SPECTRUM: Early data from a global real-world study of aflibercept 8 mg in diabetic macular edema

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Disclosures

- **Brian Ballios:** Advisory board member for Astellas, Bayer, Biocon Biologics, Novartis, Roche, Sandoz Canada, and GelMEDIX; medical advisory board member for Endogena Therapeutics
  - **VC**: Grants from Bayer, Novartis, and Roche; consultancy fees from EyePoint Pharmaceuticals; advisory board member for Apellis, Bayer, Boehringer Ingelheim, EyePoint Pharmaceuticals, Novartis, and Roche. **HO**: Consultant for AbbVie, Bayer, Novartis, and Roche. **MRM**: Consultant for AbbVie, Alcon, Alimera, Allergan, Amgen, Apellis Pharmaceuticals, Astellas, Aviceda Therapeutics, Bayer, Boehringer Ingelheim, Dandelione, Eyegnos consulting, EyePoint Pharmaceuticals, Evolve Medical Education, GenSight Biologics, Isarna Therapeutics, Iveric Bio, Kubota, LumiThera, Novartis, Oculis, OD-OS, ONL Therapeutics, OcuTerra Therapeutics, RetinAI, Roche, UBS analytics, and Zeiss. **CB**: Honoraria from Alimera Sciences, Apellis, Bayer, and Roche; advisory board member for Alimera Sciences, Apellis, Bayer, Boehringer Ingelheim, Janssen, and Roche. **PL**: 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. **TM**: Employee of Bayer AG. **HA** and **PM-W**: Employees of Bayer Consumer Care AG. **CL**: Honoraria from Apellis, Bayer, Biogen, and Novartis
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SPECTRUM: Global real-world study of aflibercept 8 mg

A **24-month, non-interventional country** and **global cohort** study planned in **18 countries**

Two indications, four patient cohorts

Treatment-naïve **DME** and previously treated **DME**
Treatment-naïve **nAMD** and previously treated **nAMD**

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

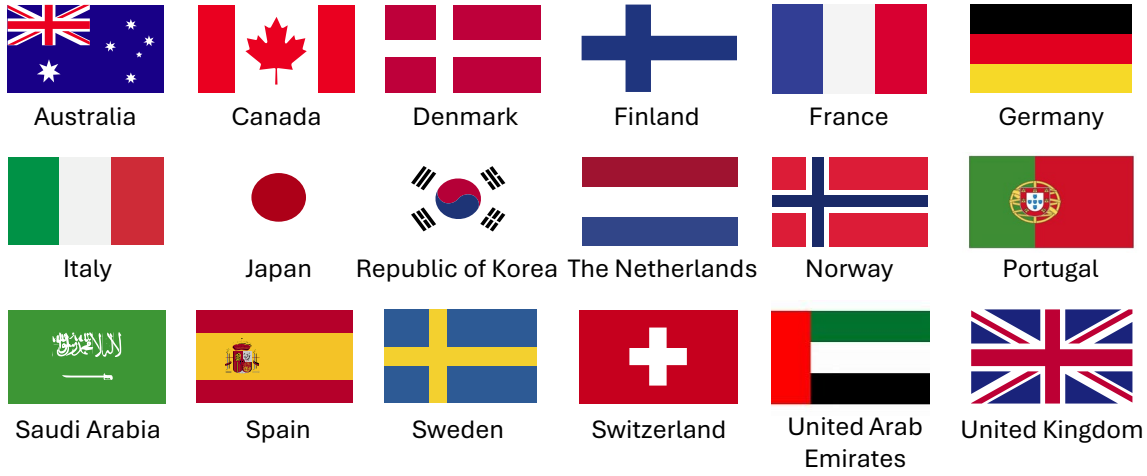
Secondary endpoints include:

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

Patient enrollment to date:

