

Aflibercept 8 mg showed improvements in visual and anatomic outcomes through Week 24: An interim analysis of the global previously treated DME cohort in the SPECTRUM real-world study

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Disclosures

- **Clemens Lange**: Receives honoraria from AbbVie, Amgen, Apellis, Bayer, and Novartis
  - **HO**: Consultant for AbbVie, Bayer, Novartis, and Roche. **MRM**: Consultant for AbbVie, Alcon, Alimera, Allergan, Amgen, Apellis, Astellas, Aviceda Therapeutics, Bayer, Boehringer Ingelheim, Dandelion Pharmaceuticals, Evolve Medical Education, eye.gnos consulting, EyePoint Pharmaceuticals, GenSight Biologics, Isarna Therapeutics, Iveric Bio, Kubota, LumiThera, Novartis, Ocular Therapeutix, Oculis, OcuTerra Therapeutics, OD-OS, ONL Therapeutics, RetinAI, Roche, Sitalis, UBS Analytics, and Zeiss.
    CB: Consultant for Alimera Sciences, Apellis, Bayer, Boehringer Ingelheim, Johnson & Johnson, and Roche.
    PL: Consultant for 4DMT, AbbVie, Adverum, Annexon, Apellis, Bausch + Lomb, Bayer, Biogen, Boehringer Ingelheim, Celltrion, EyePoint Pharmaceuticals, Genentech, I-Care, MSD, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche.
    MK and **TM**: Employees and stockholders of Bayer AG. **SS**: Employee of Bayer AG. **SO**: Employee of Bayer Consumer Care AG and stockholder of Bayer AG. **RG**: Employee of Bayer Consumer Care AG. **VC**: Consultant for Apellis, Bayer, Boehringer Ingelheim, EyePoint Pharmaceuticals, Janssen, Novartis, and Roche; and has received research grants from Bayer, Novartis, and Roche
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- The data cut-off date for the presented analyses was May 15, 2026

SPECTRUM study design and patient baseline characteristics of the PT DME cohort

SPECTRUM study overview

Study design

A 24-month, prospective, non-interventional country and global cohort study in 18 countries from February 2024 to September 2027

Objective

To evaluate the effectiveness and safety of aflibercept 8 mg in patients with TN and PT DME or nAMD in routine clinical practice

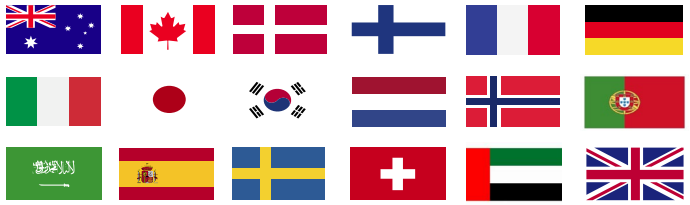
Primary endpoint

Change in VA from BL to Month 12

Patient enrollment

Patient enrollment is complete:

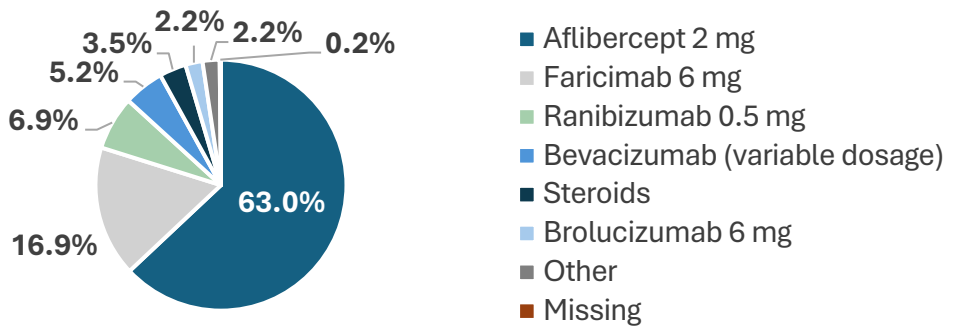
3733	723	716
DME + nAMD	TN DME cohort	PT DME cohort



