SPECTRUM: Early clinical outcomes in the first global real-world study of aflibercept 8 mg in patients with treatment-naïve neovascular age-related macular degeneration

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on behalf of the SPECTRUM study investigators

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Disclosures

- Clare Bailey: Received honoraria from Alimera Sciences, Apellis, Bayer, and Roche; and has served on advisory boards for Apellis, Bayer, Boehringer Ingelheim, Janssen, and Roche
- VK: Receives honoraria from AbbVie, Bayer, Novartis, and Roche. CL: Receives honoraria from Apellis, Bayer, Biogen, and Novartis. 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. PL: Consultant for Aerie Pharmaceuticals, Allergan, Annexon, Apellis, Bausch + Lomb, Bayer, Biogen, Boehringer Ingelheim, EyePoint, Genentech, I-Care, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche. VC: Consulting fees from EyePoint Pharmaceuticals; receives grants from Bayer, Novartis, and Roche; and serves on advisory boards for Apellis, Bayer, Boehringer Ingelheim, EyePoint Pharmaceuticals, Novartis, and Roche. HO: Consultant for AbbVie, Bayer, Novartis, and Roche. TM: Employee of Bayer AG. HA, ZH, and XZ: Employees of Bayer Consumer Care AG
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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

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

Secondary endpoints include:

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

Patient enrollment to date:

1123/1200 in the TN nAMD cohort and 3463 overall

Australia, Canada, Denmark, Finland, France, Germany, Italy, Japan, Republic of Korea, The Netherlands, Norway, Portugal, Saudi Arabia, Spain, Sweden, Switzerland, United Arab Emirates, United Kingdom

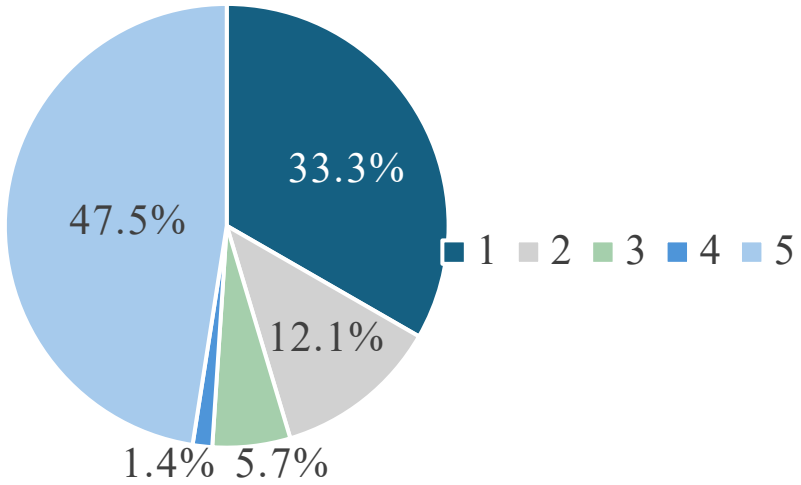
BL, baseline; CRT, central retinal thickness; DME, diabetic macular edema; nAMD, neovascular age-related macular degeneration; TN, treatment-naïve; VA, visual acuity.

Baseline characteristics: Treatment-naïve nAMD

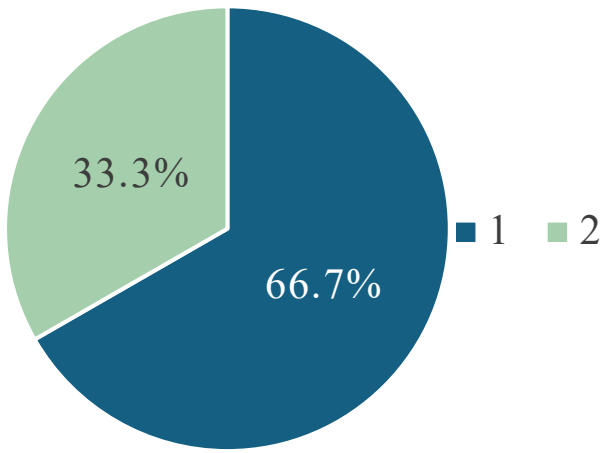
Month 6 analysis of the first ~150 patients enrolled[a]

