SPECTRUM: Latest clinical data from the first global real-world study of aflibercept 8 mg in patients with treatment-naïve and previously treated nAMD

Javier Zarranz-Ventura,[1] Clare Bailey,[2] Clemens Lange,[3,4] Varun Chaudhary,[5] Paolo Lanzetta,[6,7] Hassiba Oubraham,[8] Martin Kirchner,[9] Tobias Machewitz,[10] Susanne Oesch,[11] Peter Morgan-Warren,[11] Marion R. Munk,[12–14] on behalf of the SPECTRUM study investigators

[1]Hospital Clínic de Barcelona, Universitat de Barcelona, Barcelona, Spain; [2]Department of Ophthalmology, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK; [3]Eye Center, Faculty of Medicine, Albert-Ludwig University Freiburg, Freiburg, Germany; [4]Department of Ophthalmology, St Franziskus Hospital, Münster, Germany; [5]Department of Surgery, McMaster University, Hamilton, ON, Canada; [6]Department of Medicine – Ophthalmology, University of Udine, Udine, Italy; [7]Istituto Europeo di Microchirurgia Oculare – IEMO, Udine, Italy; [8]Centre OPHTA-45, Montargis, France; [9]Bayer AG, Leverkusen, Germany; [10]Bayer AG, Berlin, Germany; [11]Bayer Consumer Care AG, Basel, Switzerland; [12]Augenarzt Praxisgemeinschaft Gutblick AG, Pfäffikon, Switzerland; [13]Department of Ophthalmology, University Hospital Bern, Bern, Switzerland; [14]Northwestern University, Feinberg School of Medicine, Chicago, IL, USA

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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, four patient cohorts

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

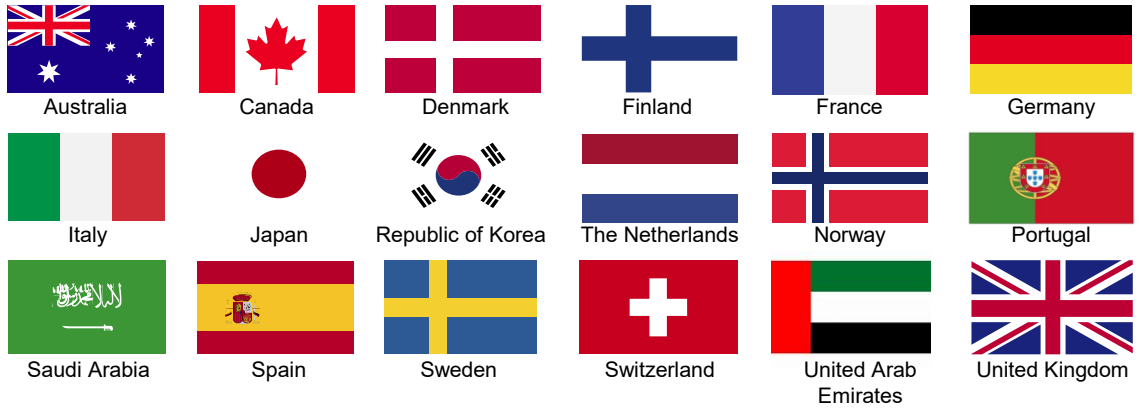
Primary endpoint: Change in **VA** from **BL to Month 12**

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	**1169**	**1125**
nAMD + DME	TN nAMD cohort	PT nAMD 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 subfield 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 nAMD

