SPECTRUM: Early real-world treatment patterns with aflibercept 8 mg in patients with treatment-naïve and previously treated DME

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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**

Two indications, 4 patient cohorts

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

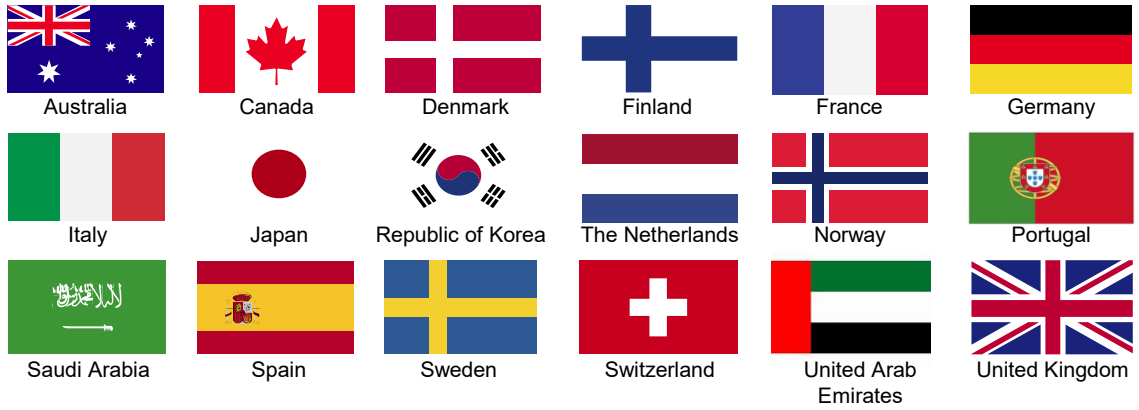
Primary endpoint: Change in **VA** from **BL to Month 12**

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:

3733	**723**	**716**
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 and previously treated DME

Week 24 treatment patterns for the first ~150 patients enrolled globally in each cohort

Baseline characteristics: Treatment-naïve and previously treated DME

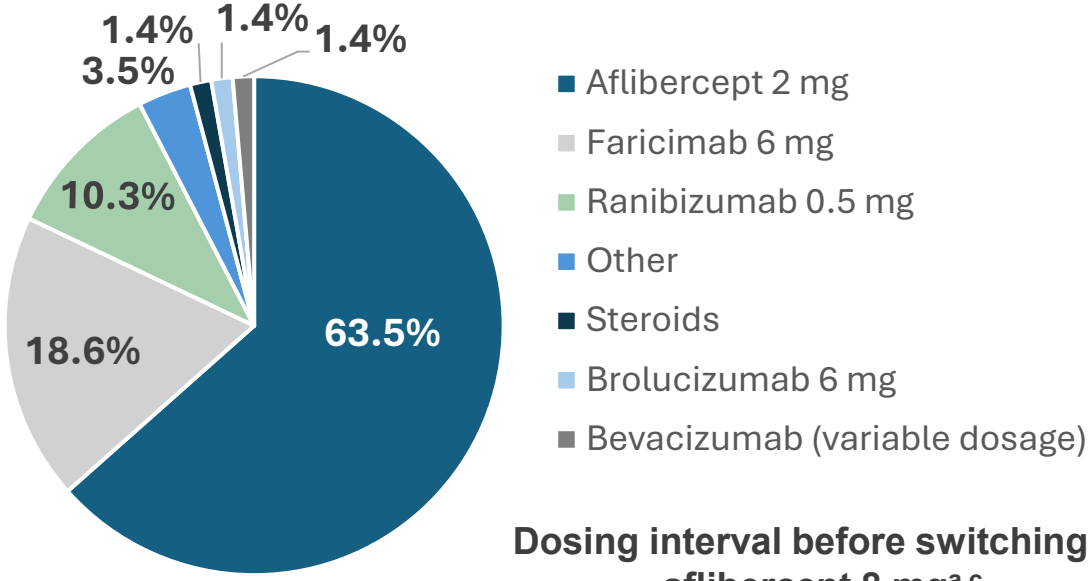
Week 24 analysis of the first ~150 patients enrolled

	Global TN DME	Global PT DME
FAS, n	142	145
Age, years	66.1±11.5	65.3±11.0
Sex, %		
Male	63.4	69.7
Female	36.6	30.3
Median (min, max) time from DME diagnosis, months	0.4 (0.0, 109.2)	45.6 (2.1, 178.2)
Median last completed dosing interval prior to switch, weeks	–	8
Median (min, max) time from first prior treatment, days	–	639 (32, 4665)

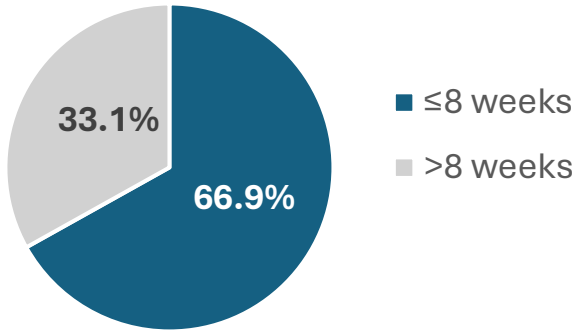
FAS. Week 24 = visits closest to 180 (150–210) days after BL. FAS, full analysis set; Max, maximum; Min, minimum.

