SPECTRUM: Early results from the first global real-world study of aflibercept 8 mg in patients with pretreated neovascular age-related macular degeneration

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Purpose

- Regulatory approval of the aflibercept 8 mg formulation in patients with neovascular age-related macular degeneration (nAMD) and diabetic macular oedema (DMO)[1,2] was based on the PULSAR (Phase 3),[3] PHOTON (Phase 2/3)[4] and CANDELA (Phase 2)[5] clinical trials
- SPECTRUM is the first global Phase 4 study to collect real-world data on the effectiveness and safety of aflibercept 8 mg in the treatment of nAMD and DMO
- Here, we present early clinical outcomes at Week 8 in patients with previously treated nAMD from the SPECTRUM trial

Conclusions

- Early clinical experience indicates **stable visual acuity (VA)** and **reductions in central retinal thickness (CRT; −39 µm)** at Week 8 in patients with previously treated 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 previously treated nAMD in patients receiving aflibercept 8 mg

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Methods

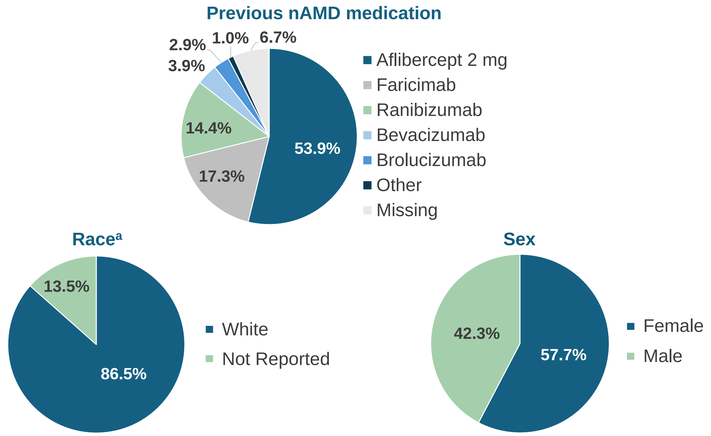
- SPECTRUM (NCT06075147) is an ongoing, 24-month, prospective observational study being conducted across 18 countries
- Patients with treatment-naïve and previously treated nAMD aged ≥50 years or DMO aged ≥18 years, who have been prescribed aflibercept 8 mg by their attending physician, are eligible for enrolment
- All treatment decisions are made by each patient's attending physician in accordance with local practice
- Patients are eligible for the previously treated nAMD cohort if they have received prior treatment (including other anti-vascular endothelial growth factor therapies) up to prespecified timepoints before study start
- 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 +1.4 and 0.0 Early Treatment Diabetic Retinopathy Study (ETDRS) letters, respectively, from an overall baseline of 61.6 ETDRS letters (**Figure 2**)
- The mean change in CRT at Week 4 and Week 8 was −56 and −39 µm, respectively, from an overall baseline of 316 µm (**Figure 3**)
- Ocular treatment-emergent adverse events (TEAEs) in the study eye occurred in 3.9% of patients; no serious ocular TEAEs occurred (**Table 1**)
- No non-ocular TEAEs were reported
- No new safety signals for aflibercept 8 mg were observed in this cohort

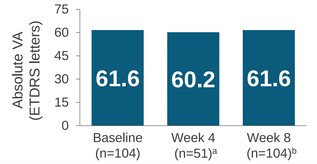
Figure 1: Analysis of patients with a VA assessment at Week 8

- **Total:** 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



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, age-related macular degeneration; SD, standard deviation; VA, visual acuity.

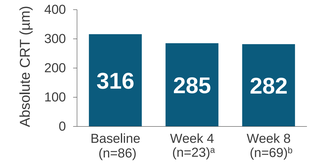
Figure 2: Absolute VA (ETDRS letters) through Week 8



	Week 4 (n=51)	Week 8 (n=104)
Mean change[c]	1.4	0.0
95% CI	−0.8, 3.5	−1.6, 1.6

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 51 and 104 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=22)	Week 8 (n=68)
Mean change[c]	−56	−39
95% CI	−99, −13	−60, −19

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 22 and 68 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=104)
Ocular TEAEs	4 (3.9)
Serious ocular TEAEs	0
Non-ocular safety	**Total, n (%) (N=104)**
Non-ocular TEAEs	0

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

Disclosures

Clare Bailey: Honoraria: Alimera Sciences, Apellis, Bayer, and Roche; advisory boards: Apellis, Bayer, Boehringer Ingelheim, Janssen, and Roche; **CL**: Honoraria: Apellis, Bayer, Biogen, and Novartis; **VC**: Consulting fees: EyePoint; grants: Bayer, Novartis, Roche; advisory boards: Alcon, Apellis, Bayer, Boehringer Ingelheim, Novartis, and Roche; **PL**: Consultant: Aerie Pharmaceuticals, Allergan, Annexon, Apellis, Bausch + Lomb, Bayer, Biogen, Boehringer Ingelheim, EyePoint, Genentech, I-Care, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche; **HO**: Consultant: AbbVie, Bayer, Novartis, and Roche; **MK** and **TM**: Employees: Bayer AG; **HA, XZ** and **ZH**: Employees: Bayer Consumer Care AG; **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.