SPECTRUM: Early results from the first global real-world study of aflibercept 8 mg in patients with treatment-naïve diabetic macular oedema

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Purpose

- The CANDELA (Phase 2),[1] PHOTON (Phase 2/3)[2] and PULSAR (Phase 3)[3] clinical trials led to the regulatory approval of the aflibercept 8 mg formulation in patients with diabetic macular oedema (DMO) and neovascular age-related macular degeneration (nAMD)[4,5]
- SPECTRUM is the first global study to assess the real-world effectiveness and safety of aflibercept 8 mg for these indications
- Here, we outline the SPECTRUM study design, provide an update on the current enrolment status, and present an overview of baseline characteristics of the treatment-naïve DMO cohort

Conclusions

- As the **first global real-world study on aflibercept 8 mg**, SPECTRUM is generating a **wealth of long-term data** on the real-world **effectiveness and safety of aflibercept 8 mg in DMO and nAMD** across diverse patient populations
- This initial report provides insights into the **baseline characteristics** of the first **150 patients enrolled in the treatment-naïve DMO cohort**
- To date, **301 patients have been enrolled** in the **treatment-naïve DMO cohort** and the **first set of evaluations is underway**

Presented at The Royal Congress of Ophthalmologists Annual Congress, Liverpool, UK, 19–22 May, 2025.

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Acknowledgments

The SPECTRUM study was sponsored by Bayer Consumer Care AG (Basel, Switzerland). The sponsor participated in the design and conduct of the study, analysis of the data, and preparation of this poster. 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) guidelines (Ann Intern Med. 2022;175:1298–1304).

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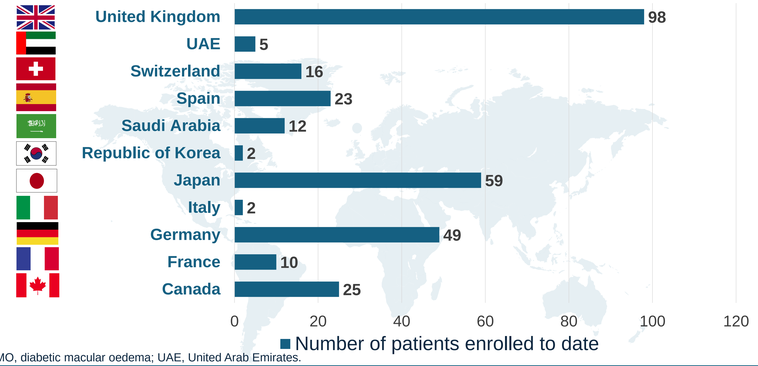
Methods

- SPECTRUM (NCT06075147) is an ongoing, 24-month, prospective observational study being conducted across 18 countries in North America, Europe, the Middle East and the Asia-Pacific region
- Treatment-naïve and previously treated patients with DMO aged ≥18 years or with nAMD aged ≥50 years, who have been prescribed aflibercept 8 mg by their attending physician, are eligible for enrollment
- Decisions regarding monitoring, retreatment and treatment schedules are made by each patient's attending physician in accordance with local clinical practice; all data are analysed descriptively
- Patients are eligible for enrolment in the treatment-naïve DMO cohort if they have never received any medical treatment for DMO and have been prescribed aflibercept 8 mg by their physician
- Patients with prior ocular treatment in the study eye, systemic treatment for DMO, or those who have received laser treatment in the study eye within 90 days prior to their first aflibercept 8 mg dose will be excluded
- Data are being collected from medical records and imaging during routine visits from February 2024 to September 2027, with a follow-up period of up to 24 months per patient
- Approximately 100 patients will be enrolled in each of the 4 study cohorts across each participating country or country cohort

