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Early global analysis of intraocular pressure changes in patients with nAMD and DME in the SPECTRUM real-world study of aflibercept 8 mg

Marco Lupidi,[1] Marion R. Munk,[2–4] Clemens Lange,[5,6] Varun Chaudhary,[7] Clare Bailey,[8] Hassiba Oubraham,[9] Martin Kirchner,[10] Tobias Machewitz,[11] Sarah Schlief,[11] Susanne Oesch,[12] Peter Morgan-Warren,[12] Paolo Lanzetta,[13,14] on behalf of the SPECTRUM study investigators

[1]Eye Clinic, Polytechnic University of Marche, Ancona, Italy; [2]Augenarzt Praxisgemeinschaft Gutblick AG, Pfäffikon, Switzerland; [3]Department of Ophthalmology, University Hospital Bern, 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 Surgery, McMaster University, Hamilton, ON, Canada; [8]Department of Ophthalmology, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK; [9]Centre OPHTA-45, Montargis, France; [10]Bayer AG, Leverkusen, Germany; [11]Bayer AG, Berlin, Germany; [12]Bayer Consumer Care AG, Basel, Switzerland; [13]Department of Medicine – Ophthalmology, University of Udine, Italy; [14]Istituto Europeo di Microchirurgia Oculare – IEMO, Udine, Italy

Purpose

- The CANDELA (Phase 2),[1] PHOTON (Phase 2/3)[2] and PULSAR (Phase 3)[3] clinical trials of aflibercept 8 mg for the treatment of neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME) demonstrated a reassuring intraocular pressure (IOP) safety profile
- SPECTRUM is an ongoing, global, prospective Phase 4 study to evaluate the real-world effectiveness and safety of aflibercept 8 mg for the treatment of nAMD and DME
- Here, we report IOP-related findings through Week 24 from SPECTRUM for patients with treatment-naïve (TN) and previously treated (PT) nAMD or DME

Conclusions

- **SPECTRUM IOP-related findings** through **Week 24** for **aflibercept 8 mg** in patients with PT and TN nAMD or DME indicate:
  - Stable pre-injection IOP
  - Very low rates of IOP-related treatment-emergent adverse events
- These **early IOP findings** from **SPECTRUM** are **consistent** with those reported for aflibercept 8 mg in **Phase 3 trials**[2,3]

Scan the QR code to access the SPECTRUM study infographic[4]

Disclosures

Marco Lupidi: Advisory boards for AbbVie, Bayer, Heidelberg Engineering, and Roche.

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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
- Patients with PT or TN nAMD (aged ≥50 years) or DME (aged ≥18 years), who were prescribed aflibercept 8 mg by their attending physician prior to study start, were eligible for enrollment
- Decisions regarding monitoring and treatment, including the assessment of IOP, are made at the discretion of each patient's attending physician in accordance with local clinical practice
- 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
- Enrollment is complete, comprising 2294 patients across the 2 global nAMD cohorts and 1439 patients across the 2 global DME cohorts
- This exploratory analysis reports IOP-related data for injections received through Week 24 (closest visit to 180 days [150–210] from baseline) for the first ~150 patients enrolled globally in each of the 4 SPECTRUM cohorts
- All results were analyzed descriptively
- The latest data cuts are reported here: April 9, 2025 (TN nAMD), August 14, 2025 (TN DME), and January 5, 2026 (PT nAMD and PT DME)

Results

- Up to Day 210 from baseline, the global TN (n=141) and PT (n=148) nAMD cohorts received a mean±SD of 4.7±1.2 and 4.5±1.6 injections, and the global TN (n=142) and PT (n=145) DME cohorts received 4.0±1.2 and 4.4±1.8 injections
- Low proportions of patients were assessed for pre-injection IOP and post-injection IOP measurements through Week 24, with an average of 2.4 and 0.4 assessments per patient, respectively, across the 4 global SPECTRUM cohorts
- Baseline demographics and IOP-related characteristics across the 4 global cohorts are described in **Table 1**
- At baseline, the mean pre-injection IOP (n=patients with reported values) was 14.3 (n=101), 13.9 (n=94), 14.1 (n=112), and 14.8 (n=116) mmHg in the global TN nAMD, PT nAMD, TN DME, and PT DME cohorts, respectively (**Table 1**)
- The mean±SD change (n=assessments) in pre-injection IOP from baseline through Week 24 was −1.3±3.5 (n=214) and −0.4±2.7 (n=250) mmHg for the global TN and PT nAMD cohorts, and −1.0±3.8 (n=129) and +0.4±3.1 (n=301) mmHg for the global TN and PT DME cohorts (**Figure 1**)
- Through Week 24, rates of IOP-related treatment-emergent adverse events were very low and similar across the 4 global SPECTRUM cohorts (**Table 2**)