FAS, n	141
Age (years)	80.8±6.9
Median (min, max) time from nAMD diagnosis (months)	0.1 (0.0, 21.9)
Baseline VA (ETDRS letters)	61.6±17.6
Baseline CRT (µm)	365±129

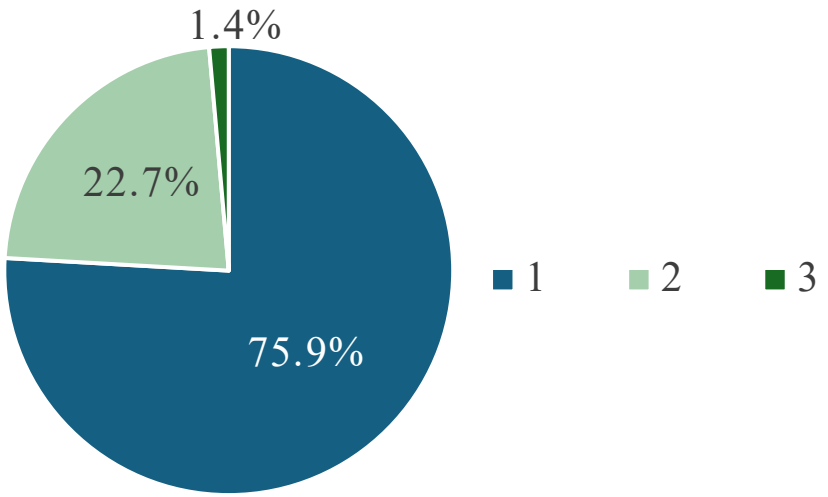
MNV type[b]



Sex



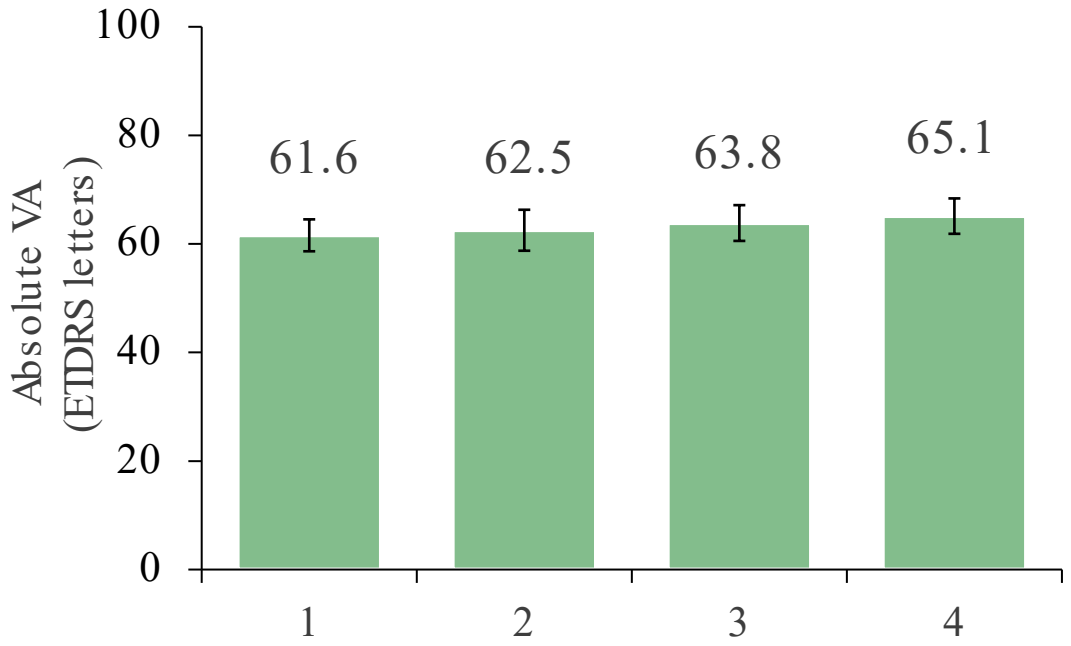
Race[c]



