RETINAL PIONEERS Poster series

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Latest updates on real-world evidence with EYLEA (aflibercept) 8 mg: The SPECTRUM study

BACKGROUND

- EYLEA (aflibercept) 8 mg was approved for use in the UK in **January 2024**, for the management of retinal conditions including neovascular age-related macular degeneration (nAMD) and visual impairment due to diabetic macular oedema (DMO).[1]
- The pivotal **CANDELA** (Phase II), **PULSAR** (Phase III) and **PHOTON** (Phase II/III) clinical trials assessed effectiveness and safety of EYLEA 8 mg in nAMD and DMO in a controlled setting, with Year 3 results from PHOTON and PULSAR presented in Q1 2025.[2–4]
- **SPECTRUM is the first global study to assess the long-term, real-world effectiveness and safety of EYLEA 8 mg for these indications.[5]**

SPECTRUM

METHODS

- SPECTRUM is a Phase IV, multicentre, real-world observational study in 18 countries, designed to explore the effectiveness and safety profile of EYLEA 8 mg in treatment-naïve and previously treated patients with nAMD or DMO.[5]

INCLUSION criteria: nAMD[5,6]

- Adults ≥50 years of age
- A diagnosis of nAMD
- Patients prescribed EYLEA 8 mg as part of routine clinical practice

INCLUSION criteria: DMO[5,6]

- Adults ≥18 years of age with type 1 or type 2 diabetes mellitus
- A diagnosis of DMO
- Patients prescribed EYLEA 8 mg as part of routine clinical practice

Treatment regimen[6]

- Any treatment decision (including those regarding EYLEA 8 mg) is at the discretion of the attending physician*

Data collection[5]

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

Enrolment[5]

- Total patients enrolled as of 10 June 2025: 3,005[7]
- Minimum expected patient enrolment: 4,055[7]

Primary endpoint:[5,6]

Change in VA from baseline to Month 12

Secondary endpoints:[5,6]

1. Change in **VA** from baseline to Weeks 4 and 8, and Months 6 and 24
2. Change in **CRT** from baseline to Weeks 4 and 8, and Months 6, 12 and 24
3. Number of **EYLEA 8 mg injections** from baseline to Months 6, 12 and 24
4. Number of **adverse events** and **serious adverse events**

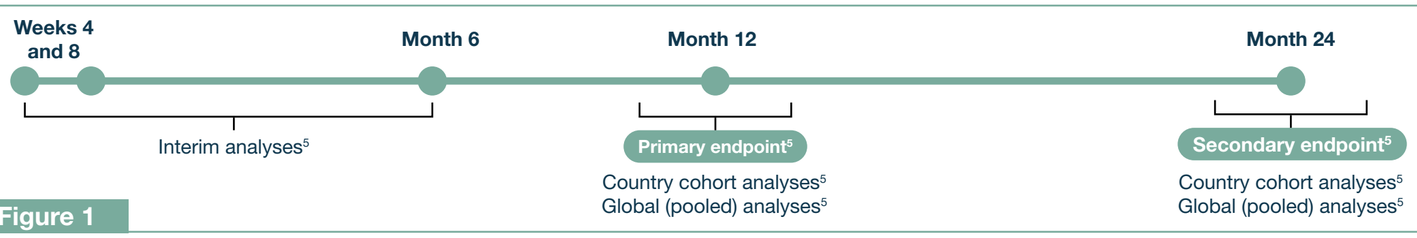

Figure 1

- The study design of SPECTRUM enables analyses on both **a global and a regional level (Figure 1)**[5]
- This allows for rolling interim analyses of endpoints in each participating country/cohort 1 year after enrolment is complete†; all analyses will be **exploratory** and **descriptive** in nature[5]

DMO cohorts: Baseline characteristics

Treatment-naïve DMO cohort: 301 out of 950 (31.7%) planned patients from 11 countries have been enrolled as of 17 April 2025; 98 of these patients are from the UK (Figure 2).[8] Month 6 data are expected in **Q3 2025**.[8]