Baseline characteristics: PT DME

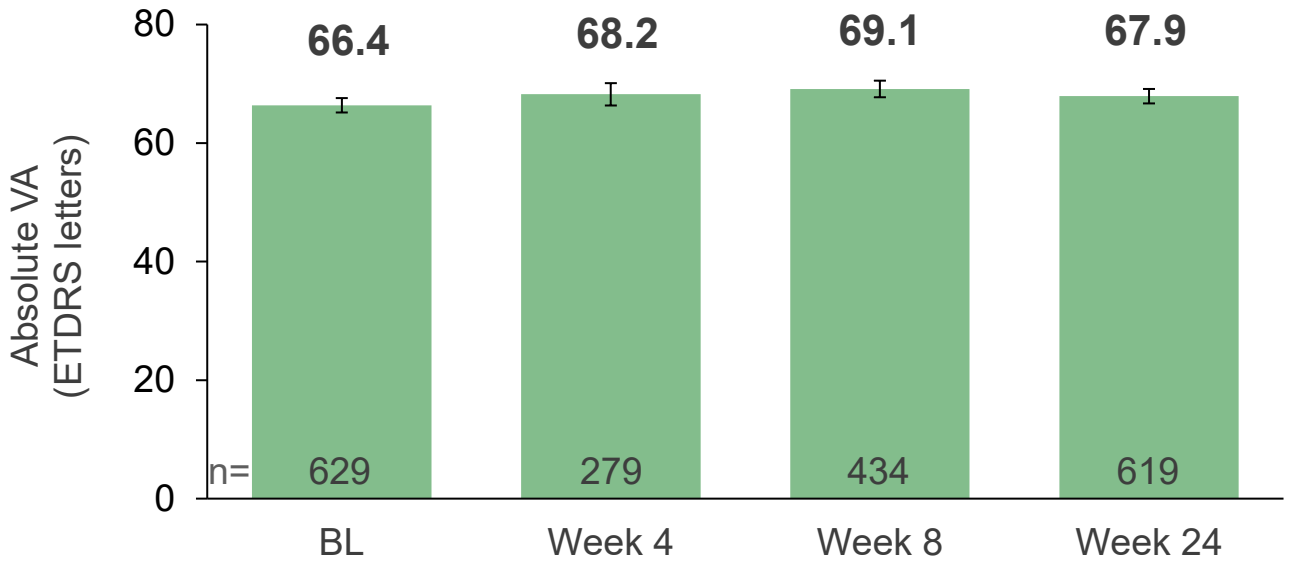
	Global PT DME (n=635)
Age, years	66.3±11.4
Sex, %	
Male	64.1
Female	35.9
Race,[a] %	
White	48.2
Asian	15.3
Black or African American	1.1
American Indian and Alaska Native	0.2
Not reported	35.3
Median (min, max) time from DME diagnosis, months	41.0 (0.0, 331.2)
Patients with a dosing interval of ≤8 weeks prior to switching,[b] %	57.1

Previous DME medication[c]



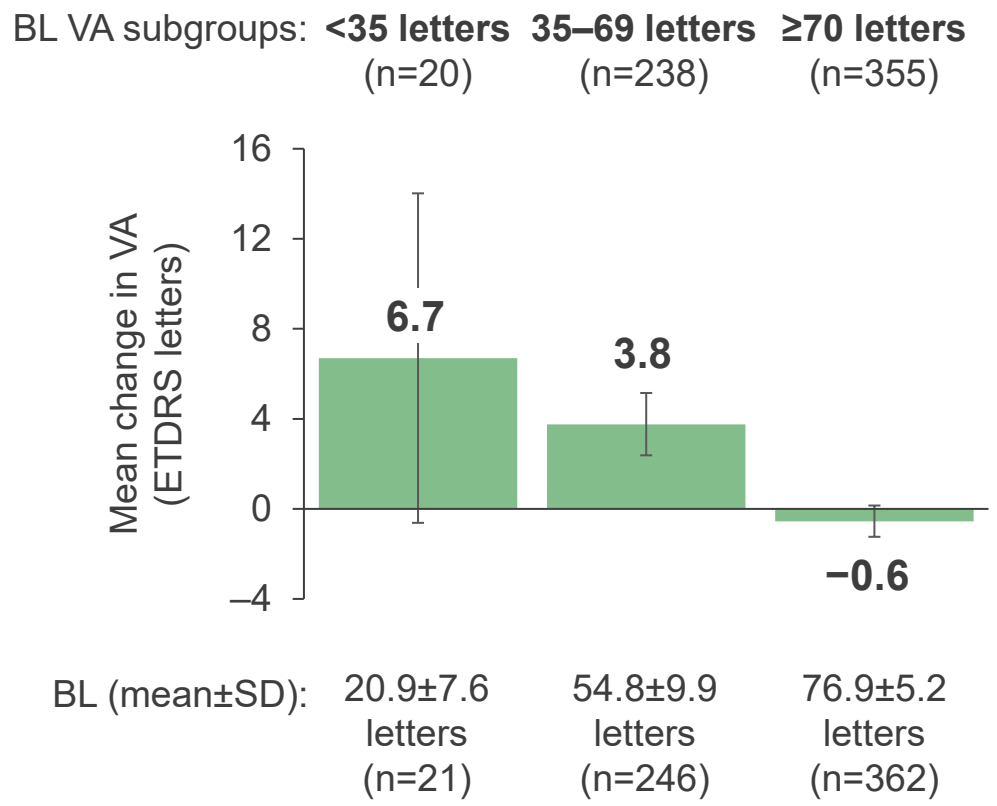
FAS. Percentages may not add up to 100 due to rounding. Data are mean±SD unless otherwise indicated. [a]In SPECTRUM, data on race were collected in all participating countries, where permitted by local laws and regulations. [b]Calculated for patients with last completed dosing interval data prior to switching (n=585). [c]Biosimilars are included within each medication option. BL, baseline; DME, diabetic macular edema; FAS, full analysis set (all patients receiving ≥1 dose of study drug and ≥1 post-baseline assessment); max, maximum; min, minimum; nAMD, neovascular age-related macular degeneration; PT, previously treated; SD, standard deviation, TN, treatment-naïve; VA, visual acuity.

