SPECTRUM: Latest clinical data from the first global real-world study of 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**

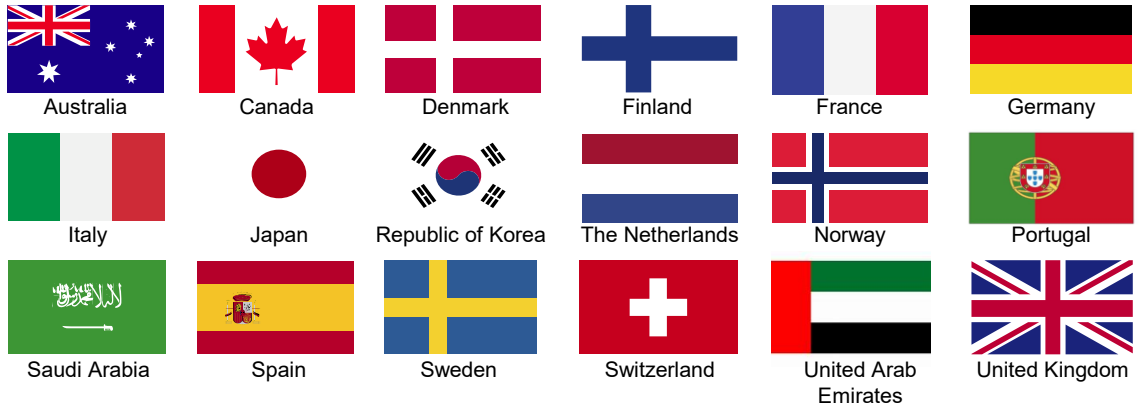
Primary endpoint: Change in **VA** from **BL to Month 12**

Secondary endpoints include:

- Change in **VA** and **CRT**[a] from BL to Week 12
- Number of **injections, visits**, and **safety** from BL to Week 12

Patient enrollment is complete:

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



Week 12 = visits closest to 90 (76–118) days after BL. [a]CRT was assessed by either CRT or CST, per investigator discretion; the parameter assessed at baseline (CRT or CST) for each individual patient was included through Week 12 for this analysis, or CST thereafter if no baseline value was available. BL, baseline; CRT, central retinal thickness; CST, 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

Overview of the Week 24 interim analysis of the first ~150 patients enrolled globally

Baseline characteristics: Treatment-naïve and previously treated DME

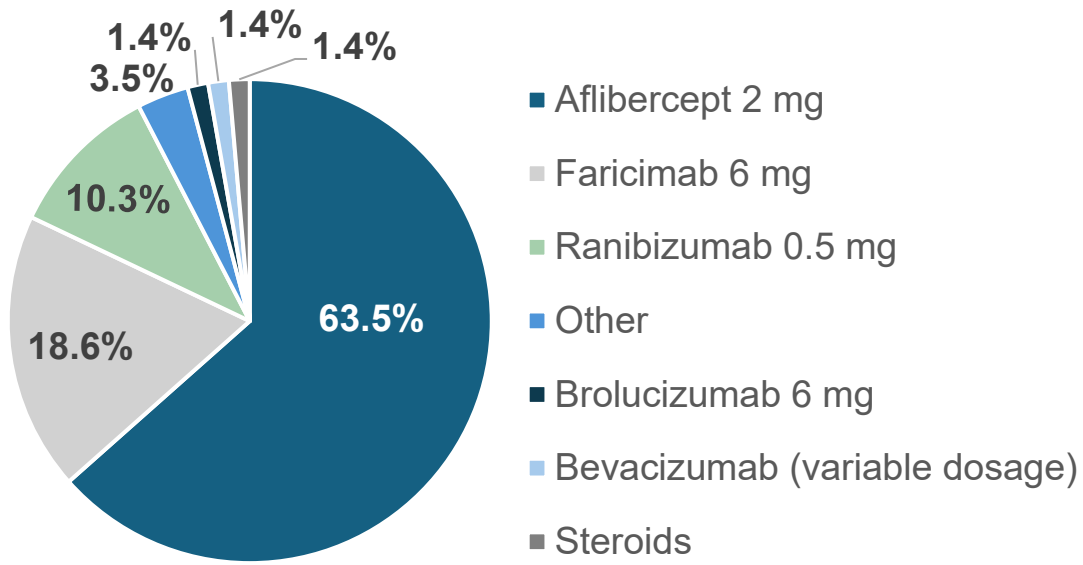
Week 24 analysis of the first ~150 patients enrolled[a]

	Global TN DME (n=142)	Global PT DME (n=145)
Age, years	66.1±11.5	65.3±11.0
Sex, %		
Male	63.4	69.7
Female	36.6	30.3
Race,[b] %		
White	55.6	76.6
Asian	30.3	6.2
Black or African American	2.1	2.1
Not reported	12.7	15.2
Median (min, max) time from DME diagnosis, months	0.4 (0.0, 109.2)	45.7 (2.1, 178.2)
Baseline VA, ETDRS letters	63.8±16.6	70.0±14.0
Baseline CRT, µm	425±114	367±136

