SPECTRUM, 6-month data from a global real-world study of aflibercept 8 mg in neovascular age-related macular degeneration

Marion R. Munk,[1,2,3] Clare Bailey,[4] Clemens Lange,[5,6] Varun Chaudhary,[7] Paolo Lanzetta,[8,9] Hassiba Oubraham,[10] Martin Kirchner,[11] Tobias Machewitz,[12] Helmut Allmeier,[13] Xin Zhang,[13] Zoran Hasanbasic,[13] on behalf of the SPECTRUM study investigators

[1]Augenarzt Praxisgemeinschaft Gutblick AG, Pfäffikon, Switzerland; [2]Department of Ophthalmology, University Hospital Bern, Bern, Switzerland; [3]Northwestern University, Feinberg School of Medicine, Chicago, IL, USA; [4]Department of Ophthalmology, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK; [5]Eye Center, Faculty of Medicine, Albert-Ludwig University Freiburg, Freiburg, Germany; [6]Department of Ophthalmology, St Franziskus Hospital, Münster, Germany; [7]Department of Surgery, McMaster University, Hamilton, ON, Canada; [8]Department of Medicine – Ophthalmology, University of Udine, Udine, Italy; [9]Istituto Europeo di Microchirurgia Oculare (IEMO), Udine, Italy; [10]Centre OPHTA-45, Montargis, France; [11]Bayer AG, Leverkusen, Germany; [12]Bayer AG, Berlin, Germany; [13]Bayer Consumer Care AG, Basel, Switzerland

Presented at the 13th FLORetina ICOOR Meeting, Florence, Italy, December 4–7, 2025

Disclosures

- **Marion R. Munk**: Consulting fees for AbbVie, Alcon, Alimera, Allergan, Amgen, Apellis Pharmaceuticals, Astellas, Aviceda Therapeutics, Bayer, Boehringer Ingelheim, Dandelione, Evolve Medical Education, eye.gnos 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**: Received honoraria from Alimera Sciences, Apellis, Bayer, and Roche; and has served on advisory boards for Alimera Sciences, Apellis, Bayer, Boehringer Ingelheim, Janssen, and Roche. **CL**: Receives honoraria from Apellis, Bayer, Biogen, and Novartis. **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. **PL**: Consulting fees from 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**: Consulting fees from AbbVie, Bayer, Novartis, and Roche. **MK** and **TM**: Employees of Bayer AG. **HA**, **XZ**, and **ZH**: Employees of Bayer Consumer Care AG
- The SPECTRUM study (NCT06075147) was sponsored by Bayer Consumer Care AG, Basel, Switzerland
- The sponsor participated in the design and conduct of the study, analysis of the data, and preparation of this presentation
- The data were originally presented at the 25th European Society of Retina Specialists Congress in Paris, France, September 4–7, 2025
- Medical writing support, under the direction of the authors, was provided by ApotheCom and funded by Bayer Consumer Care AG (Basel, Switzerland), in accordance with Good Publication Practice (GPP) guidance (*Ann Intern Med.* 2022;175:1298–1304)

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

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

Patient enrollment is complete:

3739	**1167**	**1124**
nAMD + DME	TN nAMD cohort	PT nAMD cohort

Secondary endpoints include:

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

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

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 nAMD

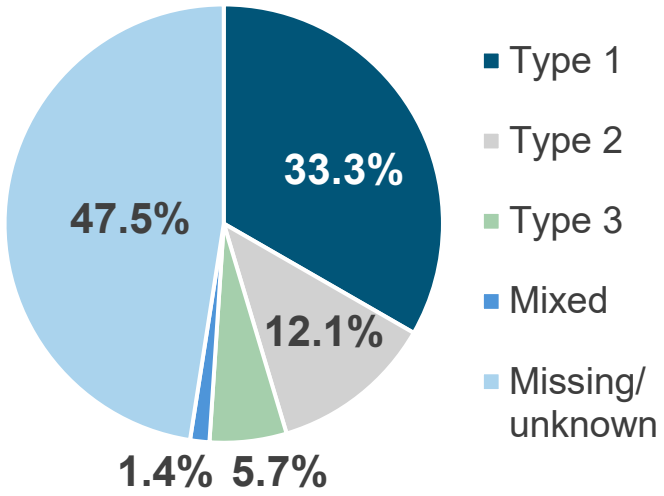
Week 24 results in the first ~150 patients enrolled

Baseline characteristics: Treatment-naïve nAMD

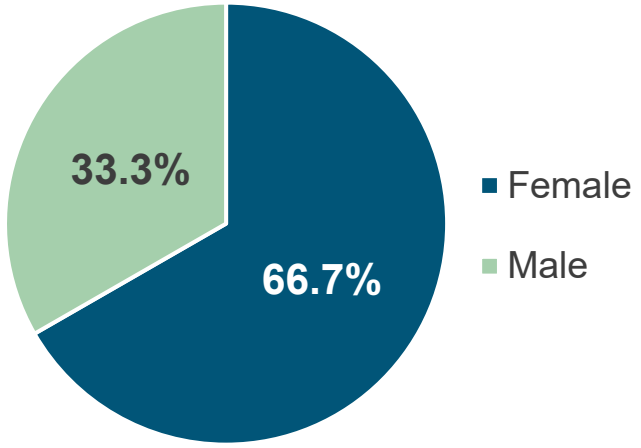
Week 24 analysis of the first ~150 patients enrolled[a]

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

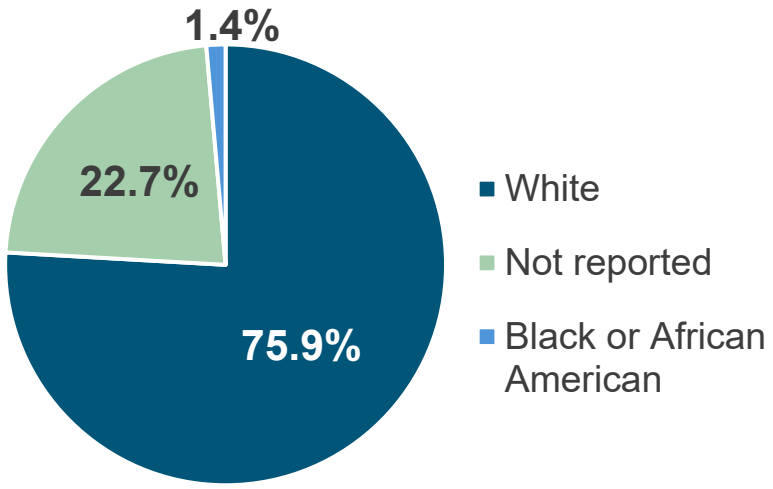
MNV type[b]



