SPECTRUM: Early results 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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Purpose

- Findings from the PULSAR (Phase 3),[1] PHOTON (Phase 2/3)[2] and CANDELA (Phase 2)[3] clinical trials supported the regulatory approval of aflibercept 8 mg for neovascular age-related macular degeneration (nAMD) and diabetic macular oedema (DMO)[4,5]
- SPECTRUM is the first global real-world evidence study to date to evaluate the effectiveness and safety of aflibercept 8 mg for the treatment of nAMD and DMO
- Here, we present early clinical outcomes at Week 8 in patients with treatment-naïve nAMD

Conclusions

- Early clinical experience indicates **improvements in visual acuity (VA; +3.2 letters)** and **central retinal thickness (CRT; −115 µm)** at Week 8 in patients with treatment-naïve nAMD in real-world settings
- To date, **no new safety signals** have been reported for aflibercept 8 mg in this cohort
- **Early insights** from the **SPECTRUM study will help inform clinical management** of treatment-naïve nAMD in patients receiving aflibercept 8 mg

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References

1. Lanzetta P, et al. *Lancet*. 2024;403:1141–1152
2. Brown DM, et al. *Lancet*. 2024;403:1153–1163.
3. Wykoff CC, et al. JAMA *Ophthalmol*. 2023;141:834–842.
4. Eylea. European Medicines Agency. 2025.
5. Drugs@FDA: FDA-Approved Drugs. U.S. Food and Drug Administration. 2023.

Methods

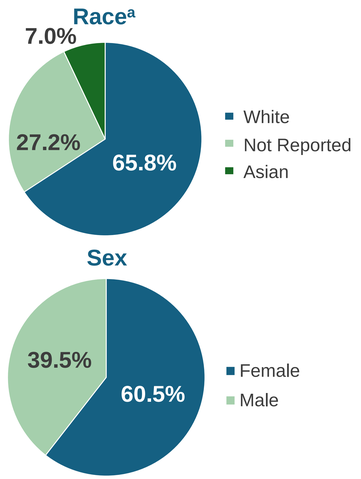
- SPECTRUM (NCT06075147) is an ongoing, 24-month, prospective observational study being conducted across 18 countries
- Treatment-naïve and previously treated patients with nAMD aged ≥50 years or with DMO aged ≥18 years, who have been prescribed aflibercept 8 mg by their attending physician, are eligible for enrolment
- Treatment-naïve patients with nAMD are eligible only if they have never received any prior medical treatment for nAMD
- All treatment decisions are made by each patient's attending physician in accordance with local practice
- This analysis describes early outcomes in the first ~100 patients in this cohort who had a visit and VA assessment at Week 8; all data are analysed descriptively

Results

- Baseline characteristics are provided in **Figure 1**
- The mean change in VA at Week 4 and Week 8 was +1.5 and +3.2 Early Treatment Diabetic Retinopathy Study (ETDRS) letters, respectively, from an overall baseline of 60.1 ETDRS letters (**Figure 2**)
- The mean change in CRT at Week 4 and Week 8 was −110 and −115 µm, respectively, from an overall baseline of 358 µm (**Figure 3**)
- Ocular treatment-emergent adverse events (TEAEs) in the study eye occurred in 2.6% of patients; no serious ocular TEAEs occurred (**Table 1**)
- Non-ocular TEAEs were reported in 4.4% of patients
- No new safety signals for aflibercept 8 mg were observed in this cohort

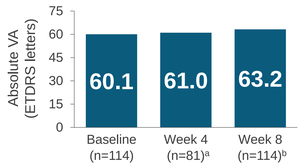
Figure 1: Analysis of patients with a VA assessment at Week 8

- **Total:** 114 patients
- **Mean age:** 80.8 ± 7.1 years
- **Median (min, max) time from nAMD diagnosis:** 0.2 (0.0, 21.9) months
- **Mean baseline VA:** 60.1 ± 17.4 ETDRS letters
- **Mean baseline CRT:** 358 ± 110 µm



FAS. Percentages may not add up to 100 due to rounding. Data are mean ± SD unless otherwise indicated. [a]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates and the United Kingdom only. CRT, central retinal thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; max, maximum; min, minimum; nAMD, neovascular age-related macular degeneration; SD, standard deviation; VA, visual acuity.

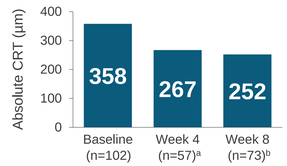
Figure 2: Absolute VA (ETDRS letters) through Week 8



	Week 4 (n=81)	Week 8 (n=114)
Mean change[c]	1.5	3.2
95% CI	−0.5, 3.5	1.2, 5.1

FAS, OC; 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. BL, baseline; CI, confidence interval; ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; OC, observed cases; VA, visual acuity.

Figure 3: Absolute CRT (µm) through Week 8



	Week 4 (n=56)	Week 8 (n=72)
Mean change[c]	−110	−115
95% CI	−142, −77	−141, −89

FAS, OC; this analysis was based on patients with a CRT assessment at Week 8. [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. BL, baseline; CI, confidence interval; CRT, central retinal thickness; FAS, full analysis set; OC, observed cases.

Table 1: Safety outcomes at Week 8

Ocular safety (study eye)	**Total, n (%) (N=114)**
Ocular TEAEs	**3 (2.6)**
Serious ocular TEAEs	0
Non-ocular safety	**Total, n (%) (N=114)**
Non-ocular TEAEs	**5 (4.4)**

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

Disclosures

Michael Grinton: Honoraria: Roche. **VK**: Honoraria: AbbVie, Bayer, Novartis and Roche; **CL**: Honoraria: Appelis, Bayer, Biogen and Novartis; **MRM**: Consulting fees: 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**: Consulting fees: 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: EyePoint; Grants: Bayer, Novartis, Roche; serves on advisory boards for Alcon, Roche, Bayer, Novartis, Appelis and Boehringer Ingelheim; **HO**: Consulting fees: AbbVie, Bayer, Novartis and Roche; **TM**: Employee of Bayer AG; **HA** and **XZ**: Employees of Bayer Consumer Care AG; **CB**: Honoraria: Alimera Sciences, Apellis, Bayer and Roche; has served on advisory boards for Apellis, Bayer, Boehringer Ingelheim, Janssen and Roche.