



SPECTRUM: Real-world data on treatment patterns through Week 24 with aflibercept 8 mg among patients with DME indicate more frequent initial monthly dosing in the treatment-naïve versus previously treated cohort

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on behalf of the SPECTRUM study investigators

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Disclosures

- **Brian G. Ballios:** Consulting fees from Apellis, Astellas, Bayer, Biocon Biologics, GelMEDIX, Novartis, Rhythm Canada, Roche, and Sandoz Canada; and serves on the medical advisory board for Endogena Therapeutics
- **PL:** Consulting fees from 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.
HO: Consulting fees from AbbVie, Bayer, Novartis, and Roche. **MRM:** Consulting fees from AbbVie, Alcon, Alimera, Allergan, Amgen, Apellis Pharmaceuticals, Astellas, Aviceda Therapeutics, Bayer, Boehringer Ingelheim, Dandelion Pharmaceutical, 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:** Consulting fees from Alimera Sciences, Apellis, Bayer, Boehringer Ingelheim, Johnson & Johnson, and Roche.
CL: Honoraria from AbbVie, Amgen, Apellis, Bayer, and Novartis. **TM:** Employee and stockholder of Bayer AG.
SO: Employee of Bayer Consumer Care AG and stockholder of Bayer AG. **RG:** Employee of Bayer Consumer Care AG.
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- The data cut-off dates for the presented analyses were May 15, 2026, for both the treatment-naïve and previously-treated cohorts



SPECTRUM: Global real-world study of aflibercept 8 mg

A 24-month, prospective, non-interventional country and global cohort study in 18 countries



Two 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



Treated with **aflibercept 8 mg** per routine clinical practice



Data collection from medical records for up to 24 months per patient
→ February 2024 to September 2027

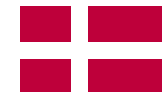
Patient enrollment **3733** **723** **716**
is complete: nAMD + DME TN DME cohort PT DME cohort