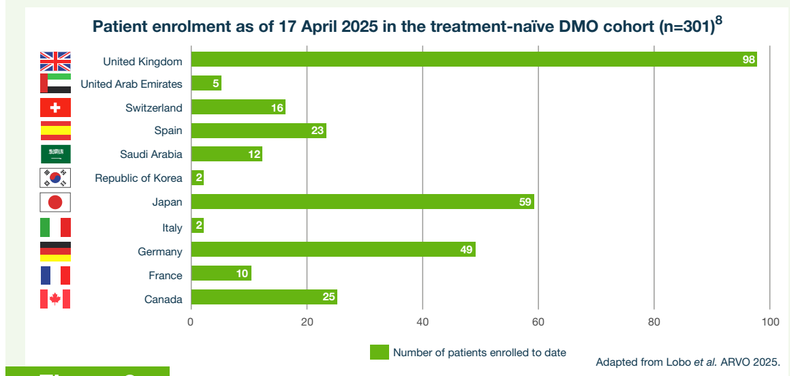

Figure 2

Previously treated DMO cohort: 476 out of 775 (61.4%) planned patients from 9 countries have been enrolled as of 17 April 2025; 87 of these patients are from the UK.[9] Month 6 data are expected in **Q2 2025**.[9]

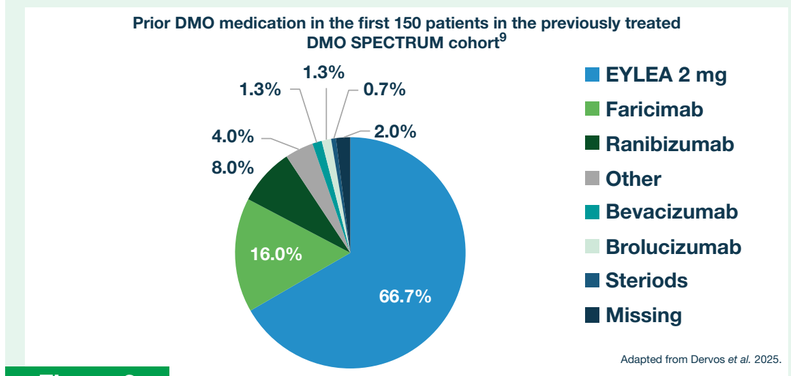

Figure 3

Baseline characteristics for the first 150 patients in each cohort	Treatment-naïve (n=150)‡,8	Previously treated (n=150)‡,9
Mean (SD) age, years	66.3 (11.2)	65.3 (11.4)
Sex, n %		
Female	49 (32.7)	46 (30.7)
Male	91 (60.7)	104 (69.3)
Not reported / data missing	10 (6.7)	0
Race§, n (%)		
White	74 (49.3)	113 (75.3)
Black / African American	4 (2.7)	3 (2.0)
Asian	45 (30.0)	12 (8.0)
Not reported	18 (12.0)	22 (14.7)
Data missing	10 (6.7)	0
Median (min, max) time from DMO diagnosis, months	0.5 (0.0, 109.2)	44.5 (2.1, 411.1)
Mean (SD) VA, ETDRS letters	63.5 (15.9)	70.2 (13.8)
Mean (SD) CRT, µm	420 (109)	364 (132)

Patients in the SPECTRUM study were treated according to study protocol, which is to follow local treatment guidelines. These guidelines may vary from the UK licence. Please refer to the EYLEA 8 mg Summary of Product Characteristics for the full licensed posology.

*Any decisions from the physician should be made in accordance with their experience and should follow approved clinical guidelines.[6] †Country and/or cohort enrolment. Protocol version 8 allows for data for each completely enrolled country cohort to be analysed separately 6 months after cohort completion as well as pooled together per cohort across countries and 12 months (primary endpoint) after cohort completion as well as pooled together per cohort across countries at the primary endpoint analysis (1 year after the predetermined last patient first visit).[7]
‡Percentages may not total to 100% because of rounding.
§Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, Republic of Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates and the United Kingdom only.[8,9]
CRT, central retinal thickness; DMO, diabetic macular oedema; ETDRS, Early Treatment Diabetic Retinopathy Study; nAMD, neovascular age-related macular degeneration; Q, quarter; SD, standard deviation; VA, visual acuity.

