



Stable intraocular pressure parameters through Week 24 in patients with nAMD and DME: Results from the global SPECTRUM real-world study of aflibercept 8 mg

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Disclosures

- **Marion R. Munk:** Consultant for AbbVie, Alcon, Alimera Sciences, Allergan, Amgen, Apellis, Astellas, Aviceda Therapeutics, Bayer, Boehringer Ingelheim, Dandelion Pharmaceutical, Evolve Medical Education, eye.gnos consulting, EyePoint Pharmaceuticals, GenSight Biologics, Isarna Therapeutics, Iveric Bio, Kubota, LumiThera, Novartis, Ocular Therapeutix, Oculis, OcuTerra Therapeutics, OD-OS, ONL Therapeutics, RetinAI, Roche, Sitalis, UBS Analytics, and Zeiss
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- The data cut-off date for the presented analyses was May 15, 2026, for all cohorts
- Pooled Week 96 IOP data from the PULSAR and PHOTON trials were first presented at the ARVO 2025 Annual Meeting, Salt Lake City, UT, USA, May 4–8, 2025



Overview

- The **CANDELA** (Phase 2)¹ and **PULSAR** (Phase 3)² trials in nAMD and the **PHOTON** (Phase 2/3)³ trial in DME demonstrated a **reassuring intraocular pressure (IOP) safety profile** for **aflibercept 8 mg**,⁴ which is **administered** in a **volume** of **70 µL**
- **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**⁴
- Here, we report **IOP-related findings** through **Week 24** from **SPECTRUM** for all patients enrolled globally with treatment-naïve and previously treated nAMD or DME



In SPECTRUM, **all decisions** regarding monitoring and treatment, including **IOP assessments**, are made at the **discretion** of the **attending physician** in accordance with local clinical practice



SPECTRUM: Global real-world study of aflibercept 8 mg

A 24-month, prospective, non-interventional country and global cohort study in 18 countries



Two indications, 4 patient cohorts

Treatment-naïve **nAMD** and previously treated **nAMD**
Treatment-naïve **DME** and previously treated **DME**



Primary endpoint: Change in **VA** from **BL** to Month 12



Treated with **aflibercept 8 mg** per routine clinical practice



Data collection from medical records for up to 24 months per patient
→ February 2024 to September 2027

Patient enrollment
is complete:

3733

nAMD + DME

2294

nAMD cohorts

1439

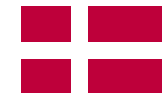
DME cohorts



Australia



Canada



Denmark



Finland



France



Germany



Italy



Japan



Republic of Korea



Netherlands



Norway



Portugal



Saudi Arabia



Spain



Sweden



Switzerland



United Arab
Emirates



United Kingdom



Aflibercept 8 mg showed improvements in VA, CRT, and retinal drying through Week 24 in the global nAMD and DME cohorts

	TN nAMD (n=1129)	PT nAMD (n=1061)	TN DME (n=650)	PT DME (n=635)
 VA, letters (Mean [95% CI] change from BL to Week 24)	+4.3 (3.5, 5.2)	+0.4 (-0.2, 1.1)	+5.0 (4.1, 6.0)	+1.4 (0.6, 2.1)
 CRT, μm^{a} (Mean [95% CI] change from BL to Week 24)	-107 (-115, -100)	-30 (-35, -25)	-98 (-107, -89)	-44 (-53, -36)
 Fluid-free status^b (% of patients with no IRF <u>and</u> no SRF)	4.4% → 62.1% from BL to W24	16.5% → 43.1% from BL to W24	6.7% → 32.0% from BL to W24	9.9% → 24.2% from BL to W24
 Injections (Mean $\pm$ SD from BL to Day 210)	4.6 $\pm$ 1.2	4.3 $\pm$ 1.5	4.1 $\pm$ 1.5	4.0 $\pm$ 1.7