Australia



Canada



Denmark



Finland



France



Germany



Italy



Japan



Republic of Korea



The Netherlands



Norway



Portugal



Saudi Arabia



Spain



Sweden



Switzerland



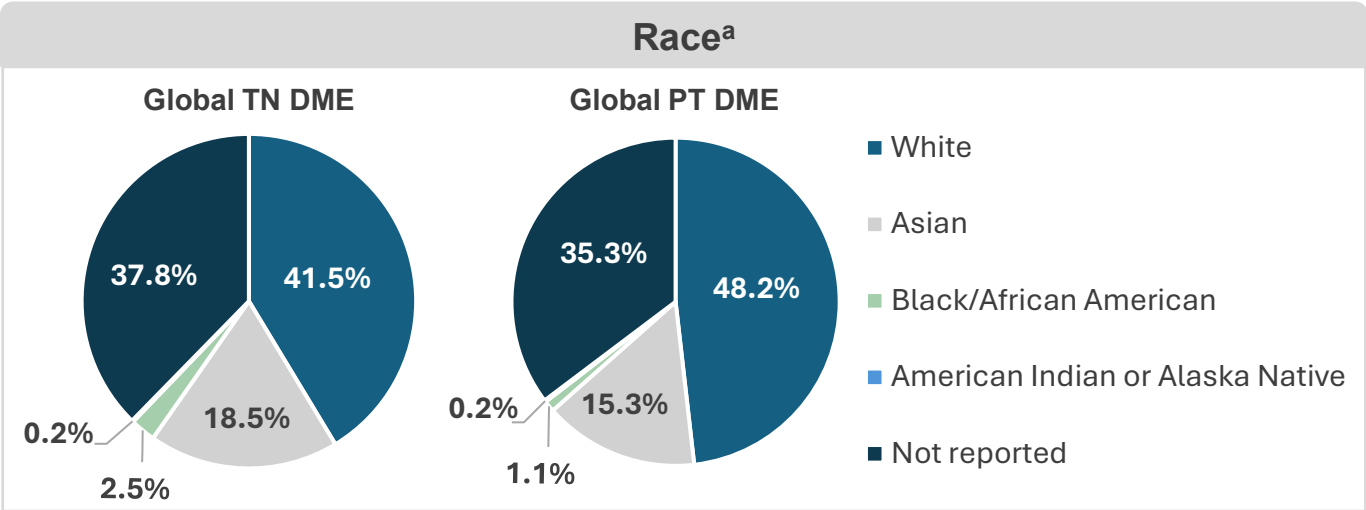
United Arab
Emirates



United Kingdom

Baseline characteristics: Treatment-naïve and previously treated DME

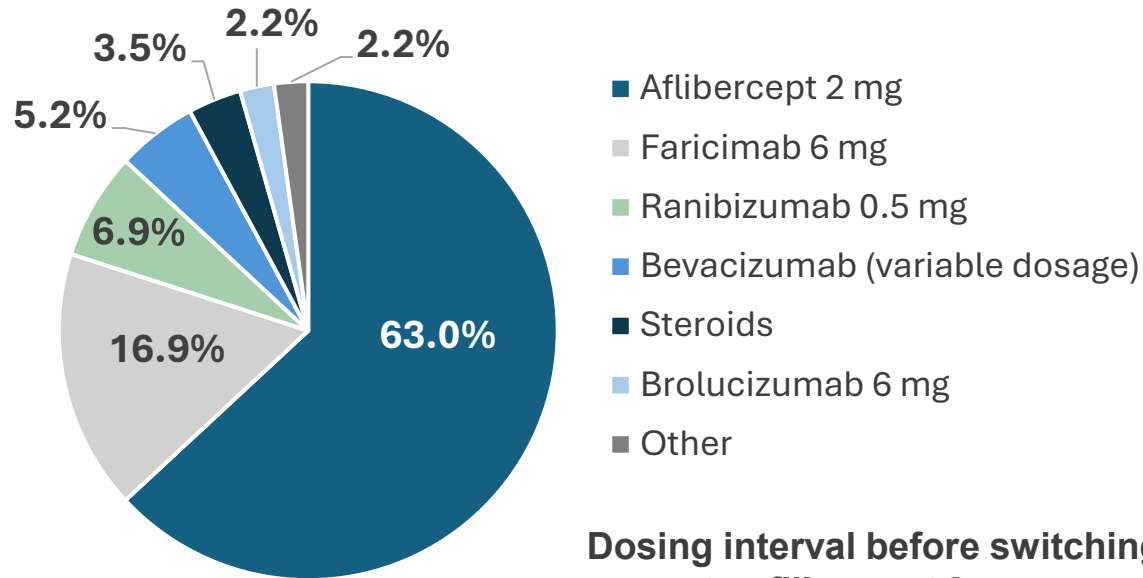
	Global TN DME	Global PT DME
FAS, n	650	635
Age, years	64.8±11.6	66.3±11.4
Sex, %		
Male	64.2	64.1
Female	35.8	35.9
Median (min, max) time from DME diagnosis, months	0.3 (0.0, 115.1)	41.0 (0.0, 331.2)
Median last completed dosing interval prior to switch, weeks	–	8
Median (min, max) time on prior treatment, days	–	704 (29, 5516)



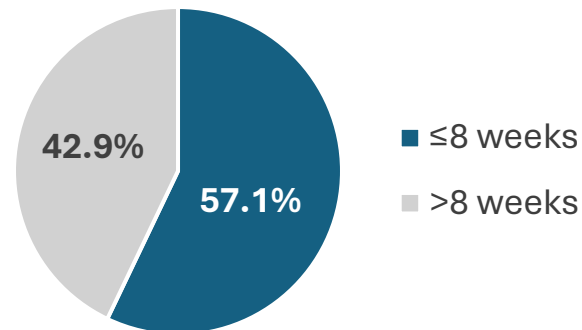
FAS (all patients receiving ≥1 dose of study drug plus ≥1 post-baseline assessment).
^aIn SPECTRUM, data on race were collected in all participating countries, where permitted by local laws and regulations.
 FAS, full analysis set; max, maximum; min, minimum.