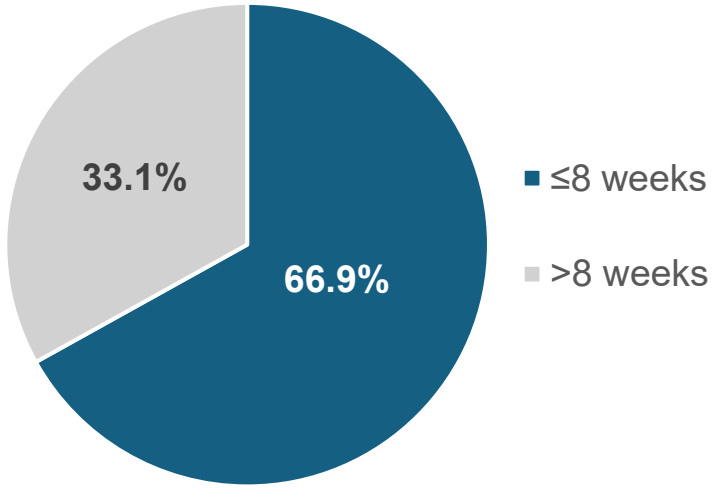
FAS. Percentages may not add up to 100 due to rounding. Week 24 = visits closest to 180 (150–210) days after BL. [a]Data are mean±SD unless otherwise indicated. [b]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, Saudi Arabia, South Korea, Spain, Switzerland, United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

Baseline characteristics: Previously treated DME

Previous DME medication[a,b]

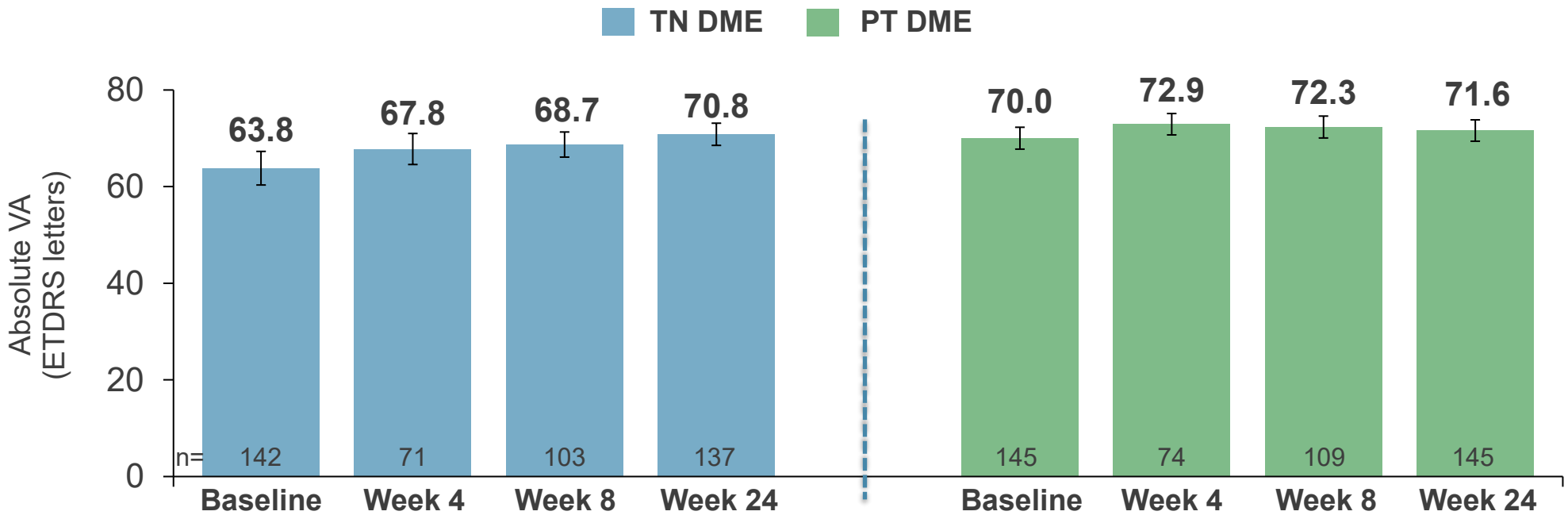


Dosing interval before switching to aflibercept 8 mg[c]



Percentages may not add up to 100 due to rounding. [a]FAS (n=145). [b]Biosimilars are included in each medication option. [c]Calculated for patients with last completed dosing interval data prior to switching (n=127).

