



SPECTRUM UK COHORT ANALYSIS: EARLY REAL-WORLD DATA FOR AFLIBERCEPT 8 MG INDICATE IMPROVED VISUAL ACUITY AND CENTRAL RETINAL THICKNESS IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

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Disclosures

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SPECTRUM: study design, endpoints and the UK cohort

A global, 24-month, prospective, observational real-world study of aflibercept 8 mg in nAMD and DMO

18 countries in the global study

24 month prospective observational study

16 UK sites in the country cohort

Population and eligibility

- Treatment-naïve: nAMD ≥ 50 years; DMO ≥ 18 years; never exposed to treatment for the relevant indication
- Previously treated: prior anti-VEGF up to prespecified timepoints before study start
- All patients prescribed aflibercept 8 mg by their physician
- Monitoring, retreatment and scheduling per local practice*
- Excluded: investigational programmes, PI contraindications, periocular infection/inflammation, other IVT in fellow eye

Endpoints and analyses

- Primary: change in BCVA from BL to Month 12
- Secondary: change in BCVA and CRT from BL and number of aflibercept 8 mg injections at various timepoints up to Month 24; adverse events during the 24-month study period
- Data collected at routine visits (February 2024–September 2027)
- Country cohort and global reporting
- All analyses are descriptive and exploratory only

*Any decisions from the physician should be made in accordance with their experience and should follow approved clinical guidelines. UK sites: Bristol Eye Hospital, Leicester Royal Infirmary, Kent and Canterbury Hospital, Southampton General Hospital, York Hospital, Sunderland Eye Infirmary, Wolverhampton New Cross Hospital, Cheltenham General Hospital, Liverpool University Hospital, Frimley Health NHS Foundation Trust, Hull University Teaching Hospitals NHS Trust, St James's University Hospital Leeds, Bedford Hospital, Newcastle Royal Victoria Infirmary, Western Eye Hospital, Worcestershire Royal Hospital. BCVA, best corrected visual acuity; BL, baseline; CRT, central retinal thickness; DMO, diabetic macular oedema; IVT, intravitreal; nAMD, neovascular age-related macular degeneration; PI, prescribing information; PT, previously treated; TN, treatment naïve; VA, visual acuity; VEGF, vascular endothelial growth factor.



The UK nAMD cohort: patient disposition and baseline characteristics

Patient disposition

Patient disposition	Treatment-naïve	Previously treated
Number of enrolled patients, n	101	100
Number of patients with discontinuation, n	14	27
Number of patients valid for safety analysis set, n	101	99

Number of patients valid for full analysis

100

treatment-naïve patients in the full analysis set

93

previously treated patients in the full analysis set

Baseline characteristics

Patient characteristics at baseline	Treatment-naïve (N=100)	Previously treated (N=93)
Study eye, % Left / Right	51/49	42/58
Age, years, mean +/-SD	81.1±10.8	79.7±6.6
Age, years, median (min-max)	82.0 (55.0 – 96.0)	80.0 (63.0 – 92.0)
Sex, % Male / Female	36/64	43/57
Race, % White / Black or African American	84/1	73/0
Race, % Asian / Not reported	0/15	0/27
Median time from nAMD diagnosis (min-max), months	0.03 (0.03-5.3)	31.9 (5.6-169.2)
Mean +/-SD VA, ETDRS letters	56.0±14.2	61.5±15.5
Mean +/-SD combined CST and CRT, um	379.7±114.8	287.6±82.9

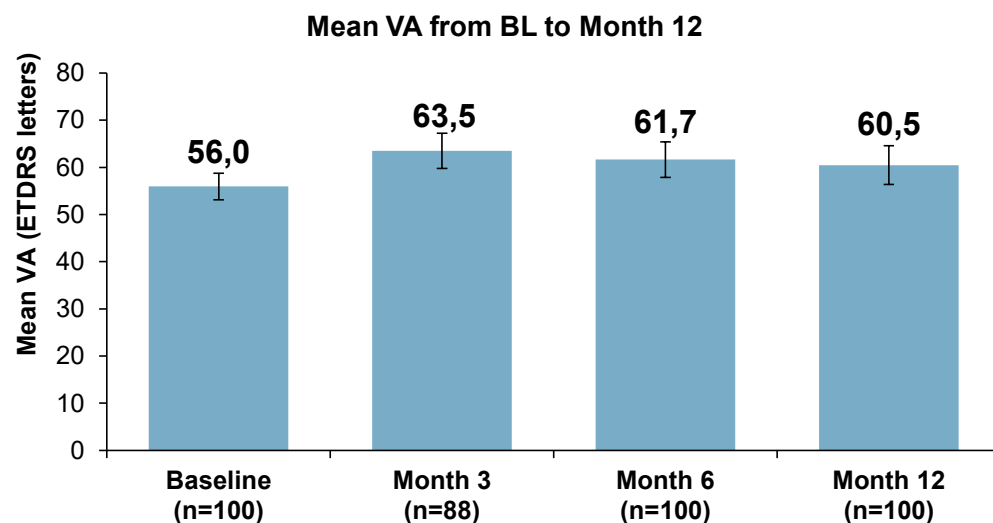
SPECTRUM UK cohort. Full analysis set (FAS). nAMD, neovascular age-related macular degeneration. — denotes data not reported in the source poster. CRT was assessed as either CRT or CST, at the investigator's discretion; CRT or CST was assessed from baseline through Week 24 for each individual patient, or CST thereafter if no BL value was available. BL, baseline; CRT, central retinal thickness; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; nAMD, neovascular age-related macular degeneration; PT, previously treated; SD, standard deviation; TN, treatment-naïve; VA, visual acuity.

