

SPECTRUM French cohort analysis: 6-month real-world effectiveness and safety of aflibercept 8 mg in treatment-naïve patients with diabetic macular edema.

By Prof. Audrey Giocanti,[1] on behalf of the investigators of the SPECTRUM study.
[1]*Avicenne Hospital, University of Paris 13, Bobigny*

Presented at the congress of EURETINA Free Paper 19 - Diabetes & Vascular Diseases

Disclosures

- Bayer
- Novartis
- Roche

SPECTRUM: Global Real-world Study of Aflibercept 8 mg [1,2]

Focus France

24-month non-interventional cohort study, ongoing in 18 countries

2 indications, 4 patient cohorts

treatment-naïve & previously-treated **nAMD patients**
treatment-naïve patients & previously-treated **DME patients**

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

Secondary endpoints include :

Change in VA and **CRT** from BL Month 3 and Month 6

Number of **injections** and **visits**, and **safety profile** through Month 3 and Month 6

Patients included (completed in September 2025[3]):
3733 all cohorts [1,2]

1169	1125	723	716
TN nAMD	PT nAMD	TN DME	PT DME

SPECTRUM in France - nAMD and DME



Patients included (as of September 2025[3]):
295 all cohorts – **29 centers involved**

100	102	93
TN nAMD	PT nAMD	TN DME

TN: treatment-naïve; PT: previously treated; DME: diabetic macular edema; nAMD: neovascular age-related macular degeneration; BL: baseline; VA: visual acuity; CRT: central retinal thickness. 1. Munk MR, et al. FLORetina 2025, 4–7 December 2025, Florence, Italy. 2. Lanzetta P, et al. FLORetina 2025, 4–7 December 2025, Florence, Italy. 3. Bayer. Data on file, November 2025.Corinne Dot, "SPECTRUM French cohort analysis: 12-month real-world effectiveness and safety of aflibercept 8 mg in treatment-naïve and previously treated patients with neovascular age-related macular degeneration", EURETINA 2026.

SPECTRUM – Treatment-naïve patients with DME : baseline characteristics and 6-month interim analysis of the French cohort and the first ~150 patients of the global cohort

Characteristics at baseline	Treatment-naïve patients[a]	Treatment-naïve patients[a]
Patients included in the interim analysis, n	142	82
Average age (SD), in years	66.1 (11.5)	62.9 (13)
Sex, n (%) Female Male	 52 (36.6) 90 (63.4)	 33 (40.2) 49 (59.7)
Median time (min, max) since DME diagnosis, in months	0.4 (0.0 ; 109.2)	3,77 (0.03 ; 115.1)
Mean VA (SD), letters ETDRS	63.8 (16.6)	66,8 (13.9)
CRT Mean (SD), µm	425 (114)	405 (126)

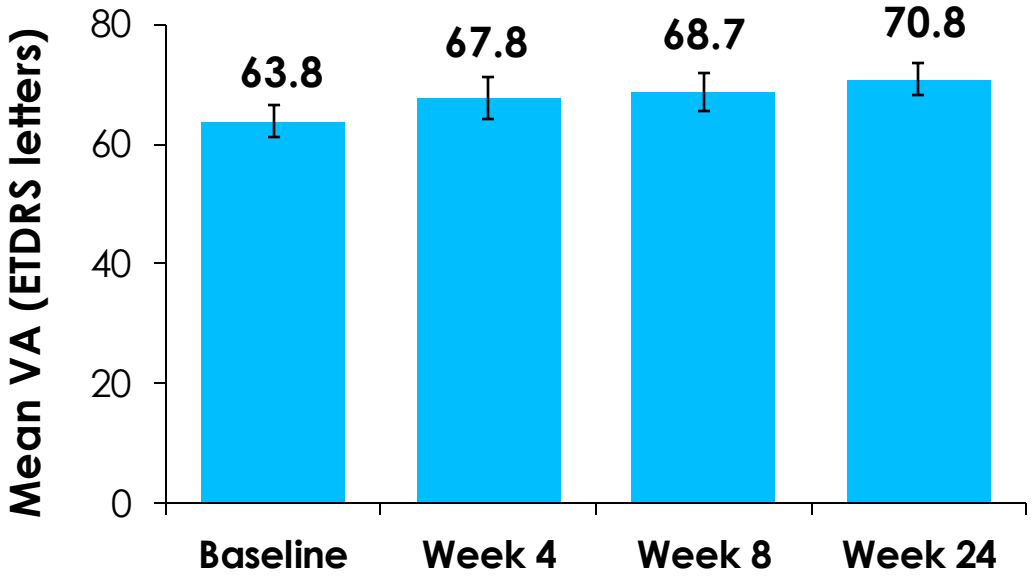
Percentages may not add up to 100% due to rounding. [a]FAS;Week 24 = visits closest to 180 (150–210) days post-BL.
VA : Visual Acuity ; CRT : Central Retinal Thickness