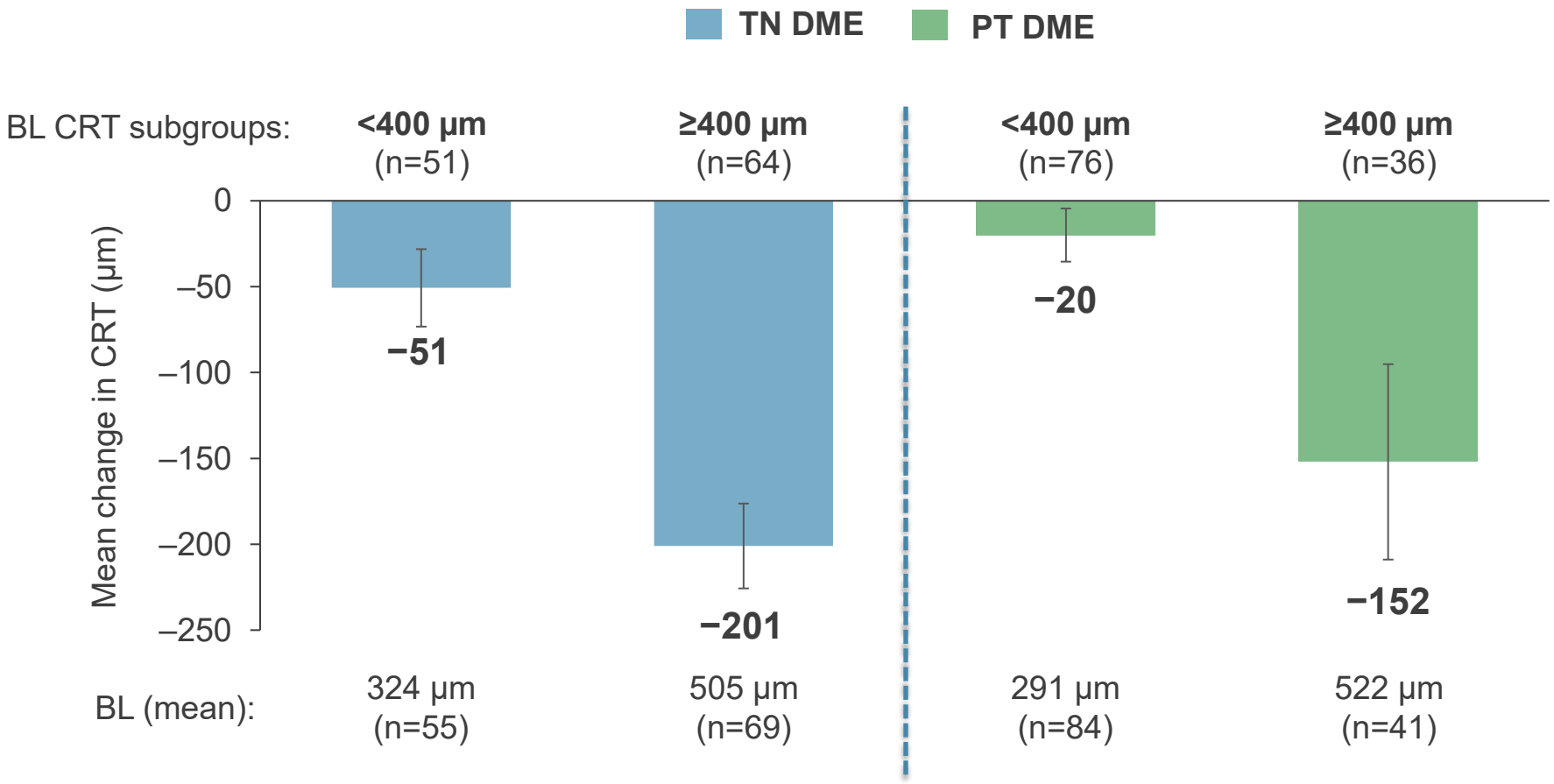
VA through Week 24



Timepoint	Mean change (95% CI) from baseline (LOCF)	
	TN DME	PT DME
Week 4	+4.5 (2.5, 6.5)	+2.2 (0.3, 4.1)
Week 8	+4.7 (2.5, 6.9)	+2.2 (0.8, 3.6)
Week 24	**+7.3 (5.2, 9.4)**	**+1.6 (0.1, 3.0)**

FAS, LOCF (TN DME: n=142; PT DME: n=145). 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. CI, confidence interval; LOCF, last observation carried forward.

Mean change in CRT grouped by baseline CRT at Week 24



FAS, LOCF (TN DME: n=142; PT DME: n=145). 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 (TN DME) and −24 and −19 µm (PT DME) for those with a baseline CRT of <400 µm, and −113 and −146 µm (TN DME) and −172 and −167 µm (PT DME) for those with a baseline CRT of ≥400 µm, respectively.

Week 24 treatment exposure and safety outcomes

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

	TN DME (n=150)	PT DME (n=150)
Ocular TEAEs, n (%)		
Any ocular TEAEs in the study eye[b]	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

SAF. [a]Week 24 = visits closest to 180 (150–210) days after BL. [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; TEAE, treatment-emergent adverse event.