Baseline characteristics: Previously treated DME

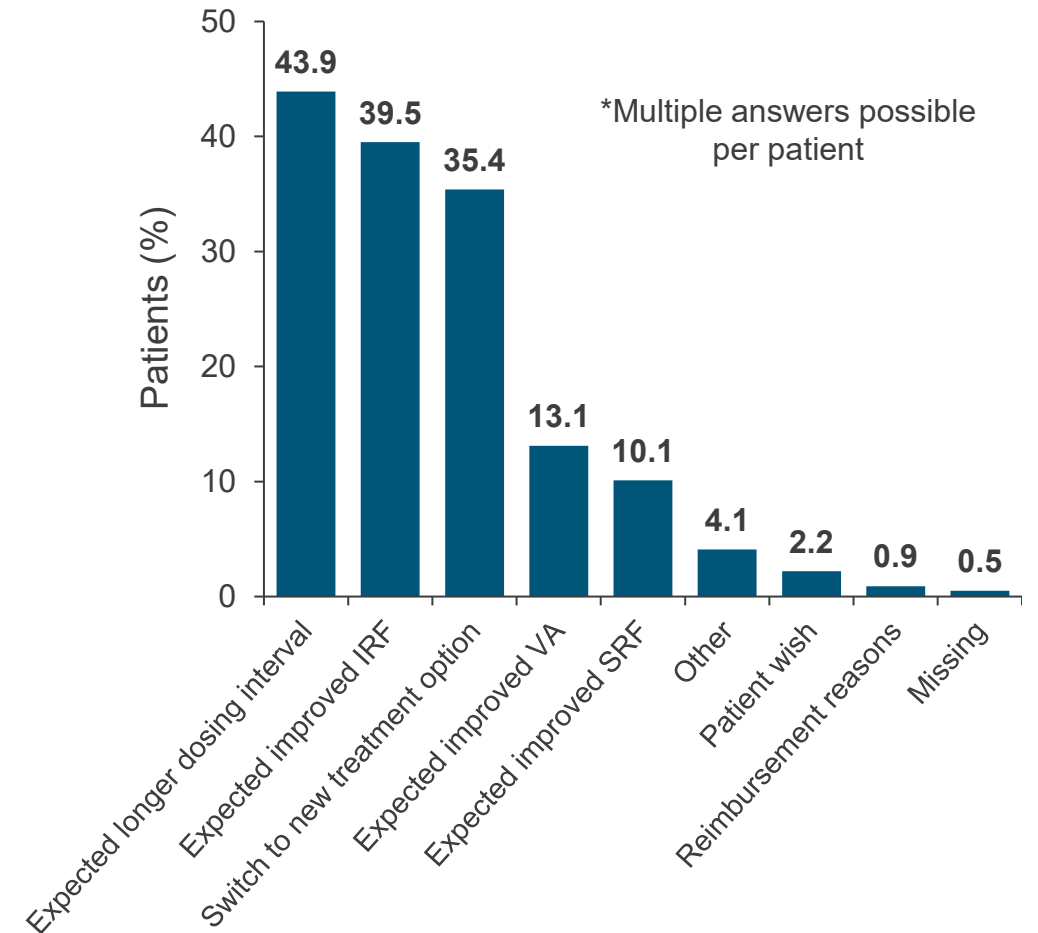
Previous DME medication^{a,b}



Dosing interval before switching to aflibercept 8 mg^c



Reasons for switching to aflibercept 8 mg*



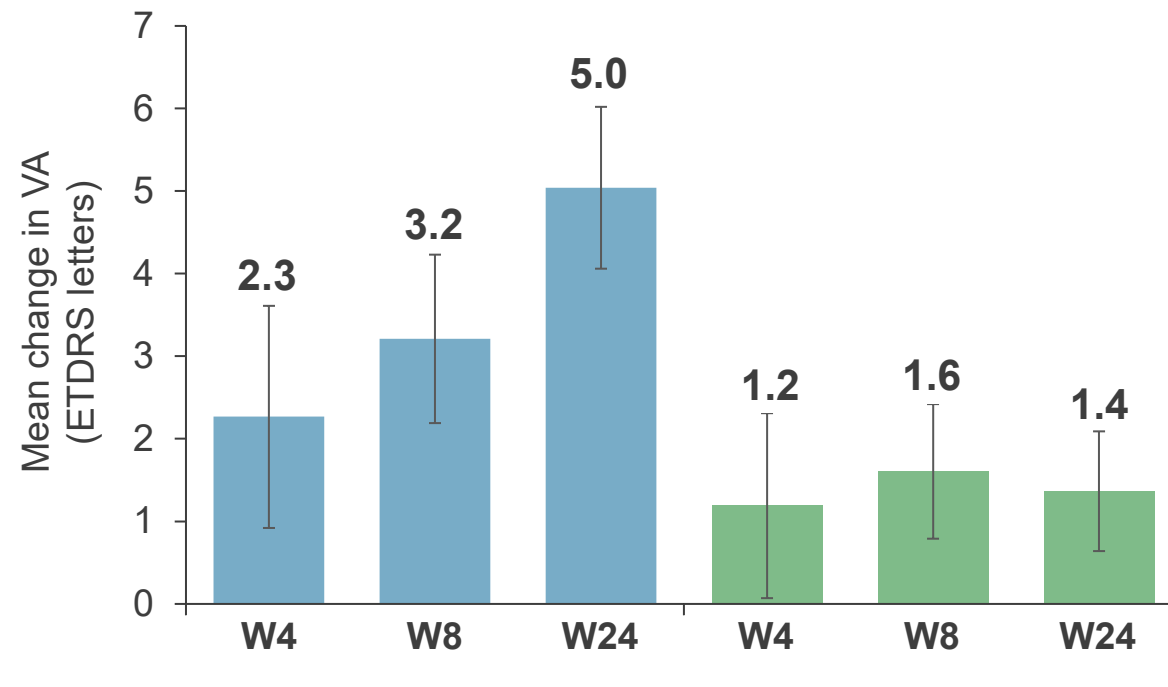
FAS (PT DME: n=635).

^aPercentages may not add up to 100 due to rounding. ^bBiosimilars are included in each medication option. ^cCalculated for patients with last completed dosing interval data prior to switching (n=585).

IRF, intraretinal fluid; SRF, subretinal fluid.

