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

Paolo Lanzetta,[1,2] Hassiba Oubraham,[3] Varun Chaudhary,[4] Marion R. Munk,[5–7] Clare Bailey,[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 Surgery, McMaster University, Hamilton, ON, Canada; [5]Augenarzt Praxisgemeinschaft Gutblick AG, Pfäffikon, Switzerland; [6]Department of Ophthalmology, University Hospital Bern, Bern, Switzerland; [7]Northwestern University, Feinberg School of Medicine, Chicago, IL, USA; [8]Department of Ophthalmology, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK; [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 4DMT, Aerie Pharmaceuticals, Adverum, Allergan, Annexon, Apellis, Bausch + Lomb, Bayer, Biogen, Boehringer Ingelheim, EyePoint Pharmaceuticals, Genentech, I-Care, Novartis, Ocular Therapeutix, Outlook Therapeutics, Roche, and TowardPi
  - **HO**: Consultant for AbbVie, Bayer, Novartis, and Roche. **VC**: Consultant for EyePoint Pharmaceuticals; grants from Bayer, Novartis, and Roche; and serves on advisory boards for Apellis, Bayer, Boehringer Ingelheim, EyePoint Pharmaceuticals, Novartis, and Roche. **MRM**: Consultant for AbbVie, Alcon, Alimera, Allergan, Amgen, Apellis Pharmaceuticals, Astellas, Aviceda Therapuetics, Bayer, Boehringer Ingelheim, Dandelion, Evolve Medical Education, Eyegnos consulting, EyePoint Pharmaceuticals, GenSight Biologics, Isarna Therapeutics, Iveric Bio, Kubota, LumiThera, Novartis, Ocular Therapeutics, Oculis, OcuTerra Therapeutics, OD-OS, ONL Therapeutics, RetinAI, Roche, Sitalis, UBS analytics, and Zeiss. **CB**: Honoraria from Alimera Sciences, Apellis, Bayer, and Roche; and has served on advisory boards for Alimera Sciences, Apellis, Bayer, Boehringer Ingelheim, Janssen, and Roche. **TM**: Employee and stockholder 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 being conducted in **18 countries**

Two indications, four patient cohorts

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

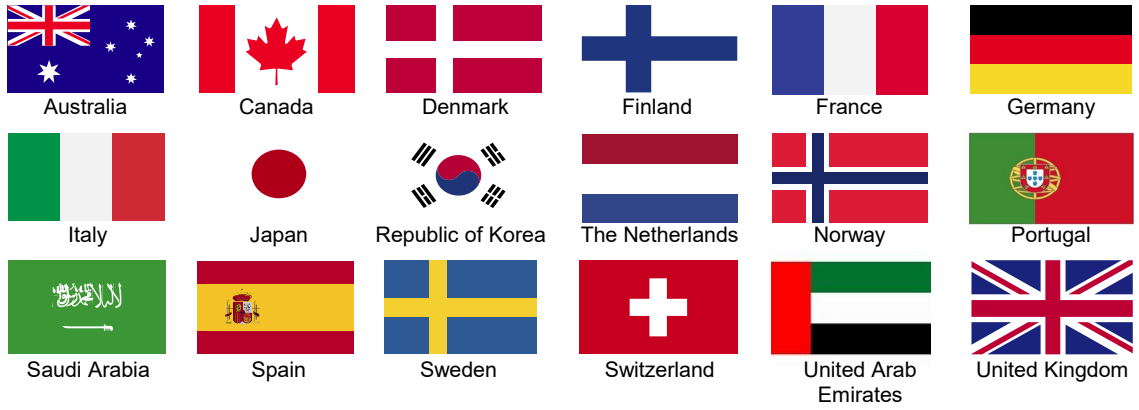
Primary endpoint: Change in **VA** from **BL to Month 12**

Secondary endpoints include:

- Change in **VA** and **CRT** from BL to Week 24
- Number of **injections, visits**, and **safety** from BL to Week 24

Patient enrollment is complete:

3739	**729**	**719**
nAMD + DME	TN DME cohort	PT DME cohort



Week 24 = visits closest to 180 (150–210) days after BL. BL, baseline; CRT, central retinal thickness; DME, diabetic macular edema; nAMD, neovascular age-related macular degeneration; PT, previously treated; TN, treatment-naïve; VA, visual acuity.