Treatment-naïve and previously treated DME

Week 12 outcomes for the full global DME cohorts

Baseline characteristics: Treatment-naïve and previously treated DME

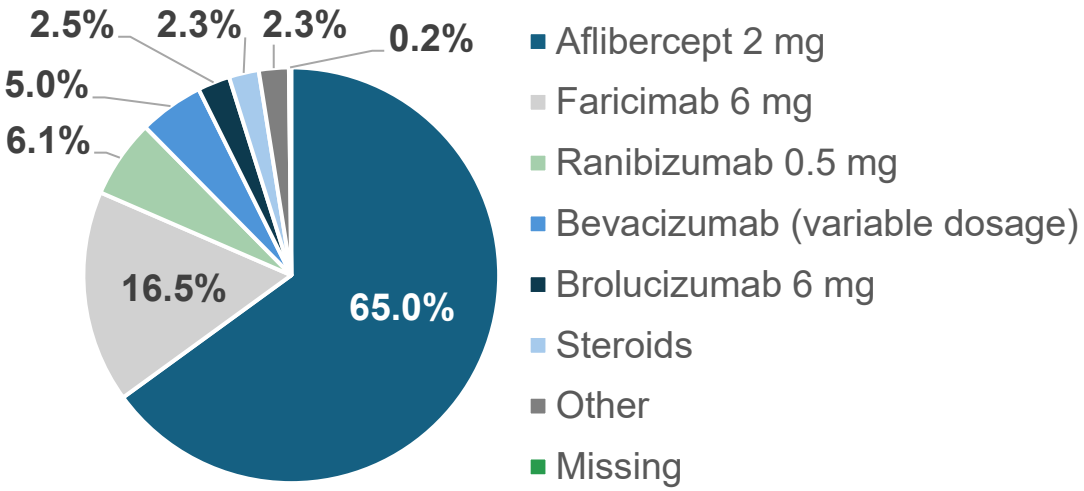
Week 12 analysis of the global DME cohorts[a]

	TN DME (n=547)	PT DME (n=557)
Age, years	64.6±11.8	66.2±11.5
Sex, %		
Male	64.4	65.4
Female	35.7	34.7
Race,[b] %		
White	42.6	50.8
Asian	19.4	16.3
Black or African American	2.6	0.9
American Indian or Alaska Native	0.2	0.2
Native Hawaiian or Other Pacific Islander	0	0
Not reported	35.7	31.8
Median (min, max) time from DME diagnosis, months	0.3 (0.0, 115.1)	41.8 (0.0, 331.2)
Baseline VA, ETDRS letters	63.6±18.2	66.8±15.4
Baseline CRT,[c] µm	400±116	373±120

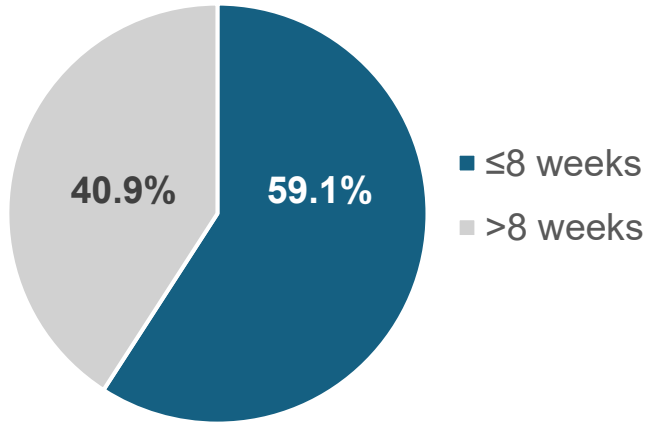
FAS. Percentages may not add up to 100 due to rounding. Week 12 = visits closest to 90 (76–118) days after BL. [a]Data are mean±SD unless otherwise indicated. [b]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, Saudi Arabia, South Korea, Spain, Switzerland, United Arab Emirates, and the UK only. [c]CRT was assessed by either CRT or CST, per investigator discretion; the parameter assessed at baseline (CRT or CST) for each individual patient was included through Month 12 for this analysis, or CST thereafter if no baseline value was available.

Baseline characteristics: Previously treated DME

Previous DME medication[a,b]