Sex

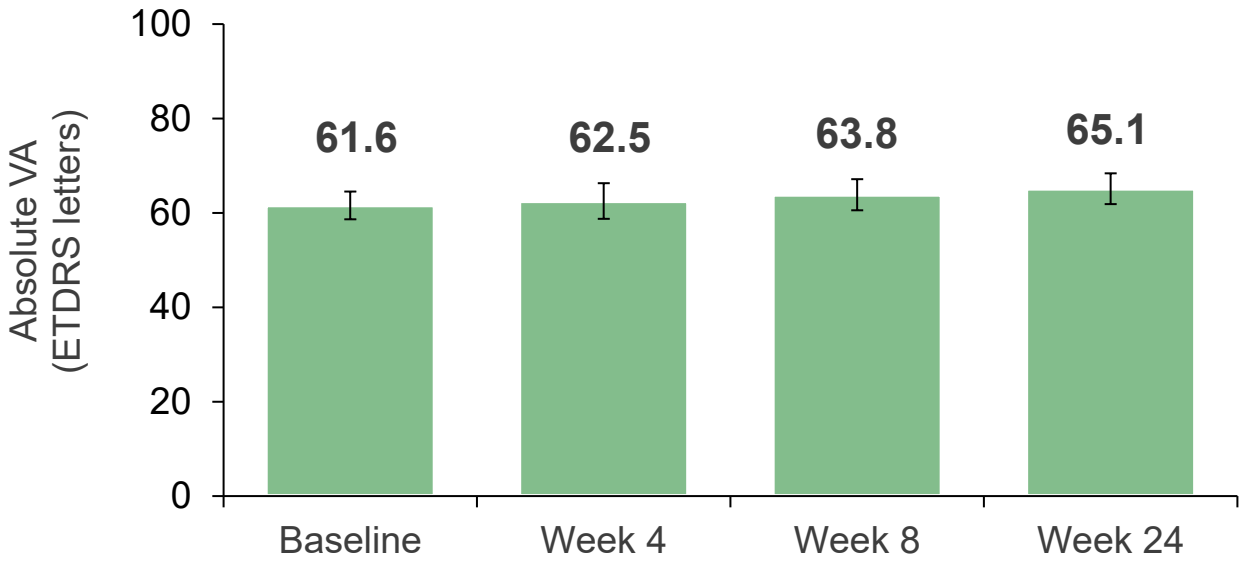


Race[c]



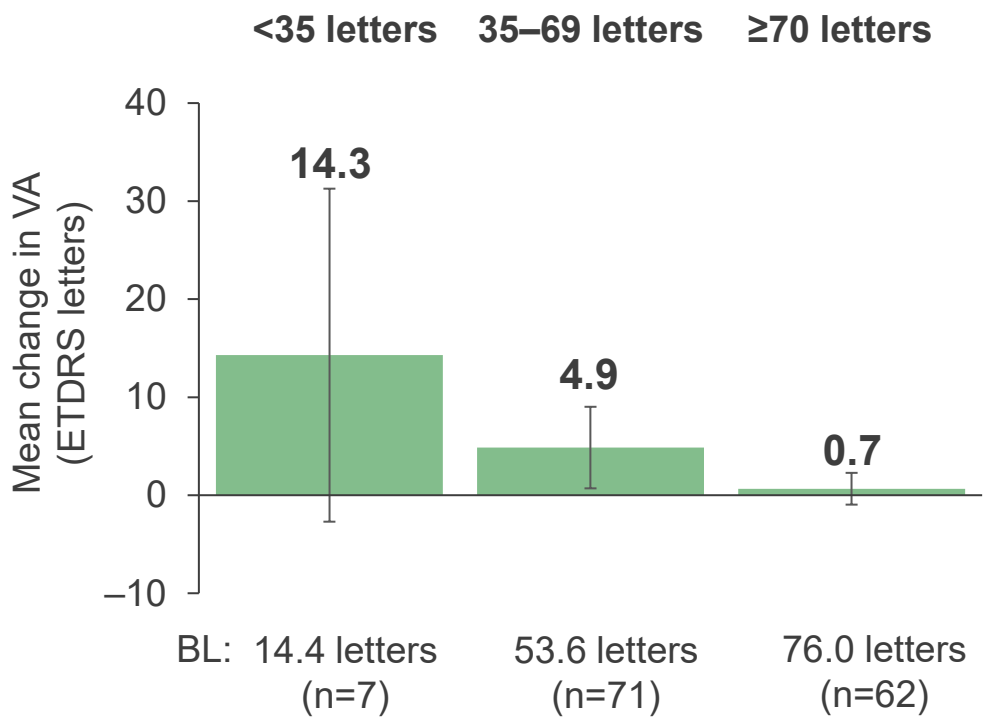
FAS. Week 24 = visits closest to 180 (150–210) days after BL. Percentages may not add up to 100 due to rounding. [a]Data are mean±SD unless otherwise indicated. [b]Mixed refers to Type 1 and Type 2 MNV combined. [c]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the United Kingdom only. ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set; Max, maximum; Min, minimum; MNV, macular neovascularization; SD, standard deviation.