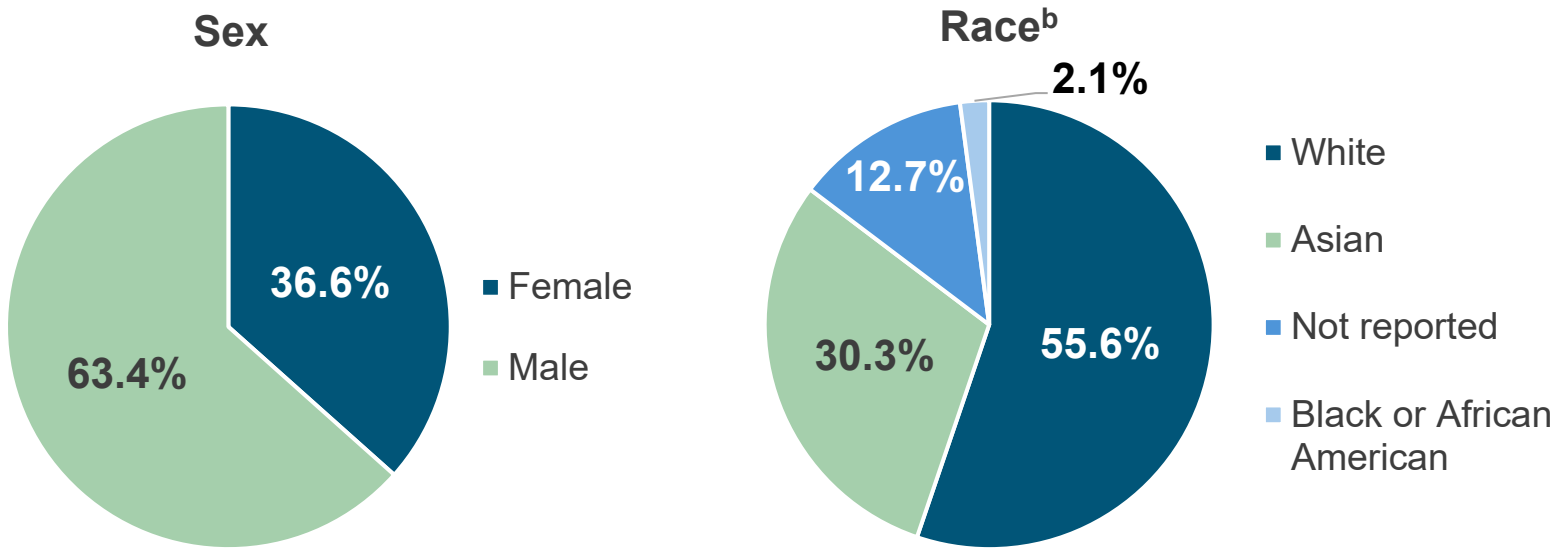
Treatment-naïve DME

Week 24 results in the first ~150 patients enrolled

Baseline characteristics: Treatment-naïve DME

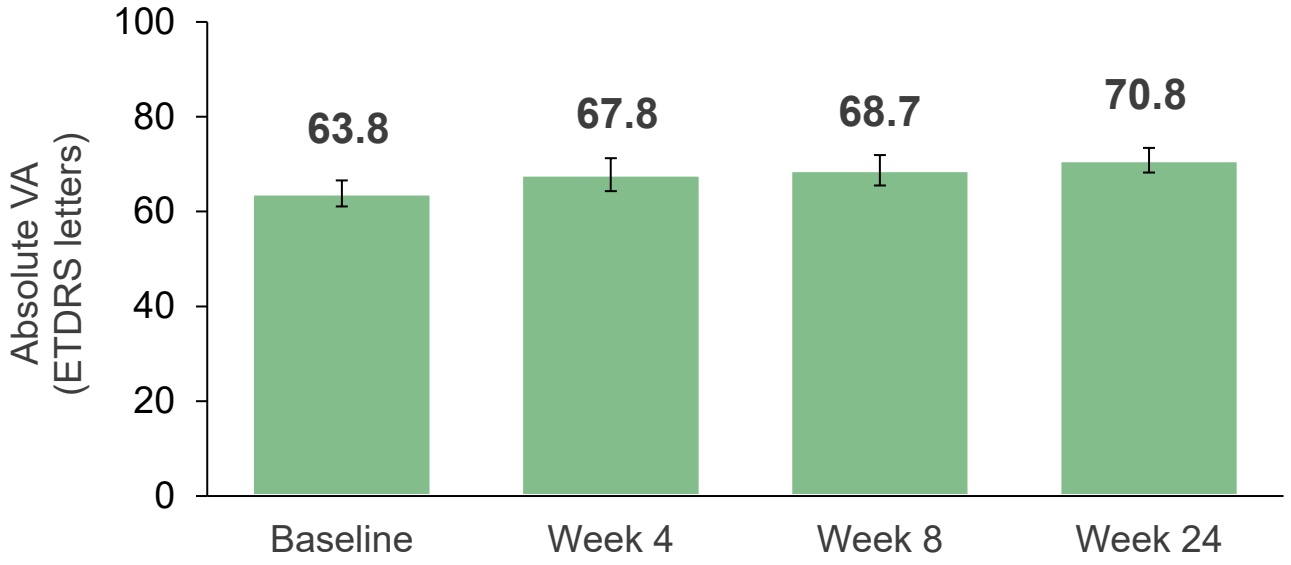
Week 24 analysis of the first ~150 patients enrolled[a]

FAS, n	142
Age, years	66.1±11.5
Median (min, max) time from DME diagnosis, months	0.4 (0.0, 109.2)
Baseline VA, ETDRS letters	63.8±16.6
Baseline CRT, µm	425±114



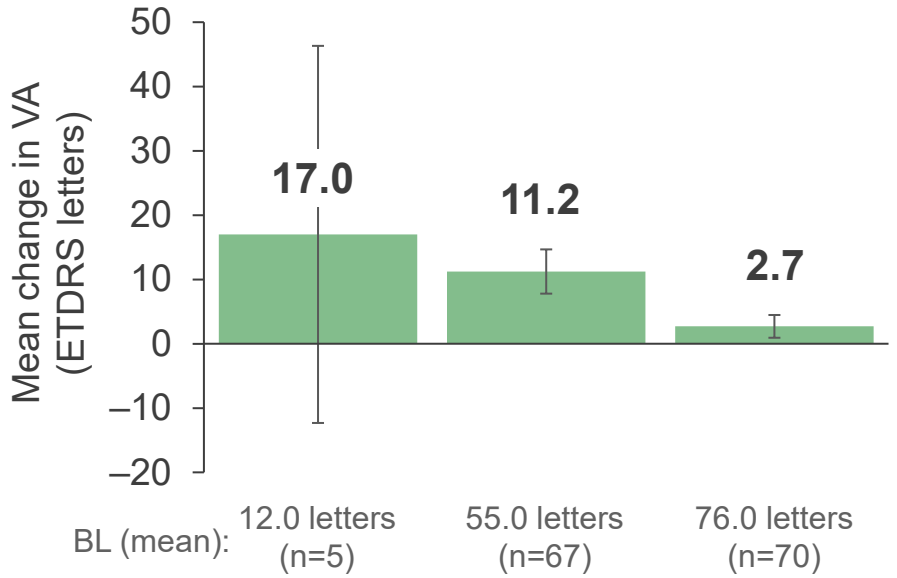
FAS; Week 24 = visits closest to 180 (150–210) days after BL. Percentages may not add up to 100 due to rounding. [a]Data are mean±SD unless otherwise indicated. [b]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the United Kingdom only; multiple answers were possible. ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; Max, maximum; Min, minimum; SD, standard deviation.