Baseline characteristics: Previously treated DME

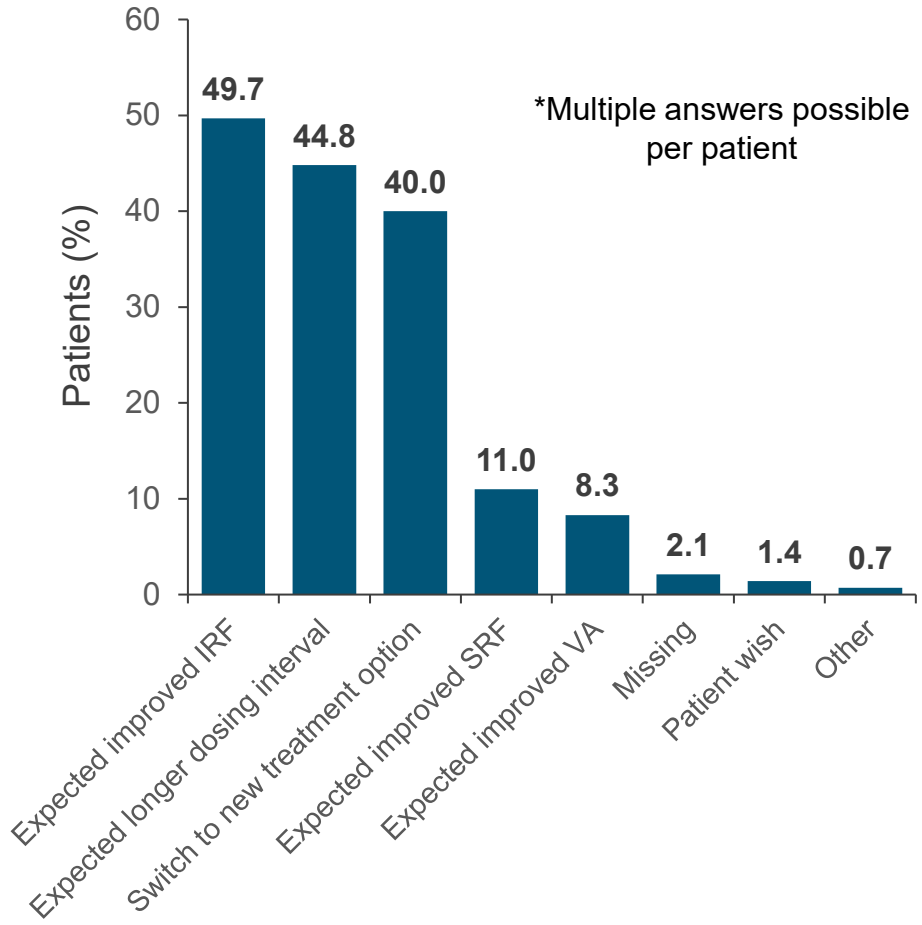
Previous DME medication[a,b]



Dosing interval before switching to aflibercept 8 mg[a,c]