671/950 in the TN DME cohort

665/775 in the PT DME cohort

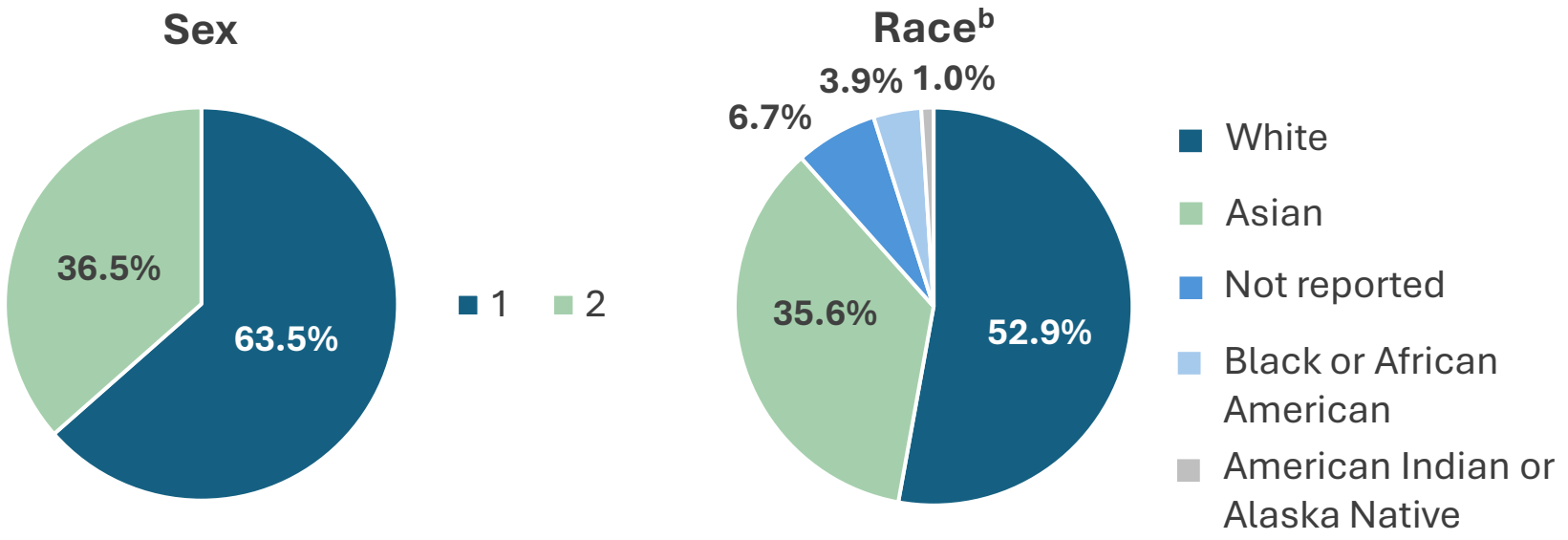


BL, baseline; CRT, central retinal thickness; DME, diabetic macular edema; nAMD, neovascular age-related macular degeneration; TN, treatment-naïve; PT, previously treated; VA, visual acuity.

Baseline characteristics: Treatment-naïve DME

Analysis of patients with a VA assessment at Week 8[a]

FAS, n	104
Age, years	67.1±10.1
Median (min, max) time from DME diagnosis, months	0.5 (0.0, 93.6)
Baseline VA, ETDRS letters	64.7±16.3
Baseline CRT, µm	412±110

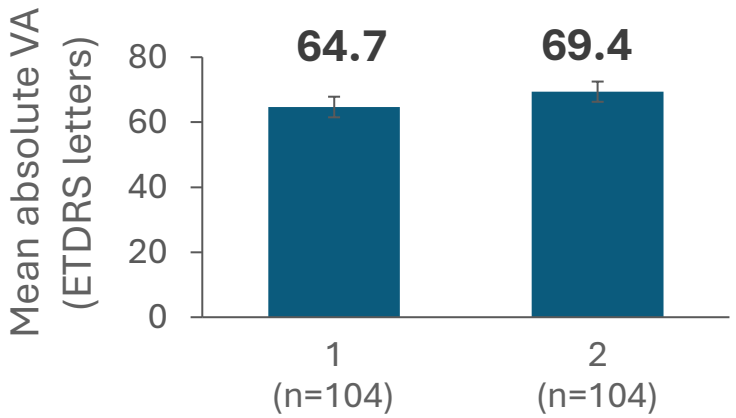


FAS. Percentages may not add up to 100 due to rounding.

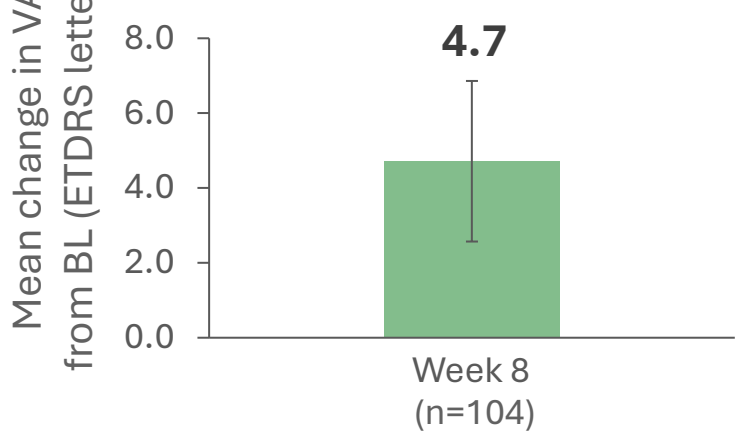
[a]Data are mean±SD unless otherwise indicated. [b]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the UK only.
ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; Max, maximum; Min, minimum; SD, standard deviation; UK, United Kingdom.