VA through Week 24



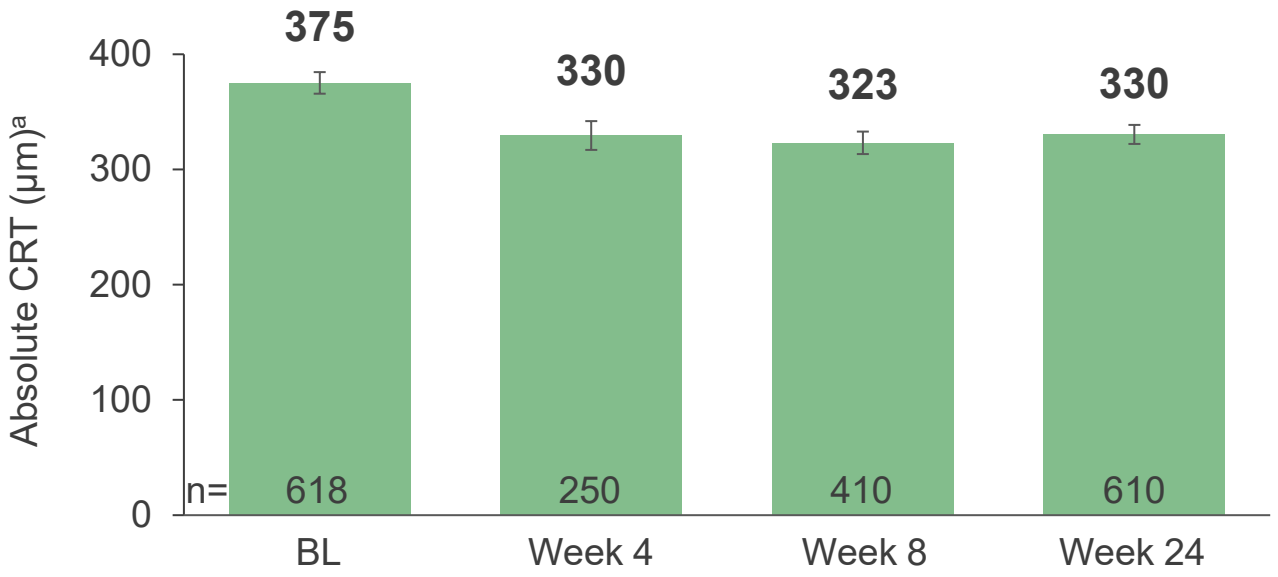
Timepoint	Mean change (95% CI) from BL (LOCF)
Week 4 (n=277)	+1.2 (0.1, 2.3)
Week 8 (n=432)	+1.6 (0.8, 2.4)
Week 24 (n=613)	**+1.4 (0.6, 2.1)**

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



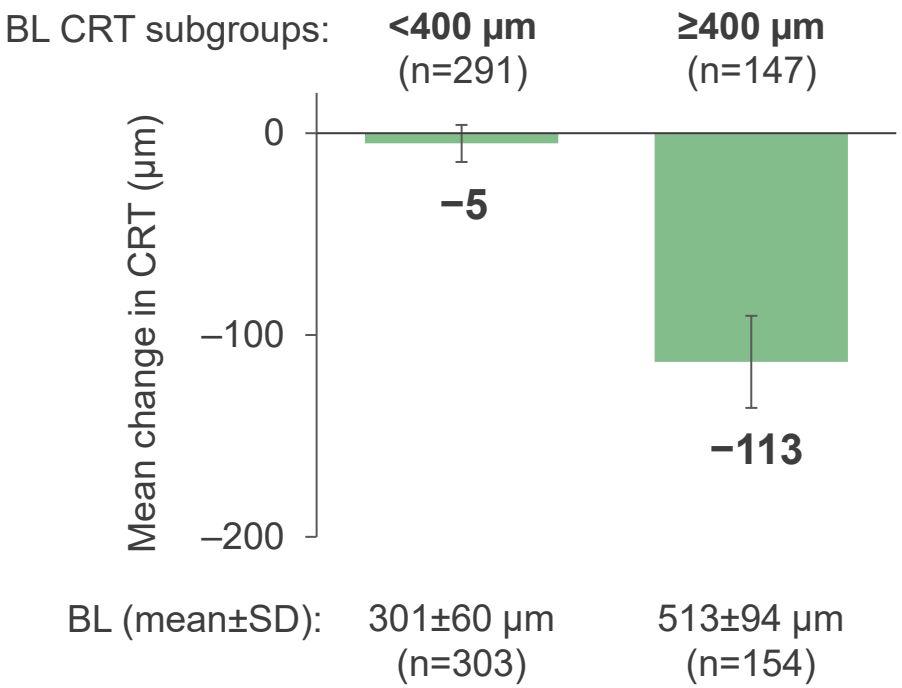
FAS, LOCF (n=635). Missing values were imputed using the LOCF approach. Error bars represent 95% CI. Week 4 = visits closest to 28 (14–42) days after BL, Week 8 = visits closest to 56 (43–70) days after BL, Week 24 = visits closest to 180 (150–210) days after BL. [a]In patients with a VA assessment at Week 4 and Week 8, the mean change in VA at Week 4 and Week 8 grouped by BL VA was +4.4 and +5.8 letters for those with a BL VA of <35 letters, +3.3 and +4.1 letters for those with a BL VA of 35–69 letters, and –0.3 and –0.1 letters for those with a BL VA of ≥70 letters, respectively. CI, confidence interval; EDTRS, Early Treatment Diabetic Retinopathy Study; LOCF, last observation carried forward.