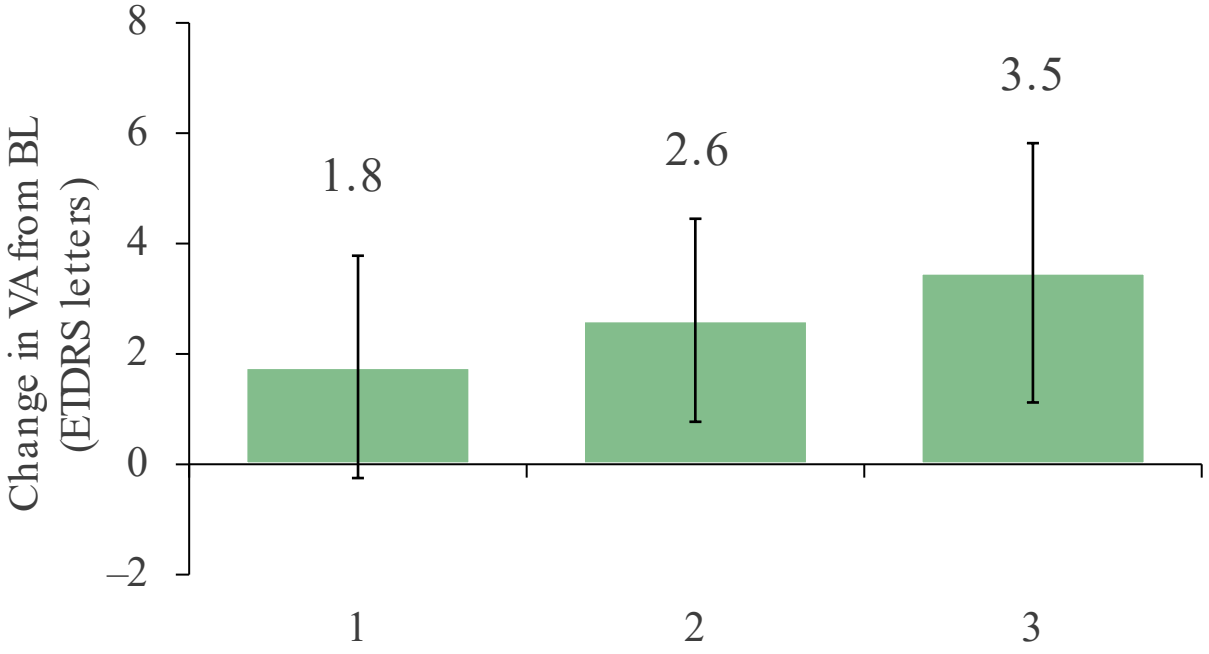
FAS. Percentages may not add up to 100 due to rounding. [a]Data are mean±SD unless otherwise indicated. [b]Mixed refers to Type 1 and Type 2 MNV combined. [c]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the UK only. ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; Max, maximum; Min, minimum; MNV, macular neovascularization; N/A, not applicable; SD, standard deviation; UK, United Kingdom.