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

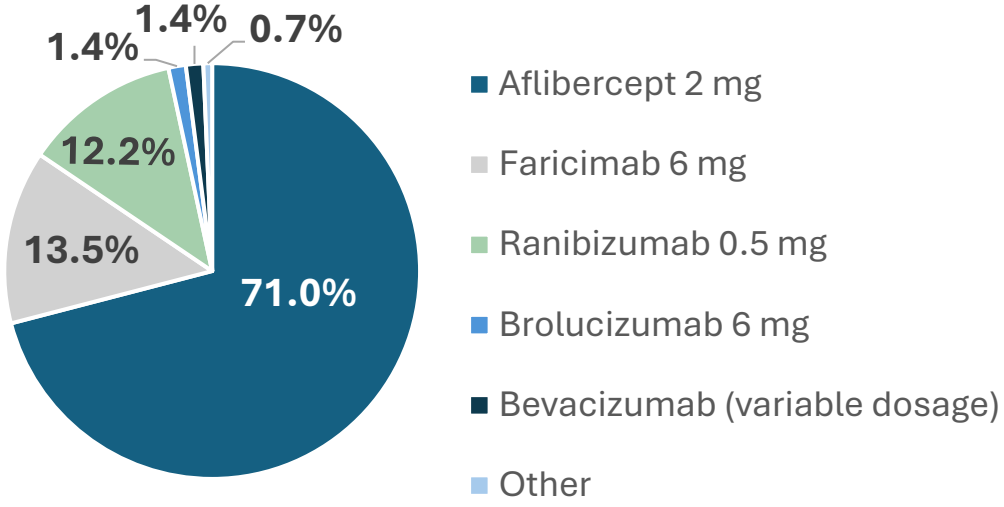
Baseline characteristics: Treatment-naïve and previously treated nAMD[a]

	Global TN nAMD (n=141)	Global PT nAMD (n=148)
Age, years	80.8±6.9	79.5±8.1
Sex, %		
Female	66.7	58.8
Male	33.3	41.2
Race,[c] %		
White	75.9	81.1
Black or African American	1.4	0
Not reported	22.7	18.9
MNV type,[b] %		
Type 1	33.3	32.4
Type 2	12.1	12.2
Type 3	5.7	2.7
Mixed	1.4	3.4
Missing/unknown	47.5	49.3
Median (min, max) time from nAMD diagnosis, months	0.1 (0.0, 21.9)	33.8 (1.3, 210.3)
Baseline VA, ETDRS letters	61.6±17.6	63.1±19.4
Baseline CRT, µm	365±129	324±115

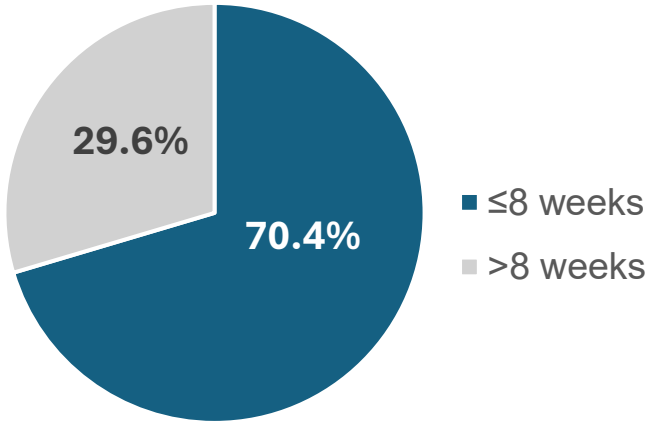
FAS. Percentages may not add up to 100 due to rounding. [a]Data are mean±SD unless otherwise indicated. [b]Mixed refers to Type 1 and Type 2 MNV combined. [c]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, Saudi Arabia, South Korea, Spain, Switzerland, United Arab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

Baseline characteristics: Previously treated nAMD

Previous nAMD medication[a,b]