CRT through Week 24



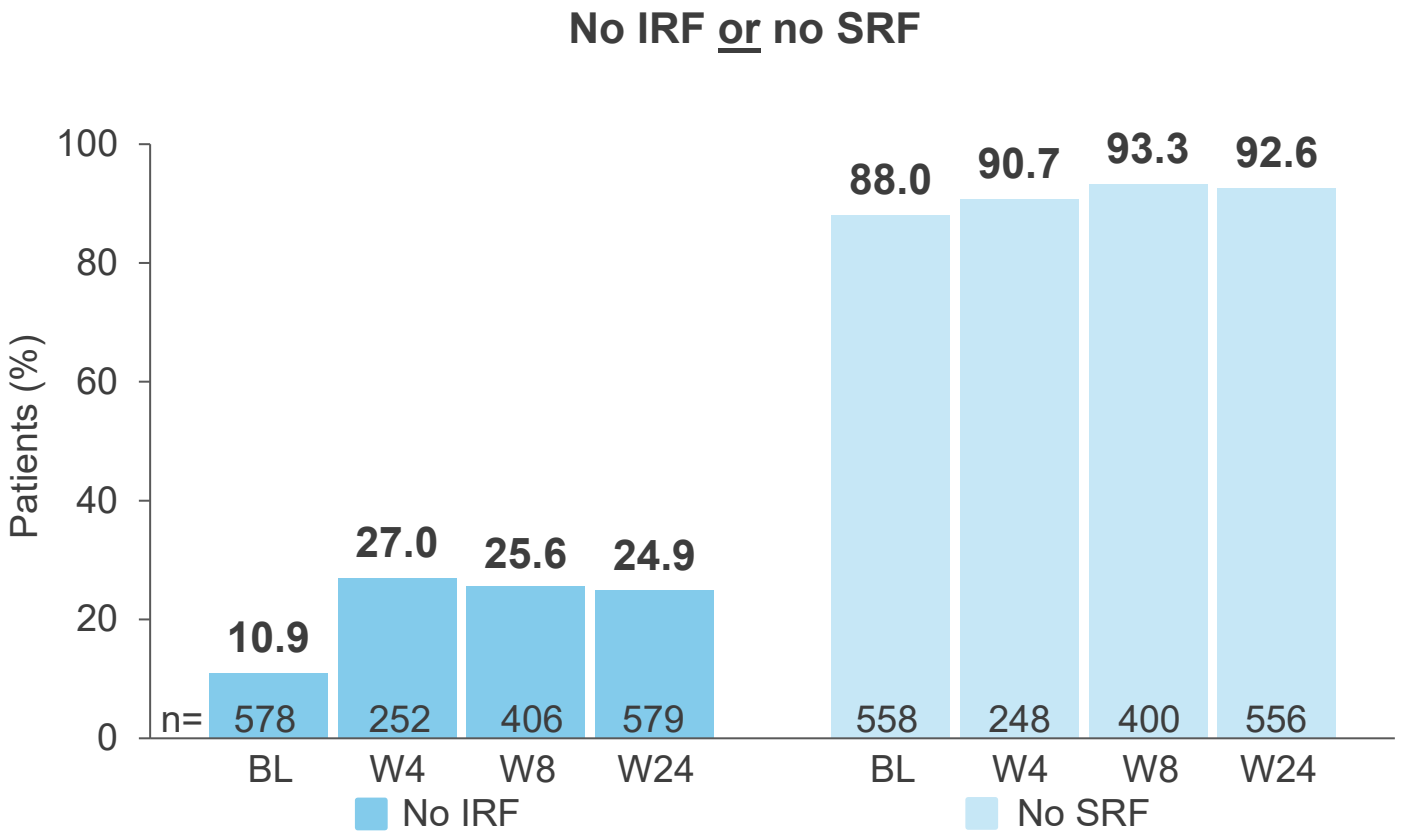
Timepoint	Mean change (95% CI) from BL (LOCF)
Week 4 (n=248)	−58 (−71, −44)
Week 8 (n=407)	−53 (−64, −43)
Week 24 (n=603)	**−44 (−53, −36)**

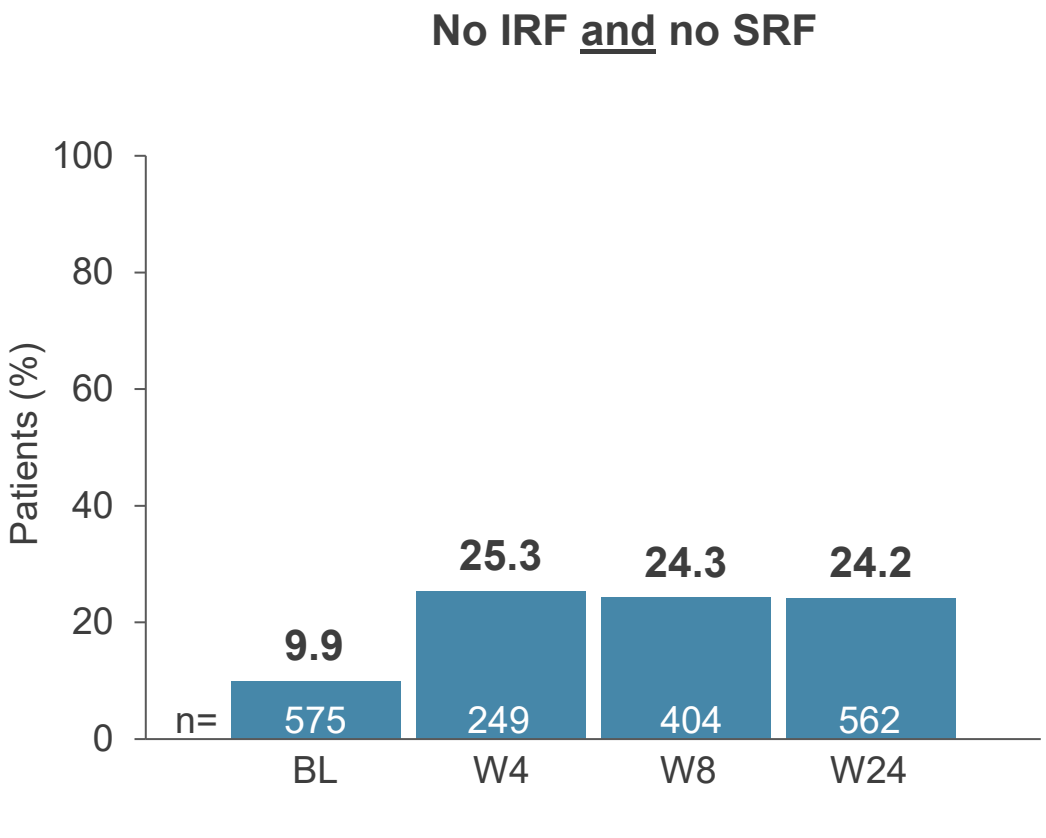
Mean change in CRT at Week 24 grouped by BL CRT[b,c]