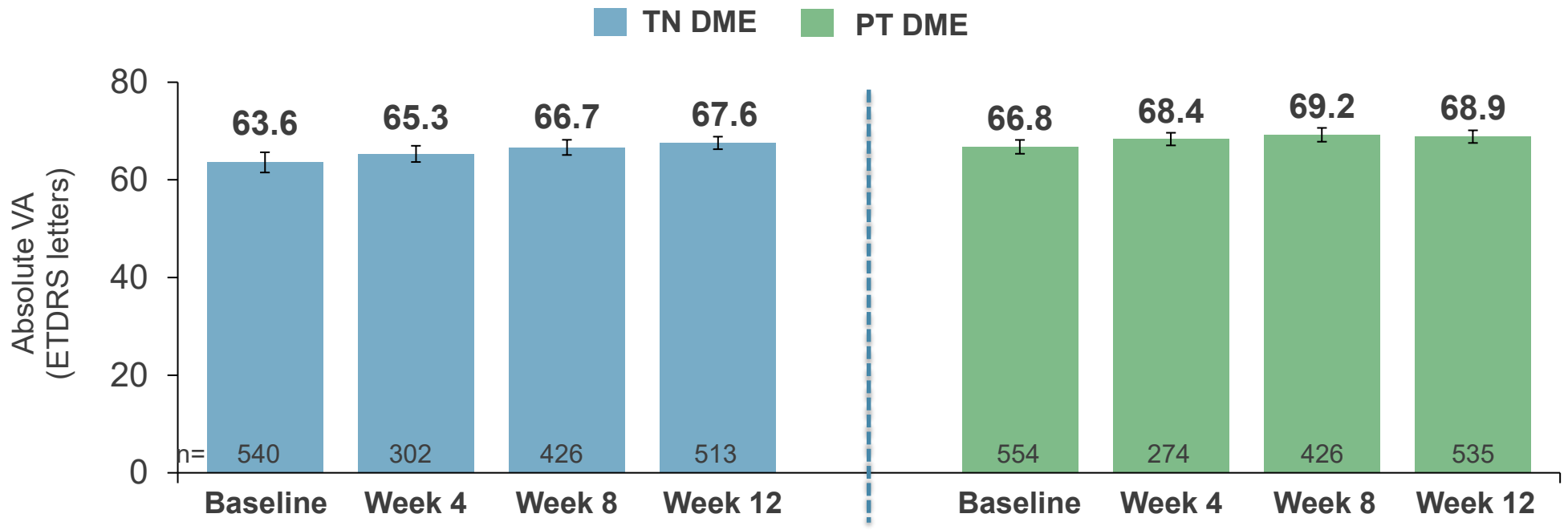


Dosing interval before switching to aflibercept 8 mg[c]



Percentages may not add up to 100 due to rounding. [a]FAS (n=557). [b]Biosimilars are included in each medication option. [c]Calculated for patients with last completed dosing interval data prior to switching (n=504).

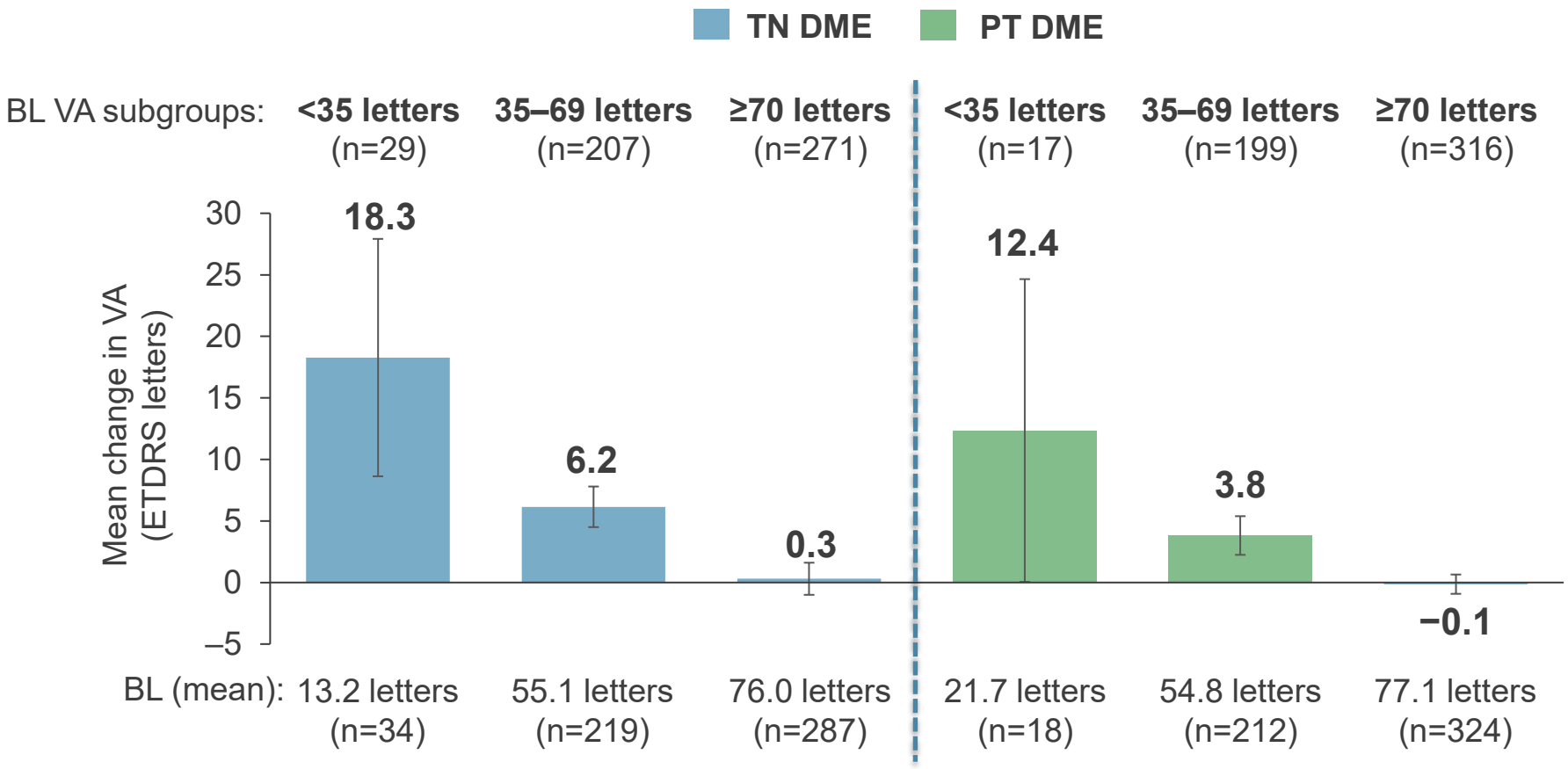
VA through Week 12



Timepoint	Mean change (95% CI) from baseline (LOCF)	
	TN DME	PT DME
Week 4	+2.5 (1.2, 3.9)	+1.4 (0.2, 2.6)
Week 8	+3.3 (2.2, 4.5)	+1.8 (1.0, 2.7)
Week 12	**+3.7 (2.6, 4.9)**	**+1.7 (0.9, 2.6)**

