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

Paolo Lanzetta,[1,2] Hassiba Oubraham,[3] Clare Bailey,[4] Varun Chaudhary,[5] Marion R. Munk,[6,7,8] Tobias Machewitz,[9] Helmut Allmeier,[10] Peter Morgan-Warren,[10] Clemens Lange,[11,12] on behalf of the SPECTRUM study investigators

[1]Department of Medicine–Ophthalmology, University of Udine, Udine, Italy; [2]Istituto Europeo di Microchirurgia Oculare (IEMO), Udine, Italy; [3]Centre OPHTA-45, Montargis, France; [4]Department of Ophthalmology, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK; [5]Department of Surgery, McMaster University, Hamilton, ON, Canada; [6]Augenarzt Praxisgemeinschaft Gutblick AG, Pfäffikon, Switzerland; [7]Department of Ophthalmology, University Hospital Bern, Bern, Switzerland; [8]Northwestern University, Feinberg School of Medicine, Chicago, IL, USA; [9]Bayer AG, Berlin, Germany; [10]Bayer Consumer Care AG, Basel, Switzerland; [11]Eye Center, Faculty of Medicine, Albert-Ludwig University Freiburg, Freiburg, Germany; [12]Department of Ophthalmology, St Franziskus Hospital, Münster, Germany

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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
  - HO: Consultant for AbbVie, Bayer, Novartis, and Roche. CB: Honoraria from Alimera Sciences, Apellis, Bayer, and Roche; and has served on advisory boards for Apellis, Bayer, Boehringer Ingelheim, Janssen, and Roche. VC: Grants from Bayer, Novartis, and Roche; consultancy fees from EyePoint Pharmaceuticals, Inc.; and serves on advisory boards for EyePoint Pharmaceuticals Inc., Appellis, Bayer, Boehringer Ingelheim, Novartis, and Roche. MRM: Consulting fees 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. 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

2 indications, 4 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:
598/950 in the TN DME 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 DME

Analysis of patients with a VA assessment at Week 4[a]

Total: 110 patients

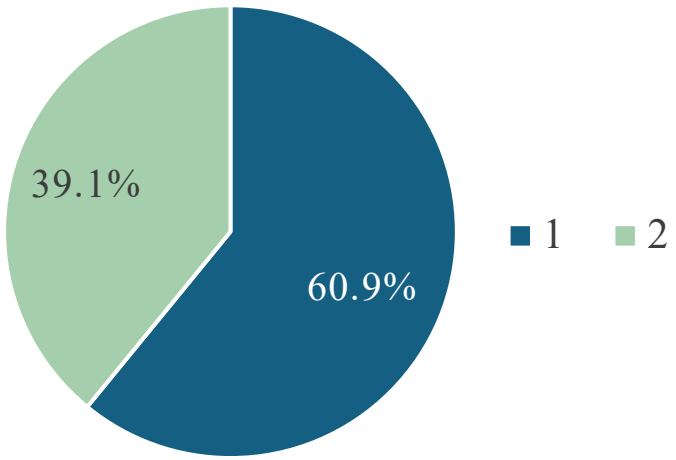
Mean age: 65.9±11.1 years

Median (min, max) time from DME diagnosis: 0.4 (0.0, 93.6) months

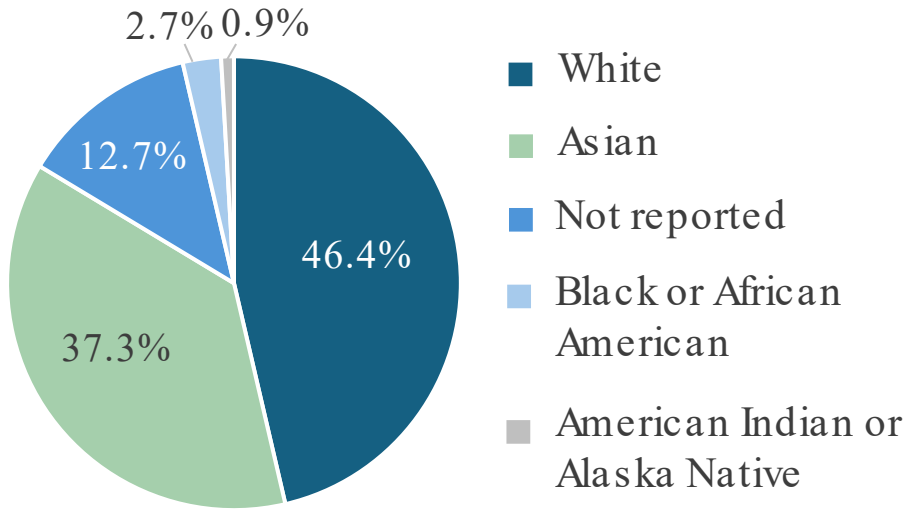
Mean baseline VA: 62.1±17.4 ETDRS letters