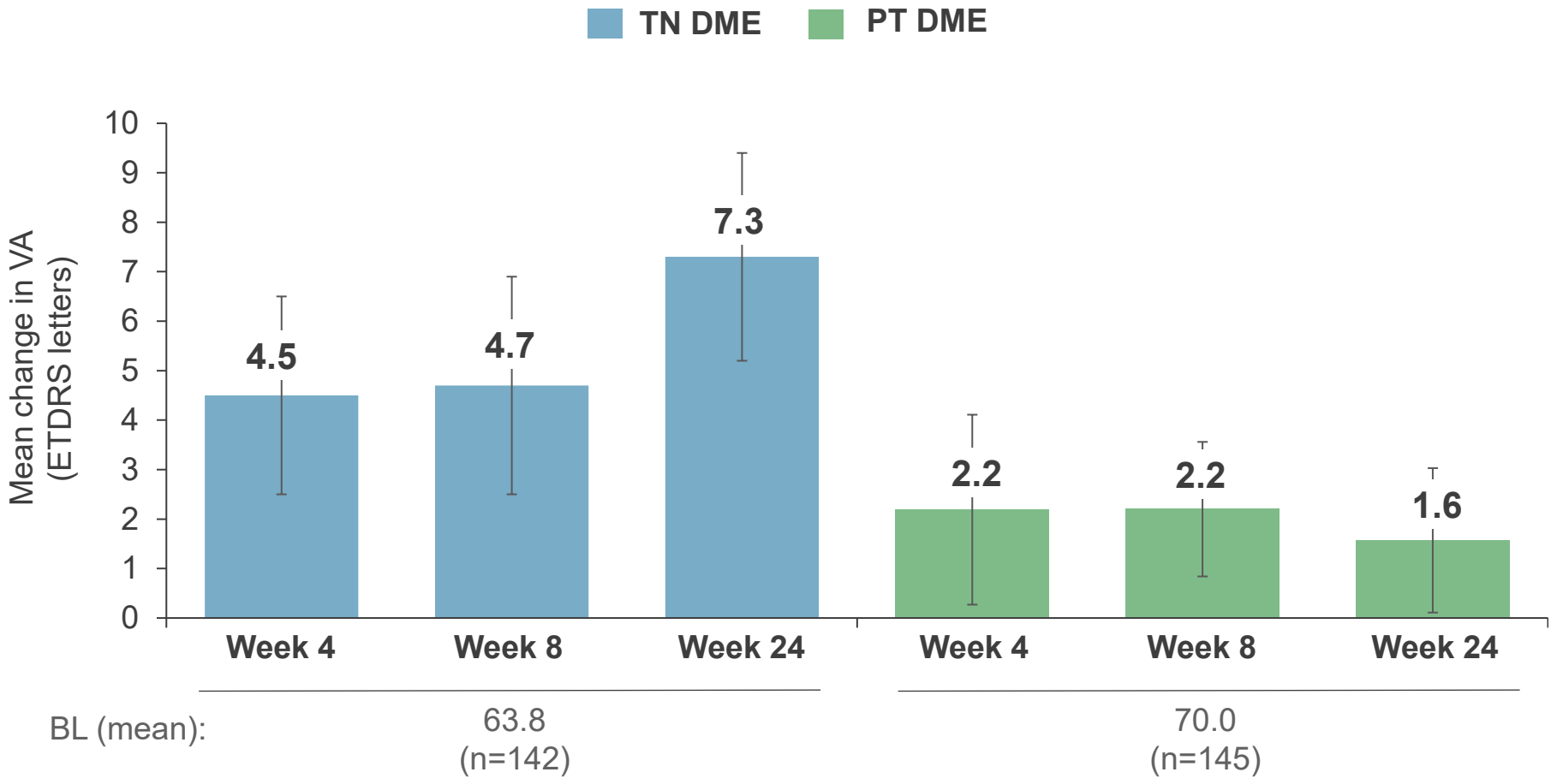


Reasons for switching to aflibercept 8 mg*



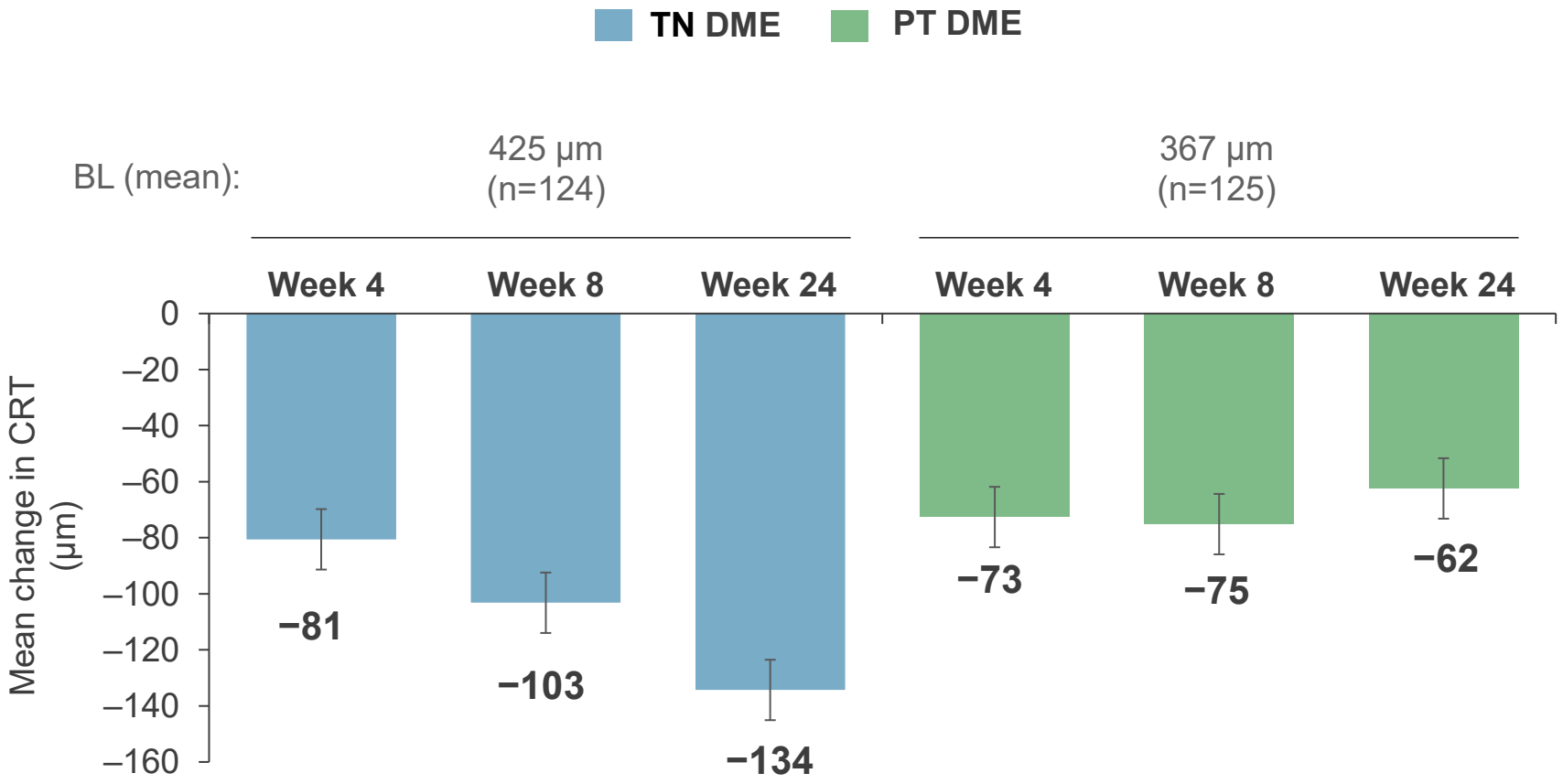
FAS (PT DME: n=145). [a]Percentages may not add up to 100 due to rounding. [b]Biosimilars are included in each medication option. [c]Calculated for patients with last completed dosing interval data prior to switching (n=127). IRF, intraretinal fluid; SRF, subretinal fluid; VA, visual acuity.

