SPECTRUM: Early clinical experience from the first global real-world study of aflibercept 8 mg in patients with previously treated diabetic macular edema

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Disclosures

- **Paolo Lanzetta:** Consultant for Aerie Pharmaceuticals, Allergan, Annexon, Apellis, Bausch + Lomb, Bayer, Biogen, Boehringer Ingelheim, Eyepoint Pharmaceuticals, Genentech, I-Care, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche
    - **MRM:** Consulting fees from AbbVie, Allergan, Apellis, Aviceda Therapeutics, Bayer, Boehringer Ingelheim, Dandelion, Eyepoint, Gensight, Iveric Bio, Isarna Therapeutics, Kubota, Lumithera, Novartis, Ocuterra, Oculis, Ocular Therapeutix, RetinAI, Roche, and Zeiss. **CL:** Receives honoraria from Apellis, Bayer, Biogen, and Novartis. **CB:** Receives honoraria from Alimera Sciences, Apellis, Bayer, and Roche; and has served on advisory boards for Apellis, Bayer, Boehringer Ingelheim, Janssen, and Roche. **HO:** Consultant for AbbVie, Bayer, Novartis, and Roche. **TM:** Employee of Bayer AG. **HA** and **PM-W:** Employees of Bayer Consumer Care AG. **VC:** Consulting fees from EyePoint; receives grants from Bayer, Novartis, and Roche; and serves on the advisory boards of Alcon, Roche, Bayer, Novartis, Apellis, and Boehringer Ingelheim
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SPECTRUM: Global real-world study of aflibercept 8 mg

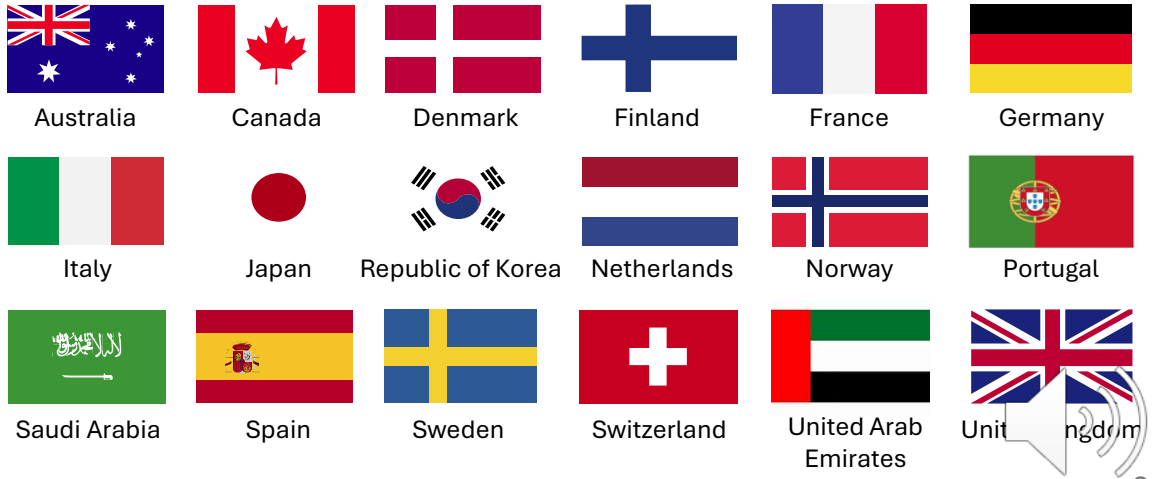
A **non-interventional country** and **global cohort** study planned in **18 countries**

2 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**

To date, **2149** patients enrolled



Secondary endpoints include:

- Change in **VA** and **CRT** from BL to Month 6
- Number of **injections** and **visits**, and **safety** through Month 6