Mean baseline CRT: 410±126 µm

Sex



Race[b]

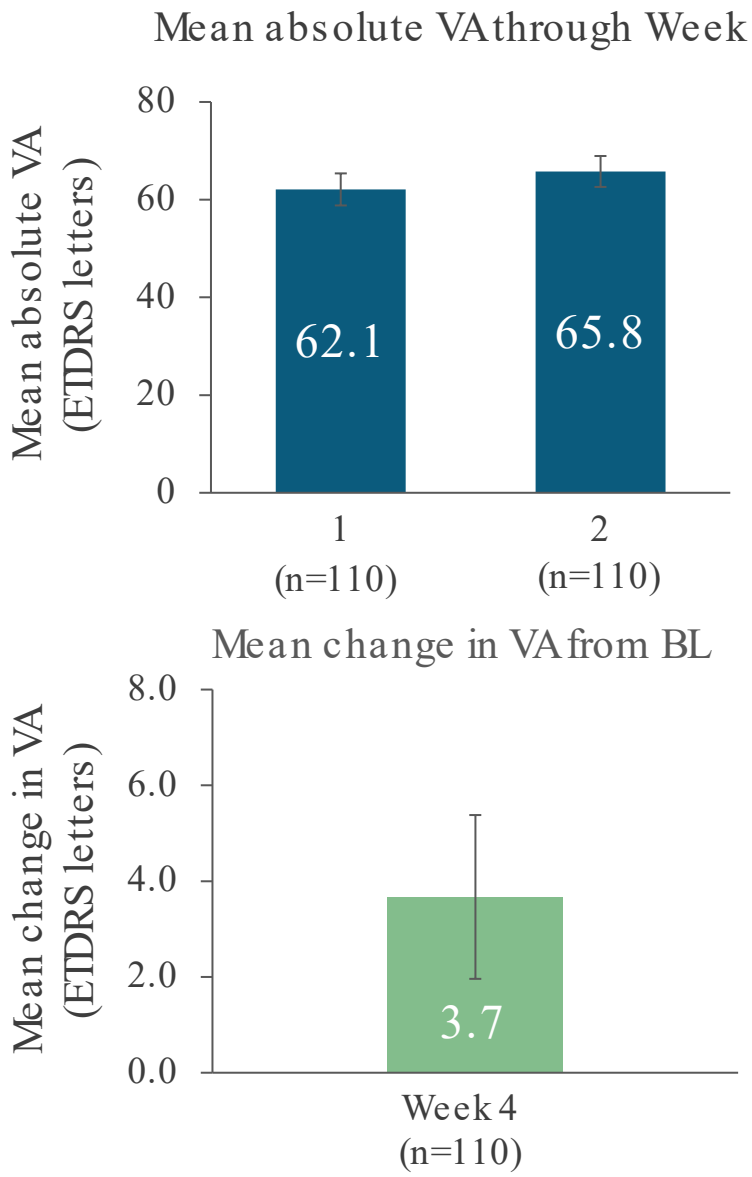


FAS. Percentages may not add up to 100 due to rounding.