Improvements in visual acuity were observed in treatment-naive patients in the global and French cohorts at 6 months

DME

Mean VA (treatment-naive cohort)[a,b]

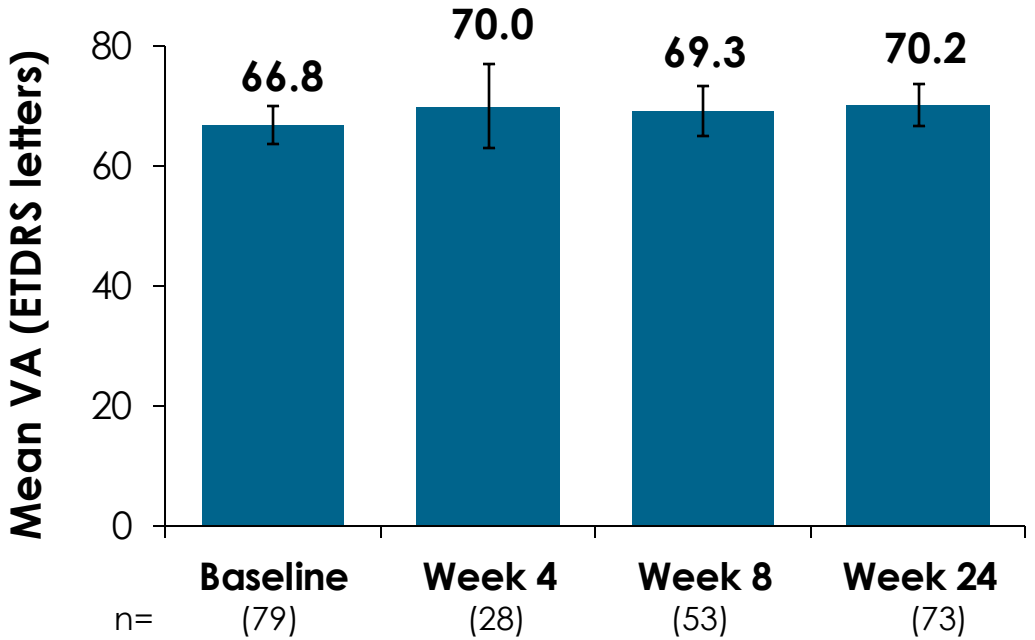
Mean change from baseline (95% CI):	+4.5 letters (2.5, 6.5)	+4.7 letters (2.5, 6.9)	+7.3 letters (5.2, 9.4)



Average number of injections : 4.0 injections
At 6 months

Mean VA (treatment-naive cohort)[a,b]

Mean change from baseline (95% CI):	+0.2 letters (-6.5; 6.9)	+2.3 letters (-2; 6.7)	+3.5 letters (0.2; 6.8)



Average number of injections : 4.77 injections
At 6 months

Adapted from Lanzetta P, *et al*. 2025.