Results

- Of the 950 patients planned, 301 patients have been enrolled to date in the treatment-naïve DMO cohort across 11 countries (**Figure 1**); the longest treatment duration thus far is 14 months
- A summary of the baseline data for the first 150 patients enrolled in SPECTRUM with treatment-naïve DMO is provided (**Figure 2**)
- In SPECTRUM, the primary endpoint is the change in visual acuity (VA) from baseline to Month 12
- Secondary endpoints include the change in VA from baseline to Month 6 and Month 24, and change in central retinal thickness (CRT) from baseline to Month 6, Month 12 and Month 24; adverse events are monitored throughout the study
- SPECTRUM's study design facilitates analyses at both regional and global levels, enabling rolling interim analyses of endpoints in each participating country/cohort (**Figure 3**)
- Month 6 data for the treatment-naïve DMO cohort are expected in the 3rd quarter of 2025

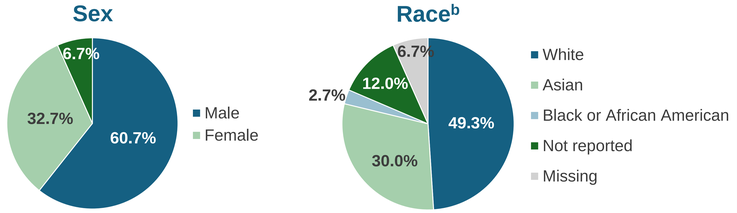
Figure 1: Patient enrolment to date (17 April 2025) in the treatment-naïve DMO cohort



DMO, diabetic macular oedema; UAE, United Arab Emirates.

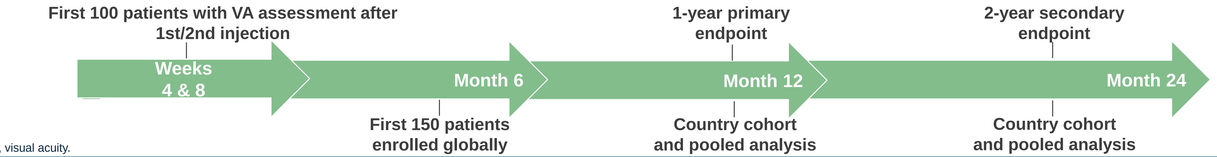
Figure 2: Baseline snapshot of the first 150 patients enrolled in the treatment-naïve DMO cohort[a]

- **Mean age:** 66.3 ± 11.2 years
- **Median (min, max) time from DMO diagnosis:** 0.5 (0.0, 109.2) months
- **Mean baseline VA:** 63.5 ± 15.9 ETDRS letters
- **Mean baseline CRT:** 420 ± 109 µm



[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 United Kingdom only. CRT, central retinal thickness; DMO, diabetic macular oedema; ETDRS, Early Treatment of Diabetic Retinopathy Study; SD, standard deviation; VA, visual acuity.

Figure 3: Planned SPECTRUM timeline and analyses



SPECTRUM's study design facilitates analyses on both regional and global levels, enabling rolling analyses of endpoints in each participating country/cohort 1 year after enrolment is complete

VA, visual acuity.

Disclosures

Aires Lobo: Advisory boards of Advanz Pharma, GSK, Nordic Pharma, Bayer and Roche; and honoraria from Bayer and Roche; **HO**: Consultant for AbbVie, Bayer, Novartis and Roche; **CB**: Received honoraria from Alimera Sciences, Apellis, Bayer and Roche; and has served on advisory boards for Apellis, Bayer, Boehringer Ingelheim, Janssen and Roche; **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 the advisory boards of Alcon, Roche, Bayer, Novartis, Apellis and Boehringer Ingelheim; **MRM**: Consulting fees from AbbVie, Allergan, Apellis, Aviceda Therapeutics, Bayer, Boehringer Ingelheim, Dandelion, EyePoint, Gensight, Isarna Therapeutics, Iveric BioKubota, Lumithera, Novartis, Oculis, Ocuterra, Ocular Therapeutix, RetinAI, Roche and Zeis; **TM**: Employee of Bayer AG; **HA and PM-W**: Employees of Bayer Consumer Care AG; **CL**: Receives honoraria from Apellis, Bayer, Biogen and Novartis.