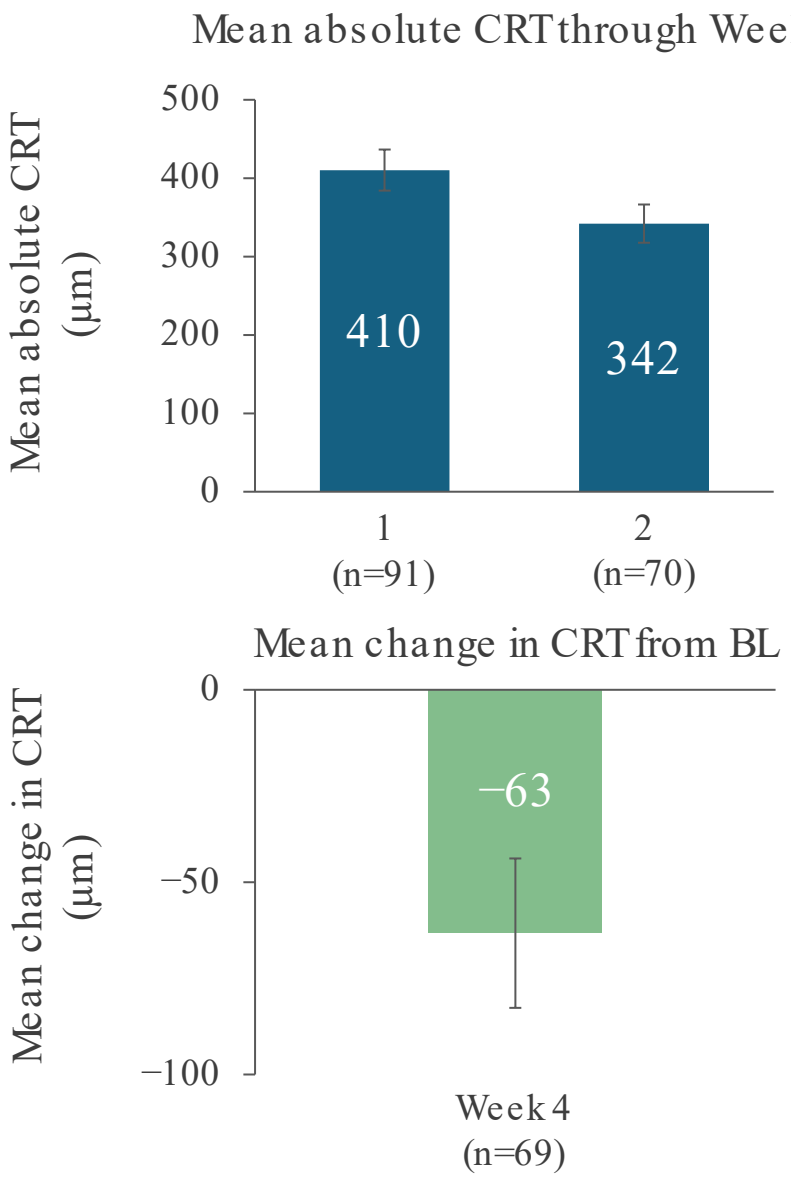
[a]Data are mean±SD unless otherwise indicated. [b]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the UK only.

ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; max, maximum; min, minimum; SD, standard deviation; UK, United Kingdom.

VA through Week 4



CRT through Week 4



FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI. This analysis was based on patients with a VA assessment at Week 4. CI, confidence interval; OC, observed cases.

Baseline characteristics: Treatment-naïve DME

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

Total: 104 patients

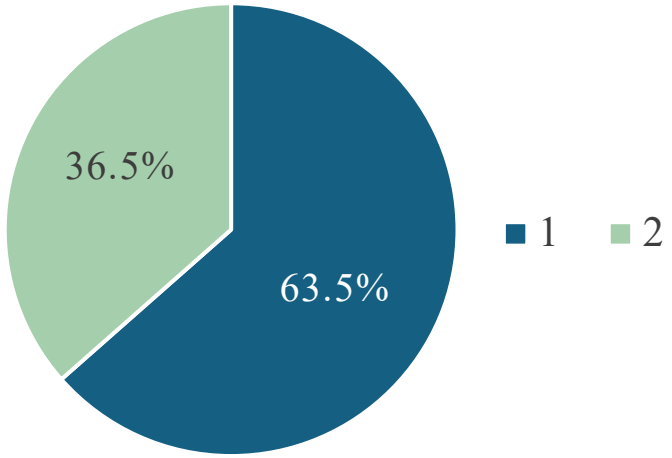
Mean age: 67.1±10.1 years

Median (min, max) time from DME diagnosis: 2.7 (0.0, 93.6) months

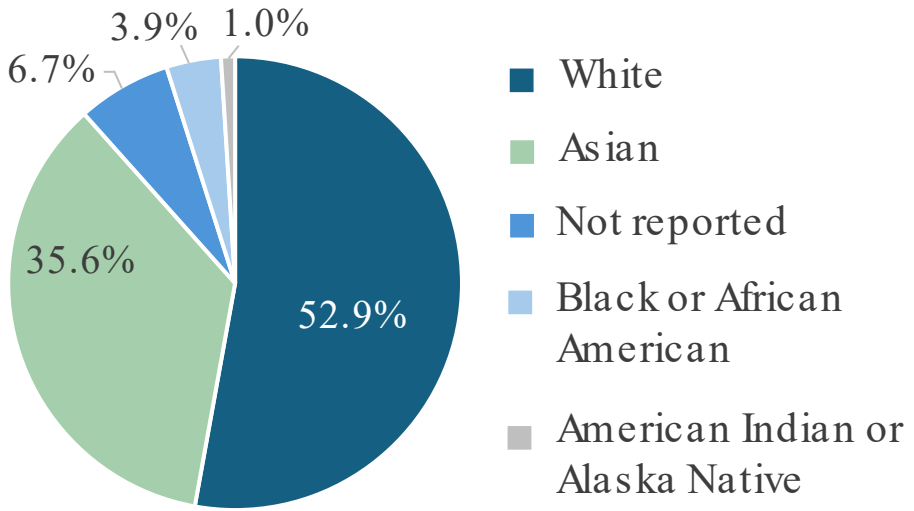
Mean baseline VA: 64.7±16.3 ETDRS letters