VA through Month 6

Absolute VA



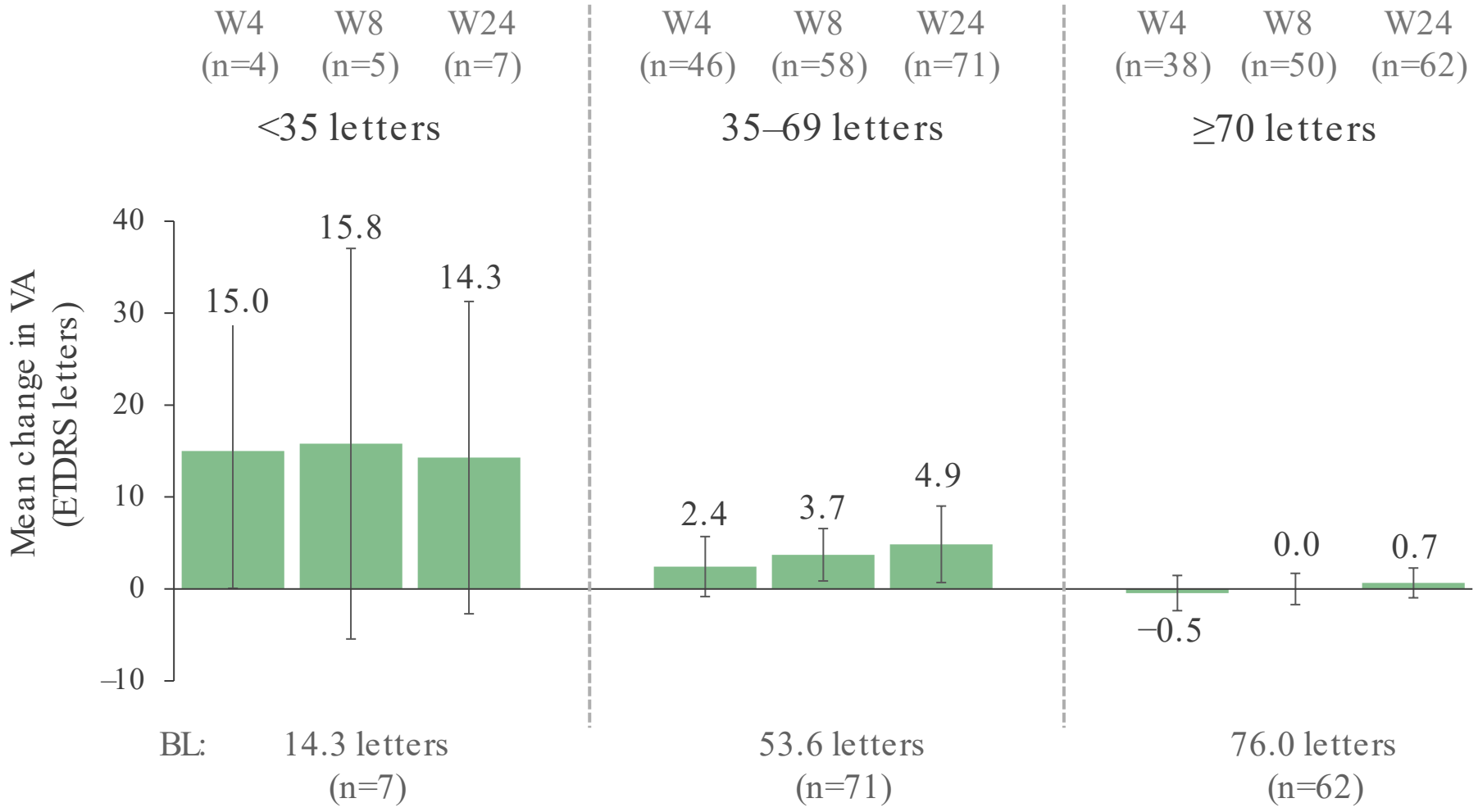
Mean change in VA



Patients received a mean of 4.7 injections up to Day 210 from baseline

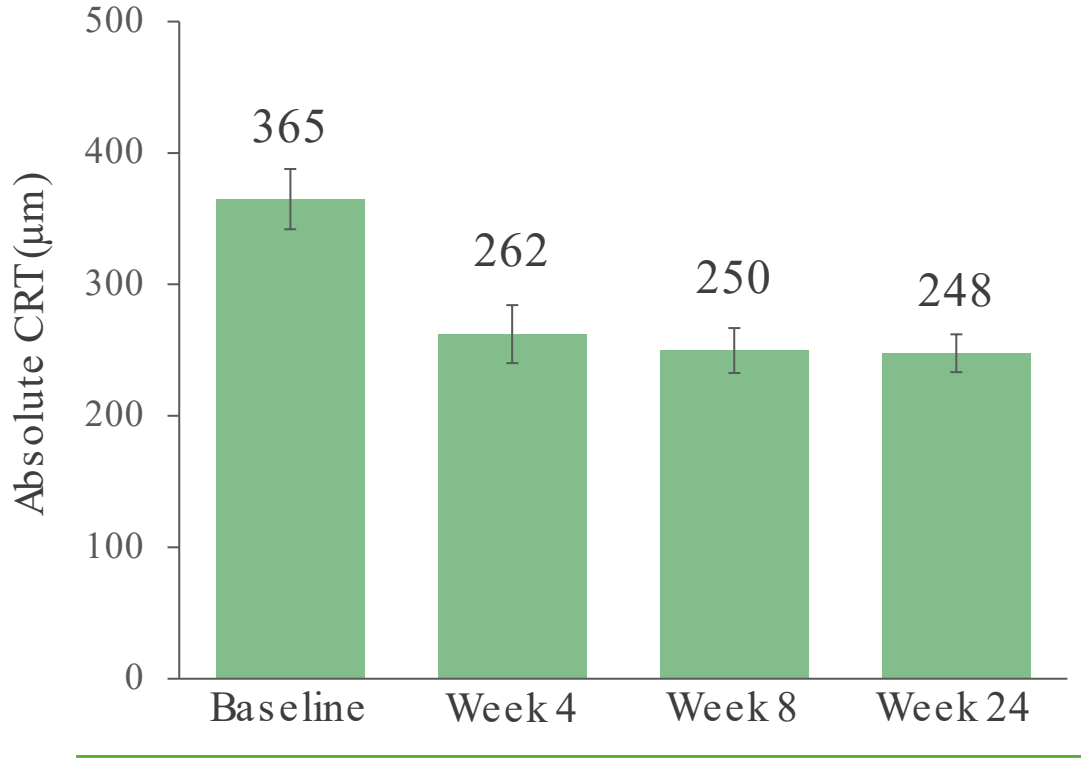
FAS, LOCF (n=141). Missing values were imputed with the LOCF approach. Error bars are 95% CI.
Week 4 = visits closest to 28 (14–42) days after BL, Week 8 = visits closest to 56 (43–70) days after BL, Week 24 = visits closest to 180 (150–210) days after BL.
CI, confidence interval; LOCF, last observation carried forward.

