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

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Presented at the 2025 Retina World Congress, Fort Lauderdale, FL, USA, May 8–11, 2025

Disclosures

- **Vasileios Konidaris:** 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 Pharmaceuticals, Genentech, I-Care, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche. **VC**: Consulting fees from EyePoint; receives grants from Bayer, Novartis, and Roche; serves on advisory boards for Alcon, Roche, Bayer, Novartis, Apellis, and Boehringer Ingelheim. **HO:** Consultant for AbbVie, Bayer, Novartis, and Roche. **TM:** Employee of Bayer AG. **HA** and **XZ**: Employees of Bayer Consumer Care AG. **CB:** Receives honoraria from Alimera Sciences, Apellis, Bayer, and Roche; has served on advisory boards for Apellis, Bayer, Boehringer Ingelheim, Janssen, and Roche
- The SPECTRUM study (NCT06075147) was sponsored by Bayer AG (Leverkusen, Germany)
- The sponsor participated in the design and conduct of the study, analysis of the data, and preparation of this presentation
- Medical writing support, under the direction of the authors, was provided by ApotheCom and funded by Bayer Consumer Care AG (Basel, Switzerland), in accordance with Good Publication Practice (GPP) guidance (*Ann Intern Med*. 2022;175:1298–1304)

SPECTRUM: Global real-world study of aflibercept 8 mg

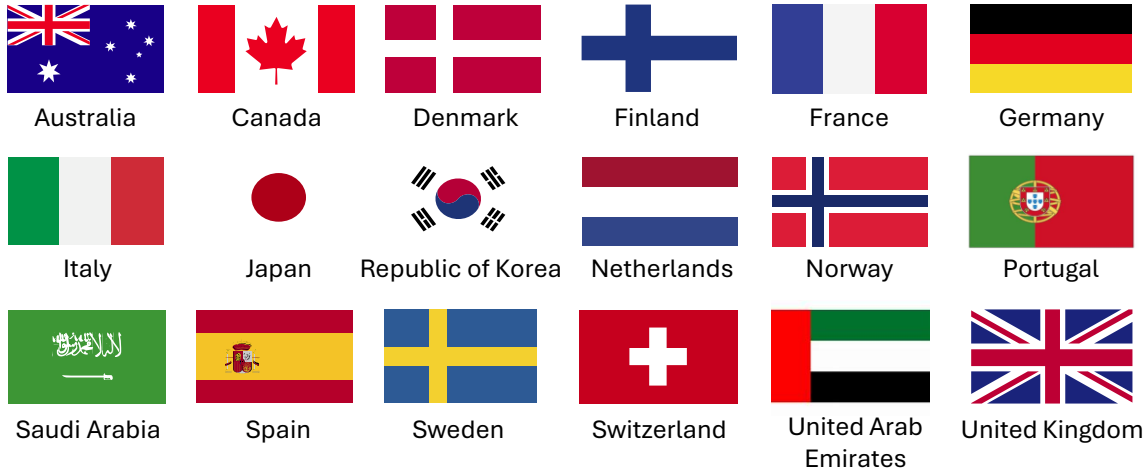
A **non-interventional country** and **global cohort** study planned in **18 countries**