Mean change in VA through Week 24



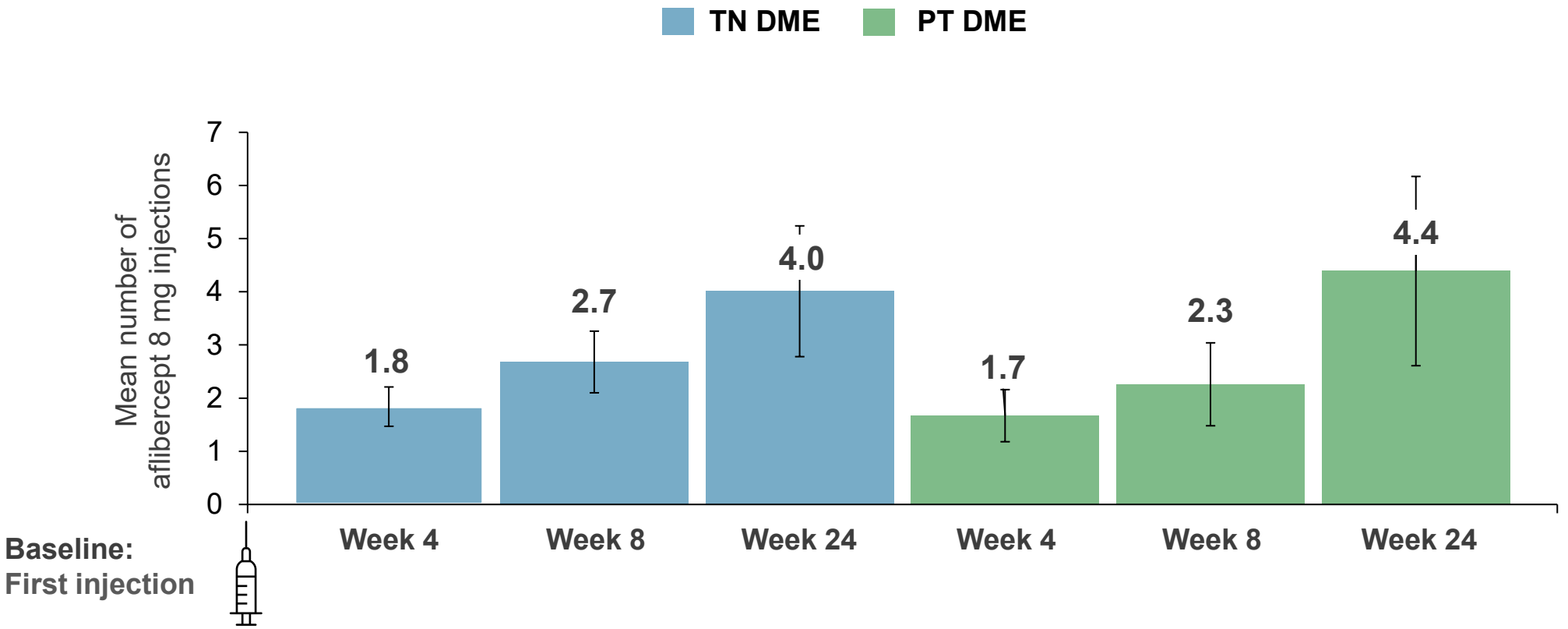
FAS, LOCF (TN DME: n=142; PT DME: n=145). Missing values were imputed with the LOCF approach. Error bars represent 95% CI. Week 4 = visits closest to 28 (14–42) days after BL, Week 8 = visits closest to 56 (43–70) days after BL, Week 24 = visits closest to 180 (150–210) days after BL. CI, confidence interval; LOCF, last observation carried forward.