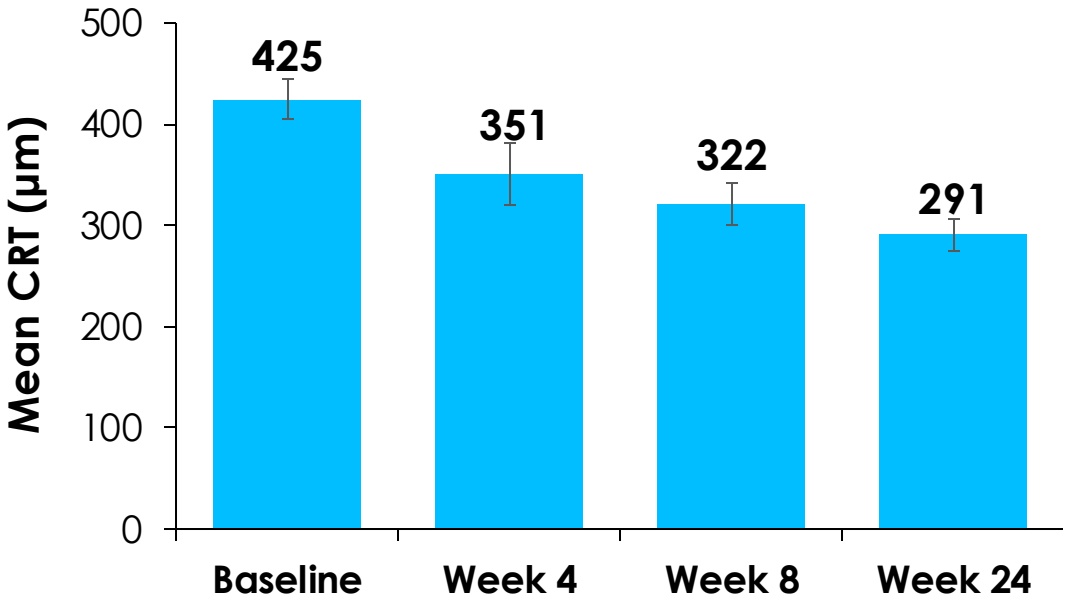
FAS, LOCF (TN world: n=142; TN France: n=82). Week 4 = visits closest to 28 (14–42) days post-BL, Week 8 = visits closest to 56 (43–70) days post-BL, Week 24 = visits closest to 180 (150–210) days post-BL. [a]Missing values were imputed using the LOCF method. [b]Error bars represent the 95% CI.

Reduction of CRT from baseline to 6 months was observed in the global and French cohorts at 6 months

DME

Mean CRT (treatment-naive cohort)[a,b]

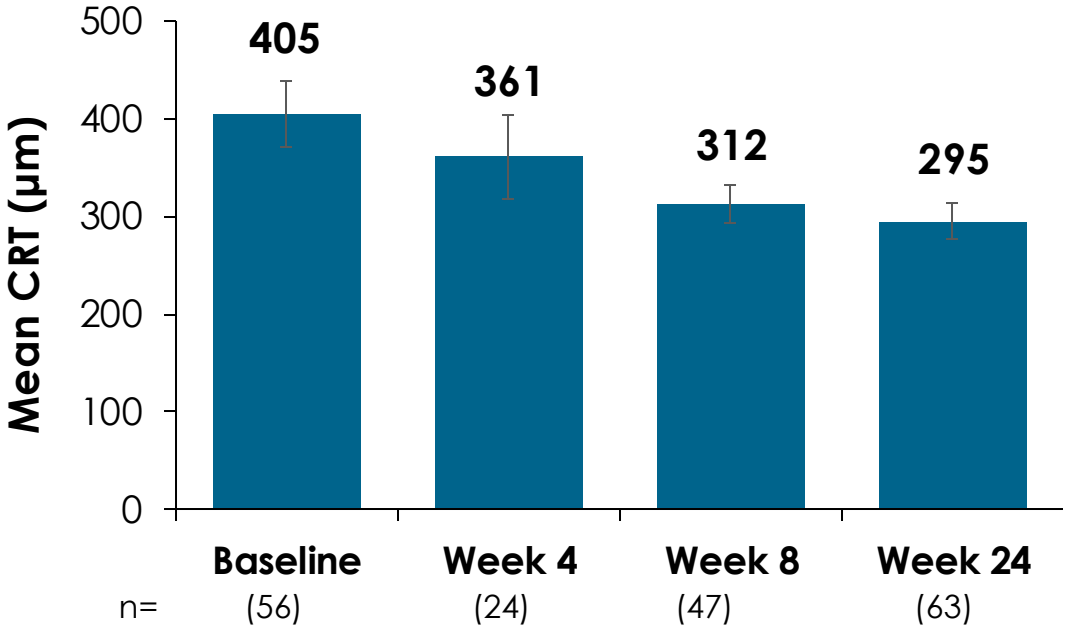
Mean change from baseline (95% CI):	−81 µm (−104, −57)	−103 µm (−124, −82)	−134 µm (−156, −113)



Adapted from Lanzetta P, *et al*. 2025.