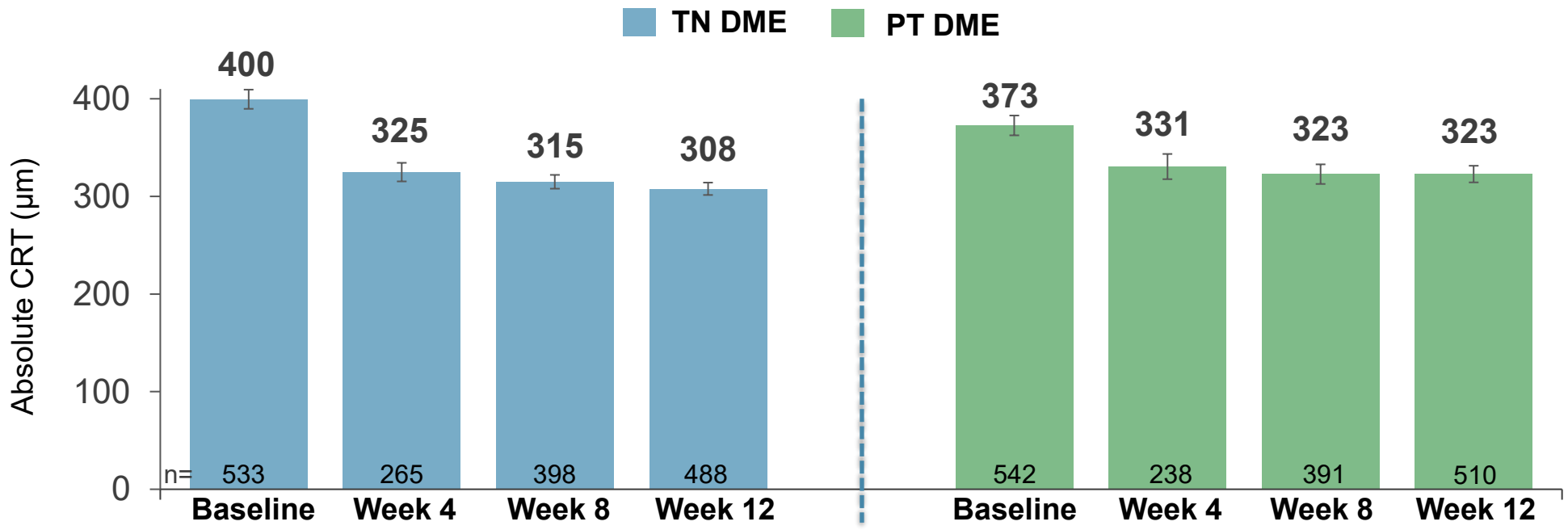
FAS, LOCF (TN DME: n=547; PT DME: n=557). Missing values were imputed using the LOCF approach. Error bars represent 95% CI. Week 4 = visits closest to 28 (14–42) days after BL, Week 8 = visits closest to 56 (43–70) days after BL, Week 12 = visits closest to 90 (76–118) days after BL.

Mean change in VA grouped by baseline VA at Week 12[a]



FAS, LOCF (TN DME: n=547; PT DME: n=557). 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 +13.8 and +15.4 letters (TN DME) and +9.5 and +11.8 letters (PT DME) for those with a baseline VA of <35 letters, +4.7 and +5.4 letters (TN DME) and +3.3 and +4.1 letters (PT DME) for those with a baseline VA of 35–69 letters, and –0.6 and +0.3 letters (TN DME) and – 0.3 and 0.0 letters (PT DME) for those with a baseline of ≥70 letters, respectively.