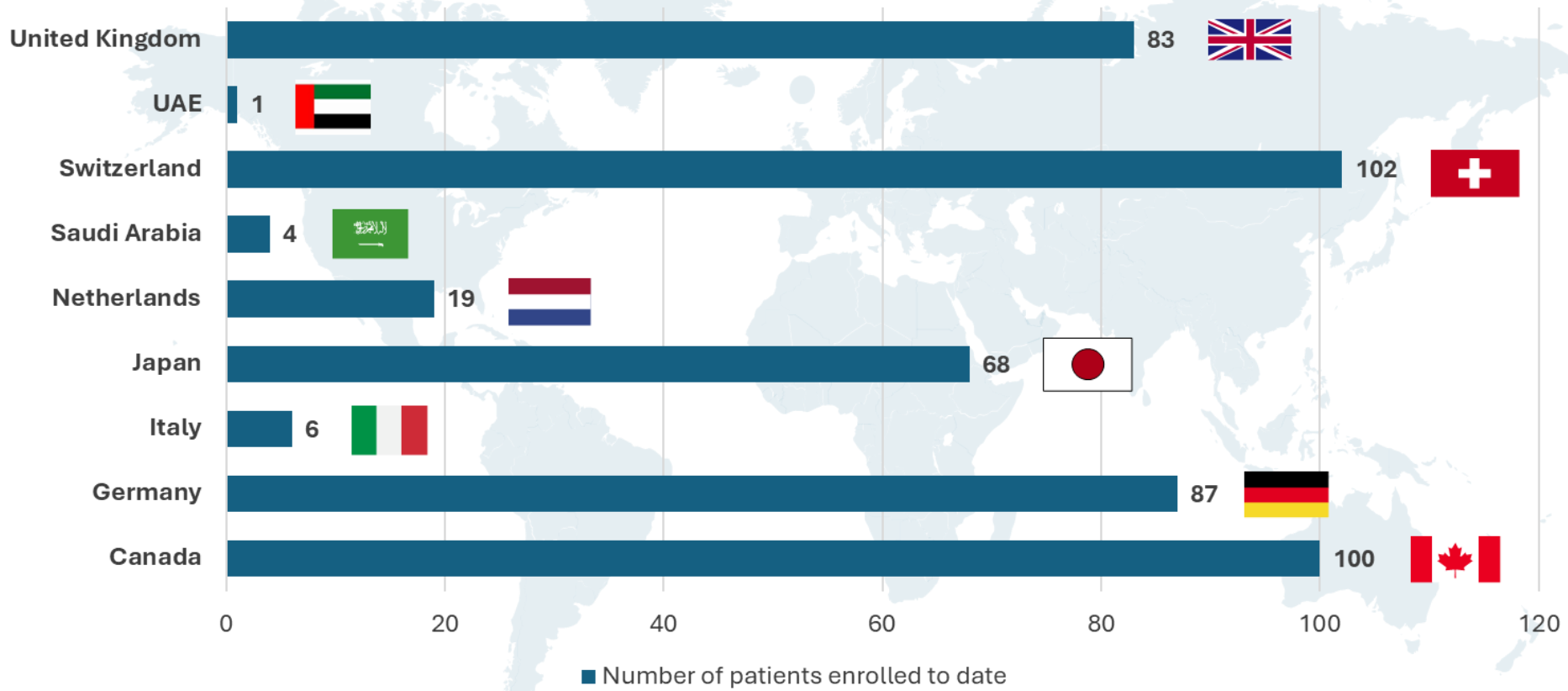
BL, baseline; CRT, central retinal thickness; DME, diabetic macular edema; nAMD, neovascular age-related macular degeneration; VA, visual acuity.

SPECTRUM: Global real-world study of aflibercept 8 mg

This presentation describes an overview of the study design, enrollment status, and interim baseline characteristics of the previously treated DME cohort

Enrollment overview

To date, **470** out of **775 (61%)** planned patients have been enrolled in the **previously treated DME** cohort



UAE, United Arab Emirates.