FAS, LOCF (n=635). Missing values were imputed using the LOCF approach. Error bars represent 95% CI. [a]CRT was assessed as either CRT or CST, at the investigator's discretion; CRT or CST was assessed from baseline through Week 24 for each individual patient, or CST thereafter if no BL value was available. [b]Data are CRT only. [c]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 BL CRT was −14 and −15 μm for those with a baseline CRT of <400 μm, and −143 and −125 μm for those with a BL CRT of ≥400 μm, respectively. CRT, central retinal thickness; CST, center subfield thickness.

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

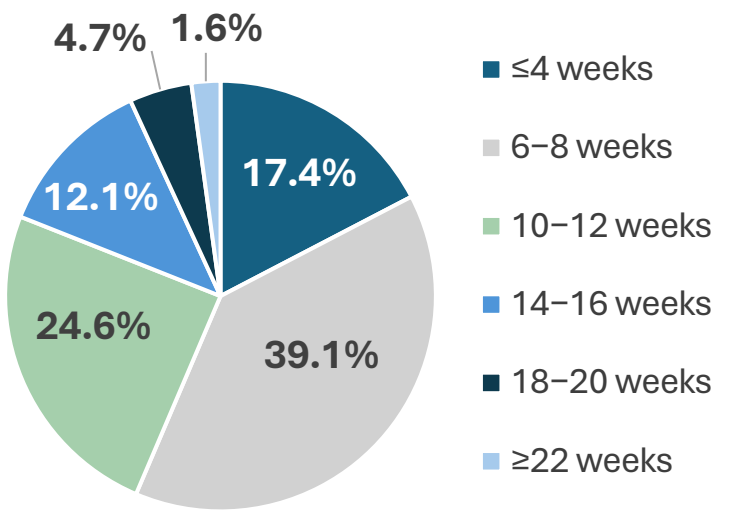




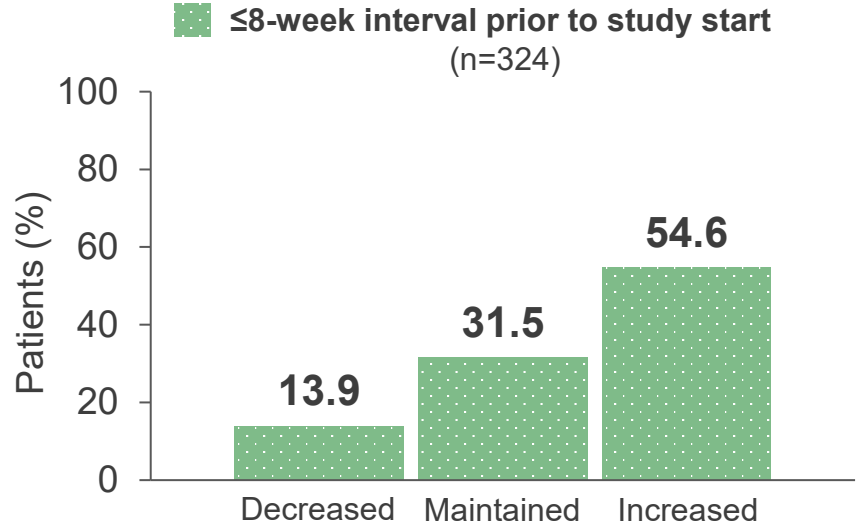
FAS, LOCF (n=635). Missing values were imputed using the LOCF approach. [a]The presence of IRF and SRF was determined by optical coherence tomography at the physician's discretion with the instrument available at each study site; the proportions presented here were calculated using the number of patients with a definitive result at each indicated time point. IRF, intraretinal fluid; SRF, subretinal fluid; W, week.

Treatment exposure and safety through Week 24

Last completed dosing interval at Week 24 (n=553)[a]



Change in last completed dosing interval at Week 24[a]



Ocular and non-ocular TEAEs (n=698)

Ocular TEAEs in the study eye,[b] n (%)	
Any ocular TEAEs	56 (8.0)
Any serious ocular TEAEs	8 (1.1)
Most frequent ocular TEAEs, n (%)	
Intraocular pressure increased	7 (1.0)
Conjunctival hemorrhage	6 (0.9)
Cataract	3 (0.4)
Dry eye	3 (0.4)
Ocular hypertension	3 (0.4)
Retinal hemorrhage	3 (0.4)
Non-ocular TEAEs, n (%)	
Any non-ocular TEAEs	46 (6.6)
Any serious non-ocular TEAEs	20 (2.9)
Most frequent non-ocular TEAE, n (%)	
Hypertension	3 (0.4)