Safety Analysis Set (SAF) - A patient will be included in the Safety Analysis Set if the patient signed the informed consent, has taken at least one dose of Aflibercept 8mg in the study eye during the observation period and nAMD or DME has been diagnosed. Full Analysis Set (FAS) - A patient will be included in the Full Analysis Set if the patient fulfilled the criteria of the Safety Analysis Set. In addition, the following criteria apply: Patient have at least one post-baseline combined or monitoring visit.



Visual Acuity Outcomes at 12 Months

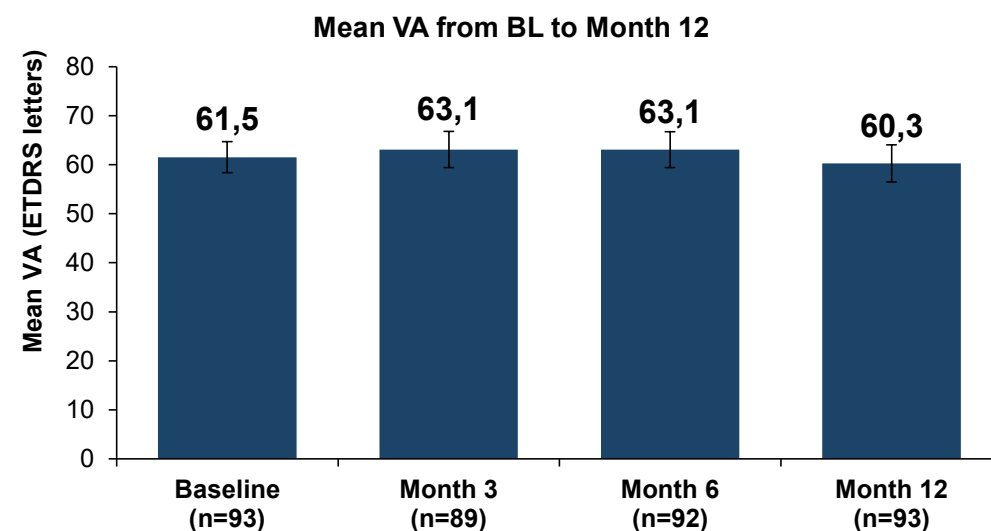
Treatment-naïve patients



Mean change in VA from BL to Month 12: +4.5 (+1.5-7.6) ETDRS letters

In the treatment-naïve cohort, the number of patients with ≥ 70 ETDRS letters increased from 23 at baseline to 48 at month 12

Previously treated patients



Mean change in VA from BL to Month 12: -1.3 (-3.7- +1.2) ETDRS letters

In the previously treated cohort, the number of patients with ≥ 70 ETDRS letters increased from 37 at baseline to 41 at month 12

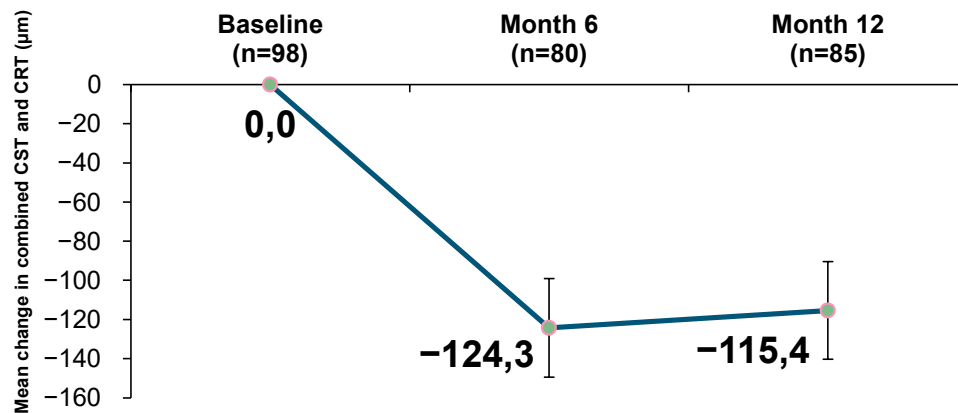


Anatomical Outcomes at Month 12

Anatomical improvements were observed in treatment naïve and previously treated patients