Baseline characteristics: Previously treated DME

Baseline characteristics of the first 150 patients enrolled[a]

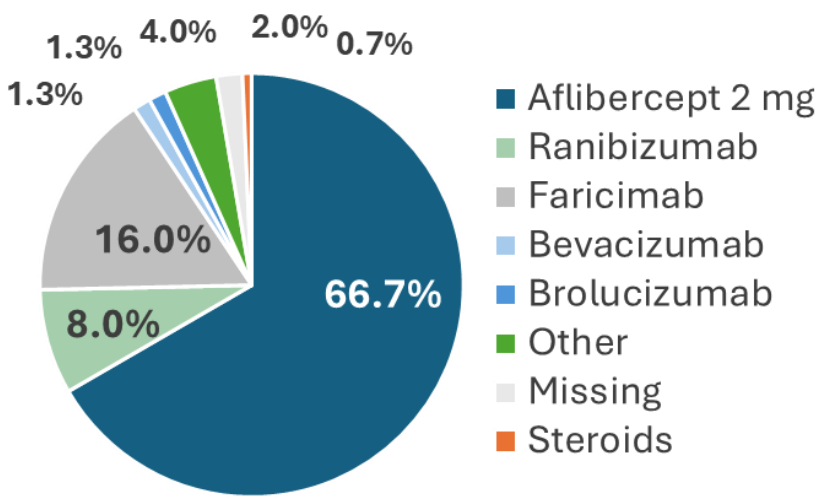
Mean age: 65.3 ± 11.4 years

Median (min, max) time from DME diagnosis: 44.5 (2.1, 411.1) months

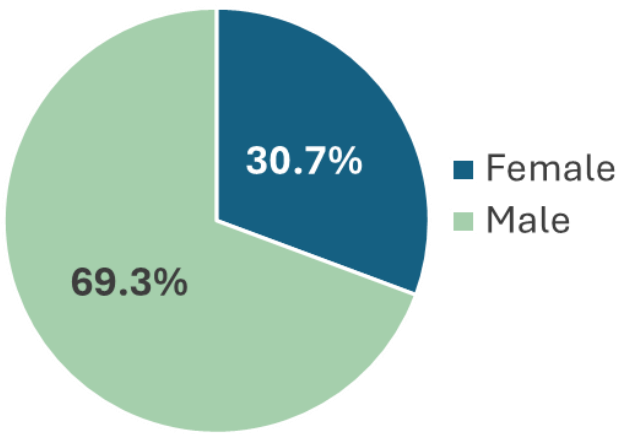
Mean baseline VA: 70.2 ± 13.8 ETDRS letters

Mean baseline CRT: 364 ± 133 µm

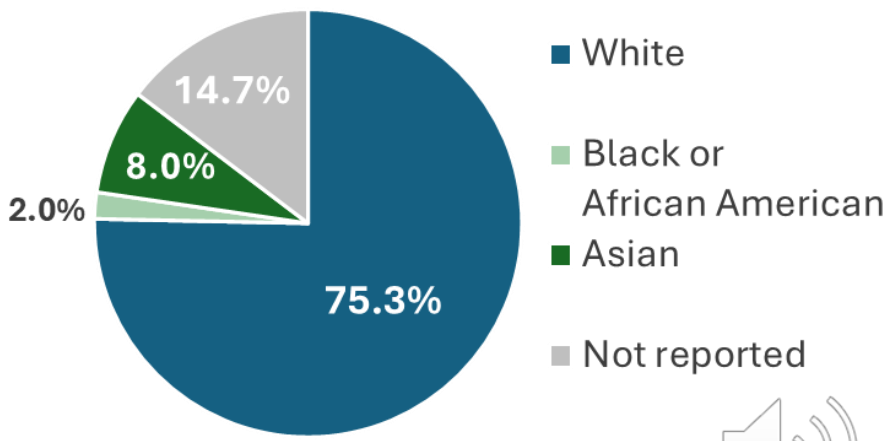
Previous DME medication



Sex



Race[b]



FAS. Percentages may not add up to 100 due to rounding.