VA through Week 24



Timepoint	Mean change (95% CI) from baseline (LOCF)
Week 4	1.8 (−0.3, 3.8)
Week 8	2.6 (0.8, 4.5)
Week 24	**3.5 (1.1, 5.8)**

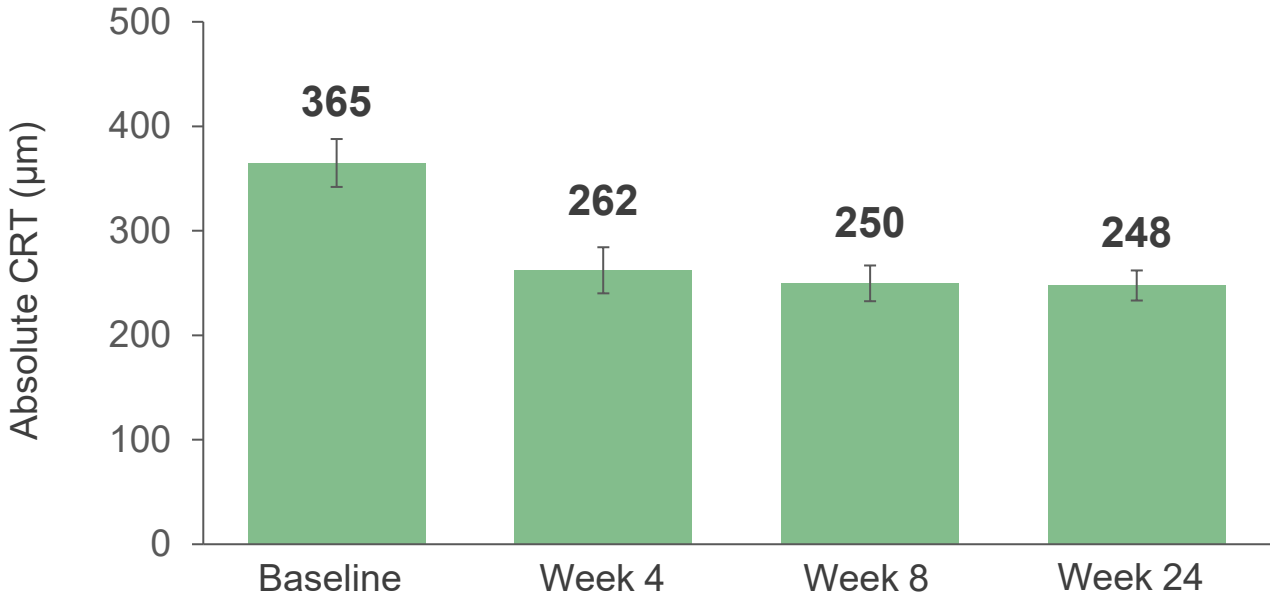
Mean change in VA at Week 24 grouped by baseline VA[a]



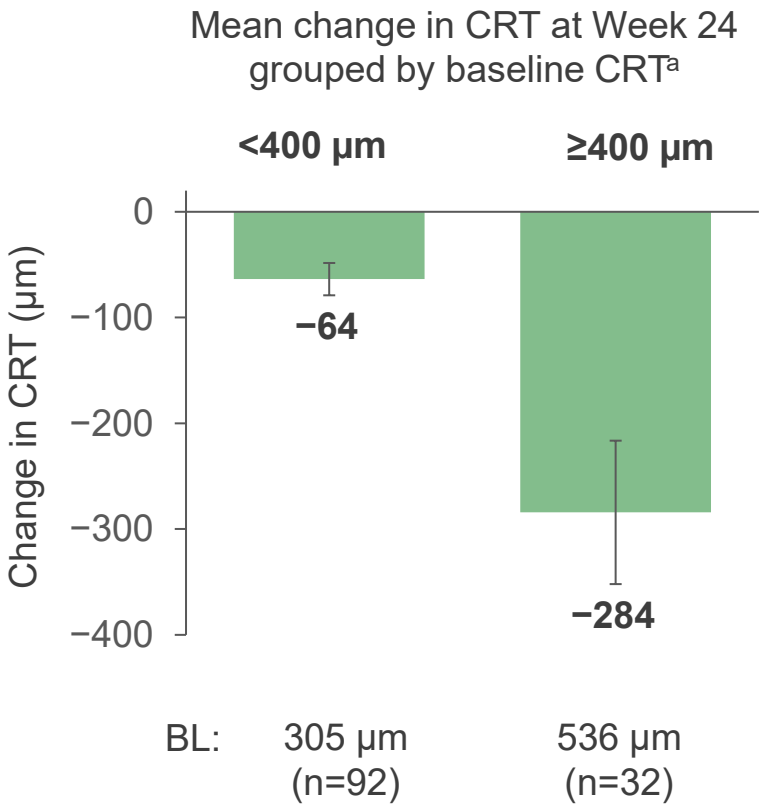
Patients received a mean of **4.7 injections** up to **Day 210** from **baseline**

FAS, LOCF (n=141). Missing values were imputed using 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 +15.0 and +15.8 letters for those with a baseline VA of <35 letters, +2.4 and +3.7 letters for those with a baseline VA of 35–69 letters, and −0.5 and 0.0 letters 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	−132 (−166, −98)
Week 8	−133 (−160, −106)
Week 24	**−119 (−146, −92)**



The proportion of **patients without IRF increased** from a **baseline of 44.7% to 68.4% 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 −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.
IRF, intraretinal fluid.