VA through Week 8

Absolute VA

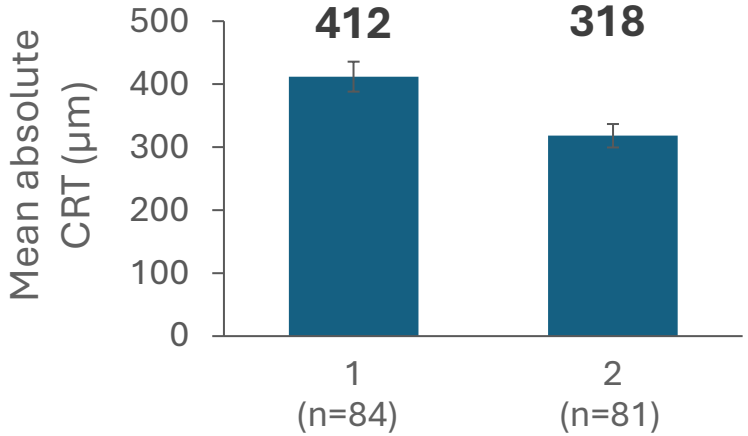


Mean change in VA

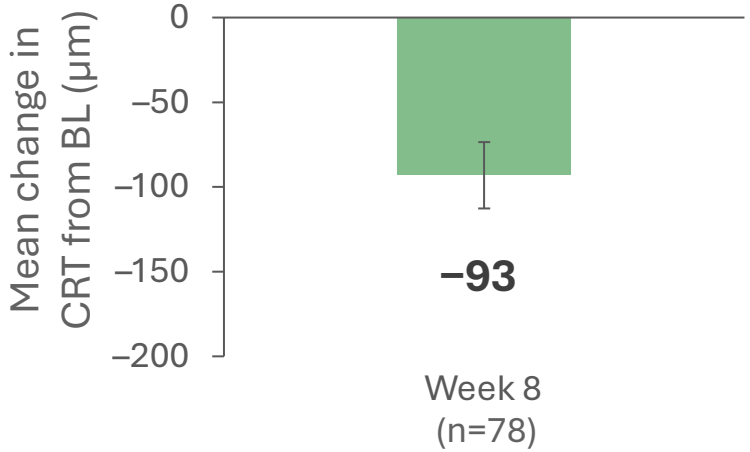


CRT through Week 8

Absolute CRT

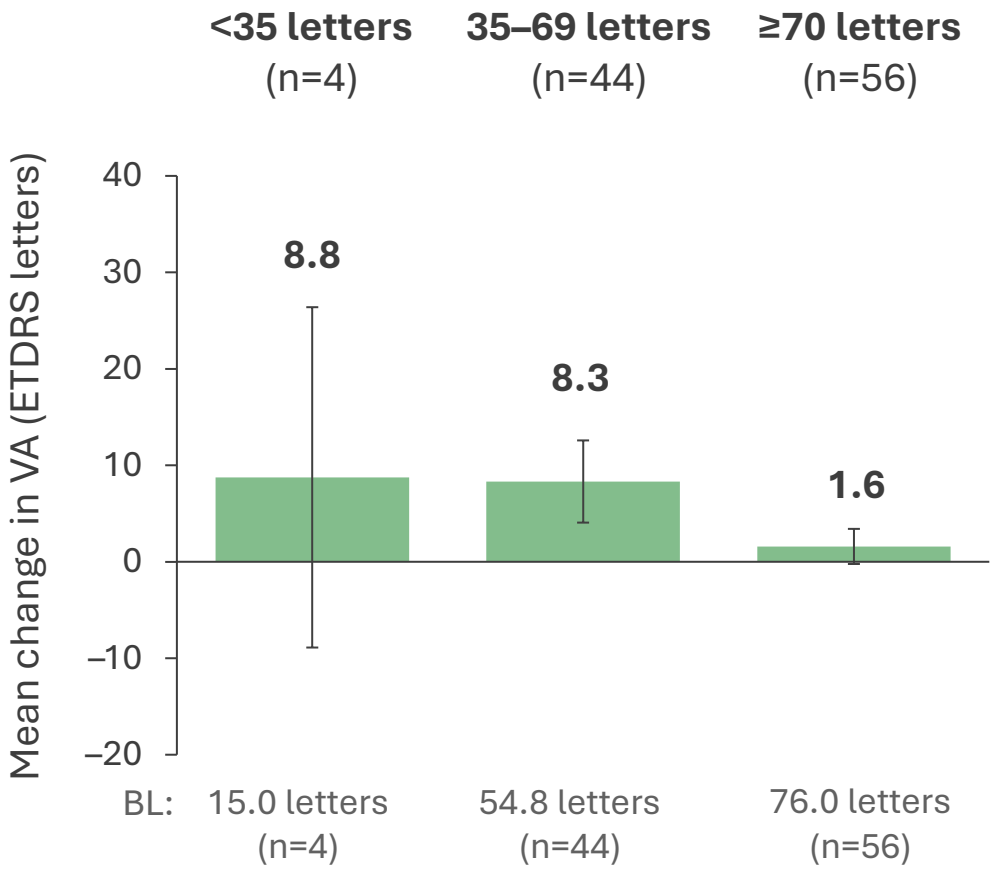


Mean change in CRT

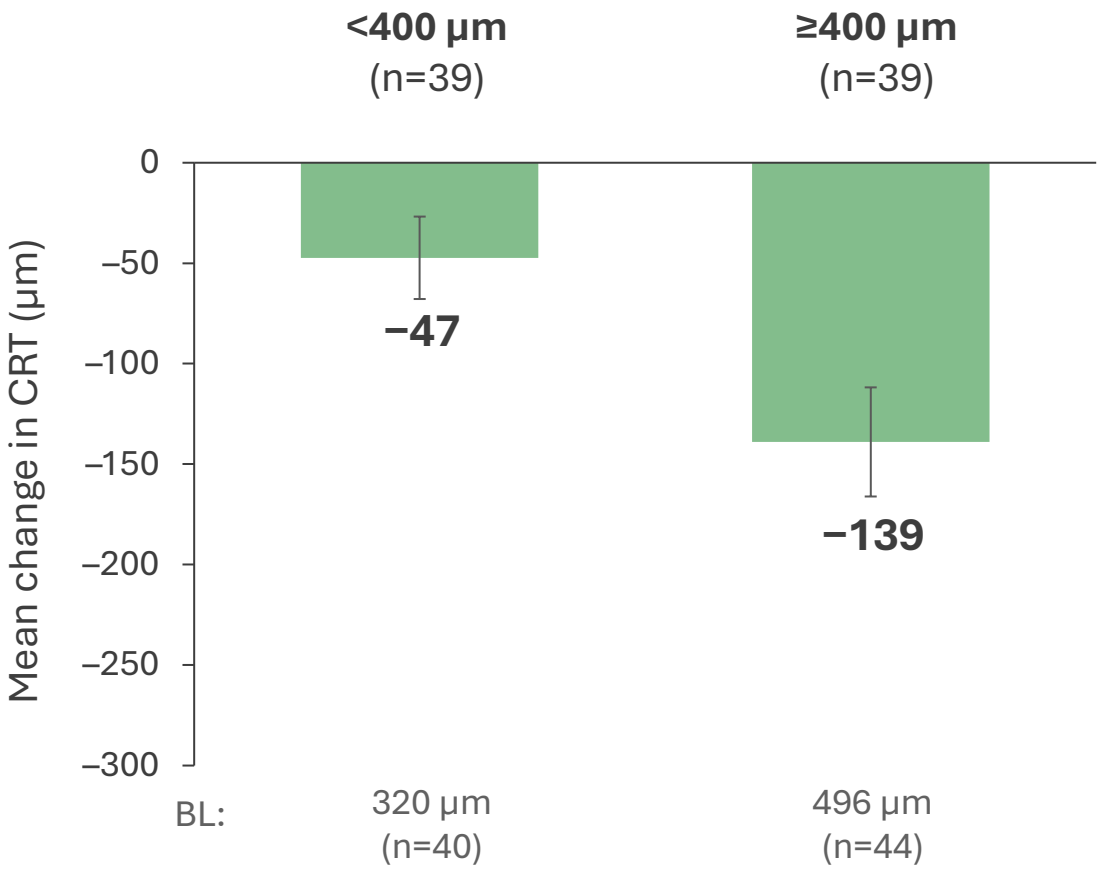


FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI. In 68 patients with a VA assessment at Week 4, the mean (95% CI) change in VA at Week 4 was +4.5 (2.3 to 6.7) letters from a BL of 63.6 letters (n=68). In 47 patients with a CRT assessment at Week 4, the mean (95% CI) change in CRT at Week 4 was −65 (−86 to −45) µm from a BL of 415 µm (n=47). CI, confidence interval; OC, observed case.