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



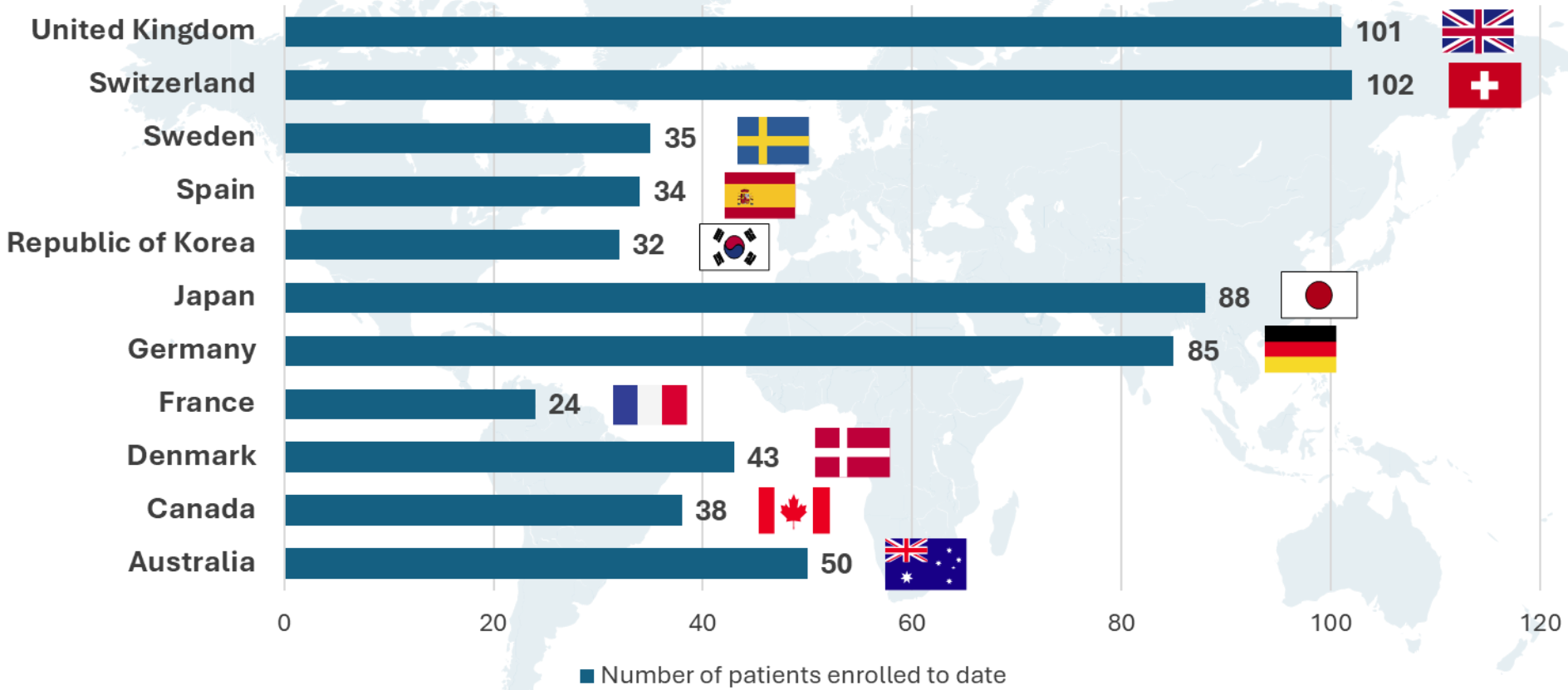
Secondary endpoints include:

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

Enrollment overview

To date, **632** out of **1200 (53%)** planned patients have been enrolled in the **treatment-naïve nAMD** cohort