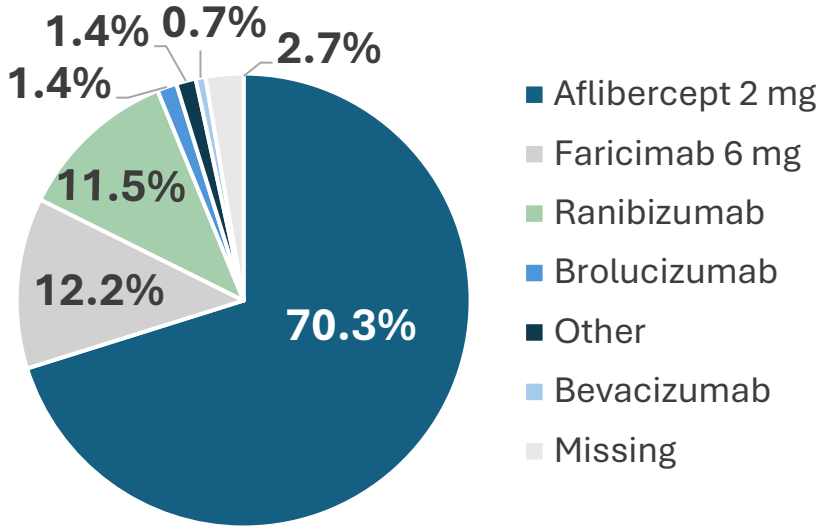
Previously treated nAMD

Week 24 results in the first ~150 patients enrolled

Baseline characteristics: Previously treated nAMD

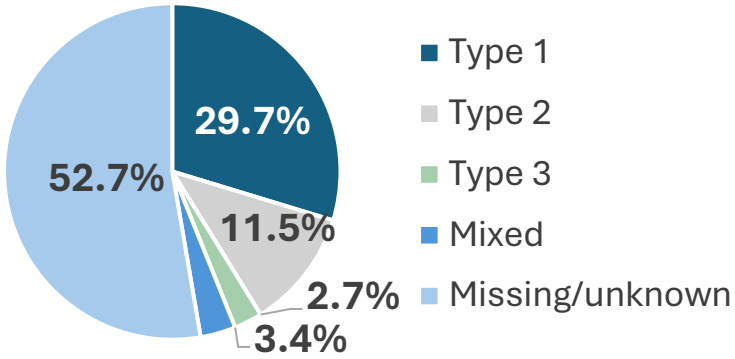
Week 24 analysis of the first ~150 patients enrolled[a]

Previous nAMD medication

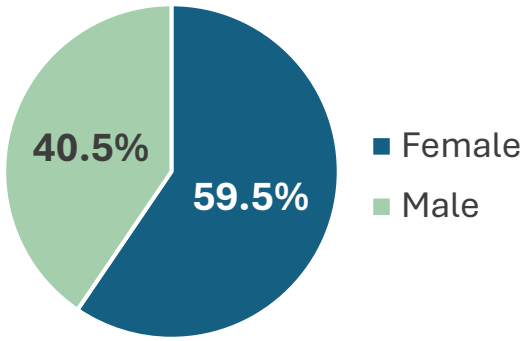


FAS, n	148
Age, years	79.4±8.4
Median (min, max) time from nAMD diagnosis, months	34.2 (1.3, 210.3)
Baseline VA, ETDRS letters	63.0±19.3
Baseline CRT, µm	320±109

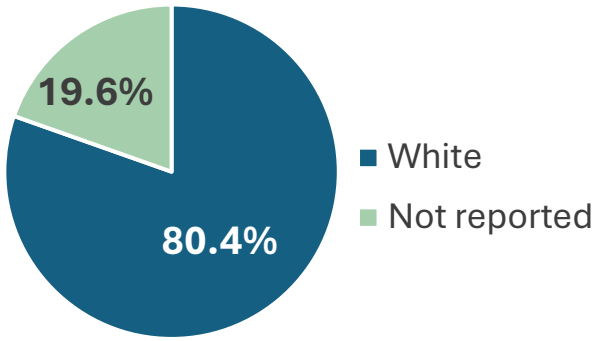
MNV type[b]



Sex

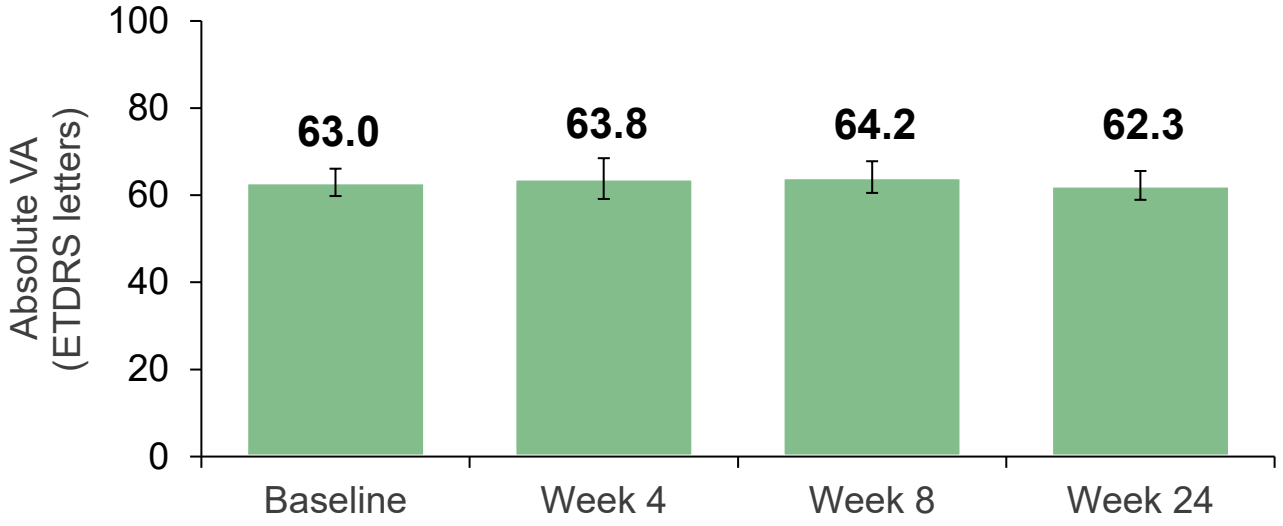


Race[c]