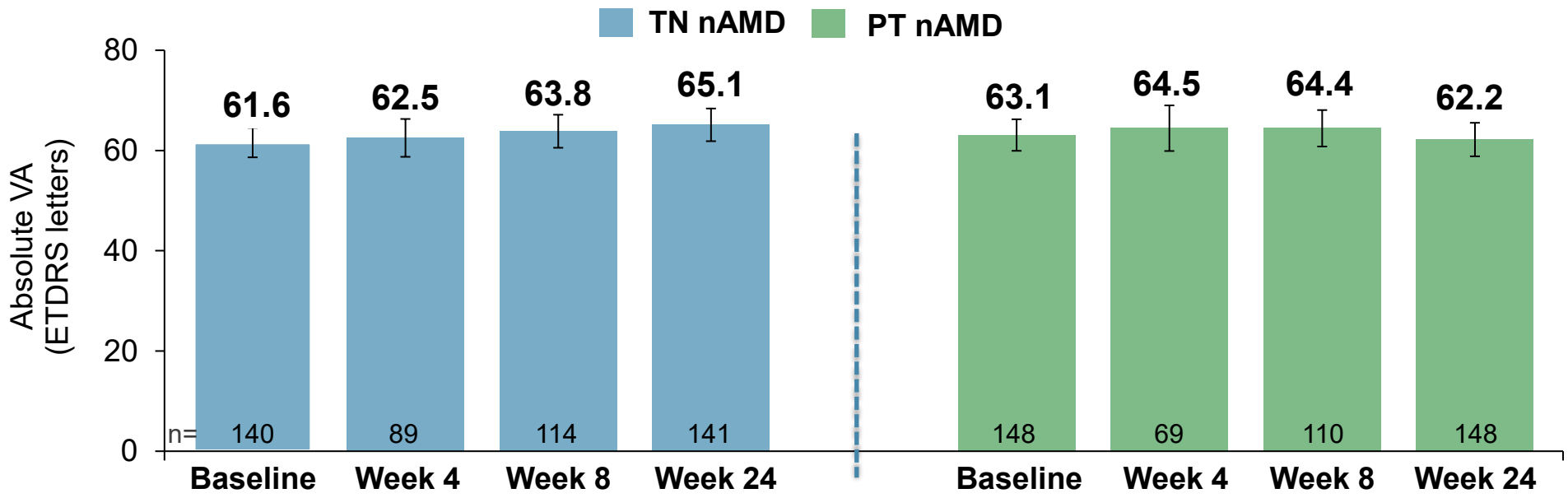


Dosing interval before switching to aflibercept 8 mg[c]



Percentages may not add up to 100 due to rounding. [a]Biosimilars are included within each medication option. [b]FAS (n=148). [c]Calculated for patients with last completed dosing interval data prior to switching (n=135).