VA through Week 24



Timepoint	Mean change (95% CI) from baseline (LOCF)
Week 4	+4.5 (2.5, 6.5)
Week 8	+4.7 (2.5, 6.9)
Week 24	**+7.3 (5.2, 9.4)**

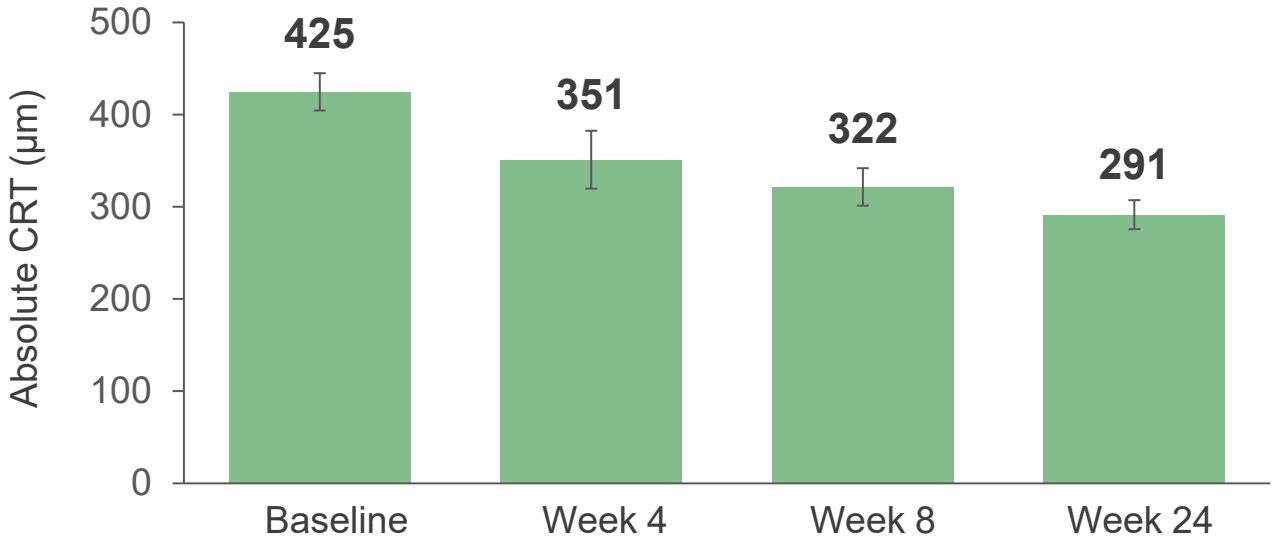
Mean change in VA at Week 24 grouped by baseline VA[a]



Patients received a mean of **4.0 injections** up to **Day 210** from **baseline**

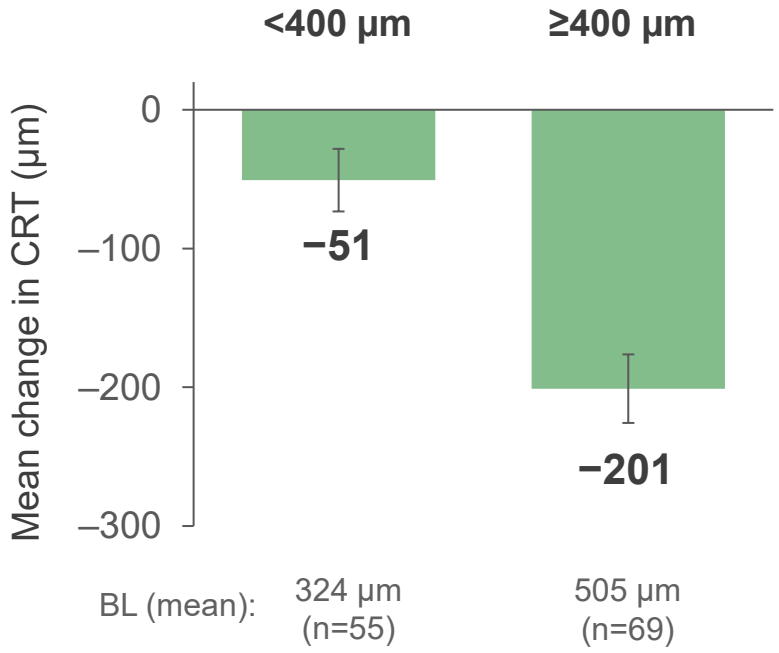
FAS, LOCF (n=142). Missing values were imputed with the LOCF approach. Error bars represent 95% CI. Week 4 = visits closest to 28 (14–42) days after BL, Week 8 = visits closest to 56 (43–70) days after BL, Week 24 = visits closest to 180 (150–210) days after BL. [a]In patients with a VA assessment at Week 4 and Week 8, the mean change in VA at Week 4 and Week 8 grouped by baseline VA was +6.7 and +8.8 letters for those with a baseline VA of <35 letters, +7.2 and +8.1 for those with a baseline VA of 35–69 letters, and +1.6 and +1.4 for those with a baseline VA of ≥70 letters, respectively. CI, confidence interval; LOCF, last observation carried forward.

CRT through Week 24



Timepoint	Mean change (95% CI) from baseline (LOCF)
Week 4	−81 (−104, −57)
Week 8	−103 (−124, −82)
Week 24	**−134 (−156, −113)**

Mean change in CRT at Week 24 grouped by baseline CRT[a]



The proportion of **patients without IRF increased** from a **baseline of 9.7% to 37.6% at Week 24**

FAS, LOCF (n=142). Missing values were imputed using the LOCF approach. Error bars represent 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 grouped by baseline CRT was −35 and −45 µm for those with a baseline CRT of <400, and −113 and −146 µm for those with a baseline CRT of ≥400 µm, respectively. IRF, intraretinal fluid.