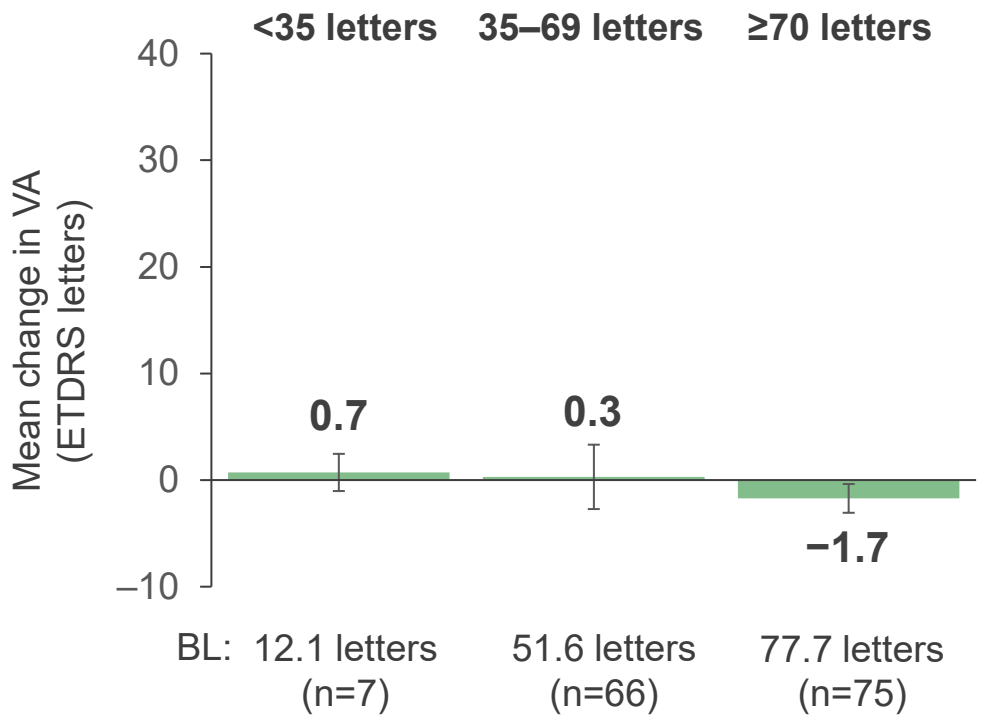
FAS. Percentages may not add up to 100 due to rounding. [a]Data are mean±SD unless otherwise indicated. [b]Mixed refers to Type 1 and Type 2 MNV combined. [c]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the United Kingdom only.

VA through Week 24



Timepoint	Mean change (95% CI) from baseline (LOCF)
Week 4	1.2 (−0.7, 3.1)
Week 8	0.7 (0.8, 2.1)
Week 24	**−0.7 (−2.2, 0.8)**

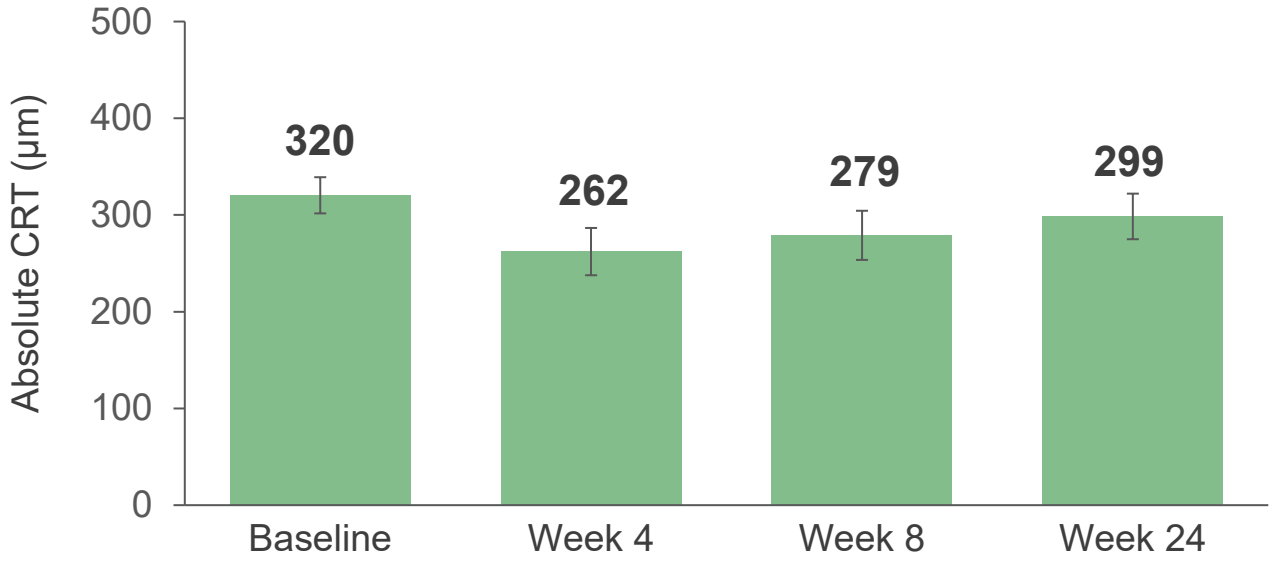
Mean change in VA at Week 24 grouped by baseline VA[a]



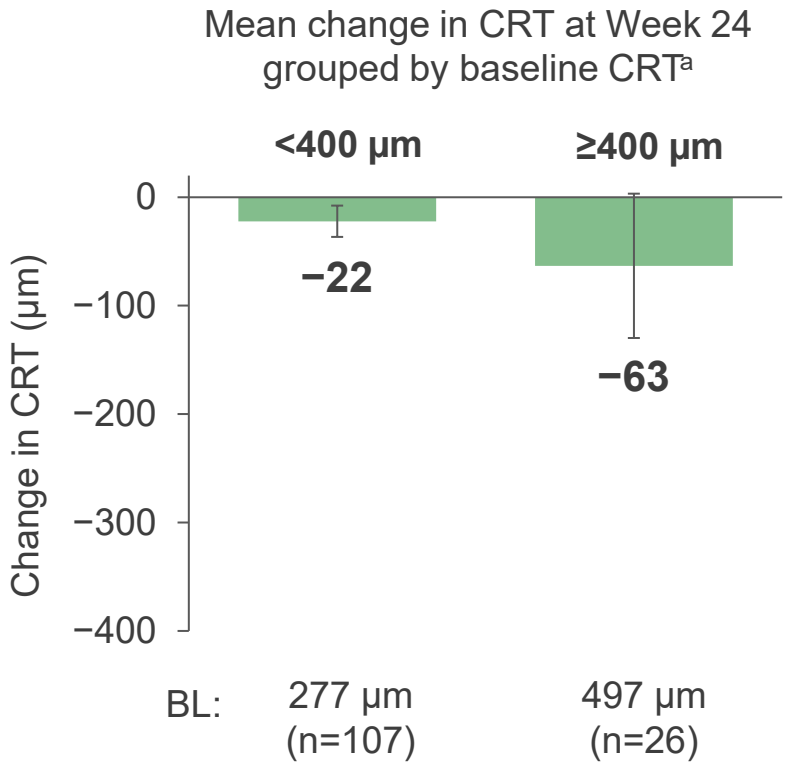
Patients received a mean of **4.4 injections** up to **Day 210** from **baseline**

FAS, LOCF (n=148). Missing values were imputed using 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 +4.0 and +1.0 letters for those with a baseline VA of <35 letters, +2.6 and +1.8 letters for those with a baseline VA of 35–69 letters, and −0.5 and −0.4 letters for those with a baseline VA of ≥70 letters, respectively.