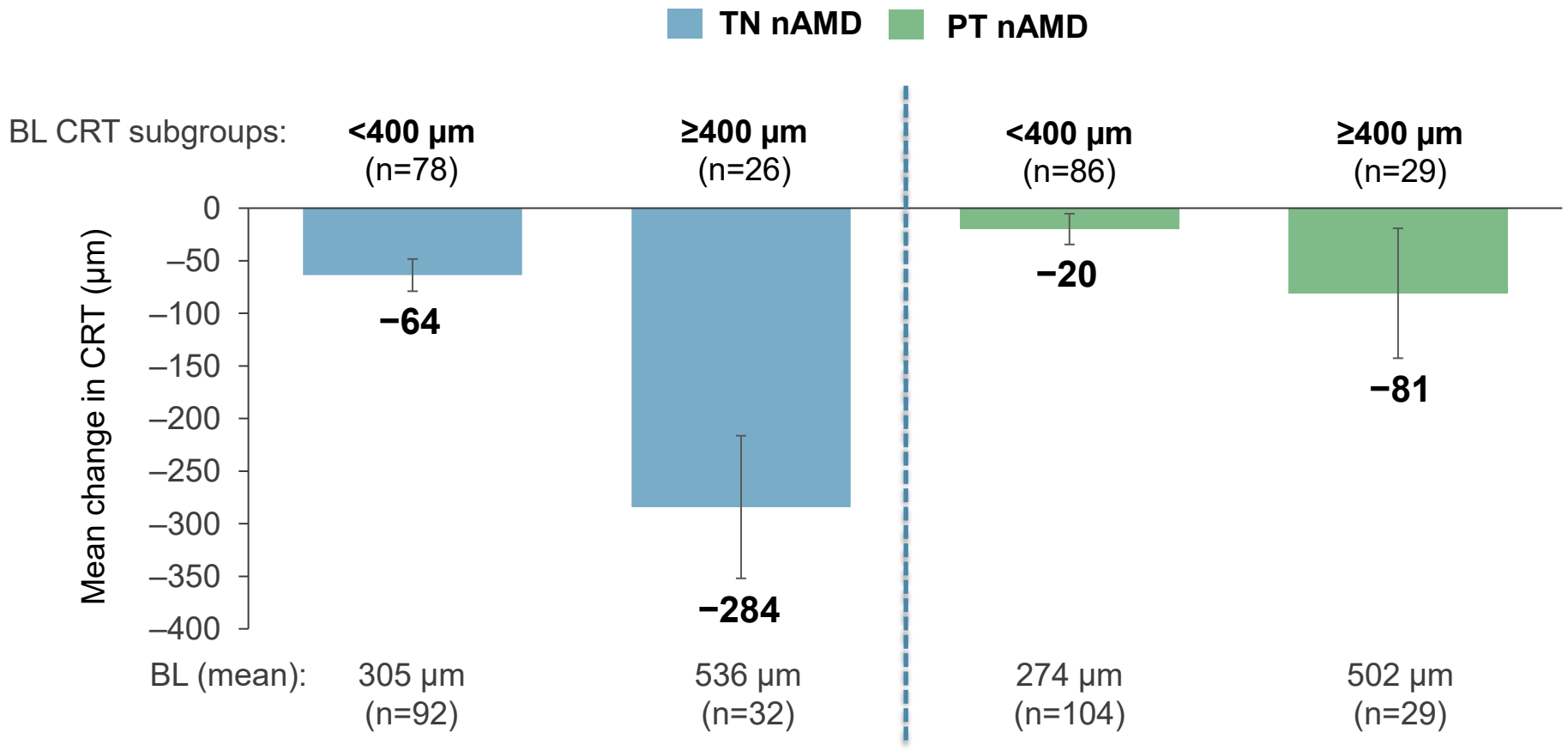
VA through Week 24



Timepoint	Mean change (95% CI) from baseline (LOCF)	
	TN nAMD	PT nAMD
Week 4	1.8 (−0.3, 3.8)	1.2 (−0.7, 3.0)
Week 8	2.6 (0.8, 4.5)	0.7 (−0.7, 2.1)
Week 24	**3.5 (1.1, 5.8)**	**−0.9 (−2.6, 0.8)**

FAS, LOCF (TN nAMD: n=141; PT nAMD: 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. CI, confidence interval; LOCF, last observation carried forward.

Mean change in CRT grouped by baseline CRT at Week 24



FAS, LOCF (TN nAMD: n=141; PT nAMD: 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 −81 and −85 (TN nAMD) and −20 and −27 (PT nAMD) µm for those with a baseline CRT of <400 µm, and −236 and −234 (TN nAMD) and −155 and −104 (PT nAMD) µm for those with a baseline CRT of ≥400 µm, respectively.

Week 24 treatment exposure and safety outcomes

Patients received a mean±SD of **4.7±1.2 and 4.5±1.6 injections** from **baseline** up to **Day 210** in the TN and PT nAMD cohorts, respectively

	TN nAMD (n=150)	PT nAMD (n=149)
Ocular TEAEs, n (%)		
Any ocular TEAEs in the study eye[a]	22 (14.7)	23 (15.4)
Any serious ocular TEAEs	3 (2.0)	4 (2.7)
Non-ocular TEAEs, n (%)		
Any non-ocular TEAEs	9 (6.0)	9 (6.0)
Any serious non-ocular TEAEs	3 (2.0)	2 (1.3)

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

SAF. Week 24 = visits closest to 180 (150–210) days after BL. [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.

Treatment-naïve and previously treated nAMD

Week 12 outcomes for the full global nAMD cohorts

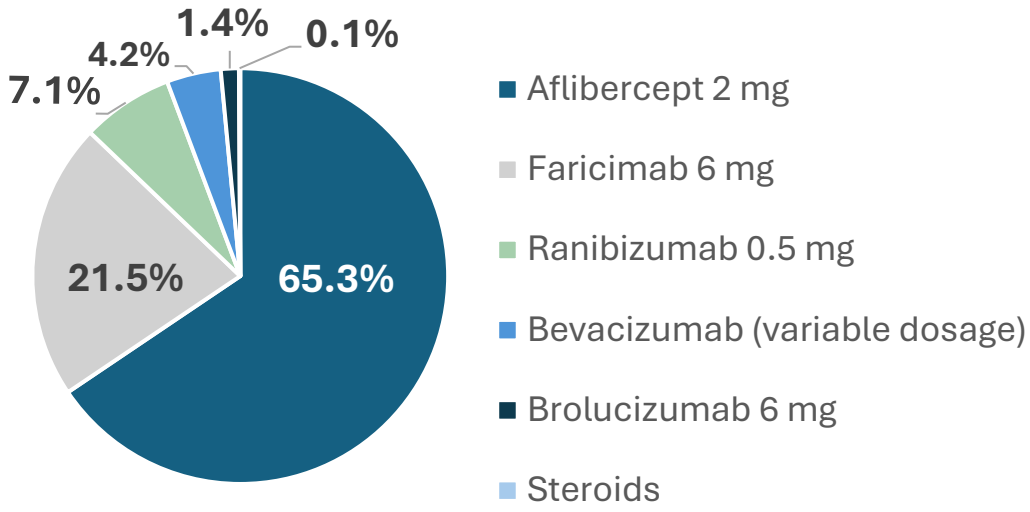
Baseline characteristics: Treatment-naïve and previously treated nAMD