Mean change in VA through Week 8 grouped by baseline VA



Mean change in CRT through Week 8 grouped by baseline CRT

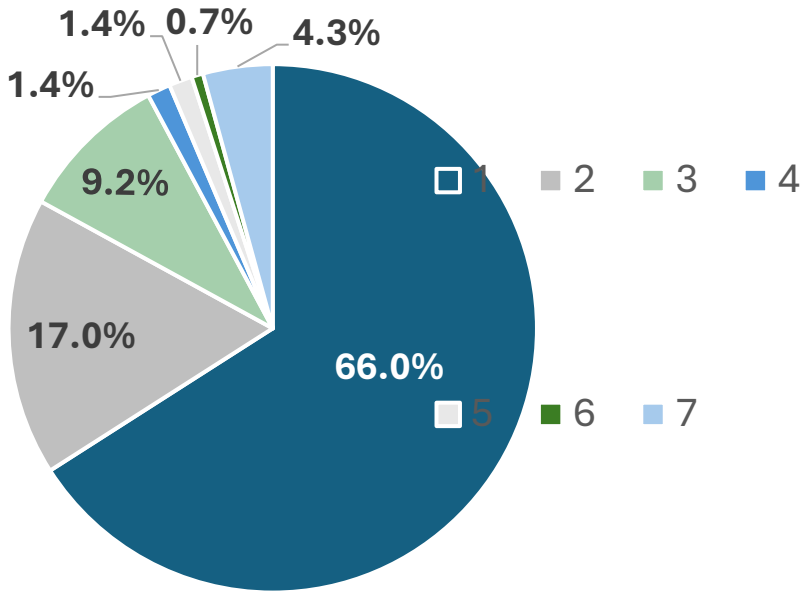


FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI. In patients with VA assessment at Week 4, the mean change in VA at Week 4 stratified by baseline VA was +6.7, +7.7, and +1.4 letters for those with a VA of <35 (n=3), 35–69 (n=31), and ≥70 (n=34) letters, respectively, at BL. In patients with a CRT assessment at Week 4, the mean change in CRT at Week 4 stratified by baseline CRT was −30 and −102 µm for those with a CRT of <400 (n=24) and ≥400 µm (n=23), respectively, at BL.

Baseline characteristics: Previously treated DME

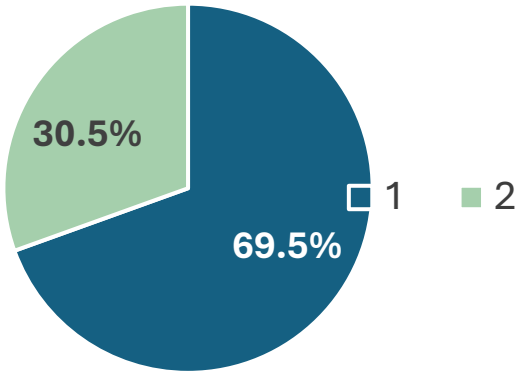
Month 6 analysis of the first ~150 patients enrolled[a]

Previous DME medication

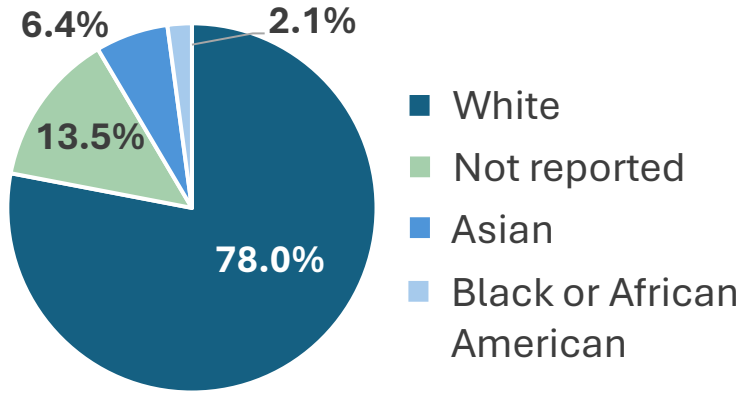


FAS, n	141
Age, years	65.3±11.0
Median (min, max) time from DME diagnosis, months	46.9 (2.1, 411.1)
Baseline VA, ETDRS letters	70.0±14.1
Baseline CRT, µm	364±136