Enrollment overview

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

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

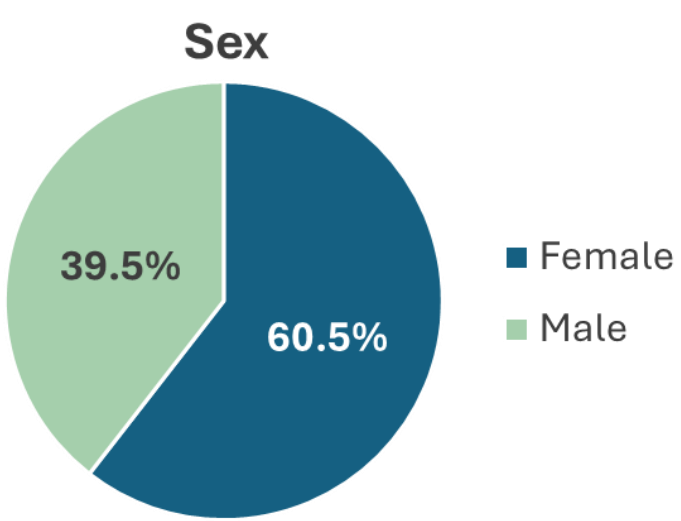
Total: 114 patients

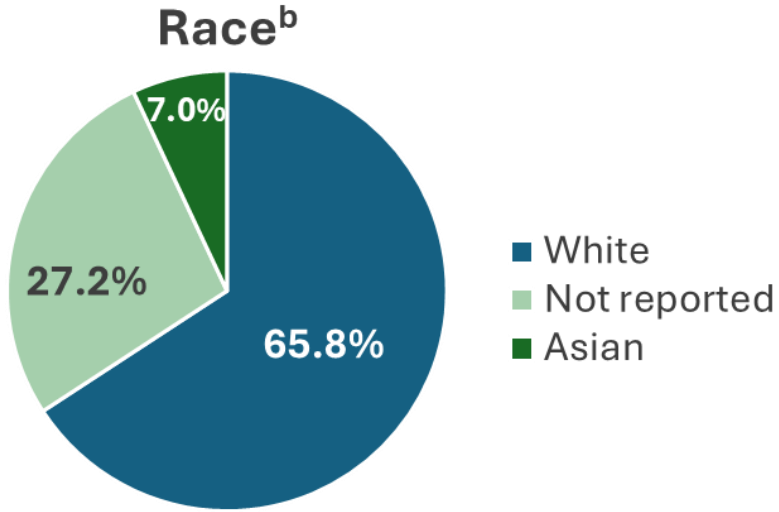
Mean age: 80.8 ± 7.1 years