	Global TN nAMD (n=1043)	Global PT nAMD (n=963)
Age, years	79.0±8.1	79.5±7.6
Sex, %		
Female	57.8	55.4
Male	42.2	44.7
Race,[b] %		
White	50.7	48.0
Asian	19.9	10.5
Black or African American	0.2	0.1
Native Hawaiian or Other Pacific Islander	0.1	0
Not reported	29.2	41.4
MNV type,[a] %		
Type 1	37.7	37.9
Type 2	15.4	9.9
Type 3	7.3	2.9
Mixed	8.0	4.1
Missing/unknown	31.6	45.3
Median (min, max) time from nAMD diagnosis, months	0.0 (0.0, 51.2)	32.9 (0.8, 210.3)
Baseline VA, ETDRS letters	57.8±19.9	64.4±17.5
Baseline CRT,[c] µm	371±131	300±92

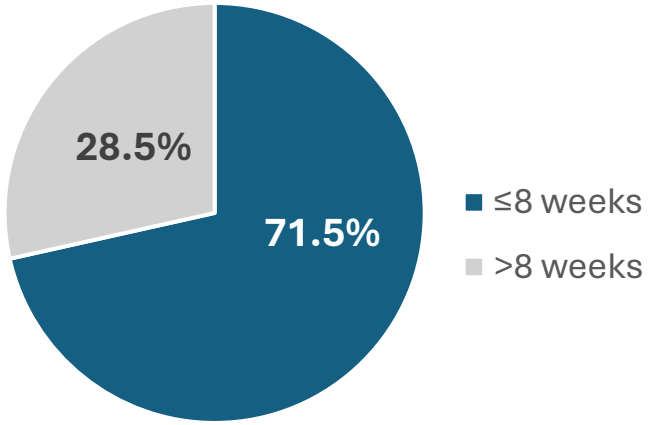
FAS. Percentages may not add up to 100 due to rounding. Data are mean±SD unless otherwise indicated. [a]Mixed refers to Type 1 and Type 2 MNV combined. [b]Data on race were collected for Australia, Canada, Germany, Italy, Japan, Portugal, Saudi Arabia, South Korea, Spain, Switzerland, United Arab Emirates, and the United Kingdom 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 Week 12 for this analysis, or CST thereafter if no baseline value was available.

Baseline characteristics: Previously treated nAMD

Previous nAMD medication[a,b]