Mean CRT (treatment-naive cohort)[a,b]

Mean change from baseline (95% CI):	−65 µm (−117, −13)	−94 µm (−127,5, −60)	−93 µm (−126,5, −60)

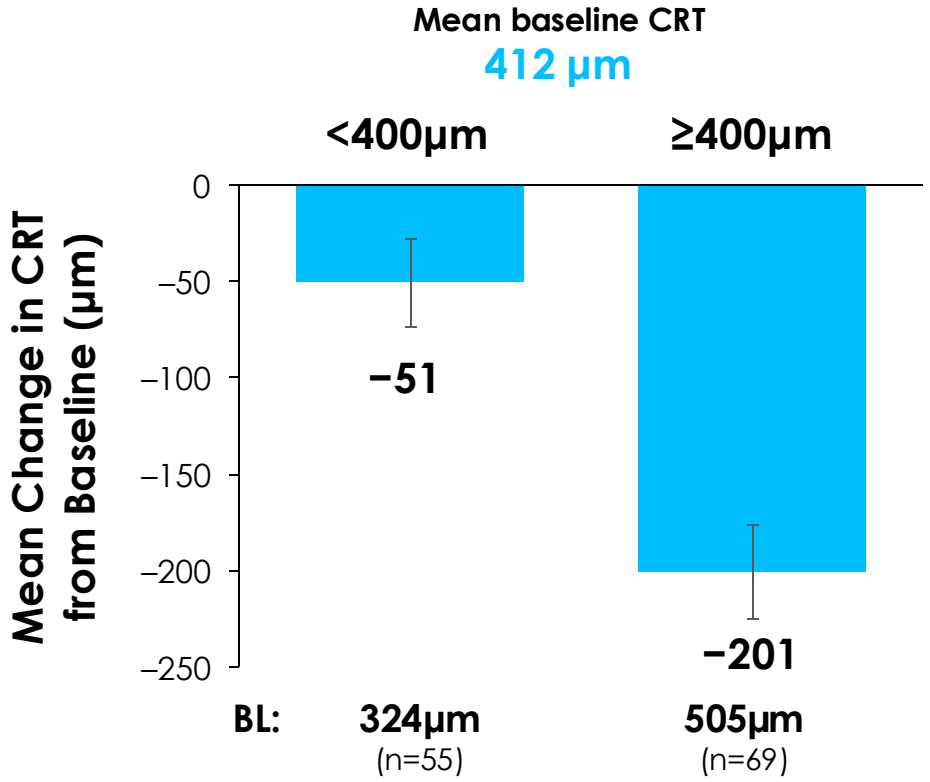


FAS, LOCF (TN overall: n=142; TN France: n=82). [a]Missing values were imputed using the LOCF method. [b]Error bars represent the 95% CI.

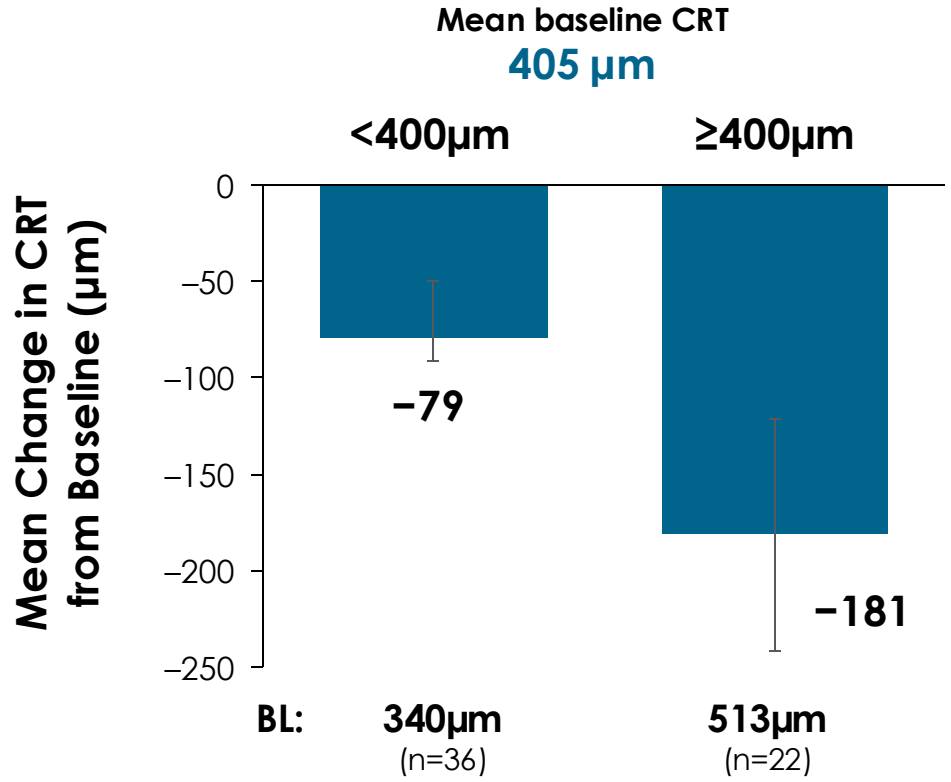
Reduction in CRT at 6 months by baseline CRT was observed

DME

Mean CRT change at Month 6 by baseline CRT (treatment-naive cohort)[a,b]



Mean CRT change at Month 6 by baseline CRT (treatment-naive cohort)[a,b]



Adapted from Lanzetta P, *et al*. 2025.