- In the **PT nAMD** and **DME** cohorts, most **patients with high treatment need** based on a prior dosing interval of ≤ 8 weeks had an **increased dosing interval at Week 24**

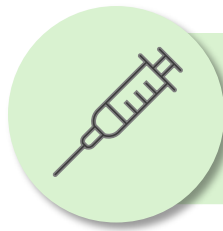
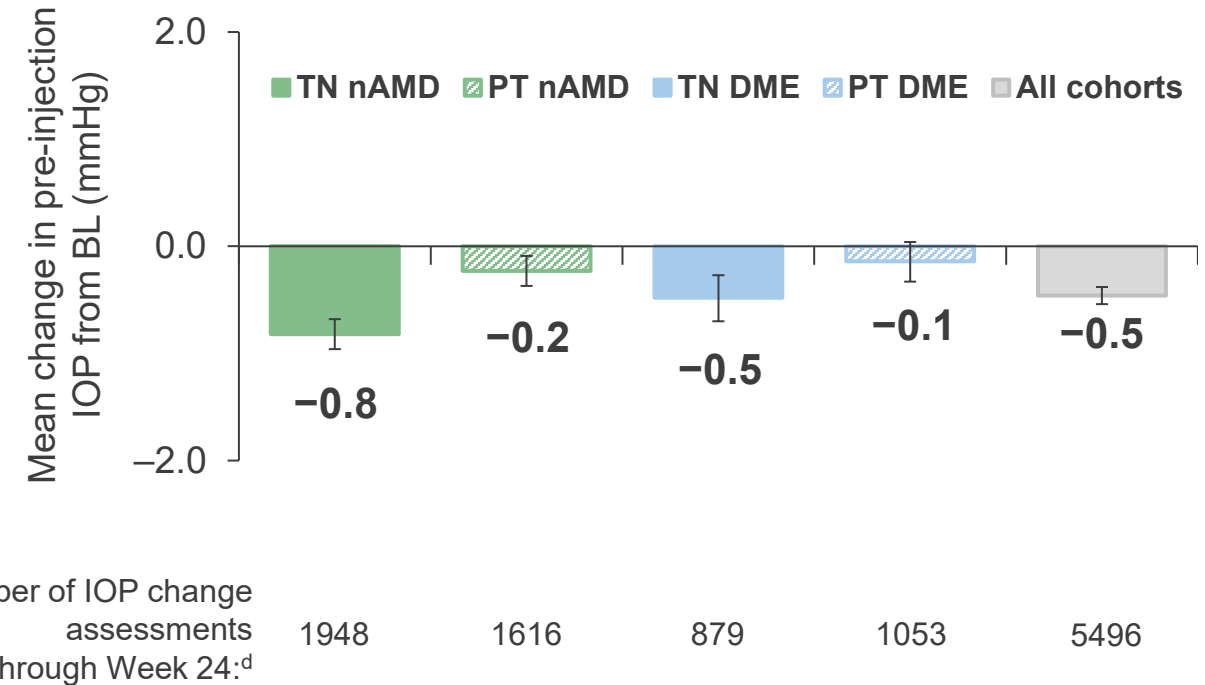
Week 24 = visits closest to 180 (150–210) days after BL. ^aCRT was assessed as either CRT or CST, at the investigator's discretion; CRT or CST was assessed from BL through Week 24 for each individual patient, or CST thereafter if no BL value was available. ^bThe proportions presented here were calculated using the number of patients with a definitive result at Week 24. CI, confidence intervals; CRT, central retinal thickness; CST, center subfield thickness; IRF, intraretinal fluid; PT, previously treated; SD, standard deviation; SRF, subretinal fluid; TN, treatment-naïve.