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

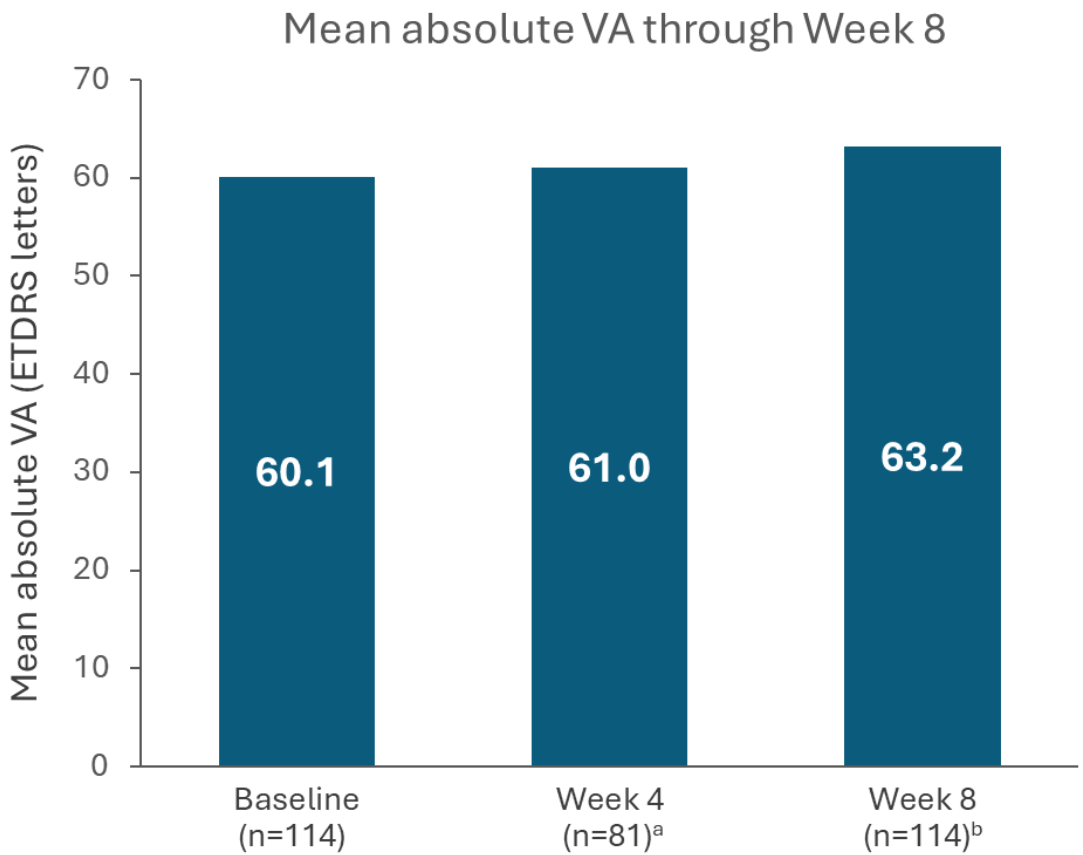


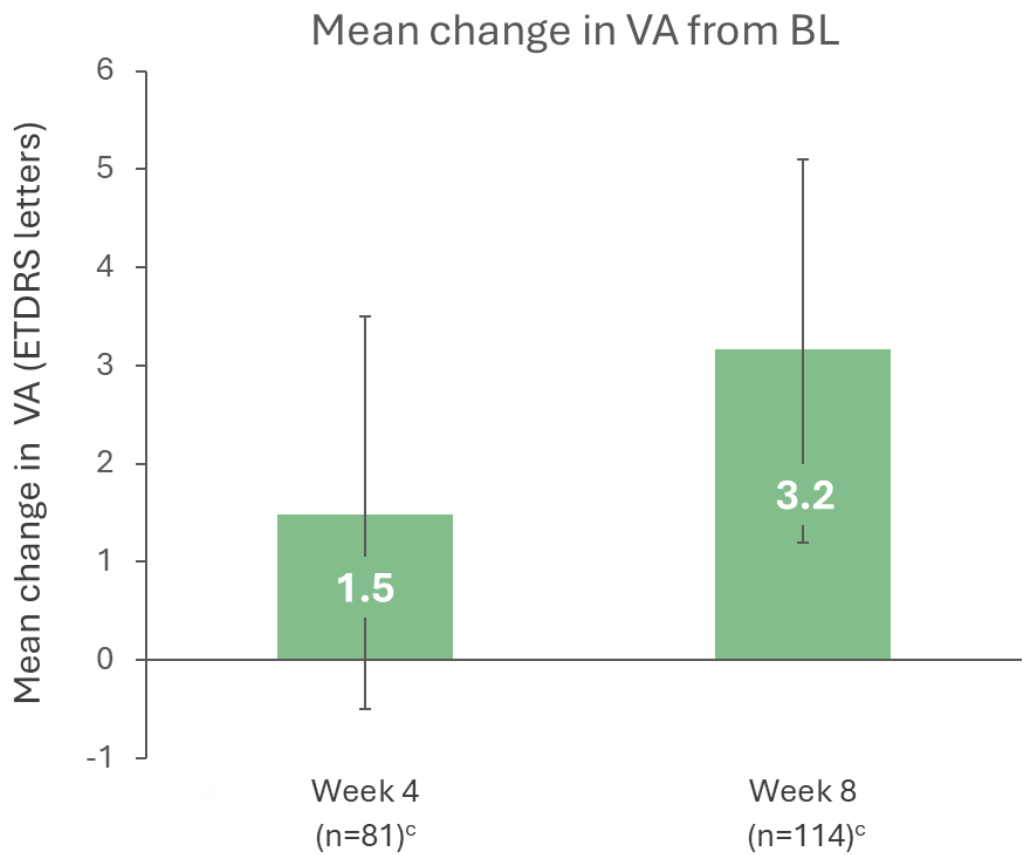


FAS. Percentages may not add up to 100 due to rounding.

[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; UK, United Kingdom.