FAS, observed cases. Values have been rounded to the nearest decimal place. [a]Error bars represent the 95% CI. [b]In treatment-naive patients with CRT assessment at Week 4 and Week 8, the mean change in CRT at Week 4 and Week 8 pooled by baseline CRT was −35 µm and −45 µm for those with a baseline CRT of <400 µm, and −113 µm and −146 µm for those with a CRT at baseline of ≥400 µm, respectively (overall cohort); and −28.8 µm and −31.8 µm for those with a baseline CRT of <400 µm, and −95.9 µm and −155.8 µm for those with a baseline CRT of ≥400 µm, respectively (France cohort).

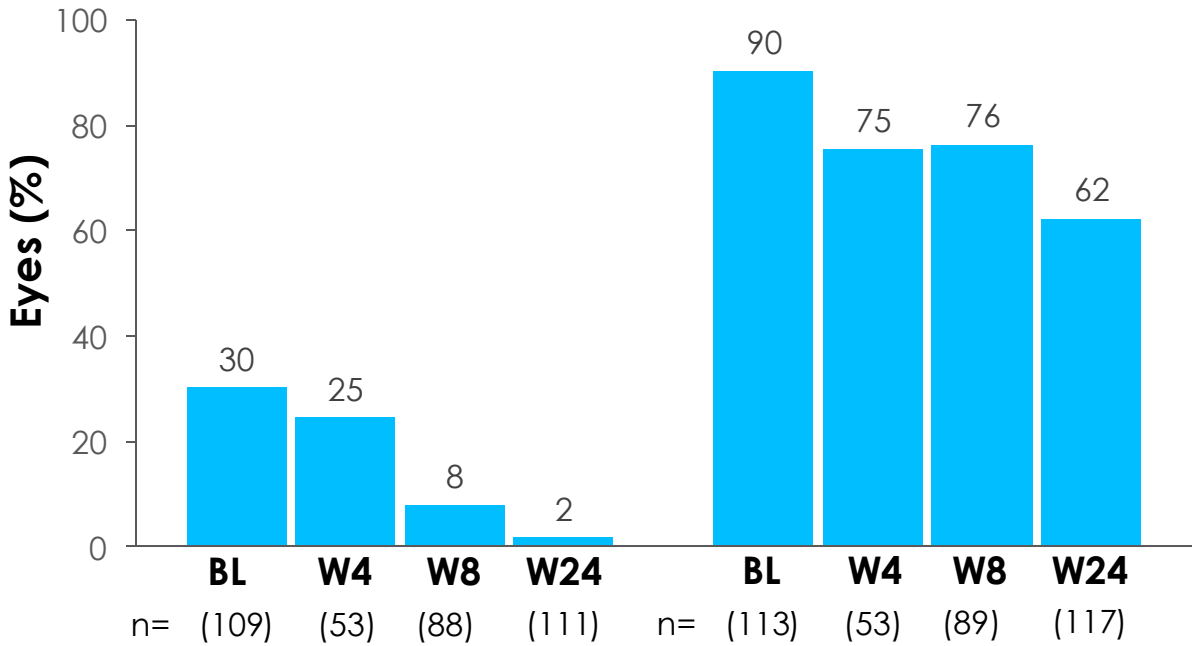
Reduction in proportion of patients with intraretinal or subretinal fluid was observed through 6 months in the global and French treatment-naive cohorts

DME

Proportion of patients with SRF or IRF through 6 months (treatment-naive cohort)[a,b]

With SRF (naive patients) | **With IRF** (naive patients)