Treatment-naïve patients

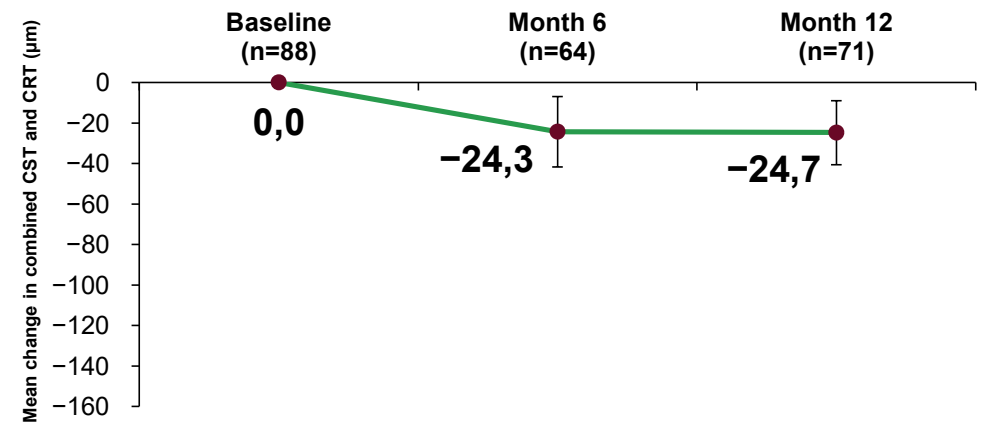
Mean change in combined CST and CRT from BL to Month 12



| Mean change in combined CST and CRT (µm); BL: 379.7 µm

Previously treated patients

Mean change in combined CST and CRT from BL to Month 12



| Mean change in combined CST and CRT (µm); BL: 287.6 µm

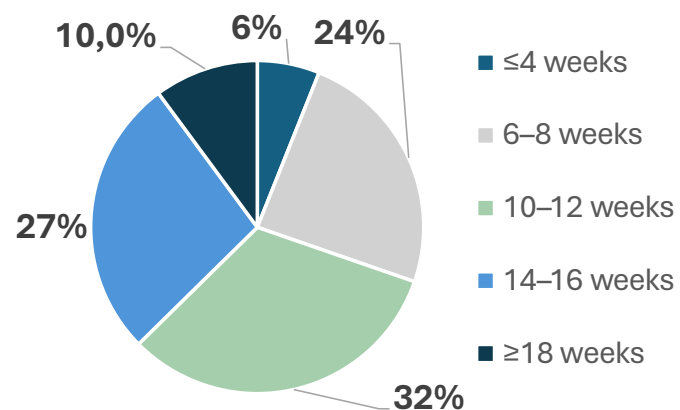
SPECTRUM UK cohort. CRT was assessed as either CRT or CST, at the investigator's discretion; CRT or CST was assessed from baseline through Week 24 for each individual patient, or CST thereafter if no BL value was available. Full analysis set. LOCF; missing values are imputed with the LOCF approach. All values are rounded to 1 decimal place.

BL, baseline; CI, confidence interval; CRT, central retinal thickness; CST, central subfield thickness; LOCF, last observation carried forward; nAMD, neovascular age-related macular degeneration; PT, previously treated; TN, treatment naïve;