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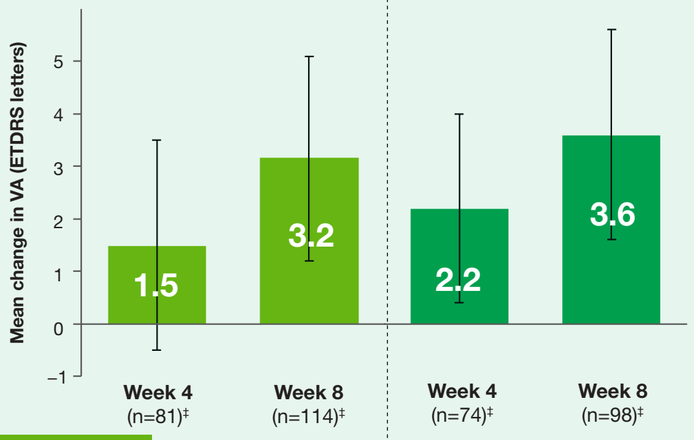
Treatment-naïve nAMD cohort (Week 4 and 8 analysis)[10]

- **703 out of 1,200 (59%)** planned patients have been enrolled as of 17 April 2025, with 101 patients from the UK
- **114 patients** with a VA assessment at Weeks 4 and 8 were included in this interim analysis
- Mean age was 80.8 ± 7.1 years; 60.5% female; 65.8% white, 7% Asian and 27.2% no reported race*
- Median (min, max) time from nAMD diagnosis was **0.2 (0.0, 21.9) months**

RESULTS

Mean change in VA from baseline through Week 8†,[10]

Mean baseline VA: 60.1 ± 17.4 ETDRS letters (n=114)



Mean change in BCVA from baseline through Week 8†,[10]

Mean baseline BCVA: 60.1 ETDRS letters (n=114)

Figure 4

Adapted from Konidaris *et al.* 2025.

Mean change in CRT from baseline through Week 8†,[10]

Mean baseline CRT: 358 ± 110 µm (n=102)

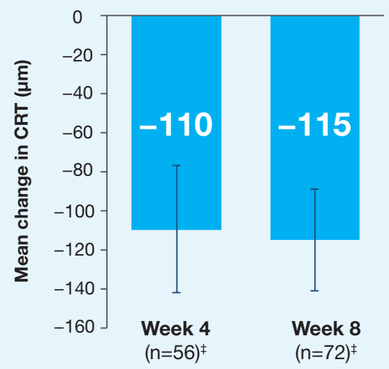


Figure 5

Adapted from Konidaris *et al.* 2025.

- From a mean baseline VA of 60.1 ± 17.4 ETDRS letters (n=114), **VA increased by 1.5 and 3.2 ETDRS letters** at Week 4 and Week 8, respectively (Figure 4)[10]
- In patients who had a BCVA assessment, the mean change in BCVA at Week 4 and Week 8 was **+2.2 (n=74)‡ and +3.6 (n=98)‡ ETDRS letters**, respectively, from an **overall baseline of 60.1 ETDRS letters** (n=114) (Figure 4)[10]
- Mean CRT decreased from baseline (358 ± 110 µm; n=102) by **110 µm at Week 4** and **115 µm at Week 8** (Figure 5)[10]

Safety profile: Treatment-naïve nAMD cohort (n=114)§,[10]

- In the study eye, 3 cases of ocular TEAEs and 5 cases of non-ocular TEAEs were reported
- No serious ocular or non-ocular TEAEs were reported
- No new safety signals were identified
- No cases of IOI were reported

Previously treated nAMD cohort (Week 4 and 8 analysis)[11]

- **828 out of 1,110 (75%)** planned patients have been enrolled as of 17 April 2025, with 100 patients from the UK
- **104 patients** with a VA assessment at Weeks 4 and 8 were included in this interim analysis
- Mean age was 79.5 ± 7.3 years; 57.7% female; 86.5% white, 13.5% no reported race*
- Median (min, max) time from nAMD diagnosis was **36.9 (1.4, 178.9) months**
- **Previous medication included EYLEA 2 mg (53.9%), faricimab (17.3%), ranibizumab (14.4%), bevacizumab (3.9%), brolucizumab (2.9%) and other (1.0%); 6.7% had missing data**

RESULTS

Mean change in VA from baseline through Week 8†,[11]

Mean baseline VA: 61.6 ± 19.4 ETDRS letters (n=104)

Mean change in BCVA from baseline through Week 8†,[11]

Mean baseline BCVA: 61.6 ETDRS letters (n=104)

Figure 6

Adapted from Bailey *et al.* 2025.