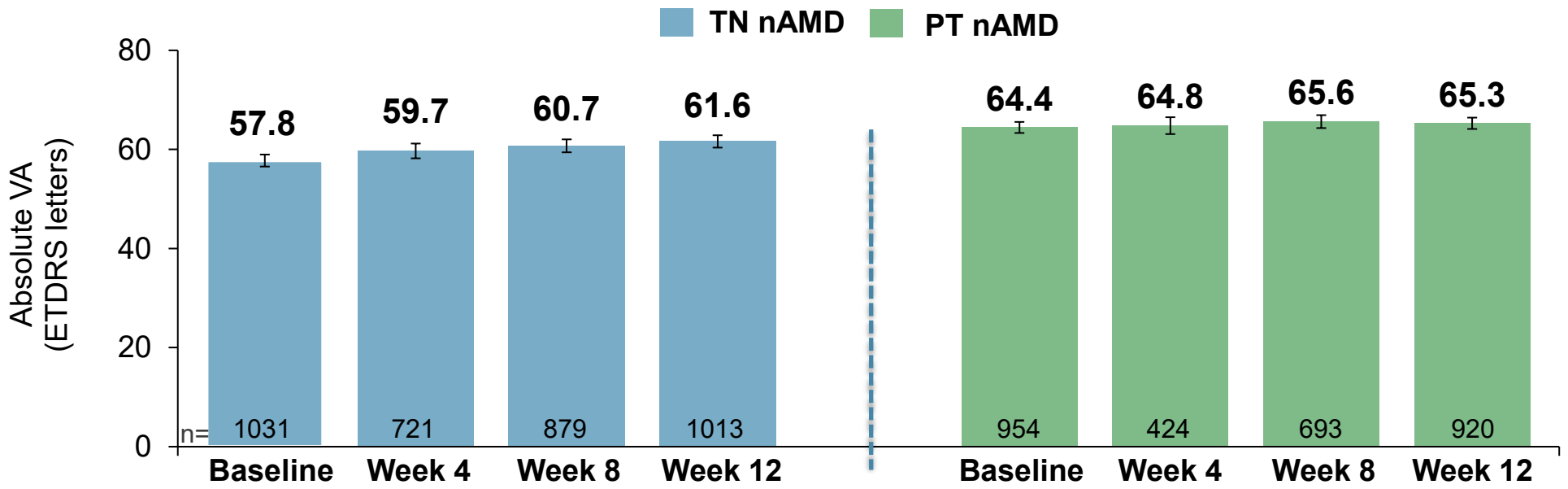


Dosing interval before switching to aflibercept 8 mg[c]



Percentages may not add up to 100 due to rounding. [a]Biosimilars are included within each medication option. [b]FAS (n=963). [c]Calculated for patients with last completed dosing interval data prior to switching (n=927).