Mean change in CRT through Week 24



FAS, LOCF (TN DME: n=142; PT DME: n=145). 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.

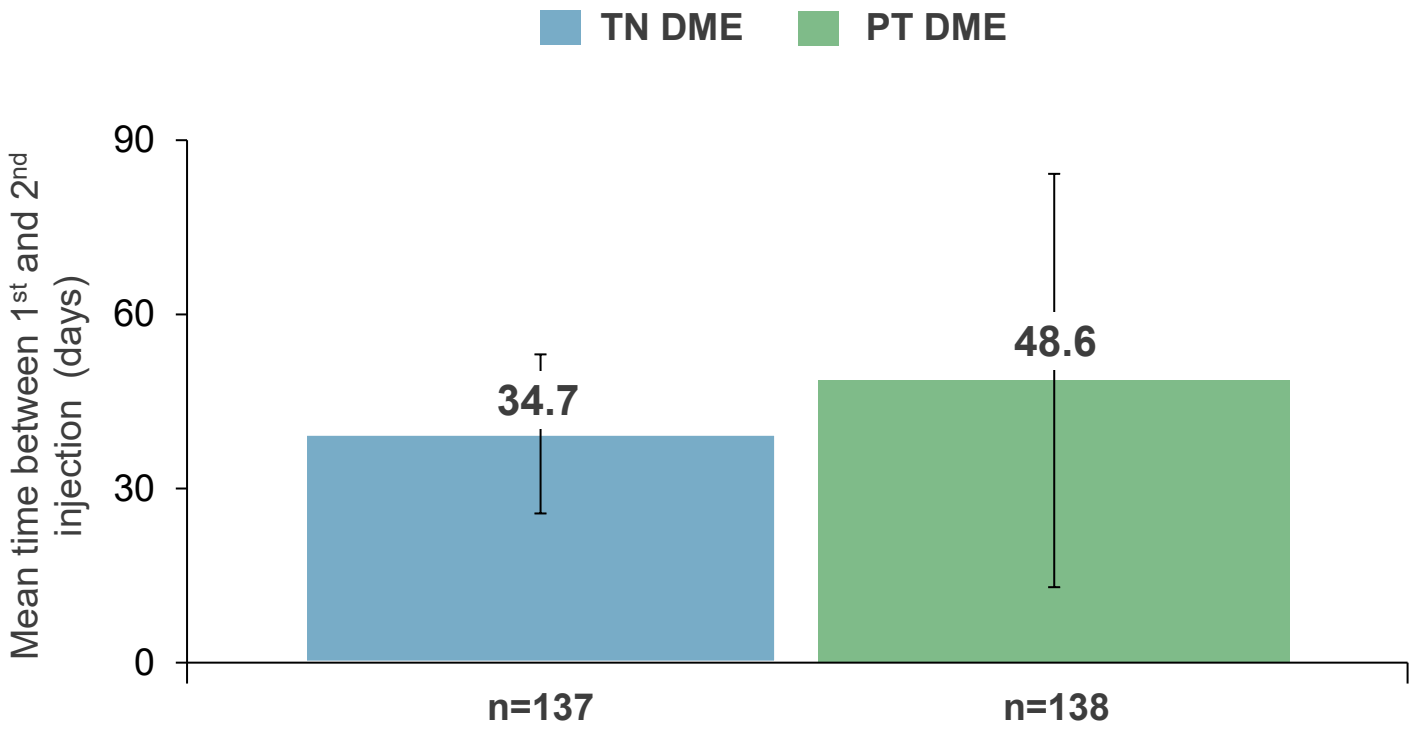
Mean number of injections administered through Week 24



