2391 - B0078

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

Aires Lobo,[1] Hassiba Oubraham,[2] Clare Bailey,[3] Paolo Lanzetta,[4,5] Varun Chaudhary,[6] Marion R. Munk,[7,8,9] Tobias Machewitz,[10] Helmut Allmeier,[11] Peter Morgan-Warren,[11] Clemens Lange,[12,13] on behalf of the SPECTRUM study investigators

[1]Ophthalmology Department, Moorfields Eye Centre, Bedford Hospital, Bedford, UK; [2]Centre OPHTA-45, Montargis, France; [3]Department of Ophthalmology, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK; [4]Department of Medicine–Ophthalmology, University of Udine, Udine, Italy; [5]Istituto Europeo di Microchirurgia Oculare (IEMO), Udine, Italy; [6]Hamilton Regional Eye Institute, St. Joseph's Healthcare Hamilton, McMaster University, Hamilton, ON, Canada; [7]Augenarzt Praxisgemeinschaft Gutblick AG, Pfäffikon, Switzerland; [8]Department of Ophthalmology, University Hospital Bern, Switzerland; [9]Northwestern University, Feinberg School of Medicine, Chicago, IL, USA; [10]Bayer AG, Berlin, Germany; [11]Bayer Consumer Care AG, Basel, Switzerland; [12]Eye Center, Faculty of Medicine, Albert-Ludwig University Freiburg, Freiburg, Germany; [13]Department of Ophthalmology, St. Franziskus Hospital, Münster, Germany

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 edema (DME) 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 enrollment status, and present an overview of baseline characteristics of the treatment-naïve DME 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 DME 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 DME cohort**
- To date, **301 patients have been enrolled** in the treatment-naïve DME cohort and the **first set of evaluations is underway**

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Disclosures

Aires Lobo: Advisory boards of Advanz Pharma, GSK, Nordic Pharma, Bayer, and Roche; and honoraria from Bayer and Roche.

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).

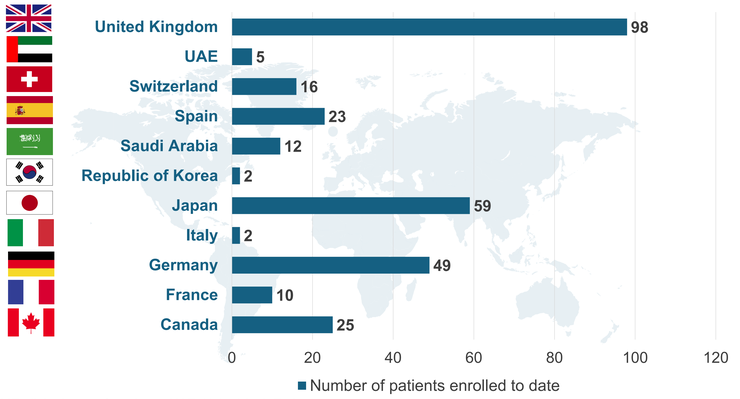
Methods

- 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 DME 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 results are analyzed descriptively
- Patients are eligible for enrollment in the treatment-naïve DME cohort if they have never received any medical treatment for DME and have been prescribed aflibercept 8 mg by their physician
- Patients with prior ocular treatment in the study eye, systemic treatment for DME, 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 DME 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 DME 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 monitored throughout the study
- SPECTRUM's study design enables analyses at both regional and global levels, enabling rolling analyses of endpoints in each participating country/cohort (**Figure 3**)
- Month 6 data for the treatment-naïve DME cohort are expected in quarter 3, 2025

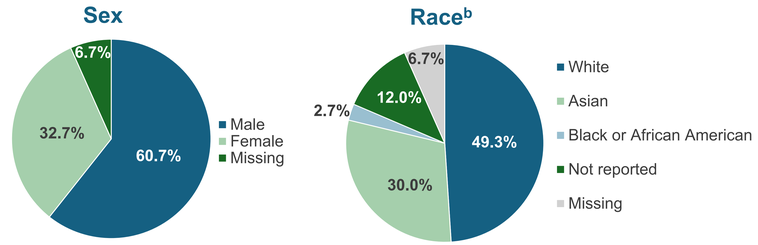
Figure 1: Patient enrollment to date (April 17, 2025) in the treatment-naïve DME cohort



DME, diabetic macular edema; UAE, United Arab Emirates.

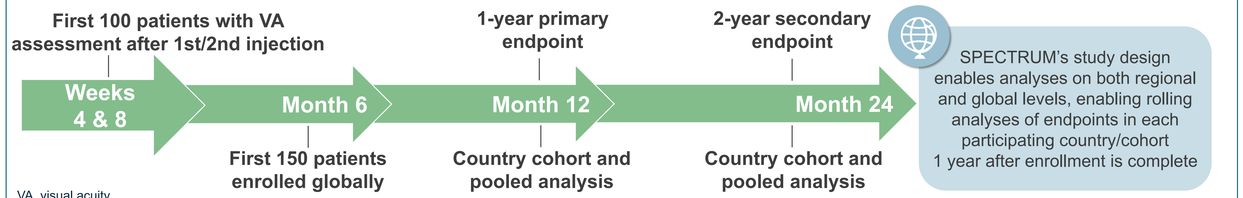
Figure 2: Baseline snapshot of the first 150 patients enrolled in the treatment-naïve DME cohort[a]

- **Mean age:** 66.3 ± 11.2 years
- **Median (min, max) time from DME 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. DME, diabetic macular edema; CRT, central retinal thickness; ETDRS, Early Treatment of Diabetic Retinopathy Study; SD, standard deviation; VA, visual acuity.

Figure 3: Planned SPECTRUM timeline and analyses



VA, visual acuity.

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Presented at The Association for Research in Vision and Ophthalmology (ARVO) 2025 Annual Meeting, Salt Lake City, UT, USA, May 4–8, 2025