Mean baseline CRT: 412±110 µm

Sex



Race[b]



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

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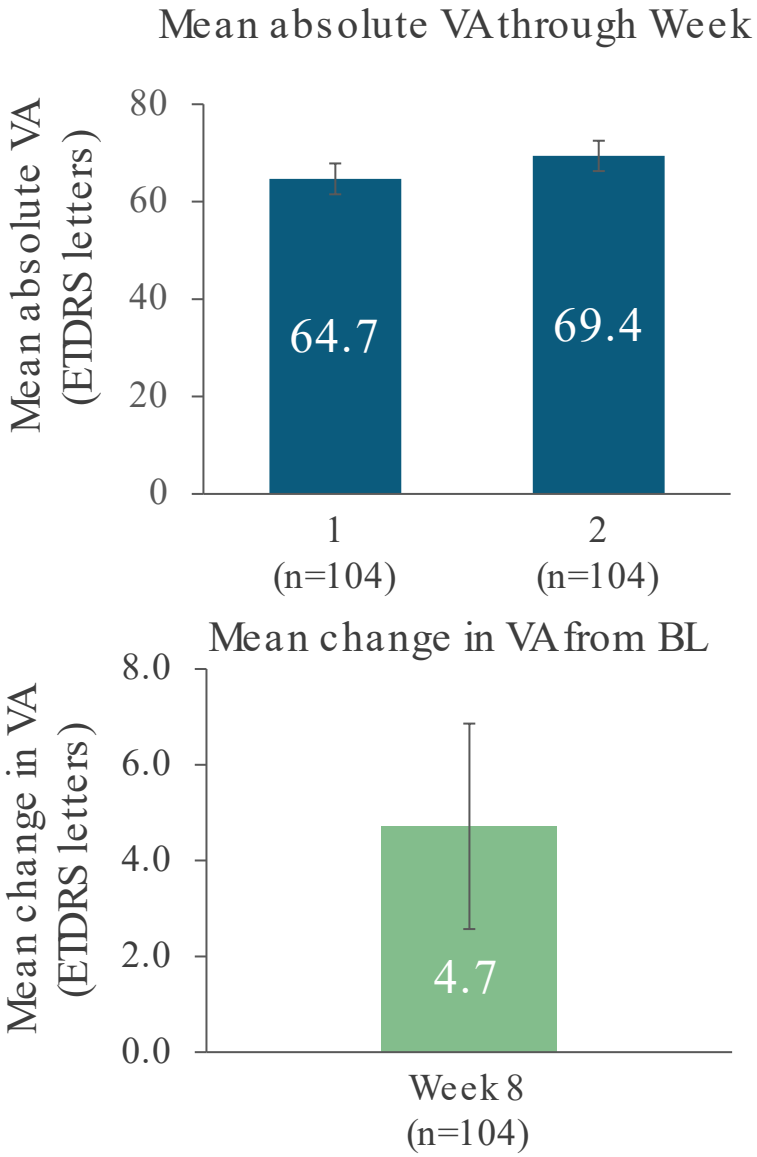
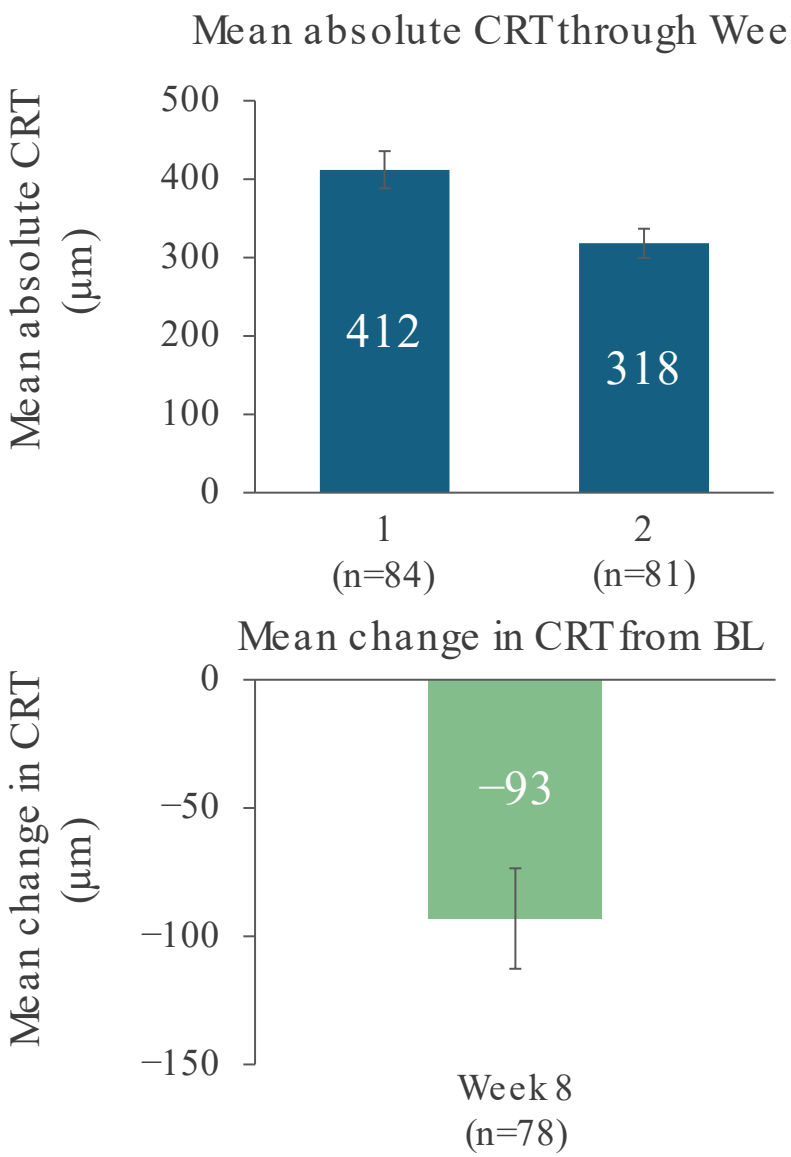
VA through Week 8



