2392 - B0079

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

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

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

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 previously treated 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 characteristics of the **first 150 patients enrolled in the previously treated DME cohort**
- To date, **476 patients have been enrolled** in the previously treated DME cohort, and **the first set of evaluations is currently underway**

Scan the QR code to access the ARVO 2025 planner and abstracts

Disclosures

Thomas Dervos: Receives honoraria from Bayer.

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).

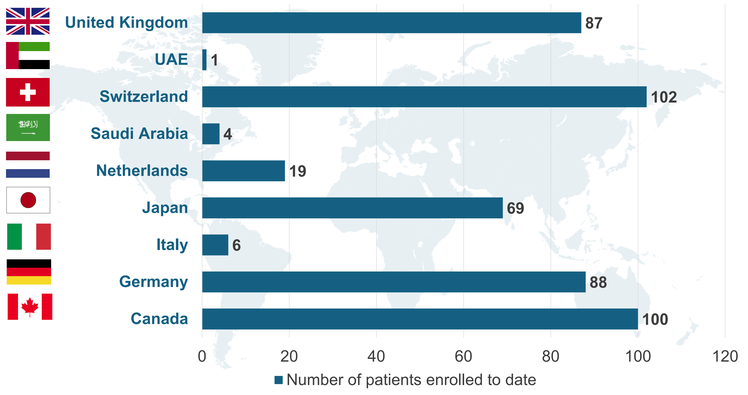
Methods

- SPECTRUM (NCT06075147) is an ongoing, 24-month, prospective observational study being conducted across 18 countries
- Treatment-naïve and previously treated patients with DME aged ≥18 years or 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 physician in accordance with local clinical practice
- All data are analyzed descriptively
- Patients are eligible for enrollment in the previously treated DME cohort if they have been prescribed treatment with aflibercept 8 mg by their physician and 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 DME 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 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 being 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 previously treated DME cohort will be available in the second quarter of 2025

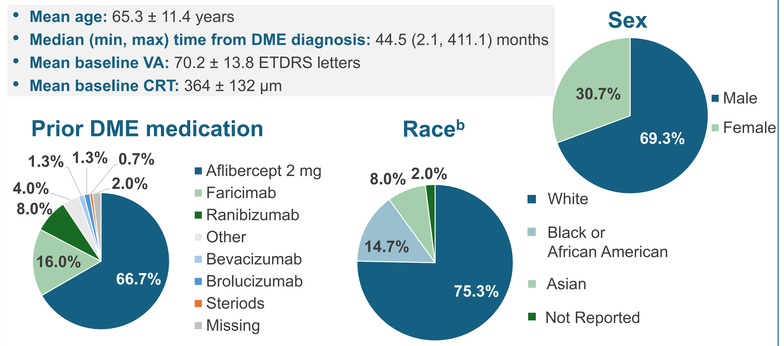
Figure 1: Patient enrollment to date (April 17, 2025) in the previously treated DME cohort



UAE, United Arab Emirates.

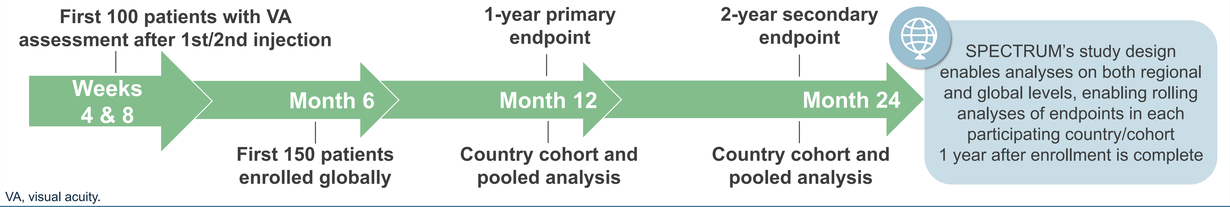
Figure 2: Baseline snapshot of the first 150 patients enrolled in the previously treated DME cohort[a]

- **Mean age:** 65.3 ± 11.4 years
- **Median (min, max) time from DME 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. ETDRS, Early Treatment of Diabetic Retinopathy Study; SD, standard deviation.

Figure 3: Planned SPECTRUM timeline and analyses



VA, visual acuity.

References

1. Wykoff CC, et al. JAMA *Ophthalmol.* 2023; 141:834–842.
2. Brown DM et al. *Lancet.* 2024;403(10432): 1153–1163.
3. Lanzetta P et al. *Lancet.* 2024;403(10432): 1141–1152.
4. Eylea. European Medicines Agency. 2025.
5. Drugs@FDA: FDA-Approved Drugs. U.S. Food and Drug Administration. 2023.

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