Sex

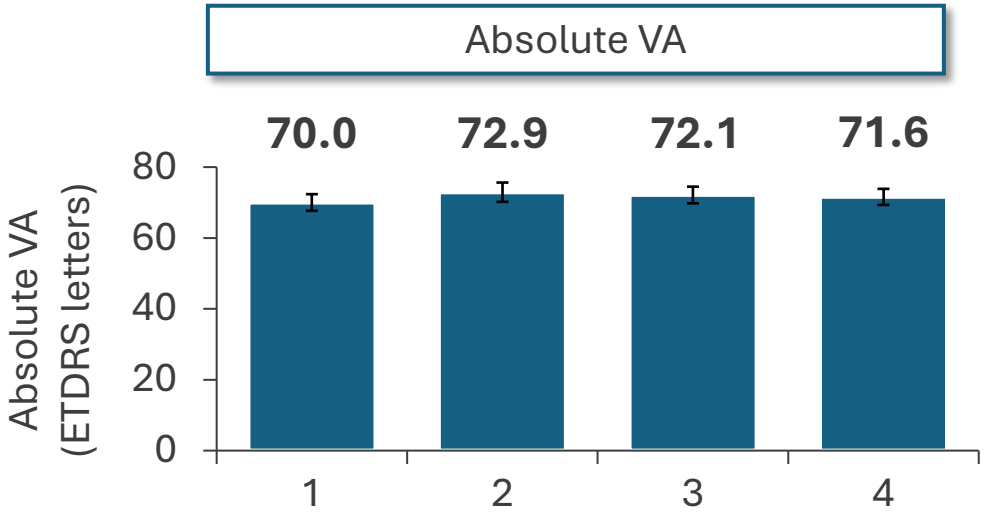


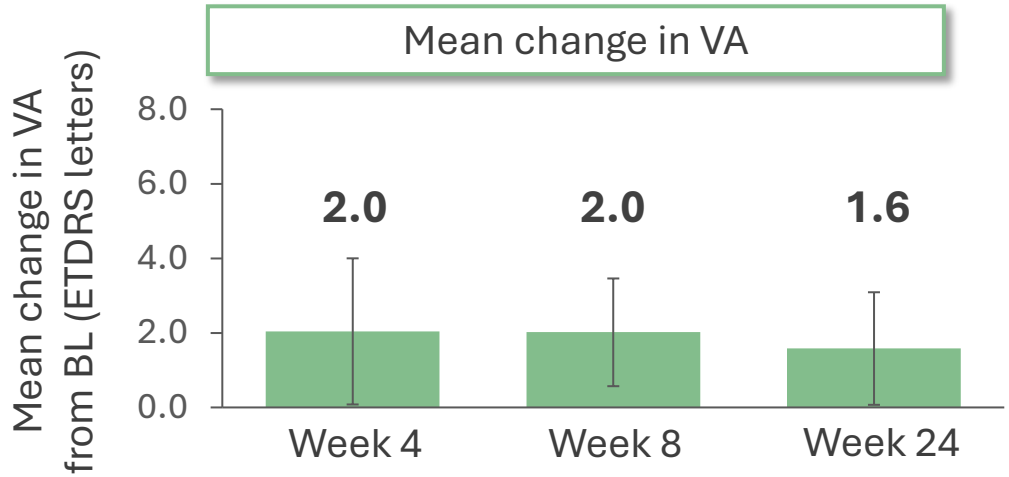
Race[b]



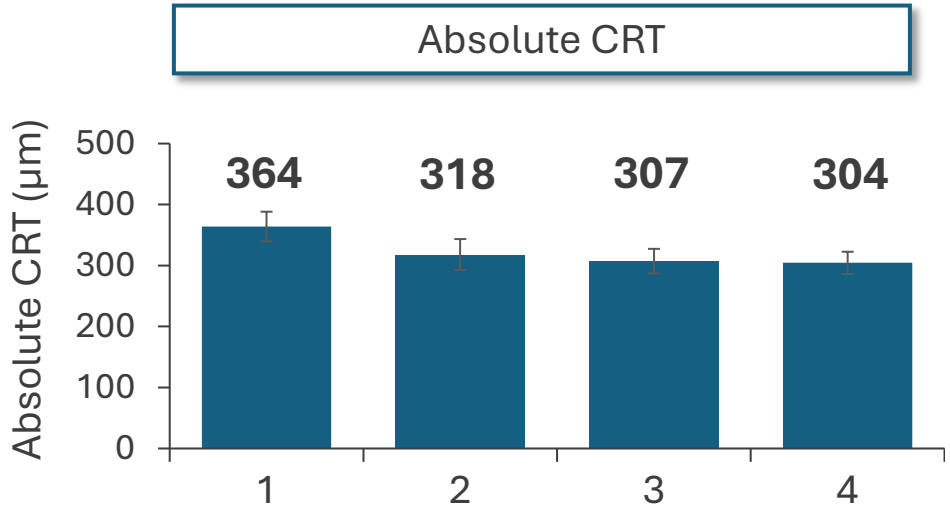
FAS. Percentages may not add up to 100 due to rounding. [a]Data are mean±SD unless otherwise indicated. [b]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the UK only.