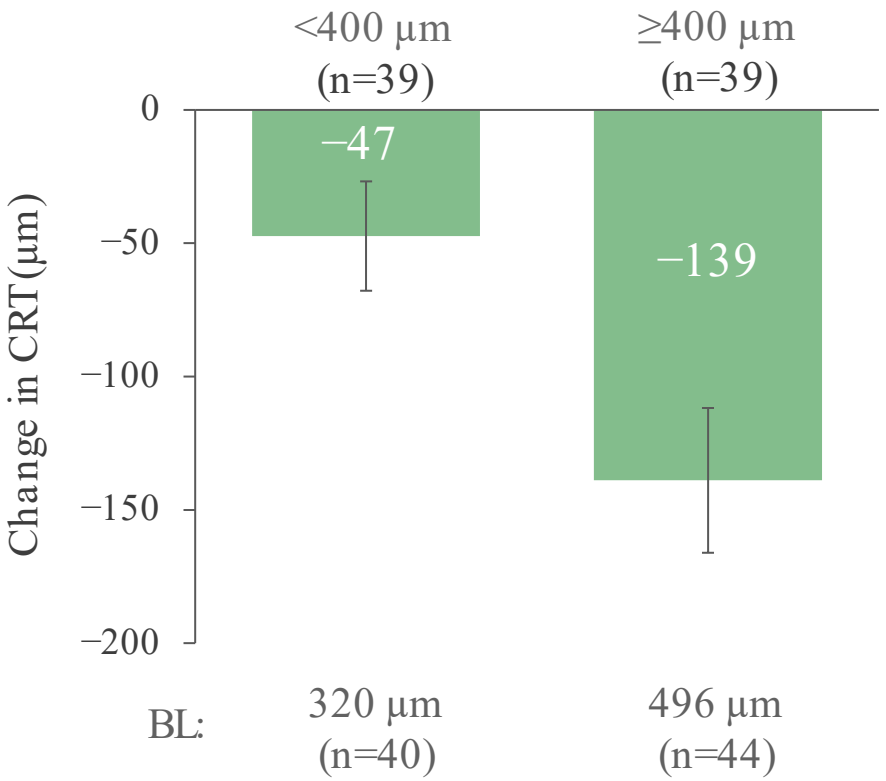
CRT through Week 8



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).