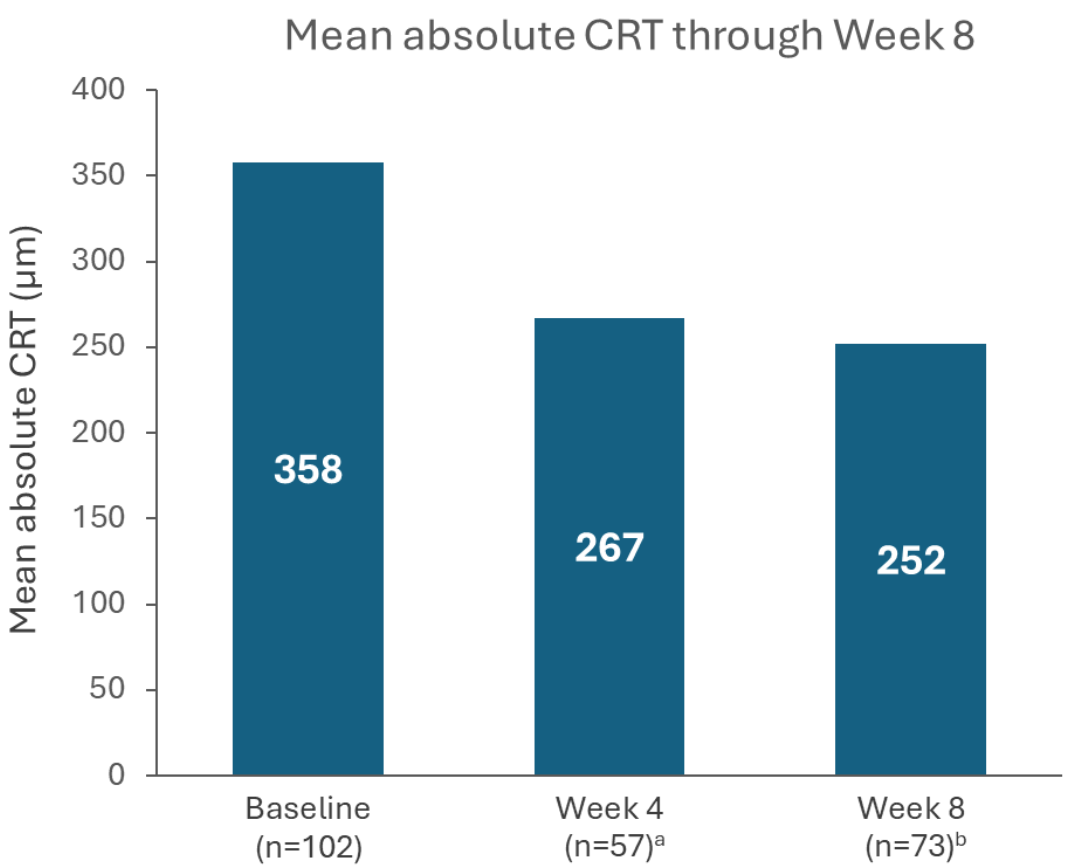
VA through Week 8

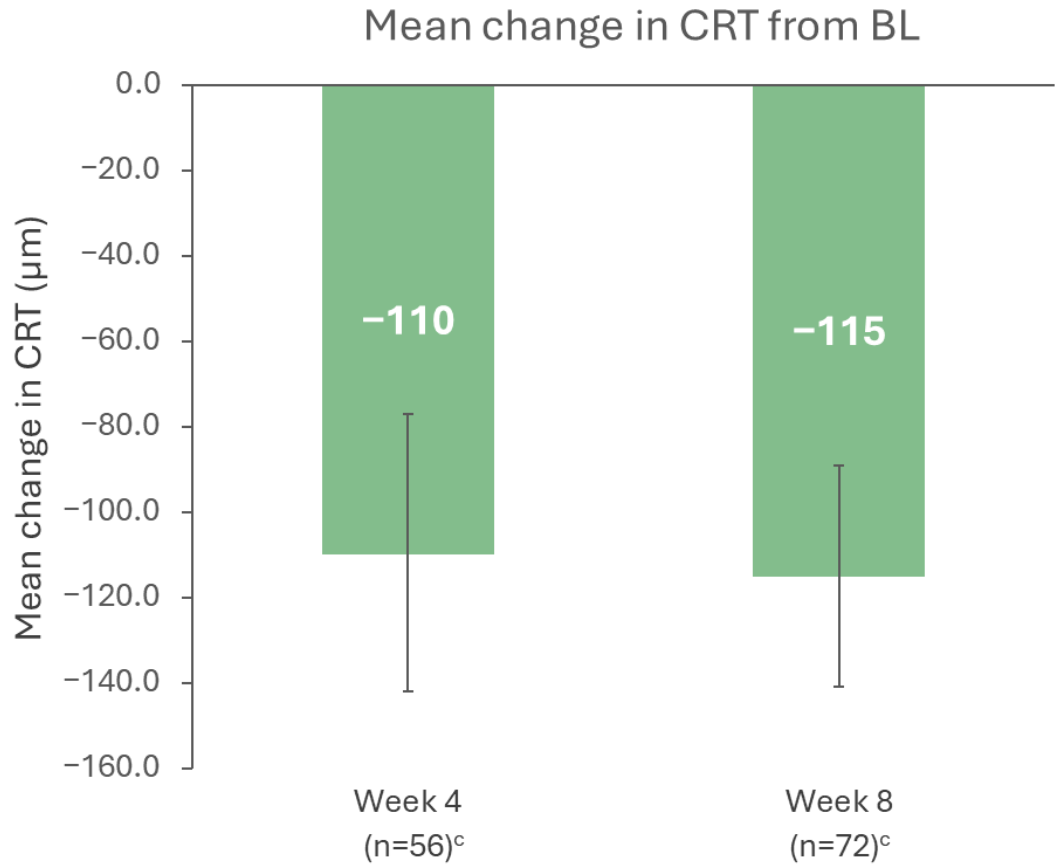




FAS, OC. Values have been rounded to the nearest decimal point. [a]Patients with a VA assessment at BL and Week 4. [b]Patients with a VA assessment at BL and Week 8. [c]Mean VA change at Week 4 and Week 8 from BL was calculated in patients with a VA assessment at Week 4 and Week 8, respectively; error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