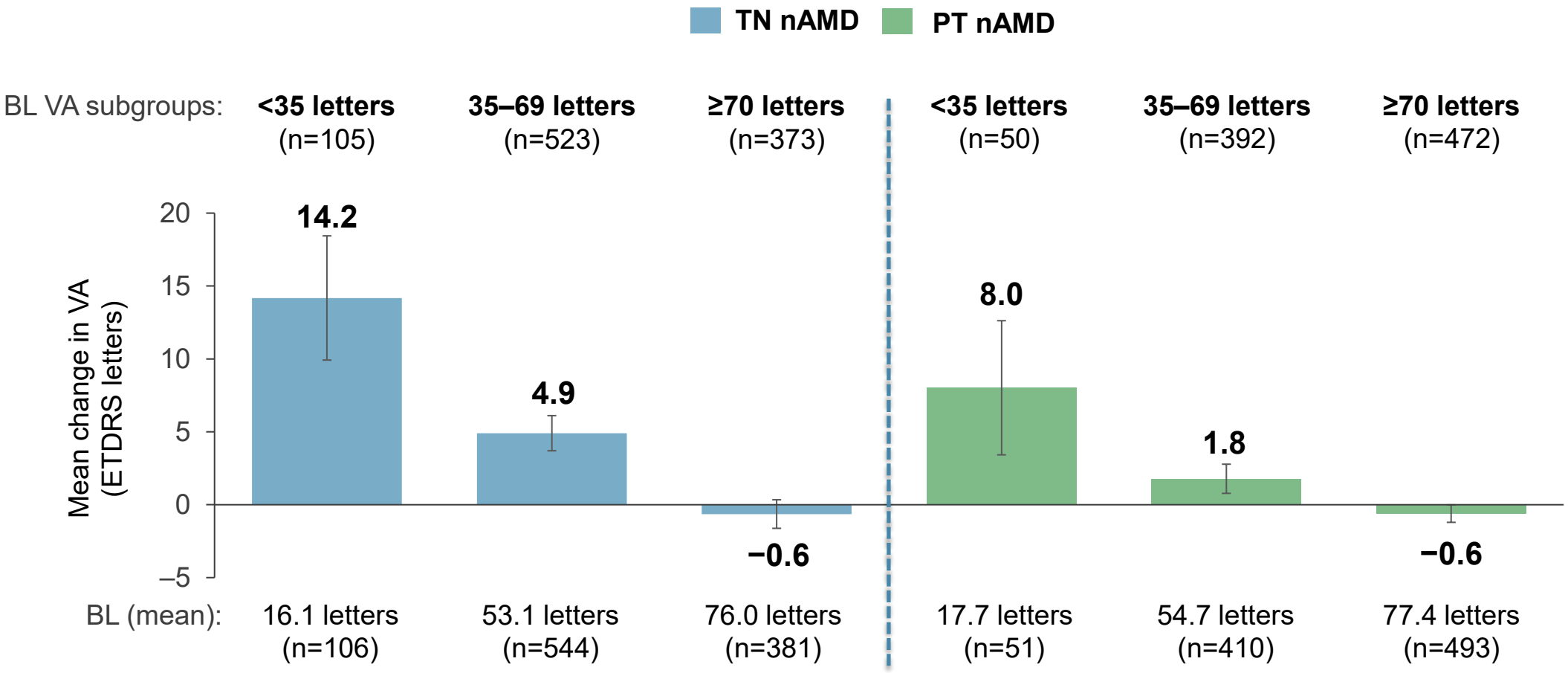
VA through Week 12



Timepoint	Mean change (95% CI) from baseline (LOCF)	
	TN nAMD	PT nAMD
Week 4	2.6 (1.7, 3.5)	1.5 (0.7, 2.2)
Week 8	3.4 (2.5, 4.2)	1.3 (0.7, 2.0)
Week 12	**3.8 (2.9, 4.7)**	**0.9 (0.3, 1.5)**

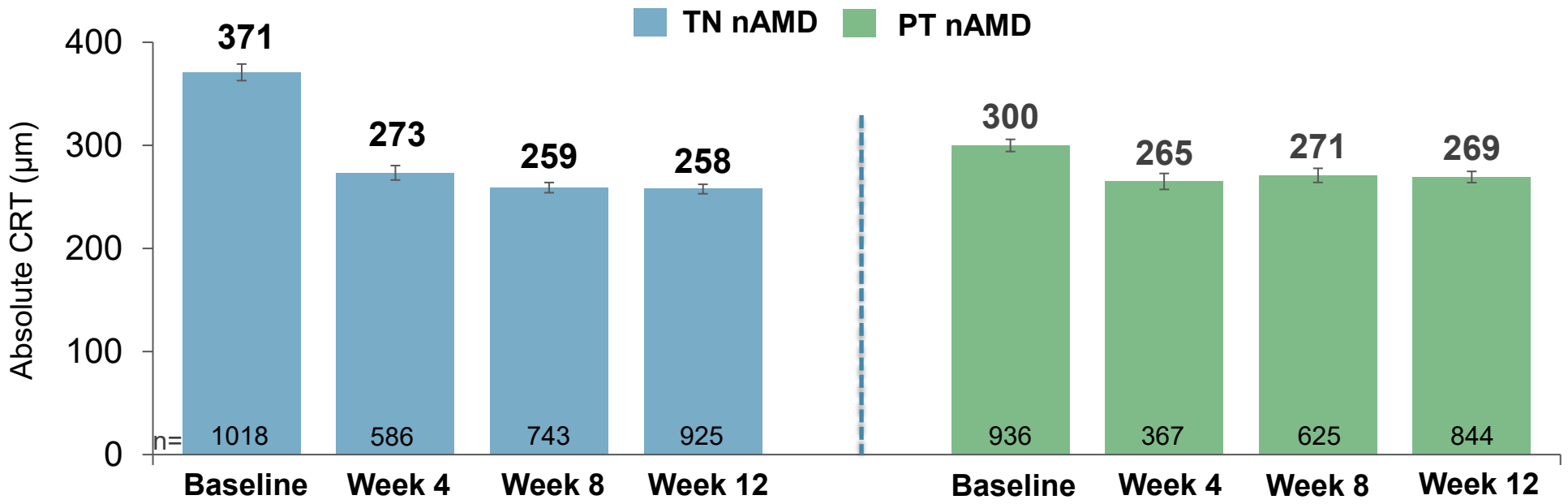
FAS, LOCF (TN nAMD: n=1043; PT nAMD: n=963). Missing values were imputed using the LOCF approach. Error bars represent 95% CI. Week 4 = visits closest to 28 (14–42) days after BL, Week 8 = visits closest to 56 (43–70) days after BL, Week 12 = visits closest to 90 (76–118) days after BL.

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



FAS, LOCF (TN nAMD: n=1043; PT nAMD: n=963). 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 +9.0 and +13.3 (TN nAMD) and +9.1 and +9.6 (PT nAMD) letters for those with a baseline VA of <35 letters, +3.5 and +4.2 (TN nAMD) and +1.8 and +2.1 (PT nAMD) letters for those with a baseline VA of 35–69 letters, and −0.9 and −0.9 (TN nAMD) and 0.1 and −0.2 (PT nAMD) letters for those with a baseline VA of ≥70 letters, respectively.