IOP-related baseline characteristics of the global SPECTRUM cohorts

Baseline characteristics ^a	TN nAMD (n=1129)	PT nAMD (n=1061)	TN DME (n=650)	PT DME (n=635)	All cohorts (N=3475)
Age, years	78.9±8.0	79.6±7.6	64.8±11.6	66.3±11.4	—
Median time on prior treatment, days	—	574	—	704	—
Pre-injection IOP, mmHg	14.3±3.4	13.8±3.6	15.2±3.4	15.2±3.6	—
IOP-related comorbidities, ^b n (%)					
Angle-closure glaucoma	3 (0.3)	4 (0.4)	1 (0.2)	1 (0.2)	9 (0.3)
Borderline glaucoma	1 (0.1)	5 (0.5)	2 (0.3)	1 (0.2)	9 (0.3)
Exfoliation glaucoma	3 (0.3)	3 (0.3)	0	0	6 (0.2)
Glaucoma	43 (3.8)	56 (5.3)	16 (2.5)	34 (5.4)	149 (4.3)
Glaucomatous optic neuropathy	0	0	0	2 (0.3)	2 (0.1)
Intraocular pressure increased	0	1 (0.1)	0	1 (0.2)	2 (0.1)
Normal-tension glaucoma	2 (0.2)	4 (0.4)	1 (0.2)	2 (0.3)	9 (0.3)
Ocular hypertension	12 (1.1)	15 (1.4)	6 (0.9)	10 (1.6)	43 (1.2)
Open-angle glaucoma	13 (1.2)	8 (0.8)	2 (0.3)	10 (1.6)	33 (0.9)
Pigment dispersion syndrome	0	2 (0.2)	0	2 (0.3)	4 (0.1)
Concomitant IOP-lowering medications, ^c n	22	62	8	43	135

Mean change in pre-injection IOP from baseline through Week 24

Mean number of IOP assessments per patient through Week 24 ^a	TN nAMD (n=1129)	PT nAMD (n=1061)	TN DME (n=650)	PT DME (n=635)	All cohorts (N=3475)
Pre-injection IOP assessments	2.6	2.4	2.3	2.6	2.5
Post-injection IOP assessments ^b	0.1	0.2	0.2	0.2	0.2
Mean pre-injection IOP, mmHg	TN nAMD (n=1129)	PT nAMD (n=1061)	TN DME (n=650)	PT DME (n=635)	All cohorts (N=3475)
Baseline	14.3±3.4	13.8±3.6	15.2±3.4	15.2±3.6	14.5±3.5
Month 6 visit ^c	13.5±3.3	13.8±3.5	14.9±3.6	15.1±3.9	14.1±3.6



Through Week 24:

Global TN and PT nAMD cohorts received 4.6±1.2 and 4.3±1.5 injections
Global TN and PT DME cohorts received 4.1±1.5 and 4.0±1.7 injections

FAS. Data are mean±SD unless otherwise stated; error bars in the graph indicate the 95% CI. Data should be interpreted with caution due to the low number of patients assessed for IOP. For each cohort, estimates were based across all patients in the FAS with available assessments at the specified timepoints. The 'All cohort' estimates were calculated by combining cohort-level summary statistics weighted by the cohort sample size with available assessments; the combined SD accounts for both the within- and between-cohort variability. ^aCalculated for each cohort based on the number of assessments conducted per number of patients in the FAS. ^bData on the mean change in post-injection IOP are not presented due to the low number of post-injection IOP assessments performed. ^cData indicated here are for patients who attended the Month 6 visit (visit closest to 180 days after BL [-14/+15 days]). ^dData indicated here are across all injections received from the second injection through Week 24 (visit closest to 180 days after BL [-30/+30 days]).