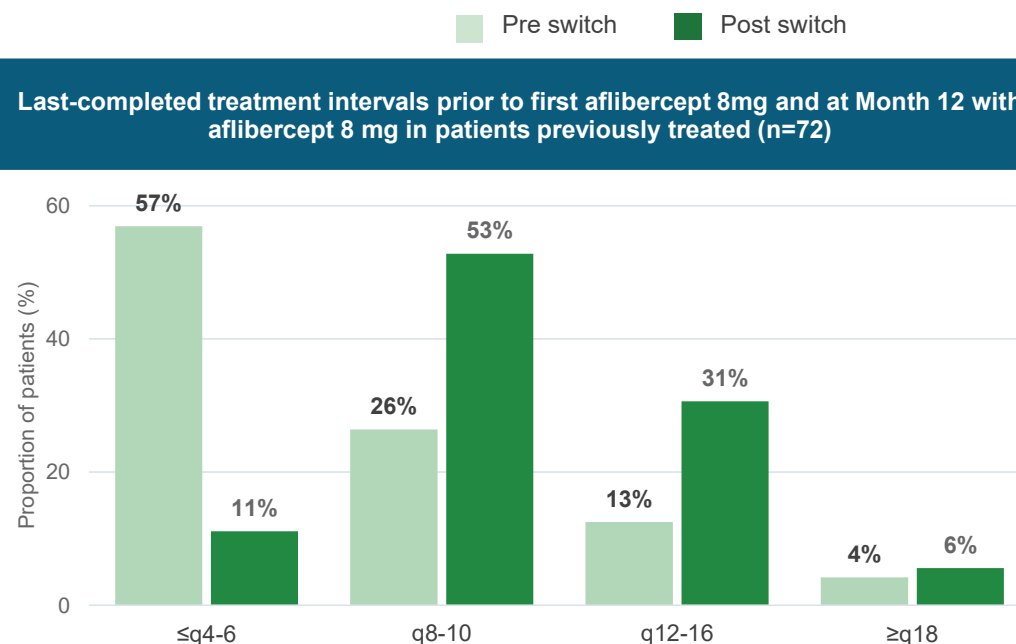
Treatment Intervals at 12 Months

Last-completed treatment intervals at Month 12 with aflibercept 8 mg in treatment naïve patients (n=99)



49% (n=49) of all treatment naïve patients (n=99) had extended to ≥q12 treatment intervals at Month 12

Last-completed treatment intervals prior to first aflibercept 8mg and at Month 12 with aflibercept 8 mg in patients previously treated (n=72)



Median injection interval for patients on ≤q8 prior to switch increased by 4 weeks (BL:6) for patients previously on aflibercept 2mg (n=45), and by 2 weeks (BL:6) for patients previously on faricimab (n=24)



Week 52 analysis: UK TN & PT nAMD cohort

Safety profile of aflibercept 8 mg in patients with nAMD

Treatment-naïve	
Ocular TEAEs in the study eye	Total (N=101)
Ocular TEAEs, n (%)	17 (16.8)
Serious ocular TEAEs, n (%)	0 (0.0)
Drug-related ocular TEAEs in the study eye	Total (N=101)
Drug-related ocular TEAEs, n (%)	6 (5.9)
Serious drug-related ocular TEAEs, n (%)	0 (0.0)
Non-ocular TEAEs	Total (N=101)
Non-ocular TEAEs, n (%)	26 (25.7)
Serious non-ocular TEAEs, n (%)	7 (6.9)

Previously treated	
Ocular TEAEs in the study eye	Total (N=99)
Ocular TEAEs, n (%)	20 (20.2)
Serious ocular TEAEs, n (%)	1 (1.0)
Drug-related ocular TEAEs in the study eye	Total (N=99)
Drug-related ocular TEAEs, n (%)	4 (4.0)
Serious drug-related ocular TEAEs, n (%)	1 (1.0)
Non-ocular TEAEs	Total (N=99)
Non-ocular TEAEs, n (%)	30 (30.3)
Serious non-ocular TEAEs, n (%)	16 (16.2)



No new safety signals were observed in the TN or PT cohort.

For the full safety profile of aflibercept 8 mg, please see the SmPC.

SPECTRUM UK cohort. Safety analysis set.

IOI, intraocular inflammation; nAMD, neovascular age-related macular degeneration; PT, previously treated; SmPC, Summary of Product Characteristics; TEAE, treatment emergent adverse event; TN, treatment naïve.



12-month analysis of the UK SPECTRUM nAMD cohort: drying, durability and safety in the real world

Drying



- **Visual acuity gains** from BL in treatment naïve patients (+4.5 ETDRS), with **maintenance of visual acuity** in previously treated patients (-1.3 ETDRS).
- **Anatomical improvements in both cohorts** from BL were maintained at 12 months, with mean change in combined CST and CRT at Month 12 of -115.4 μm (TN) and -24.7 μm (PT)

Durability



- **The mean last completed injection interval** was 11.7 weeks for TN patients and 9.9 weeks for PT patients.
- **Interval extensions** in patients previously treated with **either aflibercept 2 mg or faricimab** with intervals $\leq$ q8 prior to switch were demonstrated after switching to aflibercept 8 mg.

Safety profile



- **No new safety signals** were observed in the TN or PT cohort.
- **No concerns** were identified surrounding increased IOP and aflibercept 8mg

For the full safety profile of aflibercept 8 mg, please see the SmPC. SPECTRUM UK cohort. All analyses are descriptive and exploratory only. CRT was assessed as either CRT or CST, at the investigator's discretion; CRT or CST was assessed from baseline through Week 24 for each individual patient, or CST thereafter if no BL value was available. BL, baseline; CRT, central retinal thickness; CST, central subfield thickness; ETDRS, early treatment diabetic retinopathy study; IOP, intraocular inflammation; nAMD, neovascular age-related macular degeneration; PT, previously treated; q8, every 8 weeks; SmPC, Summary of Product Characteristics; TN, treatment-naïve; VA, visual acuity.