Mean change in CRT from baseline through Week 8†,[11]

Mean baseline CRT: 316 ± 102 µm (n=86)

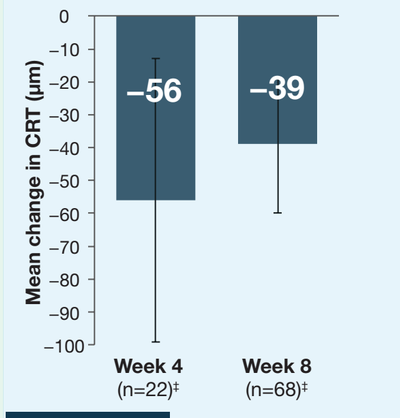


Figure 7

Adapted from Bailey *et al.* 2025.

- From a mean baseline VA of 61.6 ± 19.4 ETDRS letters (n=104), **VA increased by 1.4 and 0.0 EDTRS letters** at Week 4 and Week 8, respectively (Figure 6)[11]
- In patients who had a BCVA assessment, the mean change in BCVA at Week 4 and Week 8 was **+0.8 (n=48)‡ and +0.6 (n=94)‡ ETDRS letters**, respectively, from an **overall baseline of 61.6 ETDRS letters** (n=104) (Figure 6)[11]
- Mean CRT decreased from baseline (316 ± 102 µm; n=86) by **56 µm at Week 4** and **39 µm at Week 8** (Figure 7)[11]

Safety profile: Previously treated nAMD cohort (n=104)§,[11]

- In the study eye, 4 cases of ocular TEAEs and no cases of serious ocular TEAEs were reported
- No cases of non-ocular or serious non-ocular TAES in the study eye were reported
- No new safety signals were identified
- No cases of IOI were reported

CONCLUSIONS

- SPECTRUM is a prospective, **real-world study** in patients with **nAMD or visual impairment due to DMO** treated with EYLEA 8 mg.[5,6]
- Four patient cohorts are included, which comprise treatment-naïve and previously treated patients with nAMD or DMO; data will be collected over 24 months.[5]
- The study design of SPECTRUM enables analyses on both **a global and a regional level**; this allows for rolling interim analyses of endpoints in each participating country/cohort 1 year after enrolment is complete.[5]
- Early clinical experience with EYLEA 8 mg in **treatment-naïve patients with nAMD** indicates **improvements in BCVA** through Week 4 and 8 (+2.2 letters and +3.6 letters, respectively) and **reductions in CRT** (–110 µm, and –115 µm respectively), with **no new safety signals reported**.[10]
- Early clinical experience with EYLEA 8 mg in **previously treated patients with nAMD** indicates **improvements in BCVA** through Week 4 and 8 (+0.8 letters and +0.6 letters, respectively) and **reductions in CRT** (–56 µm and –39 µm, respectively), with **no new safety signals reported**.[11]

Patients in the SPECTRUM study were treated according to study protocol, which is to follow local treatment guidelines. These guidelines may vary from the UK licence. Please refer to the EYLEA 8 mg Summary of Product Characteristics for the full licensed posology.

Error bars are 95% CI. *Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates and the UK only.[10,11] †FAS, observed cases. ‡Mean change in VA/BCVA/CRT at Weeks 4 and 8 from baseline was calculated in patients with a VA/BCVA/CRT assessment at Weeks 4 and 8, respectively.[10,11] §Safety analysis set.[10,11] BCVA, best corrected visual acuity; CI, confidence interval; CRT, central retinal thickness; DMO, diabetic macular oedema; ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; IOI, intraocular inflammation; nAMD, neovascular age-related macular degeneration; TEAE, treatment-emergent adverse event; VA, visual acuity.

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11. Bailey C, Lange C, Chaudhary V *et al.* SPECTRUM: Early clinical experience from the first global real-world study of aflibercept 8 mg in patients with pretreated neovascular age-related macular degeneration. Presentation at the 2025 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting; Salt Lake City, UT, USA, 4–8 May 2025.

July 2025 | PP-EYL-GB-2862

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