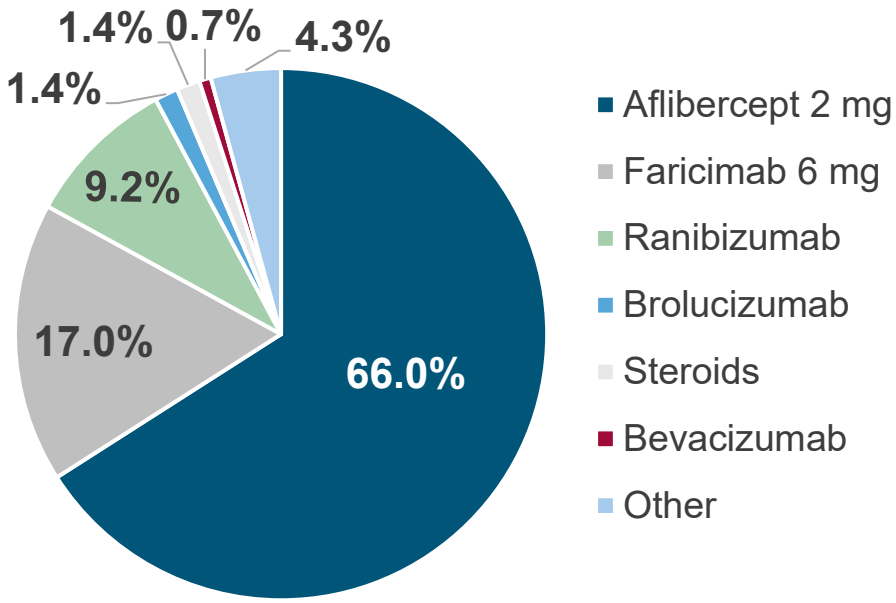
Previously treated DME

Week 24 results in the first ~150 patients enrolled

Baseline characteristics: Previously treated DME

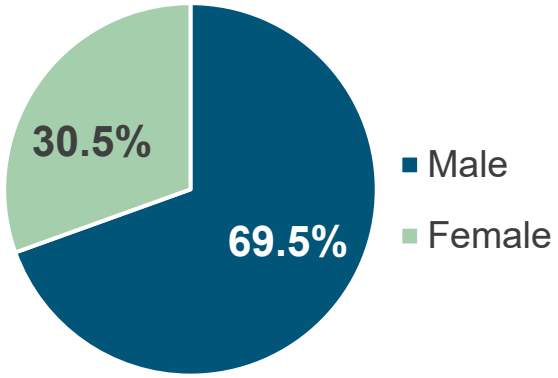
Week 24 analysis of the first ~150 patients enrolled[a]

Previous DME medication

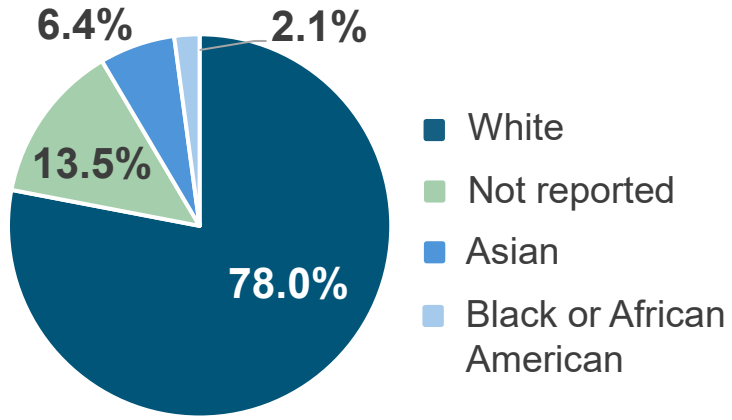


FAS, n	141
Age, years	65.3±11.0
Median (min, max) time from DME diagnosis, months	46.9 (2.1, 411.1)
Baseline VA, ETDRS letters	70.0±14.1
Baseline CRT, µm	364±136

Sex

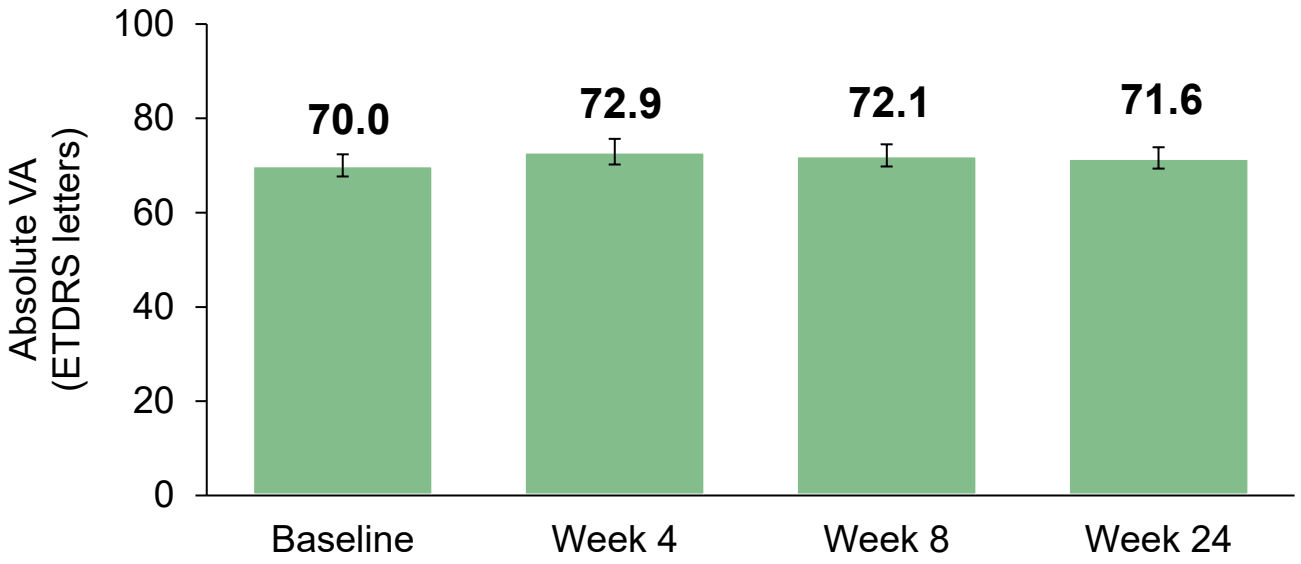


Race[b]