36.5% of patients received **3 initial monthly injections** through **Week 8** (first injection administered at BL)

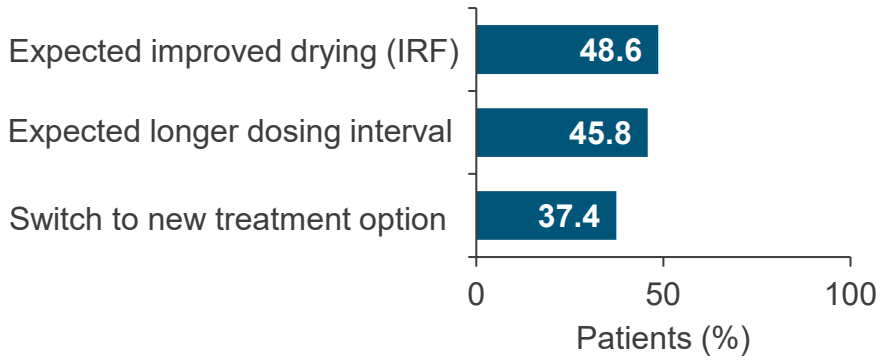
Patients received a mean of **4.0±1.7 injections** up to **Day 210** from **BL**

No cases of retinal vasculitis were reported and **no new safety signals** were identified

FAS; SAF. [a]Calculated for patients with last completed dosing interval data both prior to switching and at Week 24. [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 attending physician's discretion. SAF, safety analysis set (all patients receiving ≥1 dose of study drug in the study eye); TEAE, treatment-emergent adverse event.

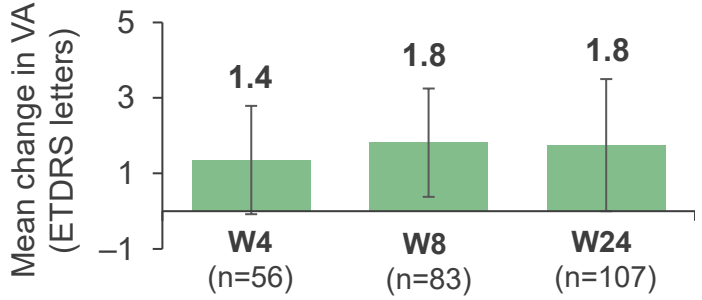
Treatment outcomes in patients who switched from faricimab 6 mg to aflibercept 8 mg (n=107)

Main reasons for switching to aflibercept 8 mg at BL[a]



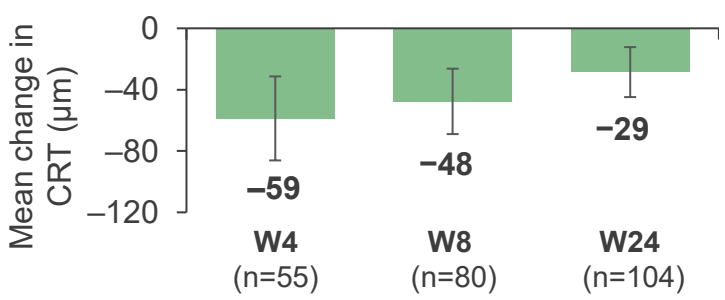
Mean change in VA

BL (mean±SD): 65.9±15.0 letters (n=107)

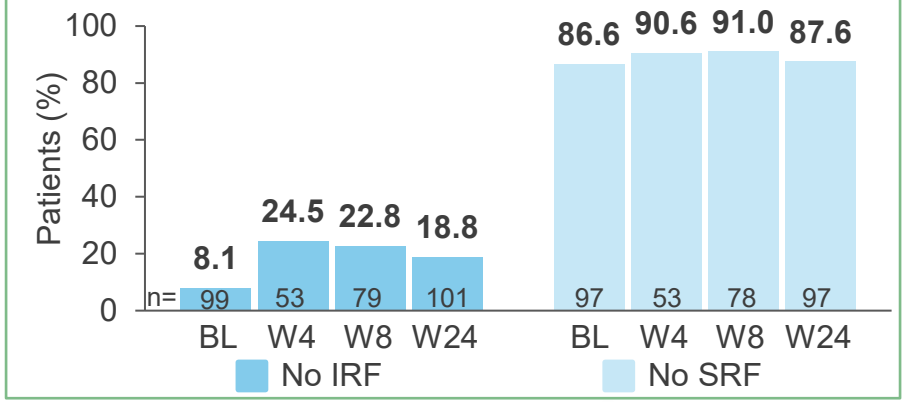


Mean change in CRT[b]

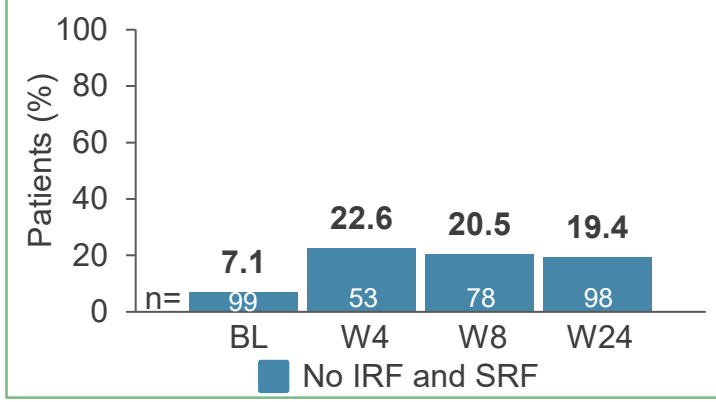
BL (mean±SD): 395±115µm (n=105)