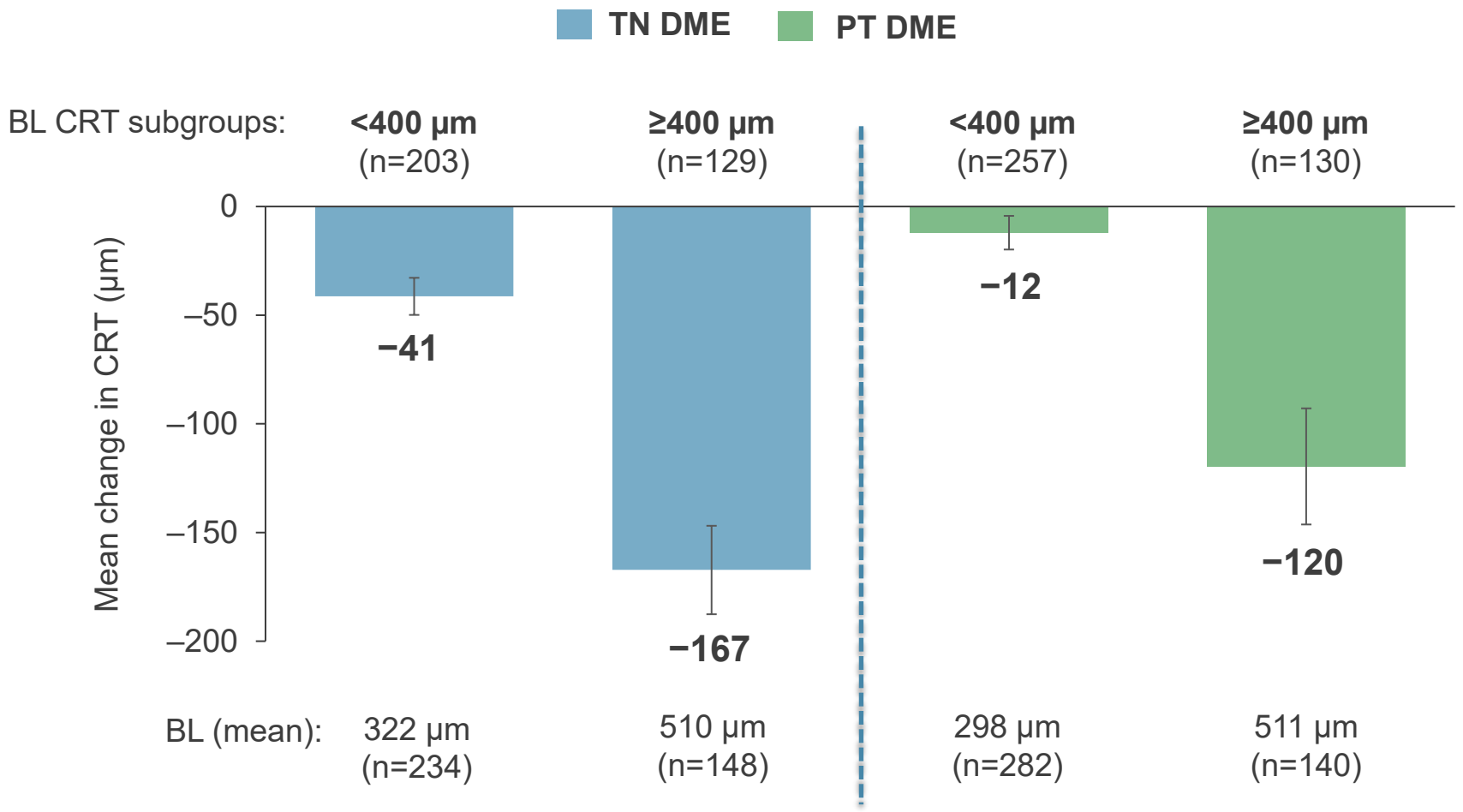
CRT through Week 12[a]



Timepoint	Mean change (95% CI) from baseline (LOCF)	
	TN DME	PT DME
Week 4	−73 (−85, −60)	−59 (−73, −44)
Week 8	−87 (−97, −76)	−54 (−65, −44)
Week 12	**−91 (−101, −82)**	**−50 (−59, −41)**

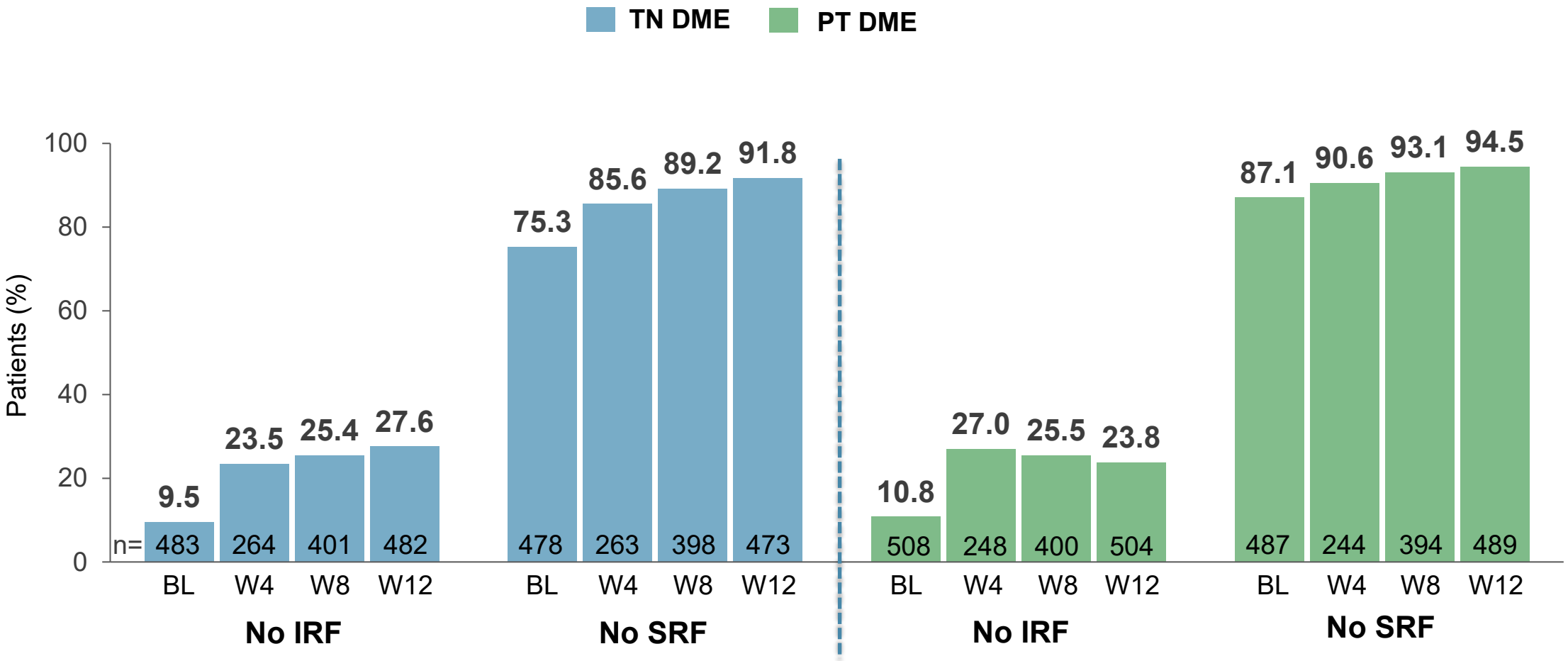
FAS, LOCF (TN DME: n=547; PT DME: n=557). Missing values were imputed using the LOCF approach. Error bars represent 95% CI. [a]CRT was assessed by either CRT or CST, per investigator discretion; the parameter assessed at baseline (CRT or CST) for each individual patient was included through Week 12 for this analysis, or CST thereafter if no baseline value was available.