Patients received a mean±SD of **4.0±1.2** and **4.4±1.8 injections** from **BL** up to **Day 210[a]** in the TN and PT DME cohorts

FAS (TN DME: n=142; PT DME: n=145). First injection was administered at BL. Error bars represent SD. Week 4 = injections up to 42 days after BL, Week 8 = injections up to 70 days after BL, [a]Week 24 = injections up to 210 days after BL. SD, standard deviation.

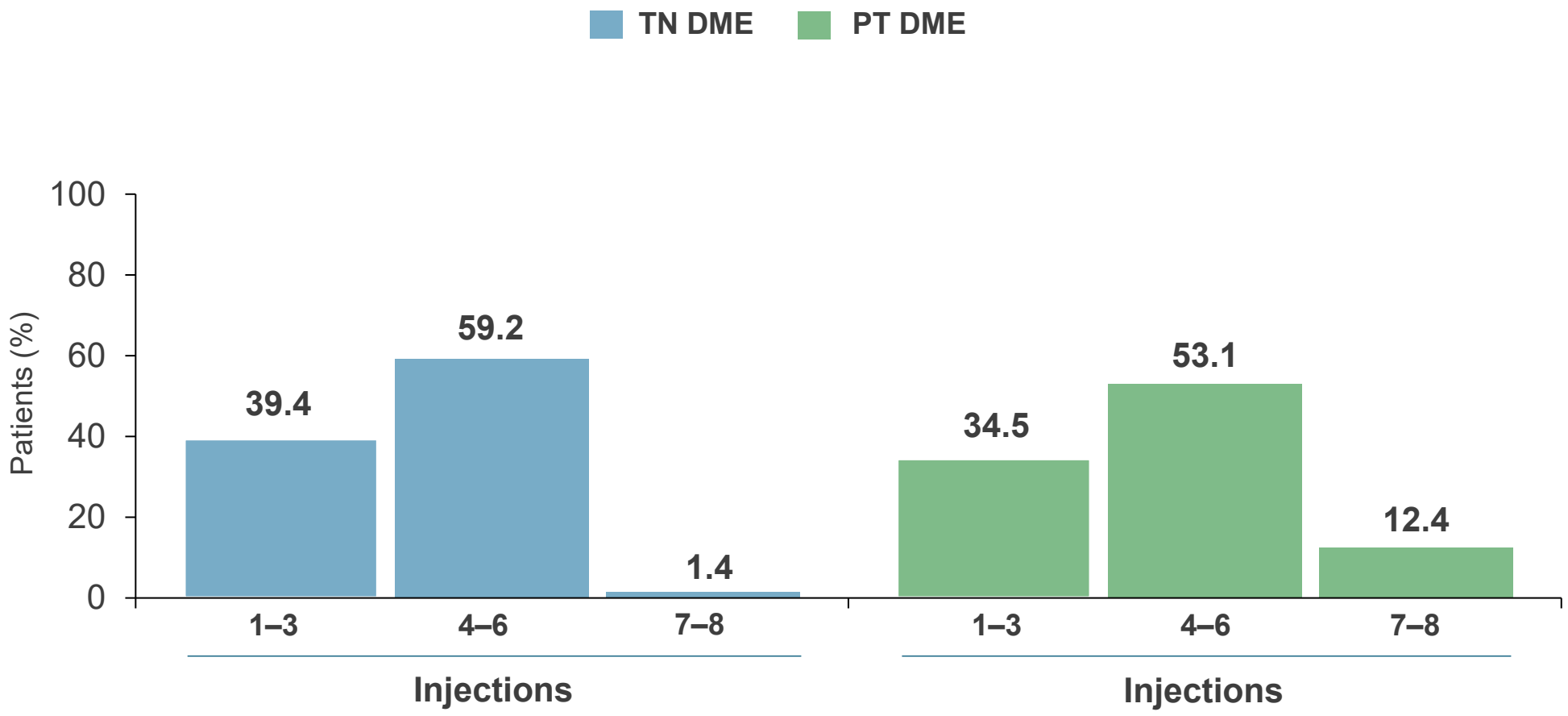
Time between the first and second aflibercept 8 mg injection