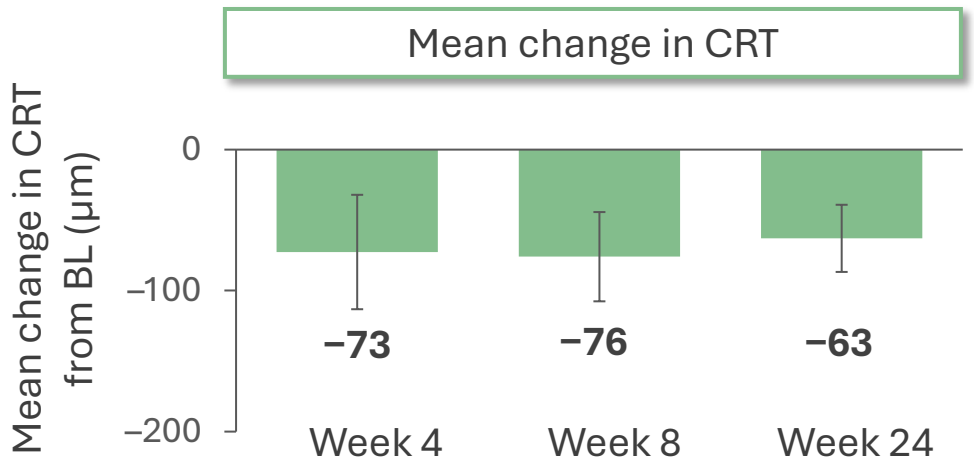
VA through Month 6





CRT through Month 6

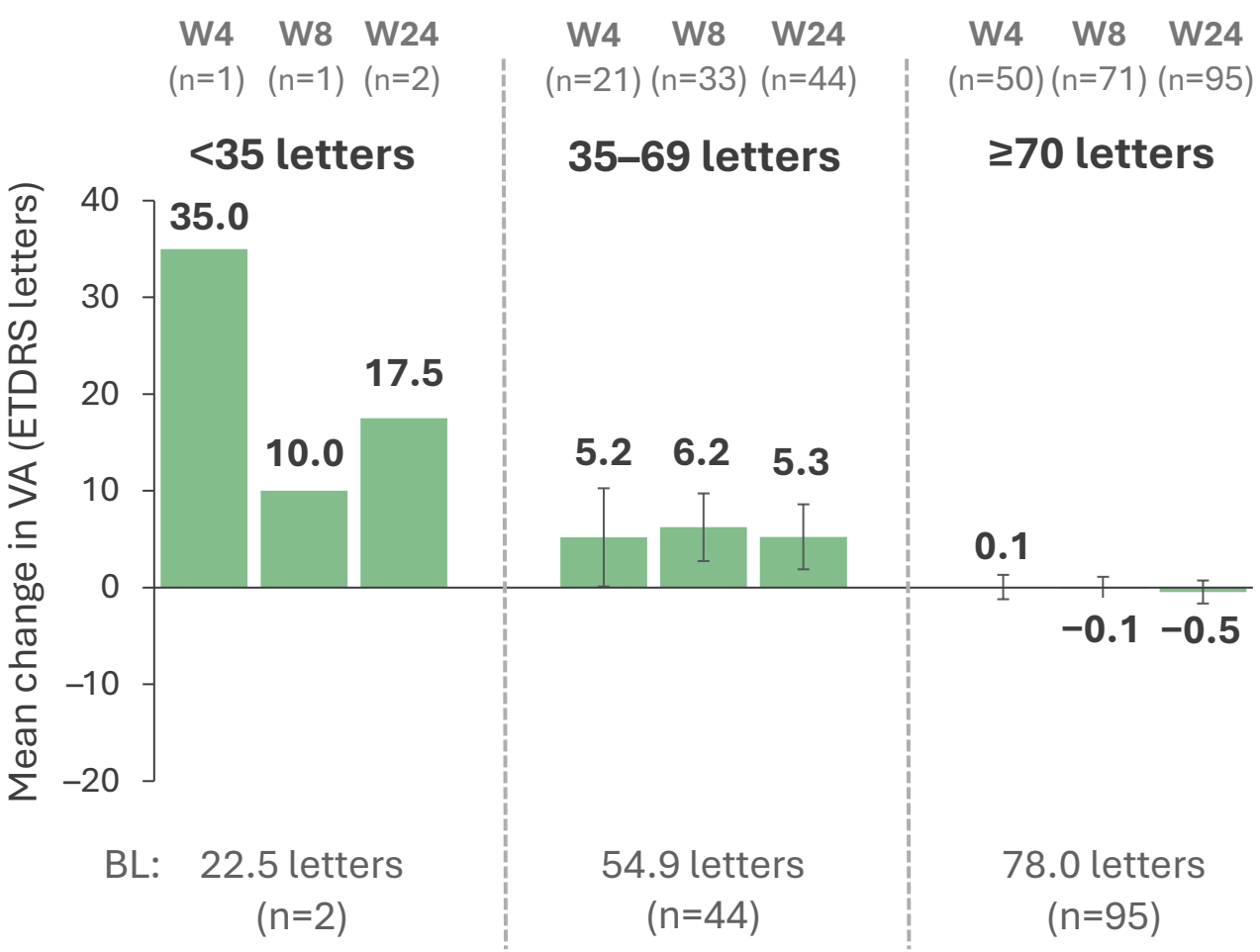




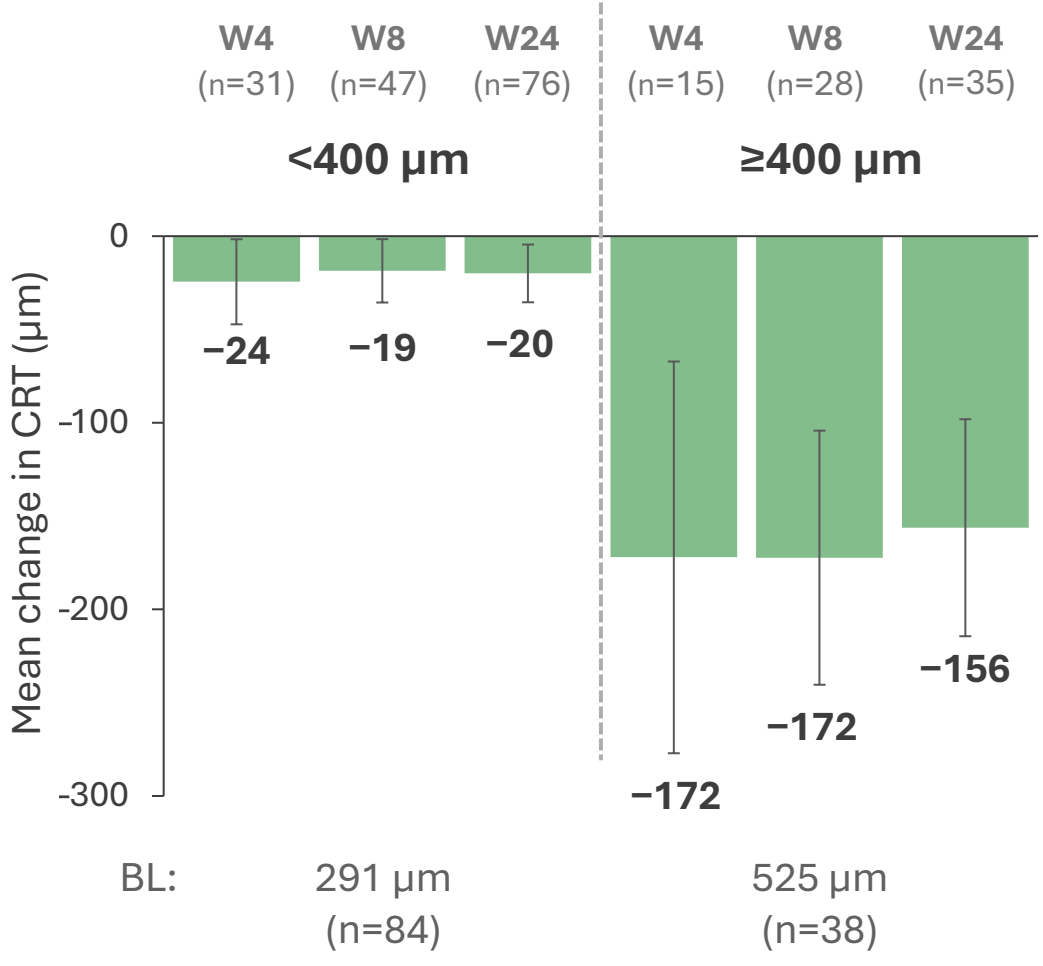
Patients received a mean of **4.3 injections** up to **Day 210** from **baseline**

FAS, LOCF (n=141). Missing values were imputed with the LOCF approach. Error bars are 95% CI. Week 24 = visits closest to 180 (150–210) days after BL.
LOCF, last observation carried forward.

Mean change in VA through Month 6 grouped by baseline VA[a]



Mean change in CRT through Month 6 grouped by baseline CRT



FAS, LOCF. Values have been rounded to the nearest decimal point. Error bars are 95% CI. [a]Error bars for the <35-letter subgroups are not shown as there were ≤2 patients in these subgroups.

Safety overview: Adverse events

	Week 8 TN DME cohort Total (N=104)	Week 24 PT DME cohort Total (N=150)
Ocular TEAEs in the study eye[a], n (%)	**2 (1.9)**	**10 (6.7)**
Serious ocular TEAEs, n (%)	0	2 (1.3)
Non-ocular TEAEs, n (%)	**6 (5.8)**	**15 (10.0)**
Serious non-ocular TEAEs, n (%)	1 (1.0)	3 (2.0)

No cases of retinal vasculitis were reported

SAF. [a]The eye treated with aflibercept 8 mg was considered the study eye; if aflibercept 8 mg treatment was decided simultaneously for both eyes, the study eye was considered the worse eye per the discretion of the attending physician. SAF, safety analysis set; TEAE, treatment-emergent adverse event.

Early findings from SPECTRUM support the real-world effectiveness and safety of aflibercept 8 mg in treatment-naïve and previously treated DME

More than **3600** patients enrolled in SPECTRUM across **18 countries** to date

More than **600** patients enrolled in the **treatment-naïve and previously treated DME cohorts** across **12 countries** to date

Early clinical outcomes at Week 8 in the TN DME cohort

- Improved VA and CRT
- No new safety signals identified

Clinical outcomes at Week 24 in the PT DME cohort

- Stable VA and improved CRT following switch to aflibercept 8 mg
- No new safety signals identified

As the **first global real-world study of aflibercept 8 mg**, early findings from SPECTRUM will help to **inform clinical management** of DME with aflibercept 8 mg

Presentation of **Month 6 data** for the treatment-naïve DME cohort is planned for **later in 2025,** with **Month 12 and Month 24** analyses for **both cohorts** on track