IOP-related TEAEs reported through Week 24

IOP-related TEAEs in the study eye, ^a n (%)	TN nAMD (n=1158)	PT nAMD (n=1113)	TN DME (n=697)	PT DME (n=698)	All cohorts (N=3666)
Increased IOP	10 (0.9)	11 (1.0)	4 (0.6)	7 (1.0)	32 (0.9)
Ocular hypertension	1 (0.1)	5 (0.4)	1 (0.1)	3 (0.4)	10 (0.3)
Glaucoma	0	1 (0.1)	0	0	1 (<0.1)



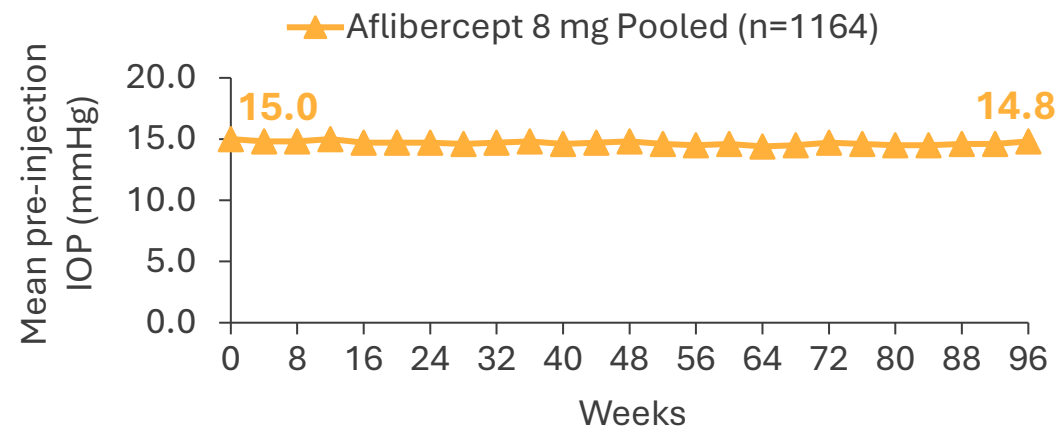
Through Week 24, rates of IOP-related TEAEs were low and similar across the 4 global SPECTRUM cohorts

Pooled Week 96 IOP data: PHOTON Phase 2/3 (DME) and PULSAR Phase 3 (nAMD) trials

Baseline characteristics	Aflibercept 8 mg Pooled (n=1164)
Mean age, years	69.3±11.2
Mean IOP, mmHg	15.0±3.2
IOP-related comorbidities, ^a n (%)	88 (7.6)



Patients received a **pooled total of 9762 injections** through **Week 96**



IOP-related TEAEs in the study eye, n (%)	Aflibercept 8 mg Pooled (n=1164)
Intraocular pressure increased	34 (2.9)
Ocular hypertension	12 (1.0)
Glaucoma	6 (0.5)
Angle-closure glaucoma	2 (0.2)
Borderline glaucoma	2 (0.2)
Open-angle glaucoma	1 (<0.1)



The **early real-world IOP findings** from **SPECTRUM** are **consistent** with those reported for **aflibercept 8 mg** in **clinical trials¹** and **early RWE²**

- Stable pre-injection IOP
- Low rates of IOP-related TEAEs



SPECTRUM Week 24 IOP data support the real-world safety of aflibercept 8 mg in patients with treatment-naïve and previously treated nAMD and DME



Enrollment in SPECTRUM is complete
>3700 patients enrolled globally across **18** countries

Global IOP metrics: Key Week 24 findings



Low proportion of patients assessed for IOP

~2.5 pre-injection and
~0.2 post-injection IOP assessments
per patient through Week 24



Stable pre-injection IOP

Patients had stable pre-injection IOP
from baseline through Week 24



Low rates of IOP-related TEAEs

Safety profile consistent
with pivotal clinical trials¹⁻³



These **early IOP findings** from **SPECTRUM** are **consistent** with those reported for **aflibercept 8 mg** in **Phase 2/3 trials**¹⁻³

SPECTRUM data on treatment outcomes and patterns with aflibercept 8 mg in patients with nAMD and DME are being presented in other EURETINA '26 sessions



Additional analyses up to Month 12 and Month 24 are ongoing