Mean change in VA through Month 6 grouped by baseline VA

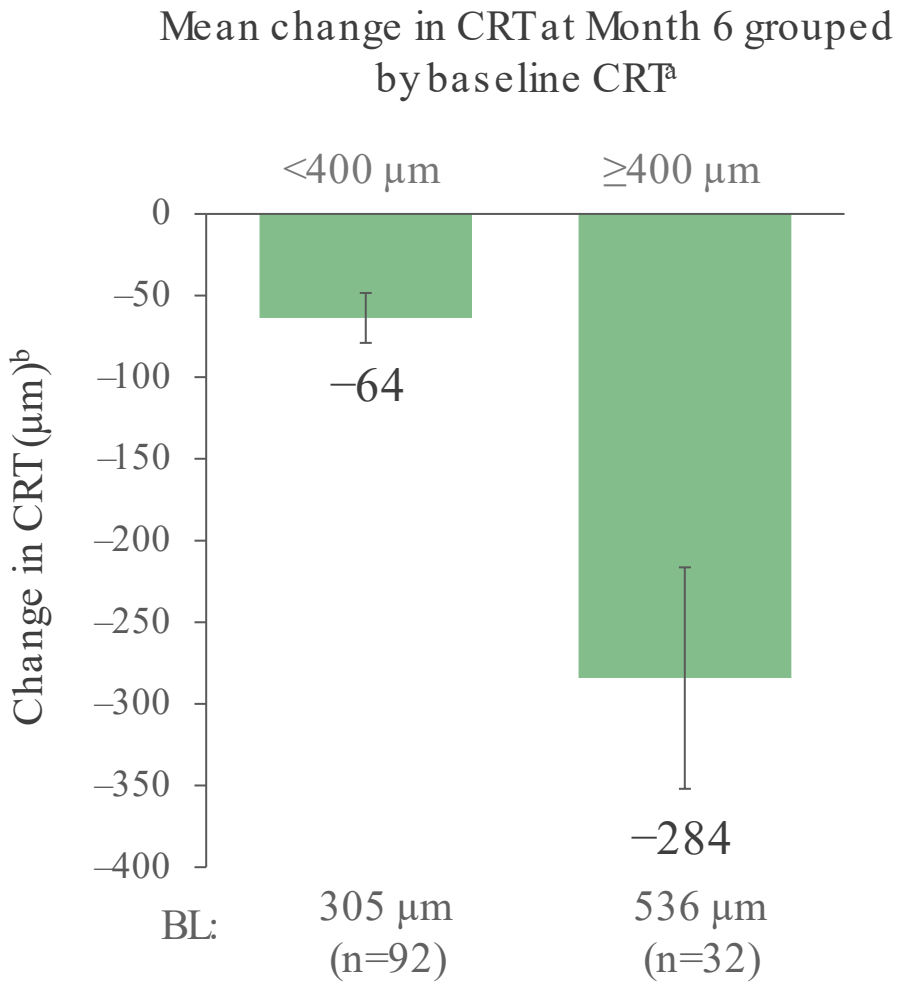


FAS, LOCF. Values have been rounded to the nearest decimal point. Error bars are 95% CI. W, Week.