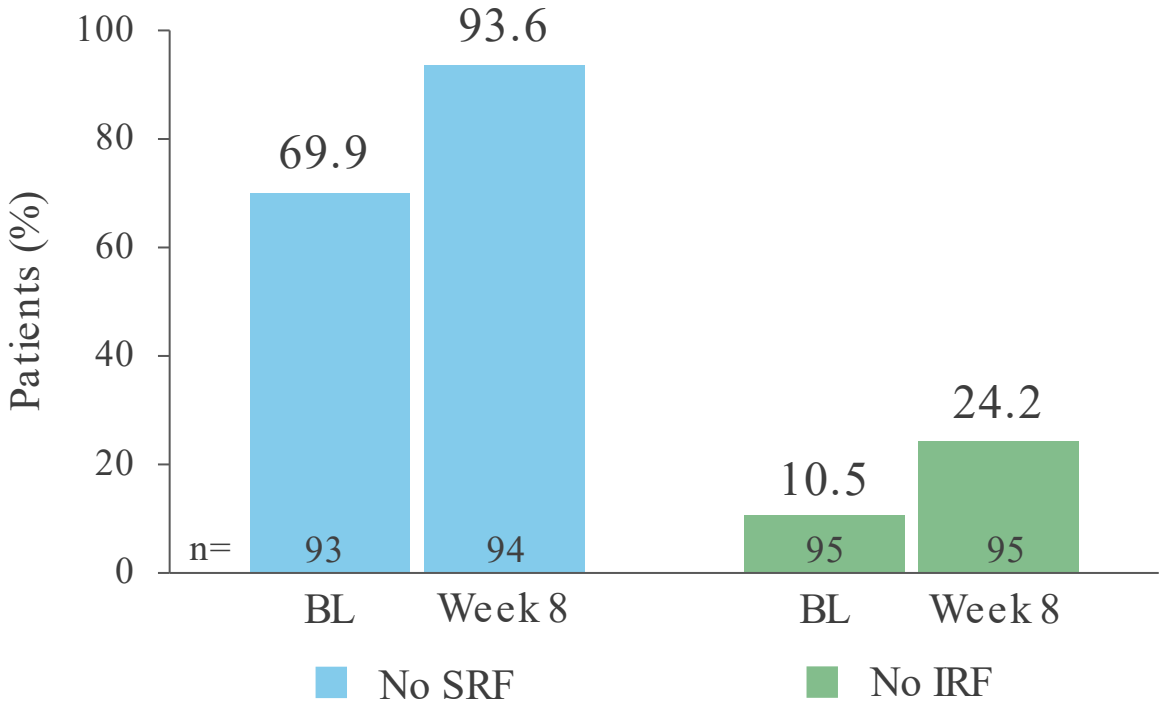
CRT through Week 8

Mean change in CRT grouped by baseline CRT



Proportion of patients without SRF or IRF through Week 8

Patients without SRF or IRF[a]



FAS, OC. Values have been rounded to the nearest decimal point. Error bars are 95% CI. 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 baseline. [a]Calculated based on the number of patients assessed at each timepoint. Based on instructions in the case report form, fluid data were collected during a macular assessment (6 mm) per investigator discretion. IRF, intraretinal fluid; SRF, subretinal fluid.

Safety overview: Adverse events

	Week 4 Total (N=110)	Week 8 Total (N=104)
Ocular TEAEs in the study eye, n (%)[a]	2 (1.8)	2 (1.9)
Serious ocular TEAEs, n (%)	0 (0)	0 (0)
Non-ocular TEAEs, n (%)	1 (0.9)	6 (5.8)
Serious non-ocular TEAEs, n (%)	1 (0.9)	1 (1.0)

No cases of intraocular inflammation or retinal vasculitis were reported

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.

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

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

More than 500 patients enrolled in the treatment-naïve DME cohort across 11 countries to date

Early clinical outcomes at Week 4/Week 8

- Improvements in VA, CRT, and fluid

Safety outcomes at Week 4/Week 8

- No cases of intraocular inflammation or retinal vasculitis were reported
- 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 treatment-naïve DME with aflibercept 8 mg

Presentation of Month 6 data is planned for later in 2025, with Month 12 and Month 24 analyses on track