CRT through Week 24



Timepoint	Mean change (95% CI) from baseline (LOCF)
Week 4	−48 (−77, −20)
Week 8	−41 (−63, −18)
Week 24	**−31 (−50, −13)**



The proportion of **patients without IRF increased** from a **baseline of 44.5% to 61.3% at Week 24**

FAS, LOCF (n=148). 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 −21 and −27 µm for those with a baseline CRT of <400, and −153 and −92 µm for those with a baseline CRT of ≥400 µm, respectively.

Safety overview: Adverse events

Ocular TEAEs, n (%)	TN nAMD (N=150)	PT nAMD (N=150)
Any ocular TEAEs in the study eye[a]	22 (14.7)	21 (14.0)
Any serious ocular TEAEs	3 (2.0)	3 (2.0)
Non-ocular TEAEs, n (%)		
Any non-ocular TEAEs	9 (6.0)	6 (4.0)
Any serious non-ocular TEAEs	3 (2.0)	2 (1.3)

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 at the attending physician's discretion.
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 nAMD

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

More than **1100** patients enrolled in each of the global **treatment-naïve and previously treated nAMD cohorts** across **16 countries**

Clinical and safety outcomes at Week 24 in the global treatment-naive nAMD cohort

- Improved VA and CRT from baseline
- Reductions in IRF
- Results achieved with a mean of 4.7 injections up to Day 210
- No new safety signals

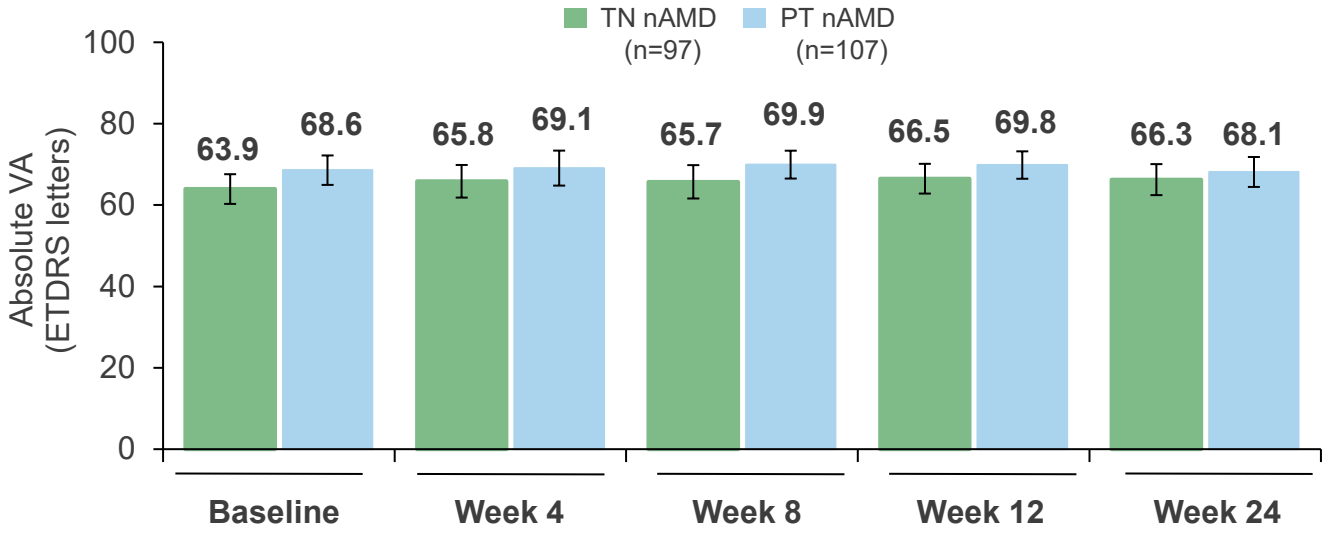
Clinical and safety outcomes at Week 24 in the global previously treated nAMD cohort

- Stable VA and improved CRT following switch to aflibercept 8 mg
- Reductions in IRF
- Results achieved with a mean of 4.4 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 previously treated and treatment-naïve nAMD in patients receiving aflibercept 8 mg

Month 12 and Month 24 analyses are on track

Country cohort analyses from Switzerland support the effectiveness and safety of aflibercept 8 mg in patients with nAMD



Timepoint	Mean (95% CI) change in VA from baseline (LOCF)	
	TN nAMD	PT nAMD
Week 4	2.2 (−0.1, 4.6)	1.0 (−0.8, 2.9)
Week 8	2.3 (0, 4.7)	0.5 (−0.9, 1.8)
Week 12	2.6 (0.4, 4.7)	1.2 (−0.9, 3.4)
Week 24	**2.3 (−0.4, 5.0)**	**−0.4 (−2.4, 1.5)**

SPECTRUM Swiss TN nAMD cohort (n=97)

- **Improved CRT** (−112 µm change from BL of 360 µm)
- **Increase in patients without IRF from 46.8%** at BL **to 68.8%** at W24
- **Increase in patients without SRF from 17.7%** at BL **to 72.2%** at W24
- **Results** achieved with **4.8 injections**[a]