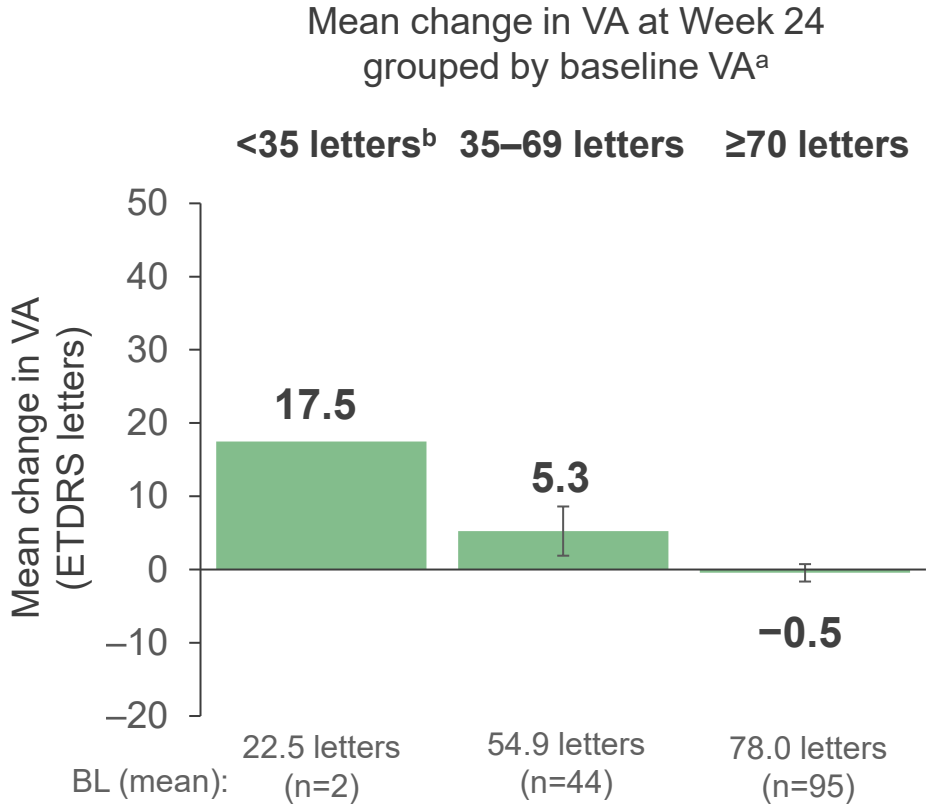


FAS. Percentages may not add up to 100 due to rounding. [a]Data are mean±SD unless otherwise indicated. [b]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the United Kingdom only; multiple answers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

VA through Week 24



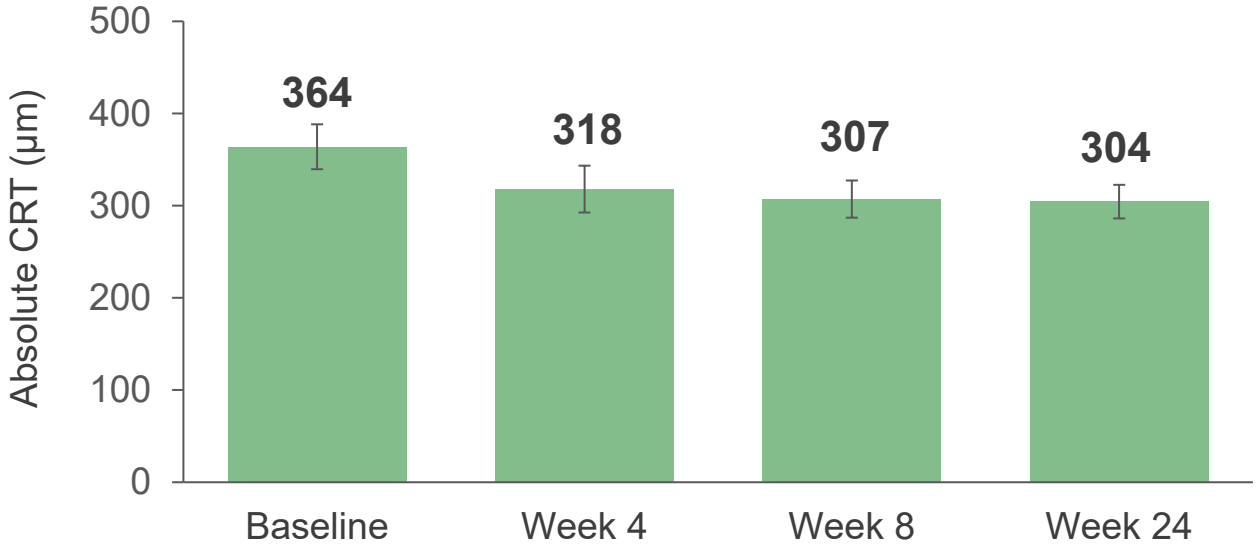
Timepoint	Mean change (95% CI) from baseline (LOCF)
Week 4	+2.0 (0.1, 4.0)
Week 8	+2.0 (0.6, 3.5)
Week 24	**+1.6 (0.1, 3.1)**



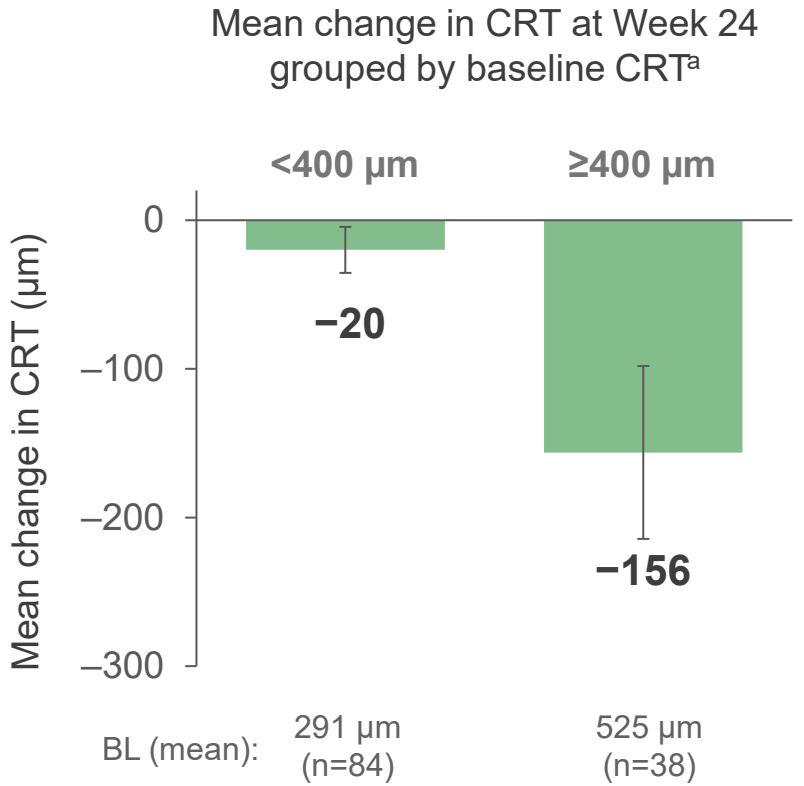
Patients received a mean of **4.3 injections** up to **Day 210** from **baseline**

FAS, LOCF (n=141). Missing values were imputed using the LOCF approach. Error bars represent 95% CI. [a]In patients with a VA assessment at Week 4 and Week 8, the mean change in VA at Week 4 and Week 8 grouped by baseline VA was +35.0 and +10.0 letters for those with a baseline VA of <35 letters, +5.2 and 6.2 letters for those with a baseline VA of 35–69 letters, and +0.1 and –0.1 letters for those with a baseline of ≥70 letters, respectively. [b]Error bar for the <35 letters subgroup is not shown as there were ≤2 patients in this subgroup.