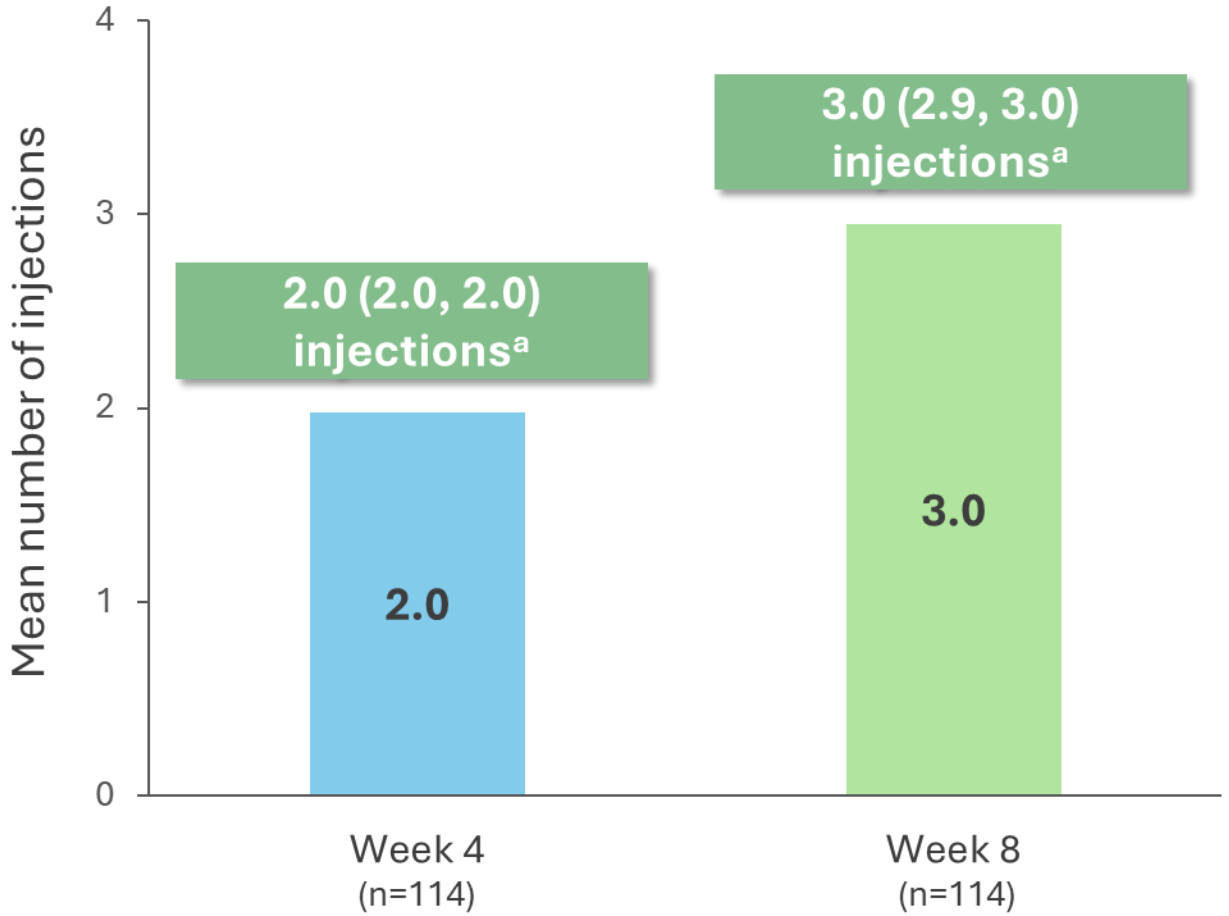
CRT through Week 8





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

	Total (N=114)
Ocular TEAEs in the study eye, n (%)	**3 (2.6)**
Conjunctival hemorrhage	1 (0.9)
Vitreous floaters	1 (0.9)
Not yet coded	1 (0.9)
Non-ocular TEAEs, n (%)	**5 (4.4)**
Nasopharyngitis	1 (0.9)
Chronic kidney disease	1 (0.9)
Cough	1 (0.9)
Hypertension	3 (2.6)

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.

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

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

632/1200 patients enrolled in the **treatment-naive nAMD cohort** across **11 countries** to date

Early clinical outcomes at Week 8

- Improved VA (+3.2 ETDRS letters)
- Reduction in CRT (−115 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 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.