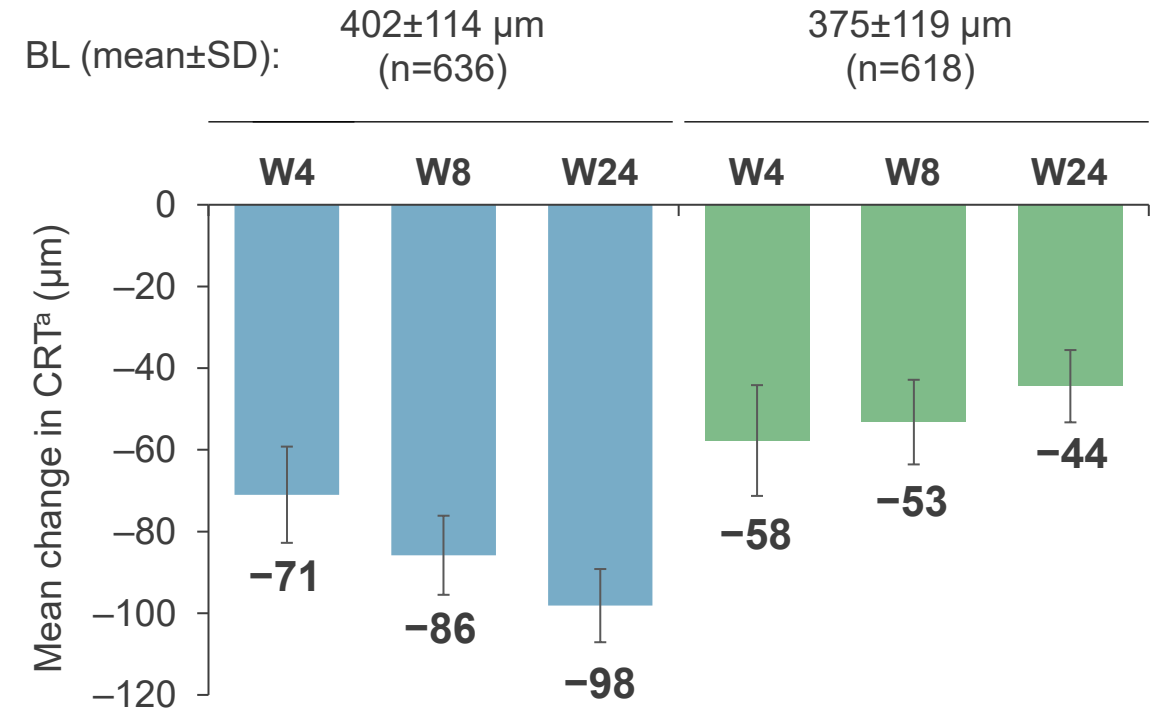
Mean change in VA and CRT^a through Week 24

TN DME PT DME



BL (mean±SD): 63.4±17.7 (n=643)

66.4±15.5 (n=629)