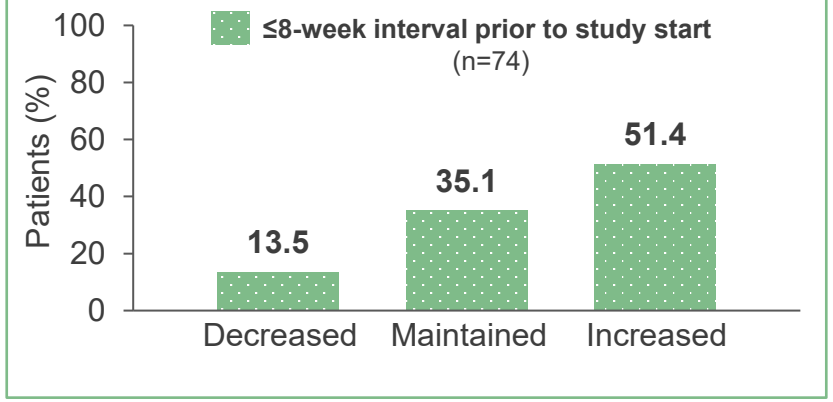
Proportions of patients without IRF or SRF[c]



Proportions of patients without IRF and SRF[c]



Change in last completed dosing interval at Week 24[d]

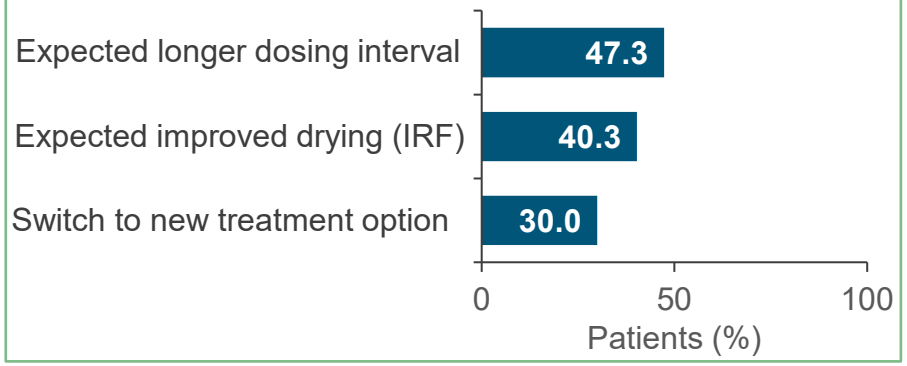


Patients received a mean of **4.3±2.0 injections up to Day 210 from BL**

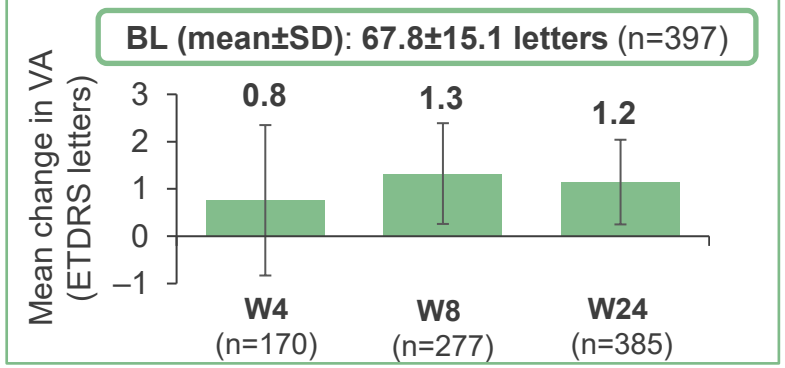
[a]Multiple reasons could be selected. [b]CRT was assessed as either CRT or CST, at the investigator's discretion; CRT or CST was assessed from BL through Week 24 for each individual patient, or CST thereafter if no BL value was available. [c]The presence of IRF and SRF was determined by optical coherence tomography per physician discretion with the instrument available at each study site; the proportions presented here were calculated using the number of patients with a definitive result at each indicated time point. [d]Calculated for patients with last completed dosing interval data both prior to switching and at Week 24.

Treatment outcomes in patients who switched from aflibercept 2 mg to aflibercept 8 mg (n=400)

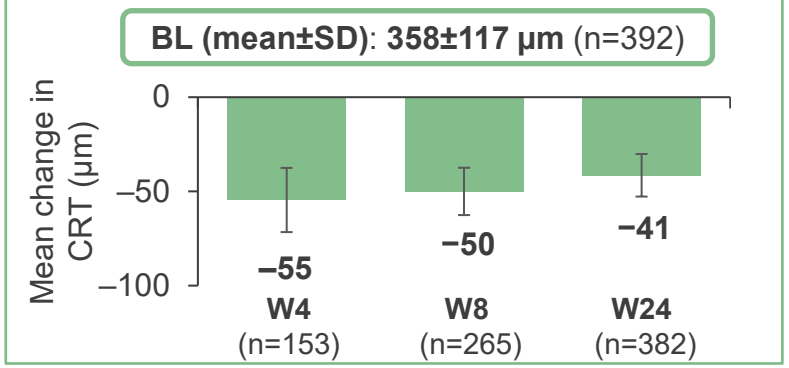
Main reasons for switching to aflibercept 8 mg at BL[a]