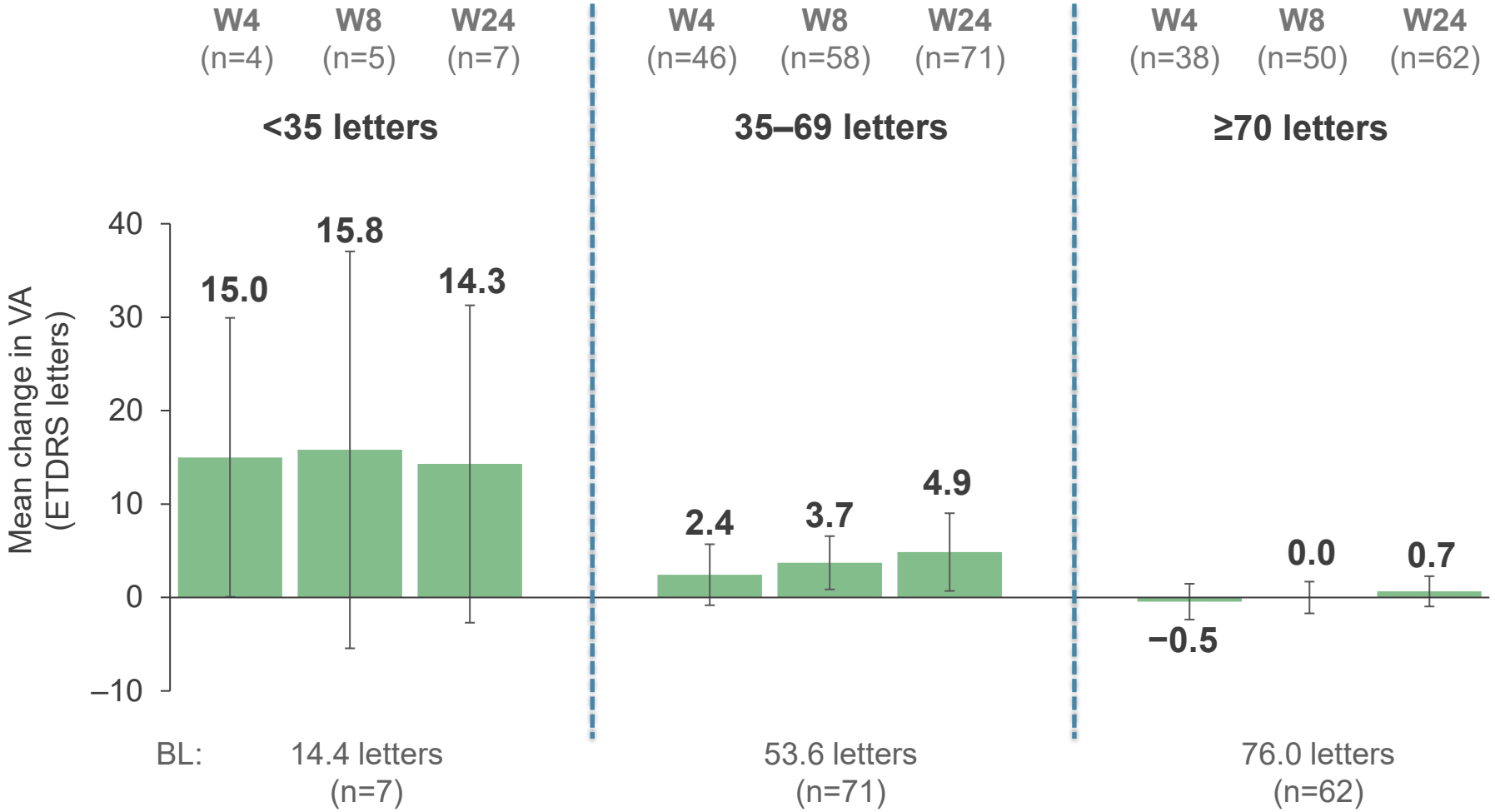
SPECTRUM Swiss PT nAMD cohort (n=107)

- **Improved CRT** (−39 µm change from BL of 315 µm) **following switch to aflibercept 8 mg**
- **Increase in patients without IRF from 50.5%** at BL **to 67.3%** at W24
- **Increase in patients without SRF from 34.0%** at BL **to 57.1%** at W24
- **Results** achieved with **4.4 injections**[a]