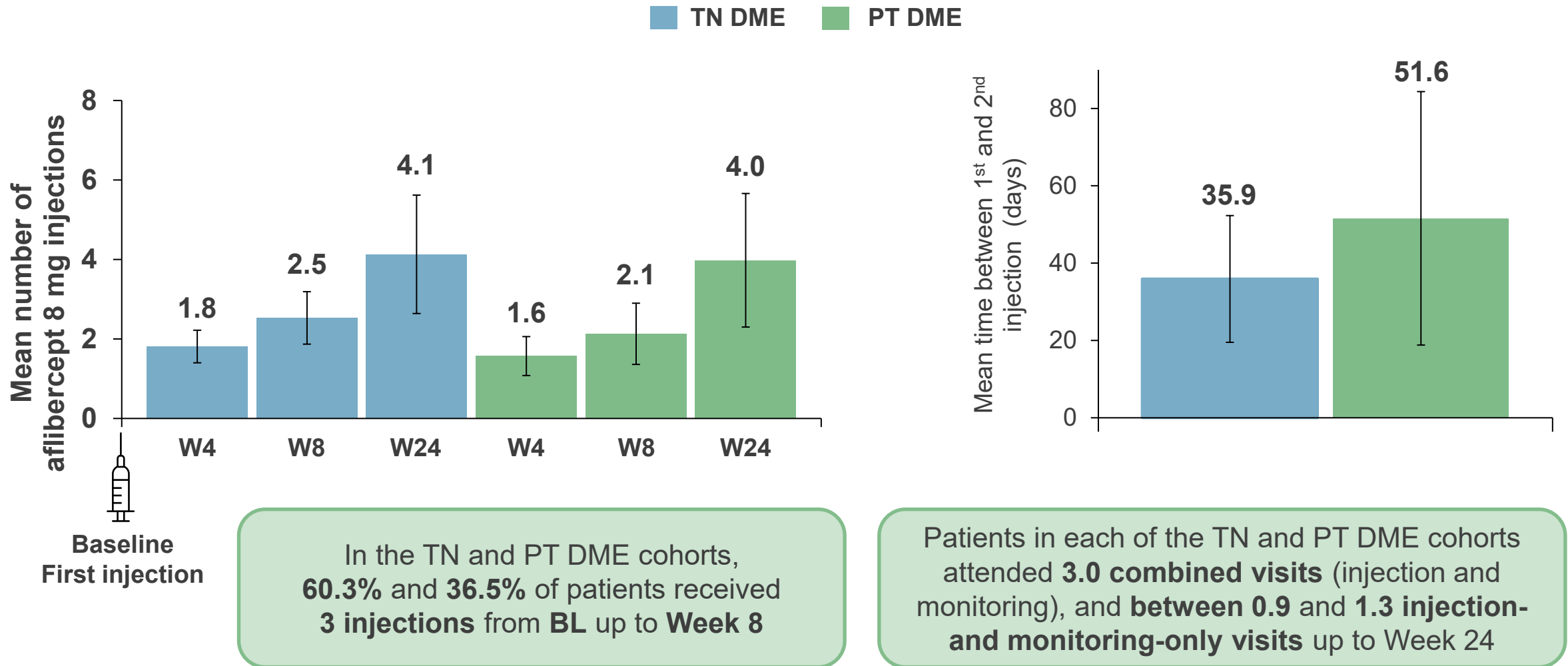


FAS, LOCF (TN DME: n=650; PT DME: n=635). Missing values were imputed using the LOCF approach. Error bars represent 95% CI. Week 4 = visits closest to 28 (14–42) days after BL, Week 8 = visits closest to 56 (43–70) days after BL, Week 24 = visits