CRT through Week 24



Timepoint	Mean change (95% CI) from baseline (LOCF)
Week 4	−73 (−113, −32)
Week 8	−76 (−108, −44)
Week 24	**−63 (−87, −39)**



The proportion of **patients without IRF increased** from a **baseline of 10.5% to 15.4% at Week 24**

FAS, LOCF (n=141). Missing values were imputed using the LOCF approach. Error bars represent 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 grouped by baseline CRT was −24 and −19 µm for those with a baseline CRT of <400, and −172 µm for those with a baseline CRT of ≥400 µm, respectively.

Safety overview: Adverse events[a]

Ocular TEAEs in the study eye[b], n (%)	TN DME (N=150)	PT DME (N=150)
Any ocular TEAEs	11 (7.3)	18 (12.0)
Any serious ocular TEAEs	1 (0.7)	3 (2.0)
Non-ocular TEAEs, n (%)		
Any non-ocular TEAEs	16 (10.7)	15 (10.0)
Any serious non-ocular TEAEs	3 (2.0)	3 (2.0)

No cases of retinal vasculitis were reported

SAF. [a]These safety data have been updated as per the final safety tables generated for this SPECTRUM Week 24 analysis. [b]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 at the discretion of the attending physician. SAF, safety analysis set; TEAE, treatment-emergent adverse event.

Week 24 results from SPECTRUM support the real-world effectiveness and safety of aflibercept 8 mg in patients with treatment-naïve and previously treated DME

More than **3700** patients enrolled in SPECTRUM across **18 countries** and **enrollement is now complete**

More than **700** patients enrolled in each of the **treatment-naïve and previously treated DME cohorts** across **12 countries**

Clinical and safety outcomes at Week 24 in the global treatment-naïve DME cohort

- Improved VA and CRT from baseline
- Results achieved with a mean of 4.0 injections up to Day 210
- No new safety signals

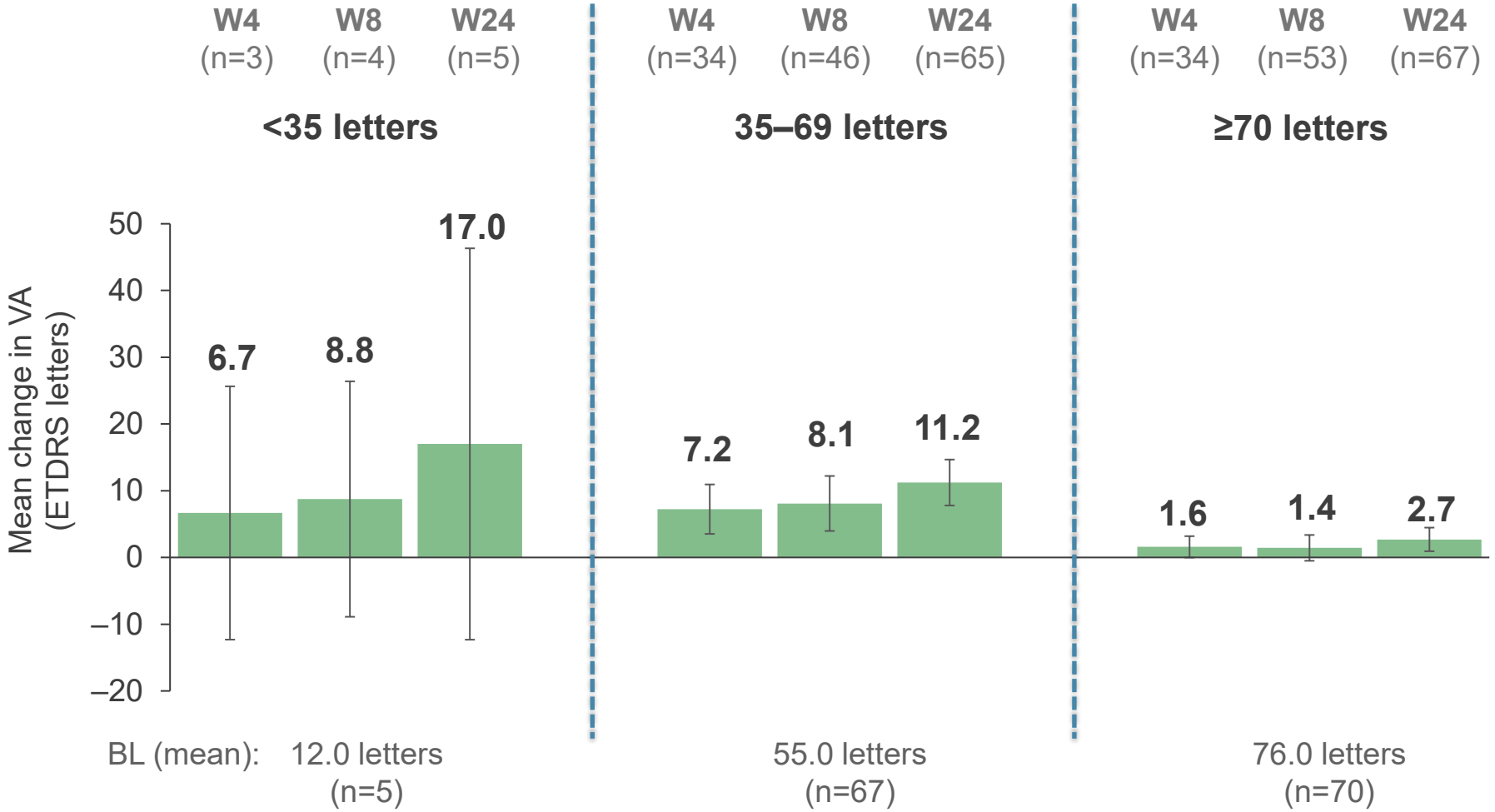
Clinical and safety outcomes at Week 24 in the global previously treated DME cohort