Table 1: IOP-related baseline characteristics of the global SPECTRUM cohorts (first ~150 patients enrolled)

Baseline characteristics[a]	TN nAMD (n=141)	PT nAMD (n=148)	TN DME (n=142)	PT DME (n=145)
Age, years	80.8±6.9	79.5±8.1	66.1±11.5	65.3±11.0
Median time since first prior treatment, days	–	644	–	639
Pre-injection IOP, mmHg	14.3±3.7	13.9±3.5	14.1±3.8	14.8±3.5
IOP-related comorbidities, n (%)[b]				
Angle-closure glaucoma	1 (0.7)	1 (0.7)	0	0
Borderline glaucoma	0	2 (1.4)	1 (0.7)	1 (0.7)
Exfoliation glaucoma	2 (1.4)	3 (2.0)	0	0
Glaucoma	2 (1.4)	5 (3.4)	5 (3.5)	12 (8.3)
Normal-tension glaucoma	0	1 (0.7)	0	0
Ocular hypertension	1 (0.7)	1 (0.7)	3 (2.1)	0
Open-angle glaucoma	0	0	0	3 (2.1)
Pigment dispersion syndrome	0	1 (0.7)	0	2 (1.4)
Concomitant IOP-lowering medications, n[c]	6	8	5	13

FAS. Data are mean±SD unless otherwise indicated. [a]All characteristics were classified and reported by the study investigators. [b]Multiple answers possible. [c]Patients could receive more than one medication and may, therefore, have been counted more than once. DME, diabetic macular edema; FAS, full analysis set; IOP, intraocular pressure; nAMD, neovascular age-related macular degeneration; PT, previously treated; SD, standard deviation; TN, treatment-naïve.

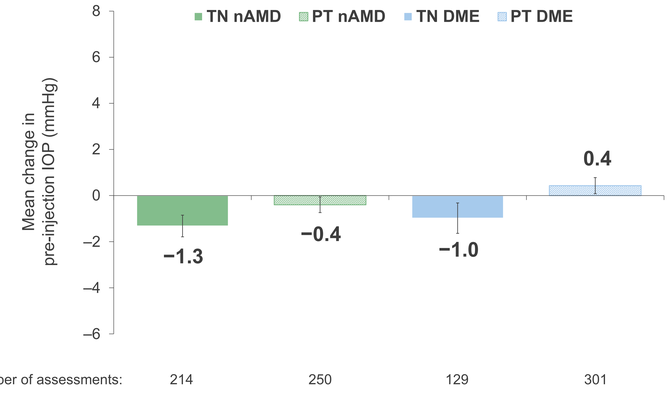
Table 2: IOP-related TEAEs reported through Week 24 in the global SPECTRUM cohorts (first ~150 patients enrolled)

IOP-related TEAE in the study eye, n (%)	TN nAMD (n=150)	PT nAMD (n=149)	TN DME (n=150)	PT DME (n=150)
Increased IOP	3 (2.0)	2 (1.3)	3 (2.0)	3 (2.0)
Ocular hypertension	0	1 (0.7)	0	3 (2.0)

No TEAEs of glaucoma reported

SAF. The eye treated with aflibercept 8 mg was considered the study eye; if aflibercept 8 mg treatment was decided simultaneously for both eyes, the study eye was considered to be the worse eye per the discretion of the attending physician. DME, diabetic macular edema; IOP, intraocular pressure; nAMD, neovascular age-related macular degeneration; PT, previously treated; SAF, safety analysis set; TEAE, treatment-emergent adverse event; TN, treatment-naïve.

Figure 1: Mean change in pre-injection IOP from baseline through Week 24 in the global SPECTRUM cohorts (first ~150 patients enrolled)



FAS. Error bars indicate the 95% CI. DME, diabetic macular edema; CI, confidence interval; FAS, full analysis set; IOP, intraocular pressure; nAMD, neovascular age-related macular degeneration; PT, previously treated; TN, treatment-naïve.

SPECTRUM data on treatment outcomes and patterns with aflibercept 8 mg in the global nAMD and DME cohorts are also being presented at **ARVO 2026**:

- Global nAMD Week 12 outcomes
- Global DME Week 12 outcomes
- Global nAMD Week 24 treatment patterns (early enrollees)
- Global DME Week 24 treatment patterns (early enrollees)

References

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