Change in CRT grouped by baseline CRT at Week 12[a,b]



FAS, LOCF (TN DME: n=547; PT DME: n=557). 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 −29 and −39 µm (TN DME) and −13 and −15 µm (PT DME) for those with a baseline CRT of <400 µm, and −141 and −159 µm (TN DME) and −142 and −125 µm (PT DME) for those with a baseline CRT of ≥400 µm, respectively. [b]In patients with a CST assessment at Week 4, Week 8, and Week 12, the mean change in CST at Week 4, Week 8, and Week 12, grouped by baseline CST was −27, −33, and −38 µm (TN DME) and −22, −15, and −19 µm (PT DME) for those with a baseline CST of <400 µm, and −128, −151, and −159 µm (TN DME) and −114, −113, and −113 µm (PT DME) for those with a baseline CST of ≥400 µm, respectively.

Proportion of patients without IRF or SRF through Week 12[a]



FAS, LOCF (TN DME: n= 547; PT DME n=557). Missing values were imputed using the LOCF approach. [a]The presence of IRF and SRF were determined by optical coherence tomography per physician discretion with the instrument available at each study site; the proportions presented here were calculated based on the number of patients who had an assessment at each of the indicated time points. IRF, intraretinal fluid; SRF, subretinal fluid.

Week 12 treatment exposure and safety outcomes

Patients received a mean±SD of **3.1±0.9** and **2.8±1.0 injections** from **baseline** up to **Day 118**[a] in the TN and PT DME cohorts

	TN DME (n=696)	PT DME (n=699)
Ocular TEAEs, n (%)		
Any ocular TEAEs in the study eye[b]	29 (4.2)	33 (4.7)
Any serious ocular TEAEs	3 (0.4)	5 (0.7)
Most frequent ocular TEAEs in the study eye, n (%)[c]		
Intraocular pressure increased	4 (0.6)	6 (0.9)
Conjunctival haemorrhage	1 (0.1)	3 (0.4)
Iridocyclitis	2 (0.3)	1 (0.1)
Ocular hypertension	1 (0.1)	2 (0.3)
Non-ocular TEAEs, n (%)		
Any non-ocular TEAEs	29 (4.2)	31 (4.4)
Any serious non-ocular TEAEs	7 (1.0)	12 (1.7)
Most frequent non-ocular TEAEs, n (%)[c]		
Nasopharyngitis	3 (0.4)	2 (0.3)
Norovirus infection	2 (0.3)	1 (0.1)
Hypertension	1 (0.1)	2 (0.3)

No cases of retinal vasculitis were reported
No safety concerns were identified

SAF. [a]Week 12 = visits closest to 90 (76–118) days after BL. [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. [c]Most frequent across both cohorts.

Week 12 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 have been enrolled in SPECTRUM across **18 countries,** and **enrollment is now complete**

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

Clinical effectiveness and safety outcomes at Week 12 in the global treatment-naive DME cohort

- Improved VA and CRT from baseline
- Increased proportions of patients with fluid-free status
- Outcomes achieved with a mean of **3.1 injections** up to **Day 118**
- No safety concerns identified

Clinical effectiveness and safety outcomes at Week 12 in the global previously treated DME cohort

- Stable VA and improved CRT from baseline
- Increased proportions of patients with fluid-free status
- Outcomes achieved with a mean of **2.8 injections** up to **Day 118**
- No safety concerns identified

SPECTRUM data on **treatment patterns** and **IOP metrics** with aflibercept 8 mg in patients with **nAMD** and **DME** are being presented in other ARVO ‘26 sessions, as well as Week 12 outcomes in patients with nAMD

These **Week 12 results** from SPECTRUM **inform** the **clinical management** of previously treated and treatment-naïve **DME** in patients receiving aflibercept 8 mg in **routine clinical practice**

Additional analyses up to Month 24 are ongoing

IOP, intraocular pressure.