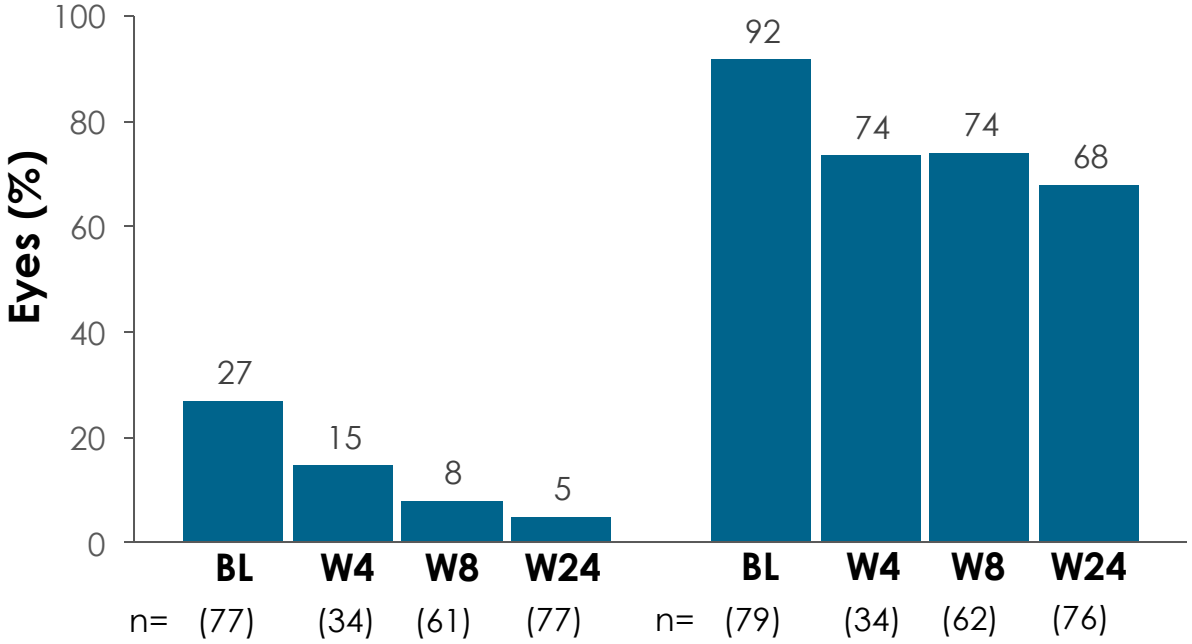
Adapted from Lanzetta P, *et al*. 2025.



The proportion of patients with IRF decreased from 90% at baseline to 76% at week 24

Proportion of patients with SRF or IRF through 6 months (treatment-naive cohort)[a,b]

With SRF (naive patients) | **With IRF** (naive patients)



The proportion of patients with IRF decreased from 92% at baseline to 68% at week 24

FAS, LOCF, fluid data were collected during macular evaluation on OCT (6 mm) at the discretion of the investigator. [a]Missing values were imputed using the LOCF method. [b]Calculated based on the number of patients assessed at each time point. Lanzetta P, et al. FLORetina 2025. December 4–7, 2025. Florence, Italy. Available on: https://congresspublications.bayer.com/ophthalmology-conference-list/floretina-icoor-2025. Accessed January 2026. W = week ; BL = baseline

Treatment-emergent adverse events through 6 months in the global and French cohorts

DME

treatment-naive - Global cohort

Ocular TEAEs	Total (N=150)
Ocular TEAEs in the study eye, n (%)[a]	11 (7.3)
Serious ocular TEAEs, n (%)	1 (0.7)

Non-ocular TEAEs	Total (N=150)
Non-ocular TEAEs, n (%)	16 (10.7)
Serious non-ocular TEAEs, n (%)	3 (2.0)

treatment-naive – French cohort

Ocular TEAEs	Total (N=91)
Ocular TEAEs in the study eye, n (%)[a]	5 (5.5)
Serious ocular TEAEs, n (%)	0

Non-ocular TEAEs	Total (N=91)
Non-ocular TEAEs, n (%)	4 (4.4)
Serious non-ocular TEAEs, n (%)	3 (3.3)

No cases of retinal vasculitis reported. No new safety signals

SAF. [a]The eye treated with aflibercept 8 mg was considered the study eye; If treatment with aflibercept 8 mg was decided simultaneously for both eyes, the study eye was considered to be the most affected eye, at the discretion of the treating physician.

Munk MR, *et al*. FLORetina 2025. 4–7 December 2025. Florence, Italy.

6-month analysis of the French SPECTRUM cohort: Drying, durability, and safety shown in the real-world

Visual acuity

At Month 6, **improvement in visual acuity** was observed, with a mean gain of **+3.5 ETDRS letters**

Drying

Reductions in retinal thickness were observed in patients with **treatment-naive** diabetic macular edema over the first 6 months in real-world clinical practice

Safety profile

No new safety signals were identified through 6 months; the safety profile of aflibercept 8 mg **was consistent with pivotal clinical trials**

Presentation of data at 12 months for the French cohort is scheduled for 2027