In the treatment-naïve and previously treated DME cohorts, **73.9%** and **44.8%** of patients received **3 injections** from **baseline** up to **Day 70[a]**

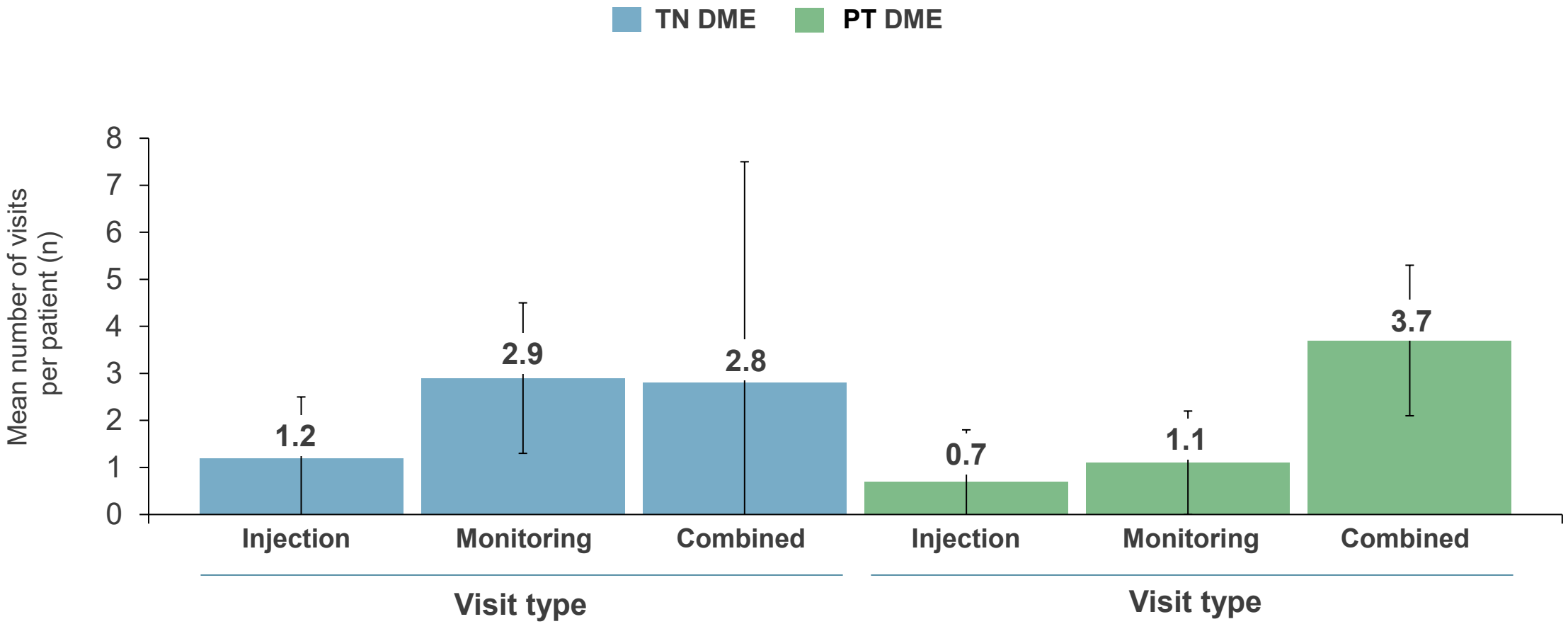
FAS (TN DME: n=142; PT DME: n=145). First injection was administered at BL. Error bars represent SD. [a]Week 8 = injections up to 70 days after BL.

Proportion of patients who received 1–3, 4–6, and 7–8 injections by Week 24



FAS (TN DME: n=142; PT DME: n=145). First injection was administered at BL. Week 24 = injections up to 210 days after BL.

