SPECTRUM: Early results from the first global real-world study of aflibercept 8 mg in patients with pretreated 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 previously treated 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 previously treated DMO cohort**
- To date, **476 patients have been enrolled** in the previously treated DMO cohort and the **first set of evaluations is currently underway**

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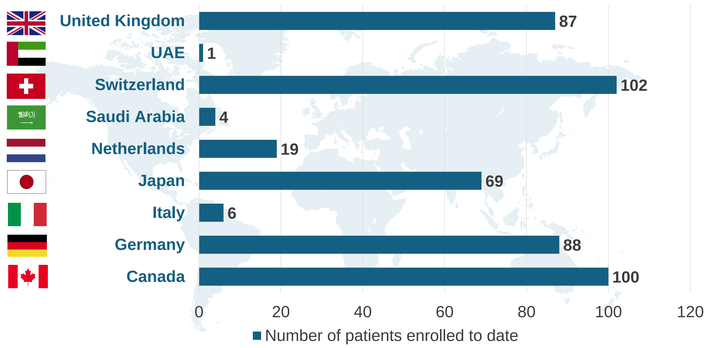
Methods

- SPECTRUM (NCT06075147) is an ongoing, 24-month, prospective observational study being conducted across 18 countries
- Treatment-naïve and previously treated patients with DMO aged ≥18 years or nAMD aged ≥50 years, who have been prescribed aflibercept 8 mg by their attending physician, are eligible for enrolment
- Decisions regarding monitoring, retreatment and treatment schedules are made by each patient's physician in accordance with local clinical practice; all data are analysed descriptively
- Patients are eligible for enrolment in the previously treated DMO cohort if they have received prior treatment, such as steroids or other anti-vascular endothelial growth factor (anti-VEGF) therapies, up to prespecified time points before the study start
- To meet eligibility criteria, within the study eye, patients must not have received intravitreal anti-VEGF treatment within the last 28 days, intravitreal corticosteroid treatment within the last 3 months, a fluocinolone implant within the last 3 years, or a dexamethasone implant within the last 6 months
- Additionally, patients with any concurrent drug-releasing implant in the study eye are 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

Results

- Of the 775 patients planned, 476 patients have been enrolled to date in the previously treated DMO cohort across 9 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 previously treated 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 at Month 6 and Month 24, and change in central retinal thickness (CRT) from baseline at Month 6, Month 12 and Month 24; adverse events are being monitored throughout the study
- SPECTRUM's study design facilitates analyses at both regional and global levels, enabling rolling analyses of endpoints in each participating country/cohort (**Figure 3**)
- Month 6 data for the previously treated DMO cohort will be available in the 2nd quarter of 2025

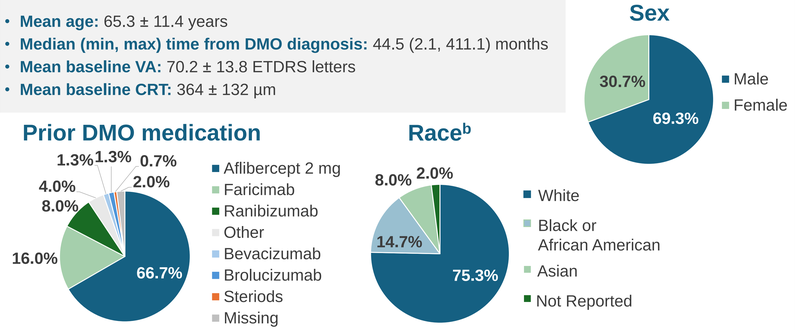
Figure 1: Patient enrolment to date (17 April 2025) in the previously treated DMO cohort



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

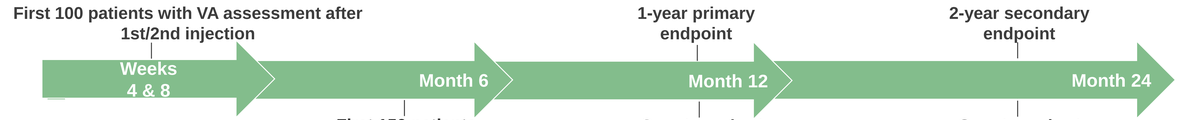
Figure 2: Baseline snapshot of the first 150 patients enrolled in the previously treated DMO cohort[a]

- **Mean age:** 65.3 ± 11.4 years
- **Median (min, max) time from DMO diagnosis:** 44.5 (2.1, 411.1) months
- **Mean baseline VA:** 70.2 ± 13.8 ETDRS letters
- **Mean baseline CRT:** 364 ± 132 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



VA, visual acuity.

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

Disclosures

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