[a]Data are mean ± SD unless otherwise indicated. [b]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.

ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; UK, United Kingdom.

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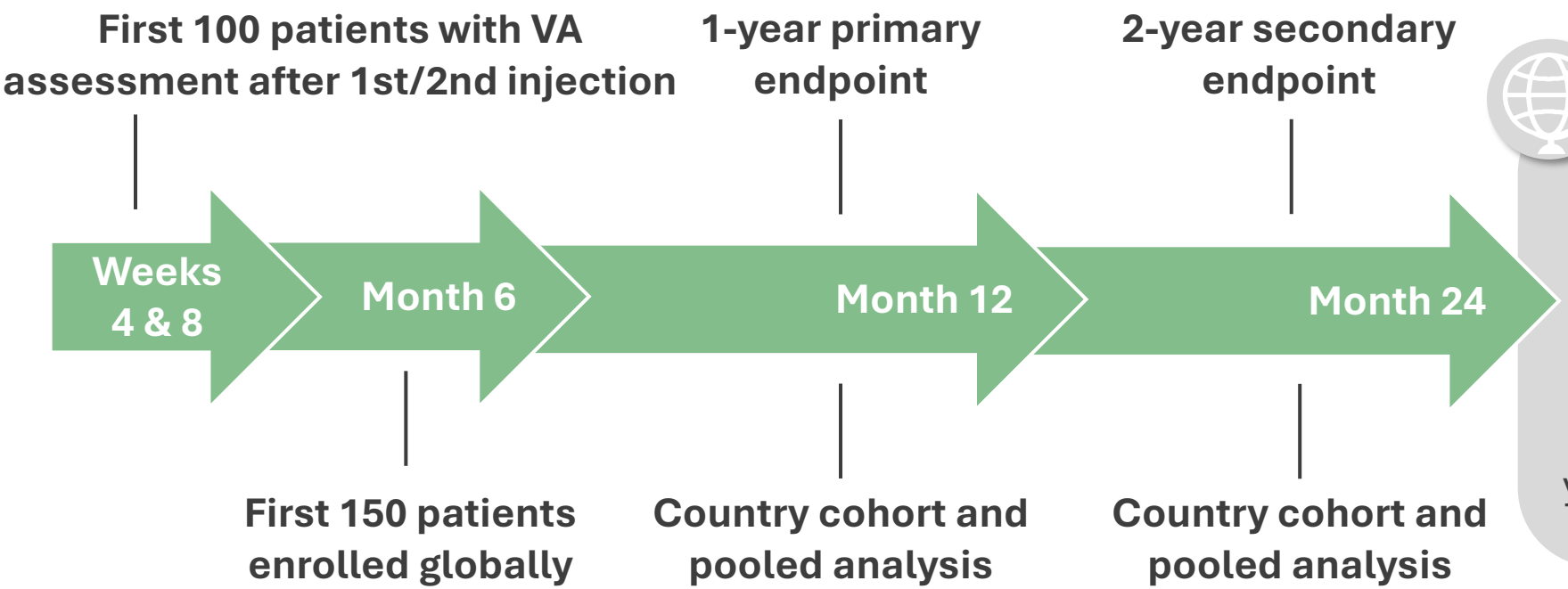
Timeline and planned analyses



SPECTRUM's study design enables analyses on both a **regional** and **global** level, allowing for **rolling interim analyses** of endpoints in each participating country/cohort a year after enrollment is complete

All analyses will be exploratory and descriptive in nature

Timeline and planned analyses

First 100 patients with VA assessment after 1st/2nd injection

1-year primary endpoint

2-year secondary endpoint

Weeks 4 & 8 → **Month 6** → **Month 12** → **Month 24**

Month 6 data for the **previously treated DME** cohort will be available in **Q2 2025**

ountry cohort and pooled analysis

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Q, quarter.