No cases of **endophthalmitis** or **retinal vasculitis**

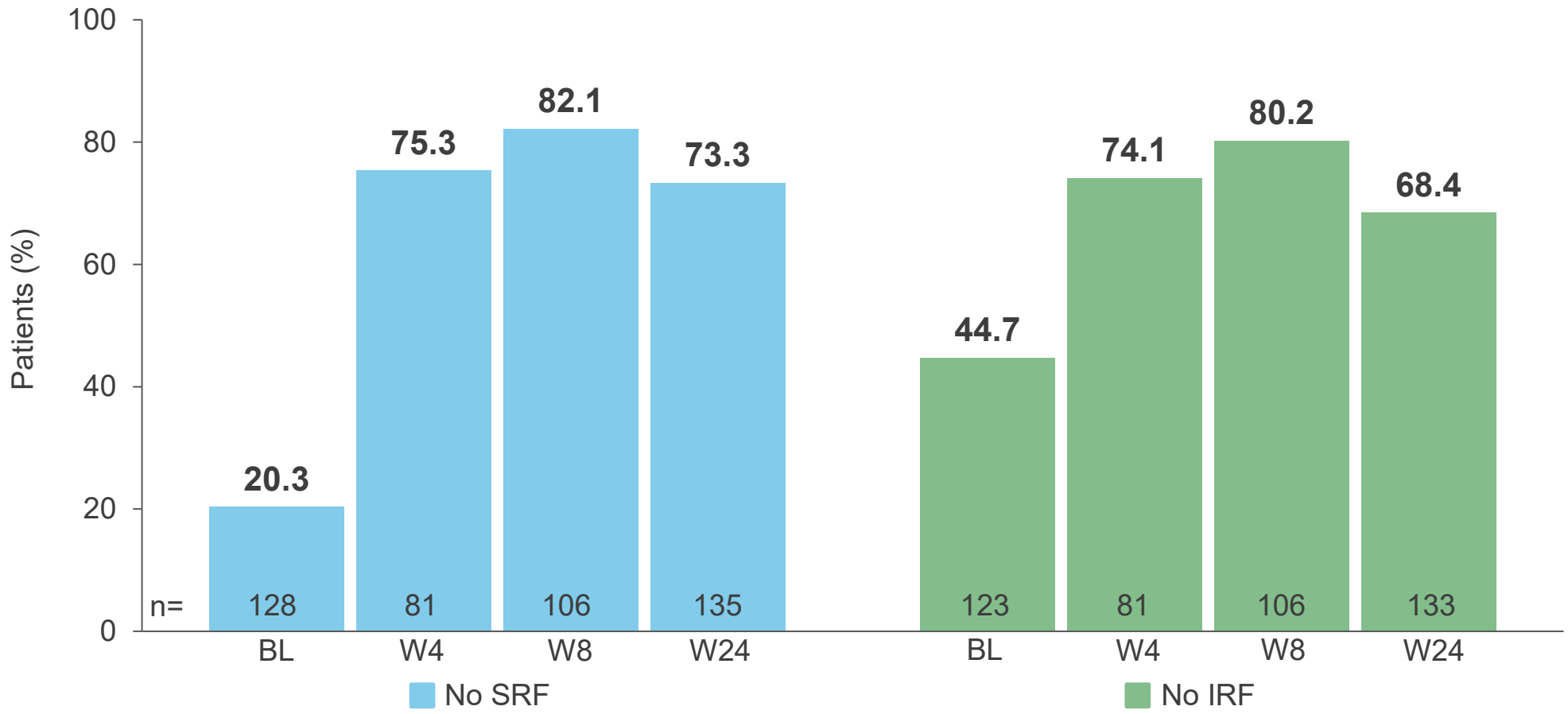
FAS, LOCF. [a]Number of injections up to Day 210 from BL.
SRF, subretinal fluid; W, week.

Mean change in VA through Week 24 grouped by baseline VA



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

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

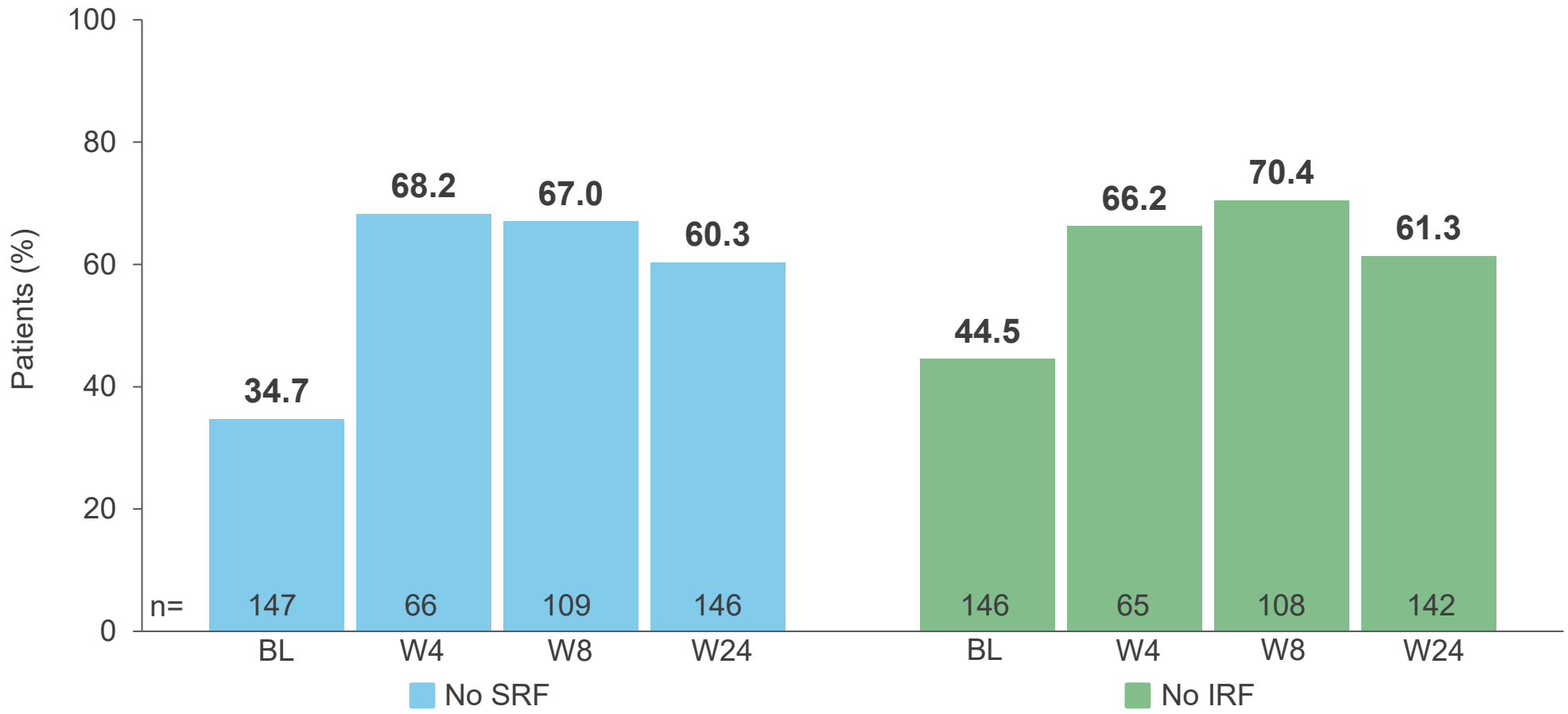


FAS, LOCF. Missing values were imputed using the LOCF approach. Values have been rounded to the nearest decimal point. Based on instructions in the case report form, fluid data were collected during a macular assessment (6 mm) at the investigator's discretion. [a]Calculated based on the number of patients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

Mean change in VA through Week 24 grouped by baseline VA

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

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



FAS, LOCF. Missing values were using 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) at the investigator's discretion. [a]Calculated based on the number of patients assessed at each timepoint.