- Stable VA and improved CRT following switch to aflibercept 8 mg
- Results achieved with a mean of 4.3 injections up to Day 210
- No new safety signals

As the **first global real-world study of aflibercept 8 mg**, Week 24 results from SPECTRUM will help to **inform clinical management** of treatment-naïve and previously treated DME in patients receiving aflibercept 8 mg

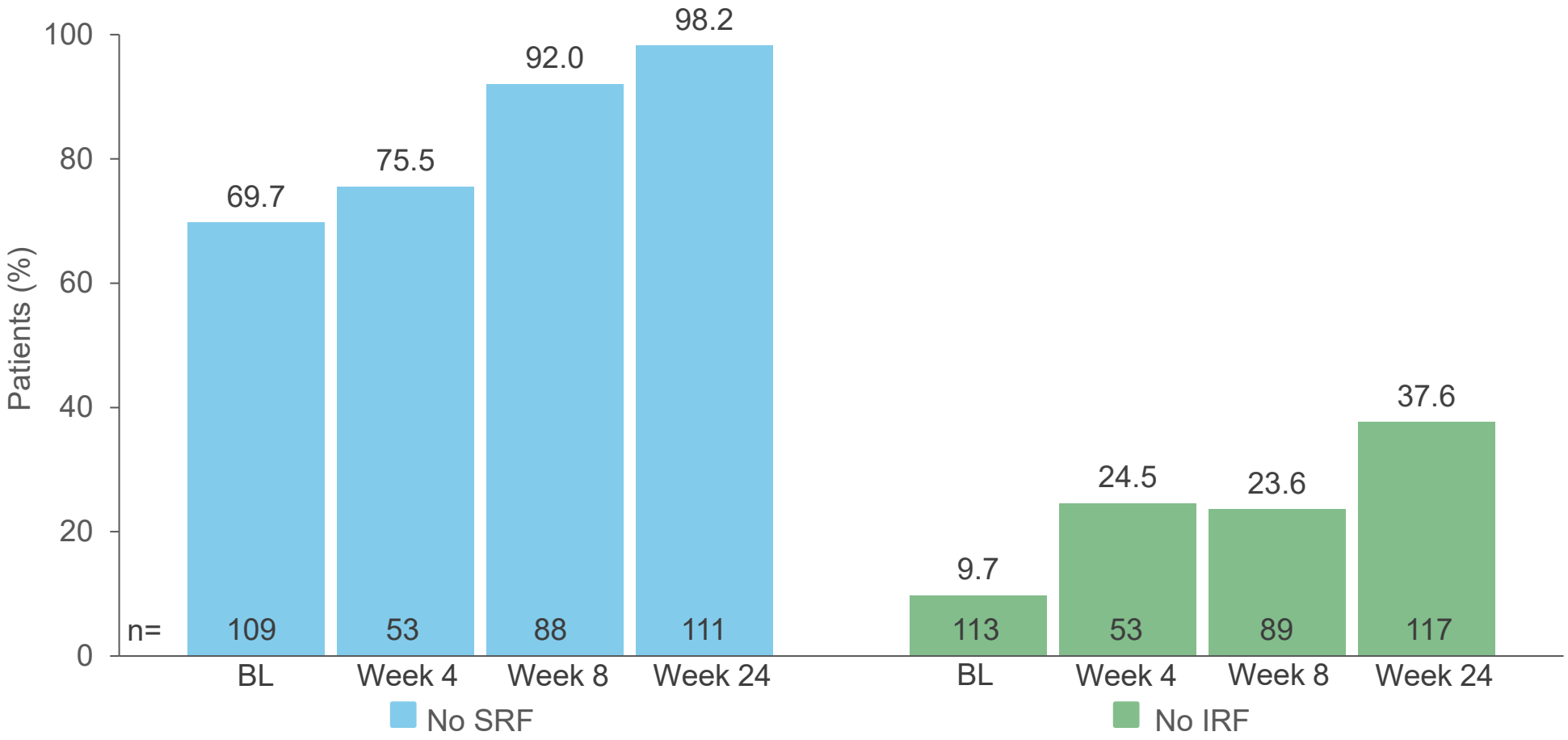
Month 12 and Month 24 analyses are ongoing

Mean change in VA through Week 24 grouped by baseline VA



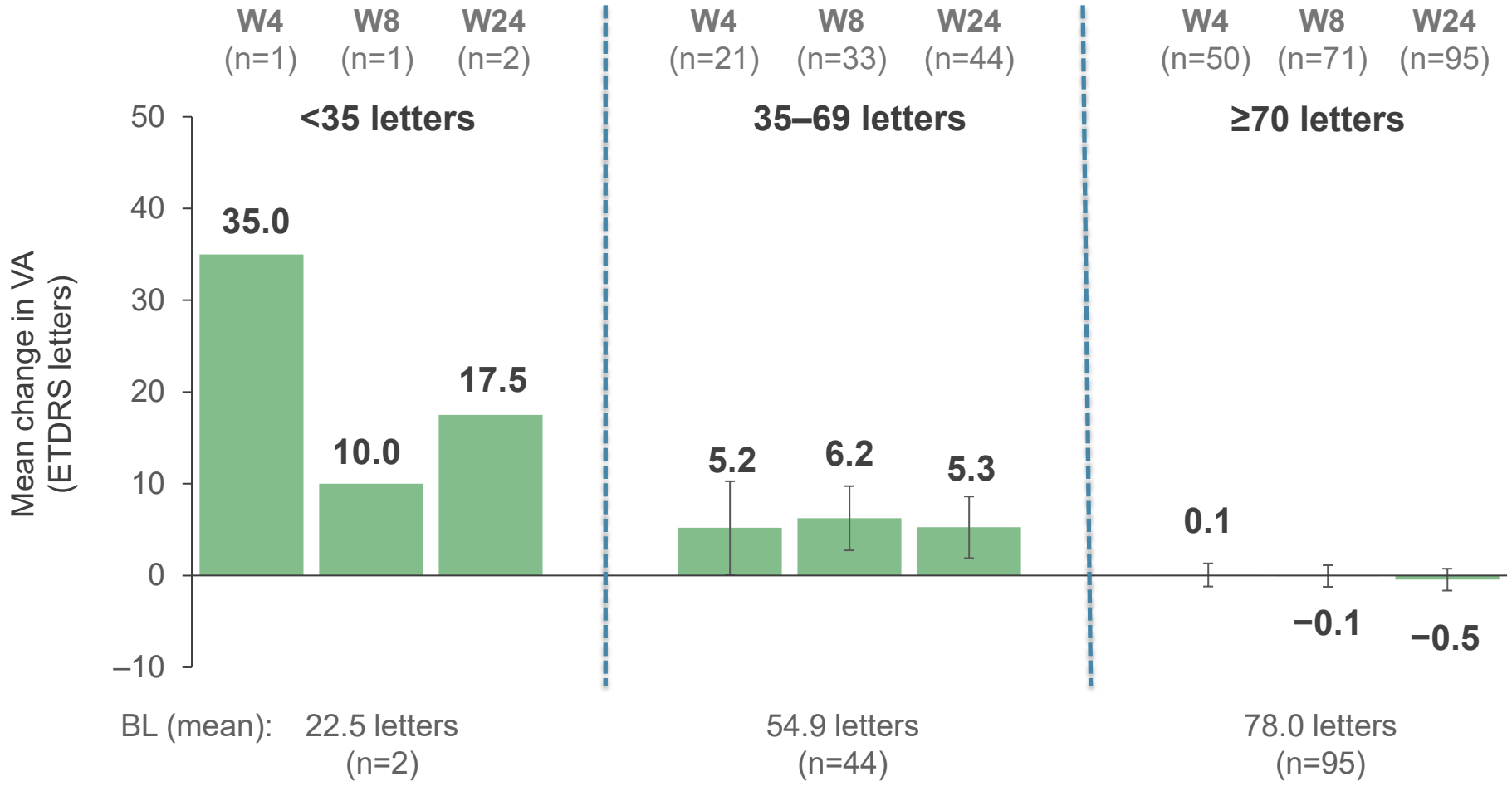
FAS, LOCF. Error bars represent 95% CI. W, Week.