closest to 180 (150–210) days after BL.

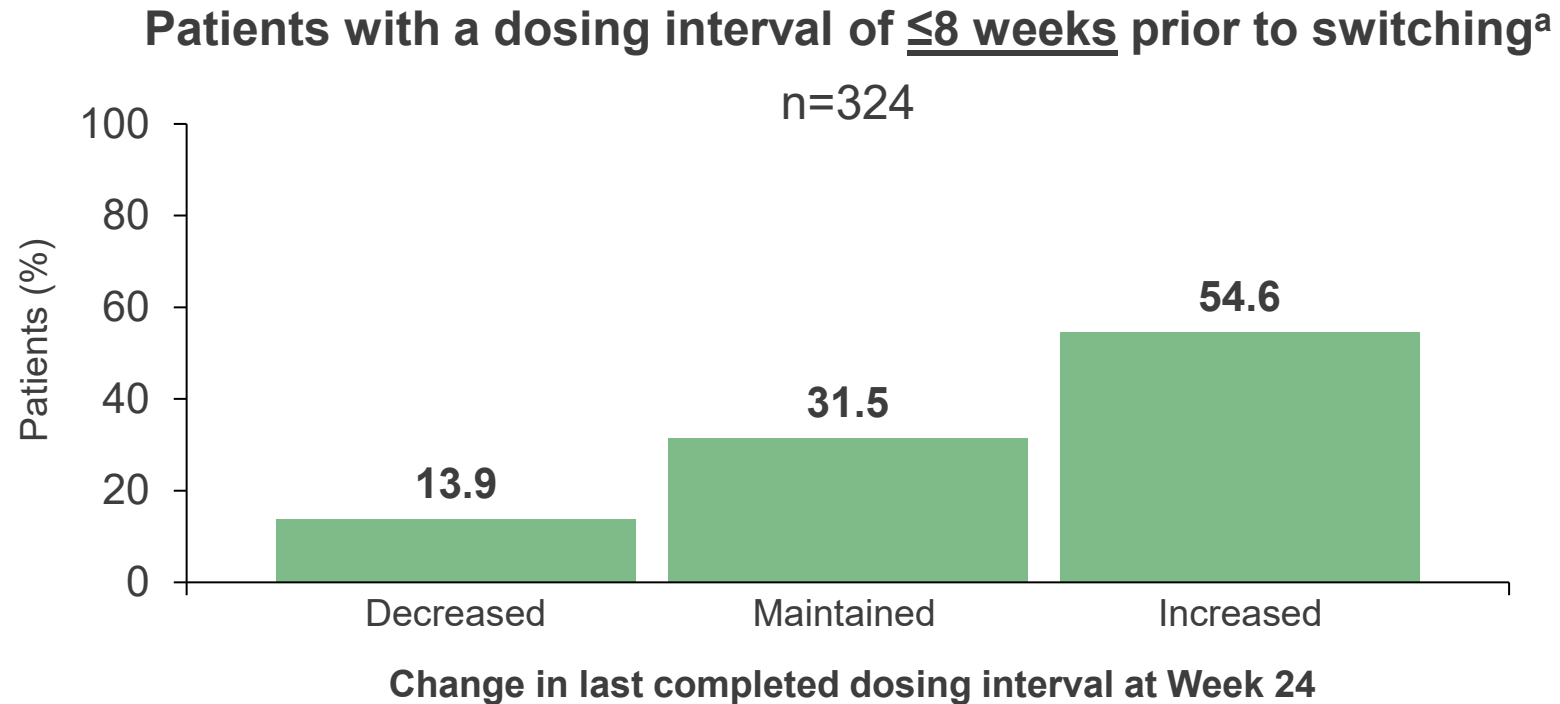
^aCRT was assessed by either CRT or CST, at the investigator's discretion; CRT or CST was assessed from BL through Week 24 for each individual patient, or CST thereafter if no BL value was available.