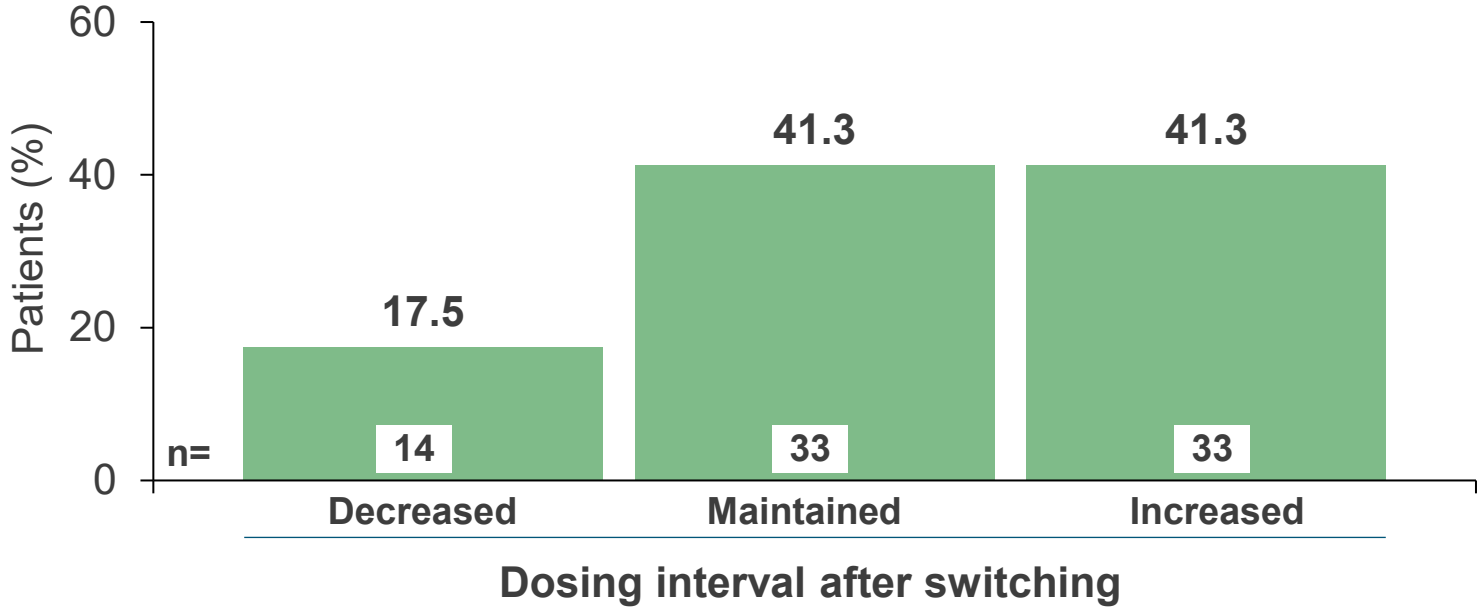
Types of clinical visits through Week 24



FAS (TN DME: n=142; PT DME: n=145). Error bars represent SD. The main visit types were injection-only (patients received an injection only); monitoring-only (patients were assessed without receiving an injection); and combined visits that included both monitoring and an injection). Week 24 = injections up to 210 days after BL.

Last completed dosing interval at Week 24: Previously treated DME

Patients with a dosing interval ≤8 weeks at BL



The **majority** of patients (**83%**) with a **dosing interval** of **≤8 weeks** prior to switching to aflibercept 8 mg **maintained** or **increased** their dosing interval at **Week 24**

Median last completed dosing interval in the FAS (n=122)[a]	Weeks
Before switching to aflibercept 8 mg	8
At Week 24	8

FAS, (PT DME: n=80). Week 24 = injections up to 210 days after BL.[a]Median last completed dosing interval data are for patients with any dosing interval data at BL and at Week 24.

Safety overview: Adverse events

	TN DME (N=150)	PT DME (N=150)
Ocular TEAEs, n (%)		
Any ocular TEAEs in the study eye[a]	11 (7.3)	21 (14.0)
Any serious ocular TEAEs	1 (0.7)	3 (2.0)
Non-ocular TEAEs, n (%)		
Any non-ocular TEAEs	16 (10.7)	17 (11.3)
Any serious non-ocular TEAEs	3 (2.0)	5 (3.3)

No cases of retinal vasculitis were reported
No safety concerns 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. [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. Week 24 = injections up to 210 days after BL. 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: 834-42. Lanzetta P, et al. *The Lancet,* 2023; 403, 1141-1152.

SPECTRUM: Treatment patterns through Week 24 in patients with DME

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

More than **1400** patients have been enrolled in each of the global **treatment-naïve and previously treated DME cohorts** across **12 countries**

Treatment-naïve DME cohort

- Outcomes achieved with a mean of **4.0 injections** up to **Day 210**
- Patients in the **TN DME cohort** received **more intensive treatment** up to **Day 70** than those in the PT DME cohort

Previously treated DME cohort

- Outcomes achieved with a mean of **4.4** injections up to **Day 210**
- In patients with a **≤8-week dosing interval prior to switching** to aflibercept 8 mg, the **dosing interval** was **maintained or increased** in **83%** of patients at Week 24

SPECTRUM data on early **real-world outcomes** and **IOP metrics** with aflibercept 8 mg in patients with **nAMD** and **DME** are being presented in other ARVO ‘26 sessions

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

Additional analyses up to Month 24 are ongoing

IOP, intraocular pressure.