Proportion of patients without SRF or IRF through week 24[a]



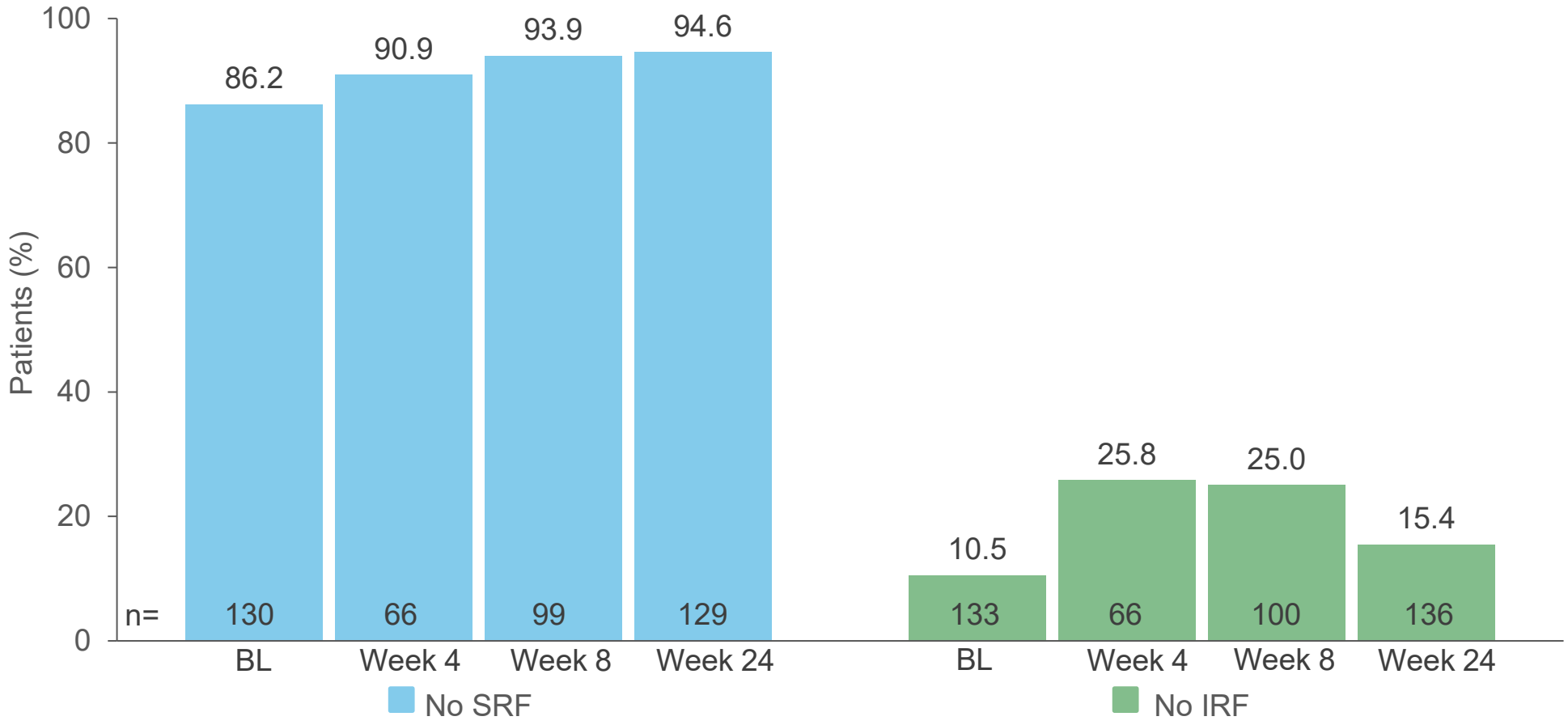
FAS, LOCF. Missing values were imputed using the LOCF approach. Based on instructions in the case report form, fluid data were collected during a macular assessment (6 mm) per the investigator discretion.
[a]Calculated based on the number of patients assessed at each timepoint. IRF, intraretinal fluid;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

Mean change in VA through Week 24 grouped by baseline VA



FAS, LOCF. Error bars represent 95% CI. [a]Error bars for the <35-letter subgroups are not shown as there were ≤2 patients in these subgroups.

Proportion of patients without SRF or IRF through Week 24[a]



FAS, LOCF. Missing values were imputed using the LOCF approach. Based on instructions in the case report form, fluid data were collected during a macular assessment (6 mm) per the investigator discretion.
[a]Calculated based on the number of patients assessed at each timepoint.