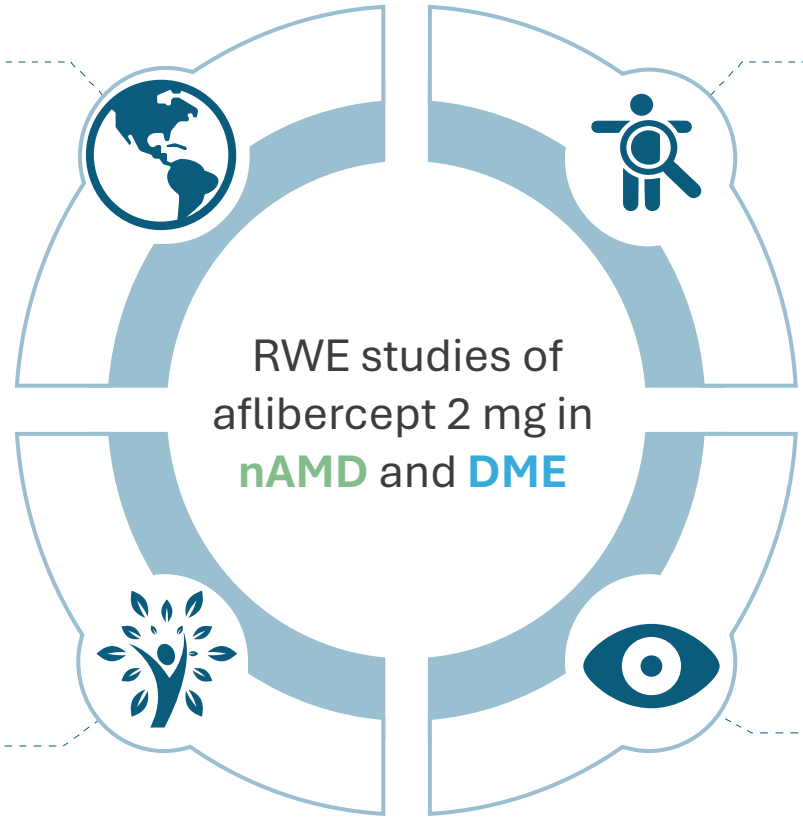
Building on prior RWE experience

AURIGA[1]

A global observational study in patients with treatment-naïve or previously treated DME or macular edema secondary to **RVO** across 11 countries/regions

XTEND[2]

A global observational study in patients with treatment-naïve nAMD across 17 countries



AQUILA[3]

An observational study in patients with treatment-naïve and previously treated nAMD and DME across 4 countries

DRAKO[4]

An observational study in patients with treatment-naïve DME in the UK

Other observational studies of aflibercept 2 mg have included APOLLON (France), PERSEUS (Germany), and PERSEUS-IT (Italy). RVO, retinal vein occlusion; RWE, real-world evidence.

1. Donati S, et al. *Ophthalmol Ther*. 2023;13(1):161–178; 2. Korobelnik JF, et al. *Ophthalmol Ther*. 2024;13(3):725–738;
3. Rodríguez FJ, et al. *Int J retina Vitreous*. 2022;8(1):52; 4. Sivaprasad S, et al. *Eye (Lond)*. 2023;37(12):2527–2534;

Conclusions

This initial report provides insights into the **baseline characteristics (including VA, CRT, and prior DME medications)** of the **first 150 patients** enrolled in the **previously treated DME** cohort

As the **first global real-world study** on aflibercept 8 mg, the **SPECTRUM** study will generate a **wealth of long-term data** on the real-world **effectiveness and safety** of **aflibercept 8 mg** in **nAMD and DME** across geographically and clinically **diverse patient populations**

To date, **470 patients** have been enrolled in the previously treated DME cohort (longest treatment duration of 14 months), and the **first set of evaluations** are underway