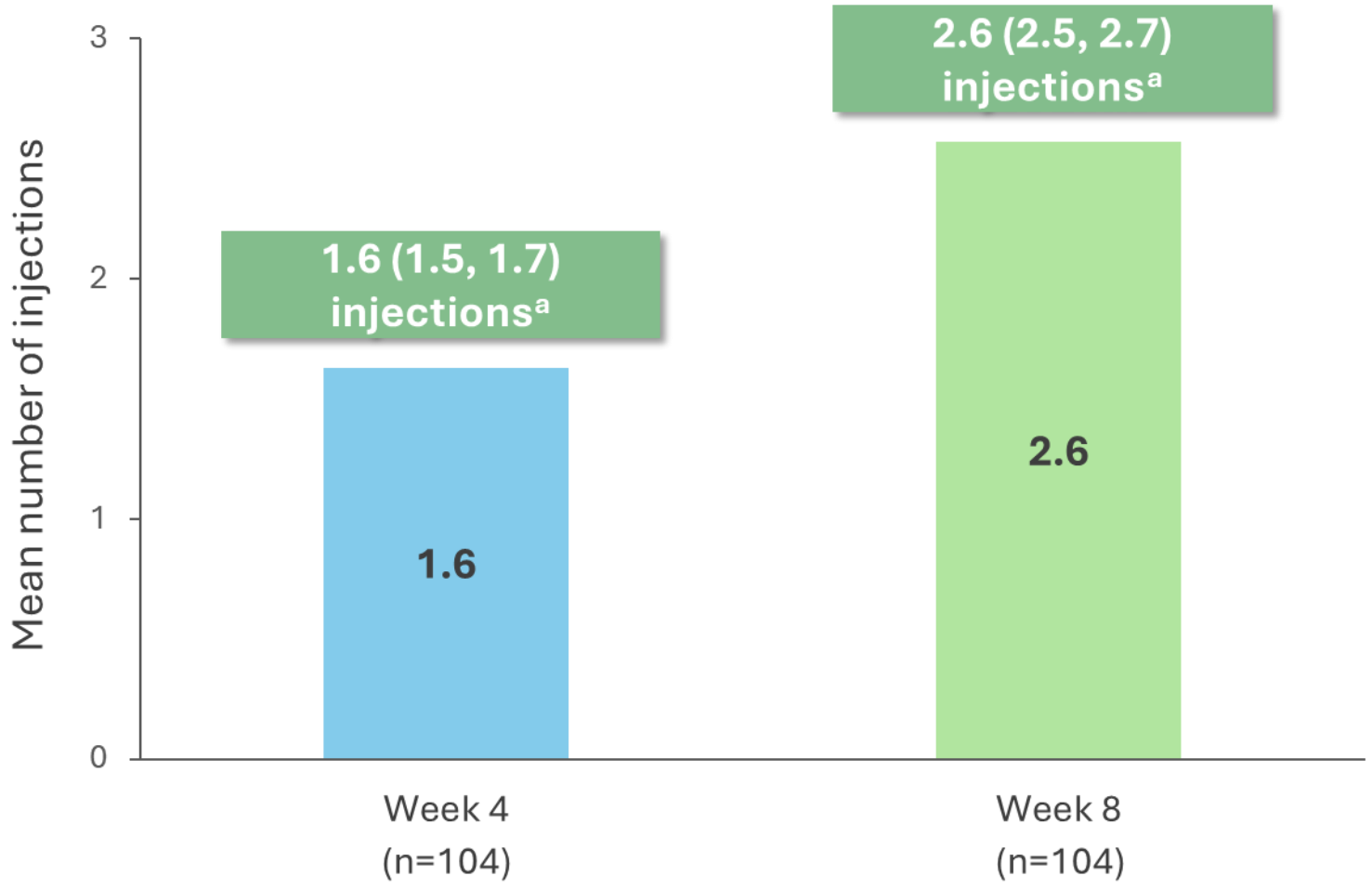
CRT through Week 8





FAS, OC. Values have been rounded to the nearest decimal point. [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 patients with a CRT assessment at Week 4 and Week 8, respectively; error bars are 95% CI.

Mean number of aflibercept 8 mg injections in the study eye through Week 8



FAS. Patients received their first injection at baseline. Values have been rounded to the nearest decimal point. [a]Data are mean (95% CI).

Safety overview

Ocular safety in the study eye	Total (N=104)
Ocular TEAEs, n (%)	**4 (3.9)**
Conjunctival hemorrhage	1 (1.0)
Vitreous floaters	1 (1.0)
Not yet coded	2 (1.9)
Study drug-related ocular TEAEs, n (%)	**2 (1.9)**
Serious ocular TEAEs, n (%)	**0**

No 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.

Early Findings From SPECTRUM Support the Real-World Effectiveness and Safety of Aflibercept 8 mg in the Treatment of Previously Treated nAMD

2149/4035 patients enrolled in SPECTRUM across **16 countries** to date

764/1110 patients enrolled in the **previously treated nAMD cohort** across **12 countries** to date

Early clinical outcomes at Week 8

- Stable VA following switch to aflibercept 8 mg
- Reduction in CRT (−39 µm)

Safety outcomes at 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 previously treated 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; Q, Quarter.