CI, confidence interval; CRT, central retinal thickness; CST, center subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; LOCF, last observation carried forward; SD, standard deviation; W, week.

Treatment exposure through Week 24



Last completed dosing interval at Week 24: Previously treated DME



Most previously treated DME patients (86%) with a dosing interval of ≤ 8 weeks prior to switching to aflibercept 8 mg maintained or increased their dosing interval at Week 24

Week 24 safety outcomes

	TN DME (N=697)	PT DME (N=698)
Ocular TEAEs in the study eye,^a n (%)		
Any ocular TEAEs	41 (5.9)	56 (8.0)
Any serious ocular TEAEs	3 (0.4)	8 (1.1)
Non-ocular TEAEs, n (%)		
Any non-ocular TEAEs	42 (6.0)	46 (6.6)
Any serious non-ocular TEAEs	18 (2.6)	20 (2.9)



No cases of retinal vasculitis were reported
No new safety signals were identified

To date, the **safety profile** of **aflibercept 8 mg** in SPECTRUM is **consistent** with that observed in the **Phase 2 and 3 clinical trials**^{1–3}

SAF (all patients receiving ≥1 dose of study drug in the study eye). ^aThe 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.

1. Brown DM, et al. *The Lancet*. 2024;403:1153–1163. 2. Wycoff CC, et al. *JAMA Ophthalmol*. 2023;141:834–842. Lanzetta P, et al. *The Lancet*. 2023;403:1141–1152.



More frequent initial monthly dosing in the treatment-naïve versus previously treated DME cohorts by Week 24 in SPECTRUM

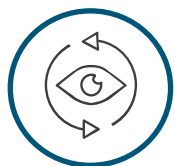


Enrollment in SPECTRUM is complete

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

>1400 patients enrolled in the TN and PT DME cohorts across **12 countries**

Global DME treatment patterns: Key Week 24 findings



Improved or stable VA and reduced CRT

Achieved with 4.0–4.1 injections from BL through Day 210



Treatment initiated with 3 monthly doses

In the TN DME cohort through Week 8



Longer dosing intervals achieved

The majority of patients with a ≤ 8 -week interval before switching achieved longer intervals



No new safety signals

Safety profile consistent with pivotal clinical trials^{1–3}



Week 24 results from **SPECTRUM** provide **real-world insights** on **treatment patterns** with **aflibercept 8 mg** in patients with **TN and PT DME**

SPECTRUM data on real-world outcomes with aflibercept 8 mg in patients with DME and nAMD are being presented in other EURETINA '26 sessions



Additional analyses up to Month 12 and Month 24 are ongoing