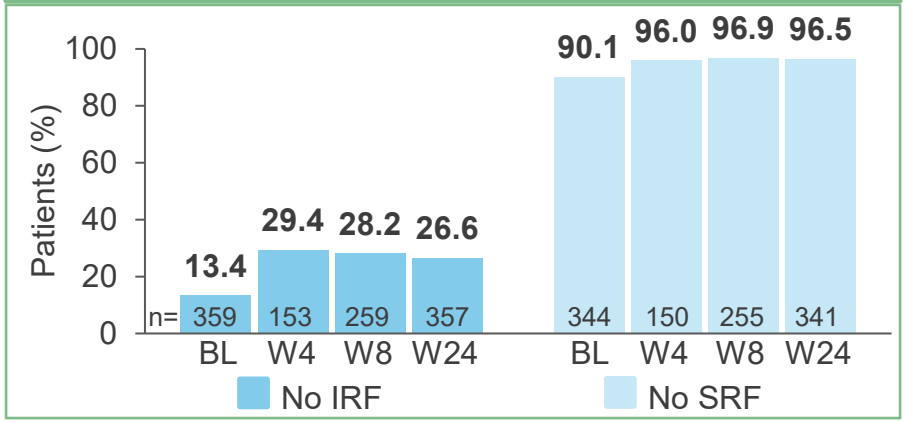
Mean change in VA



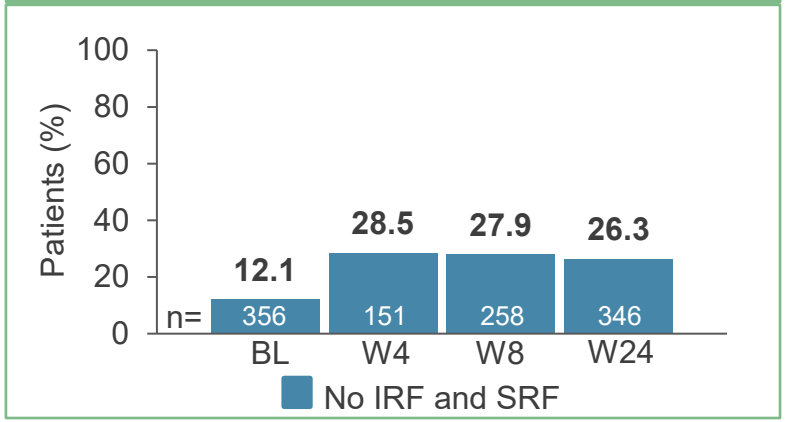
Mean change in CRT[b]



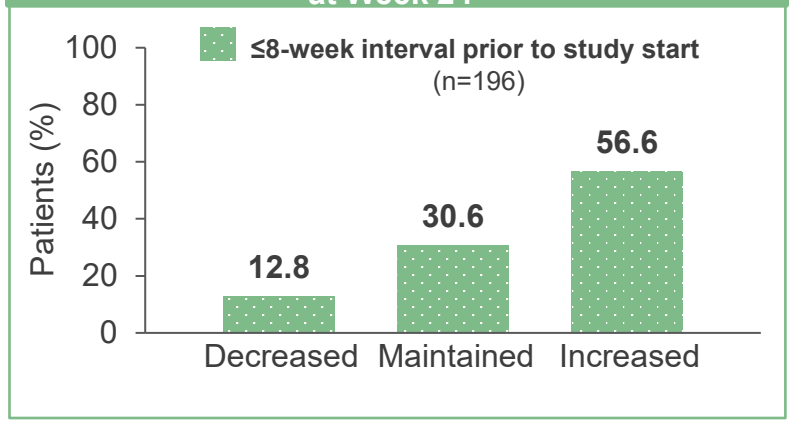
Proportions of patients without IRF or SRF[c]



Proportions of patients without IRF and SRF[c]



Change in last completed dosing interval at Week 24[d]



Patients received a mean of **3.8±1.6 injections up to Day 210 from BL**

[a]Multiple reasons could be selected; [b]CRT was assessed as either CRT or CST, at the investigator's discretion; CRT or CST was assessed from BL through Week 24 for each individual patient, or CST thereafter if no BL value was available. [c]The presence of IRF and SRF was determined by optical coherence tomography per physician discretion with the instrument available at each study site; the proportions presented here were calculated using the number of patients with a definitive result at each indicated time point. [d]Calculated for patients with last completed dosing interval data both prior to switching and at Week 24.

Stable visual acuity and improved anatomic outcomes observed at Week 24 in the global previously treated DME cohort

Enrollment in SPECTRUM is complete



>3700 patients enrolled globally across **18 countries**

>700 patients enrolled in the PT DME cohort across **9 countries**

Global PT DME: Key Week 24 findings

Stable VA and reduced CRT

After switching to aflibercept 8 mg

Increased retinal drying

Improved IRF and SRF from BL

Longer dosing intervals

Most patients with ≤8-week intervals prior to switching achieved longer intervals

No new safety signals

Safety profile consistent with pivotal clinical trial[1]

Week 24 interim results from **SPECTRUM** add to the **real-world evidence base** for **aflibercept 8 mg** in the **clinical management of previously treated DME** in patients in **routine clinical practice**

SPECTRUM data on **treatment patterns and intraocular pressure metrics** with **aflibercept 8 mg** in patients with **DME** and **nAMD** are being presented at the EURETINA ‘26 ePoster sessions

Additional analyses up to Month 12 and Month 24 are ongoing

1. Brown DM, et al. *Lancet*. 2024;403:1153–1163.