SPECTRUM: Latest clinical data from the first global real-world study of aflibercept 8 mg in patients with treatment naïve and previously treated in nAMD

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SPECTRUM

Purpose

- Aflibercept 8 mg is approved for the treatment of neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME), and visual impairment due to macular edema secondary to retinal vein occlusion (RVO)[1]
- SPECTRUM is a global study evaluating the real-world effectiveness and safety profile of aflibercept 8 mg in patients with treatment-naïve (TN) and previously treated (PT) nAMD or DME[2]

Conclusions

This Week 12 analysis of the SPECTRUM global nAMD cohorts shows **improved VA** and **CRT** in both **TN** and **PT** patients, and **no IRF or SRF** for the **majority of TN and PT patients.**

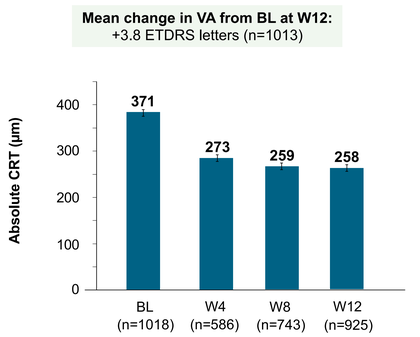
Methods

- SPECTRUM (NCT06075147) is an ongoing, 24-month, prospective observational study being conducted in 18 countries, including the UK[3,4]
- Patients (TN and PT) with nAMD aged ≥50 years or DME aged ≥18 years, who have been prescribed aflibercept 8 mg by their physician, were eligible for enrollment[4]
- Decisions regarding monitoring, retreatment, and treatment schedules are made by each patient's attending physician in accordance with local clinical practice[4]
- Data are being collected during routine clinical visits (February 2024 to September 2027)[3]
- In SPECTRUM, the primary endpoint is the change in visual acuity (VA) from BL to Month 12[3,4]
- Secondary endpoints include the change in VA from BL at Month 6 and Month 24, and change in central retinal thickness (CRT) from BL at Month 6, Month 12, and Month 24[3,4]
- Adverse events are monitored throughout the study[3,4]
- All analyses are descriptive and exploratory only[3]
- Missing data are imputed using the last observation carried forward (LOCF) approach
- The data through Week 24 for the nAMD UK cohort are reported here

Results

- In the Global TN (n=1043) and PT (n=963) nAMD cohorts, the mean age was 79.0 and 79.5 years, respectively, and the median (min, max) time from nAMD diagnosis in the TN cohort was 0.0 (0.0, 51.2) months.
- In the PT cohort, the median time from nAMD diagnosis was 33.9 months,with 65.3% receiving aflibercept 2mg, 21.5% receiving faricimab 6mg, and 7.1% receiving ranubizumab 0.5mg as previous treatment.
- The mean (95)% confidence interval [CI]) change in VA at Week (W) 12 was +3.8(2.9 to 4.7) letters and 0.9 (0.3 to 1.5) letters in the global TN and PT cohorts, from a BL of 57.8 letters and 64.4 letters, respectively (Figures 1 and 2).
- The mean (95% CI) change in CRT at W12 was -113 (-121 to -106) µm and -32 (-37 to -27) µm in the global TN and PT cohorts, from a BL of 371µm and 300µm respectively (Figure 1 and 2) (Figures 1 and 2)

Figure 1: VA and CRT outcomes with aflibercept 8mg in TN patients with nAMD.



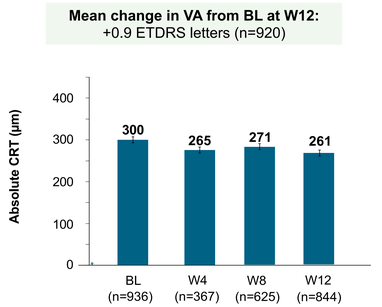
BL (95% CI), µm	375.8 (352.6, 398.9)

LOCF. Missing values are imputed with the LOCF approach. Error bars indicate 95% CI. BL, baseline; CI, confidence interval; CRT, central retinal thickness; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; LOCF, last observation carried forward; nAMD, neovascular age-related macular degeneration; TN, treatment-naïve; VA, visual acuity; W, Week. SRF, subretinal fluid, IRF, intraretinal fluid

Safety
No cases of retinal vasculitis were reported. No safety concerns were identified.

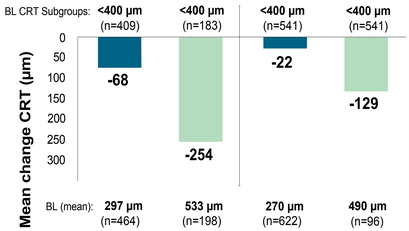
Figure 2: VA, CRT, change in CRT grouped by baseline CRT, and proportion of patients without IRF or SRF in TN and PT patients with nAMD.

Mean change in VA and CRT from BL at W12

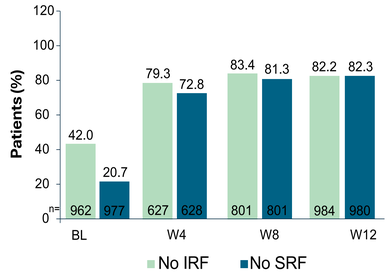


BL (95% CI), µm	288.7 (270.9, 306.4)

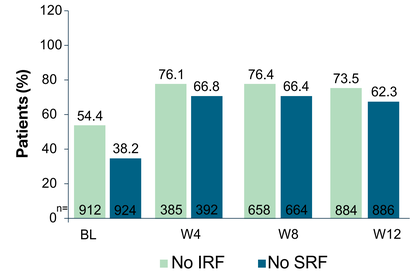
Change in CRT grouped by baseline CRT at week 12 in TN (n=662) and PT (n=718)



Proportion of patients without IRF or SRF through W12 in TN patients (n=984)



Proportion of patients without IRF or SRF through W12 in PT patients (n=886)



LOCF. Missing values are imputed with the LOCF approach. Error bars indicate 95% CI.
BL, baseline; CI, confidence interval; CRT, central retinal thickness; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; LOCF, last observation carried forward; nAMD, neovascular age-related macular degeneration; PT, previously treated; qX, every X weeks; VA, visual acuity; W, Week.

Disclosures
Vasileios Konidaris: Honoraria from AbbVie, Bayer, Novartis, and Roche.
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