CRT through Month 6

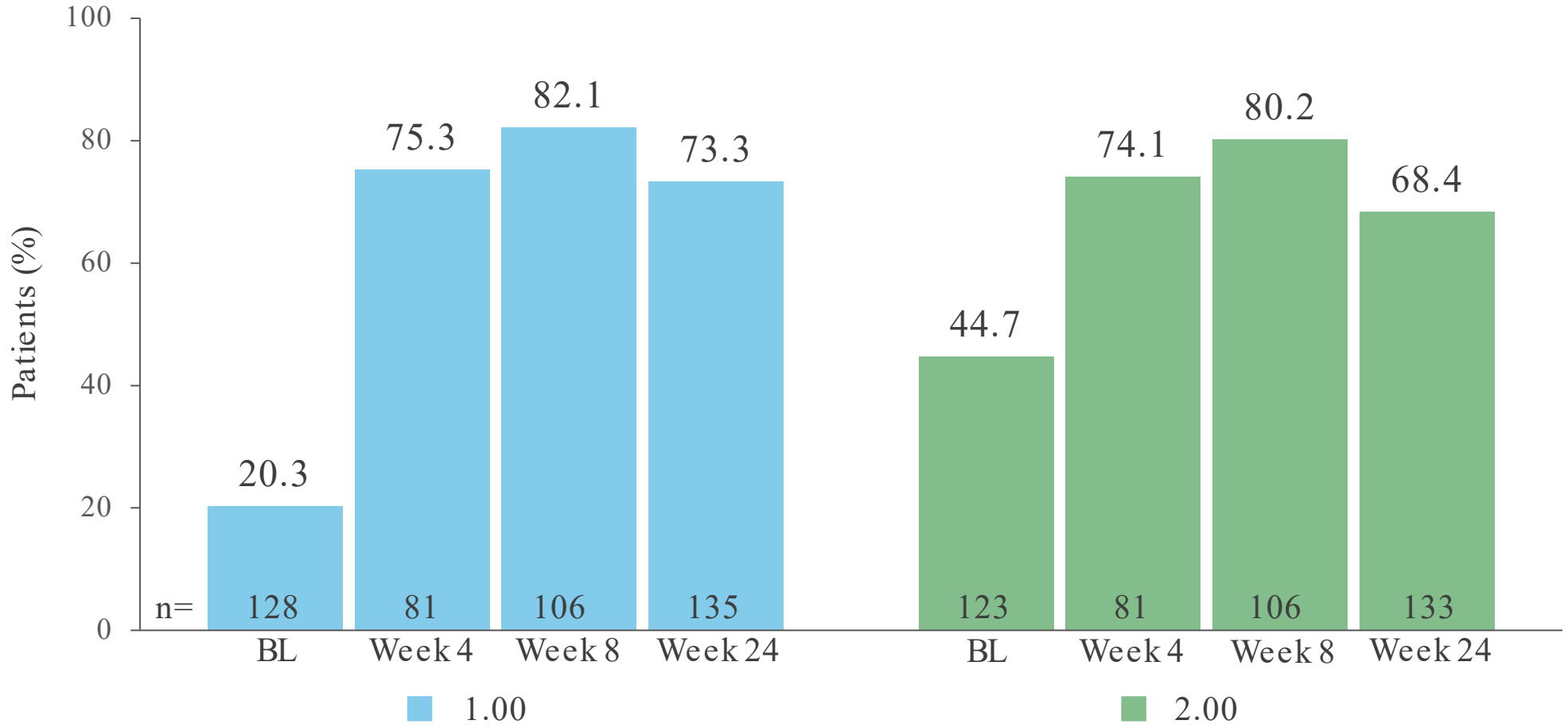


Timepoint	Mean change (95% CI) from baseline (LOCF)
Week 4	−132 (−166, −98)
Week 8	−133 (−160, −106)
Week 24	−119 (−146, −92)



FAS, LOCF (n=141). Missing values were imputed with the LOCF approach. Error bars are 95% CI. [a]In patients with a CRT assessment at Week 4 and Week 8, the mean change in CRT at Week 4 and Week 8 stratified by baseline CRT was −81 and −85 µm for those with a baseline CRT of <400, and −236 and −234 µm for those with a baseline CRT of ≥400 µm, respectively.

Proportion of patients without SRF or IRF through Month 6[a]



FAS, LOCF. Missing values were imputed with the LOCF approach. Values have been rounded to the nearest decimal point. Based on instructions in the case report form, fluid data were collected during a macular assessment (6 mm) per investigator discretion. [a]Calculated based on the number of patients assessed at each timepoint.
IRF, intraretinal fluid; SRF, subretinal fluid.

Safety overview: Adverse events

Ocular TEAEs	Total (N=150)
Any ocular TEAEs in the study eye,[a] n (%)	11 (7.3)
Any serious ocular TEAEs	2 (1.3)
Non-ocular TEAEs	**Total (N=150)**
Any non-ocular TEAEs, n (%)	9 (6.0)
Any serious non-ocular TEAEs	3 (2.0)

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

Month 6 results from SPECTRUM support the real-world effectiveness and safety of aflibercept 8 mg in patients with treatment-naïve nAMD

More than 3400 patients enrolled in SPECTRUM across all 18 countries to date

More than 1100 patients enrolled in the treatment-naïve nAMD cohort across 14 countries to date

Clinical and safety outcomes at Month 6

- Improved VA (+3.5 ETDRS letters) and improved CRT (−119 µm)
- Substantial improvements in IRF and SRF
- No new safety signals

Treatment exposure

- Results achieved with a mean of 4.7 injections up to Day 210 from BL
- Consistent with extending dosing intervals maintained through Week 48 in PULSAR[1]

As the first global real-world study of aflibercept 8 mg, Month 6 results from SPECTRUM will help to inform clinical management of treatment-naïve nAMD in patients receiving aflibercept 8 mg

Month 12 and Month 24 analyses are on track

1. Lanzetta P, et al. Lancet. 2024;403:1141–1152.