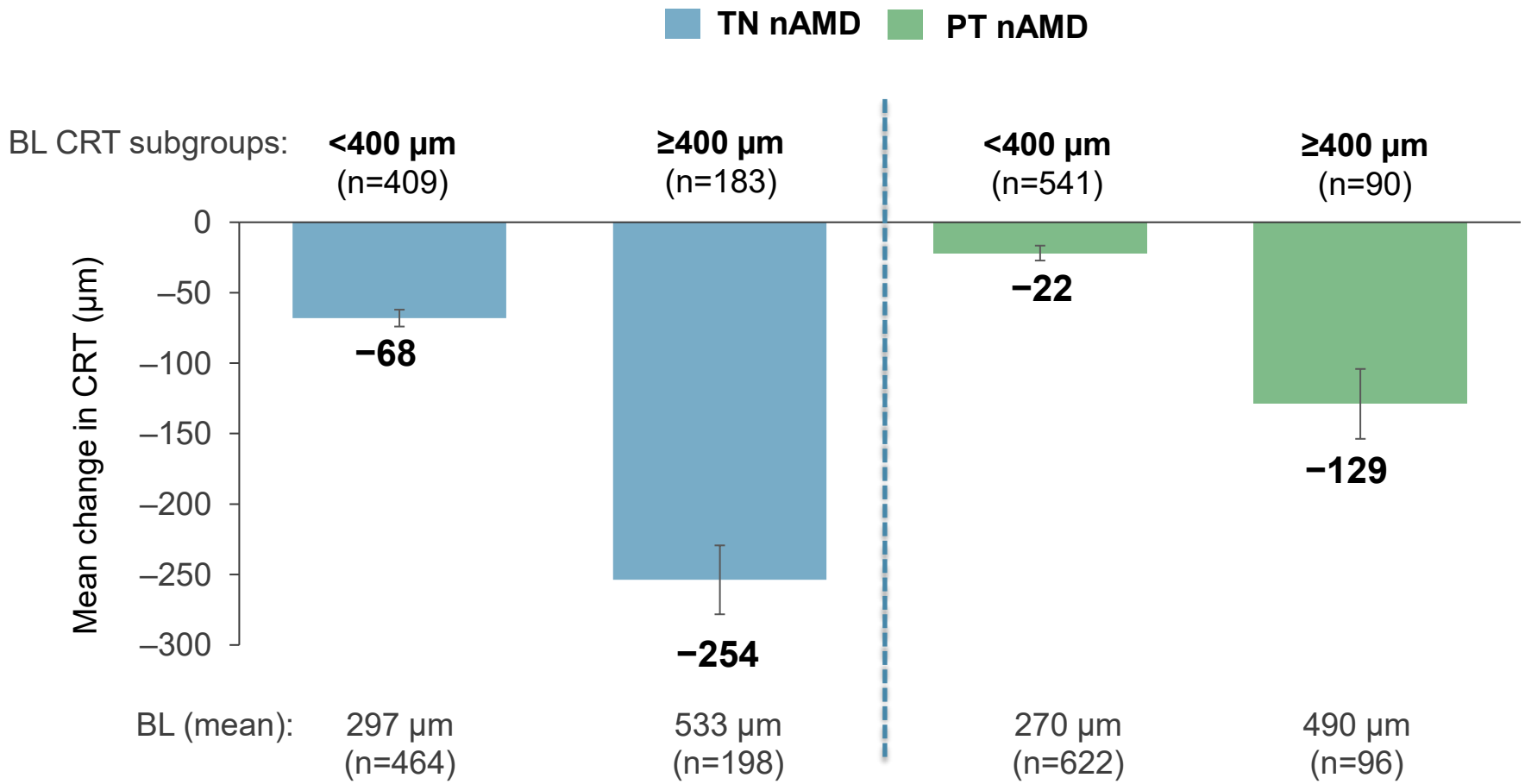
CRT through Week 12[a]



Timepoint	Mean change (95% CI) from baseline (LOCF)	
	TN nAMD	PT nAMD
Week 4	−102 (−112, −93)	−37 (−44, −30)
Week 8	−117 (−125, −108)	−30 (−36, −23)
Week 12	**−113 (−121, −106)**	**−32 (−37, −27)**

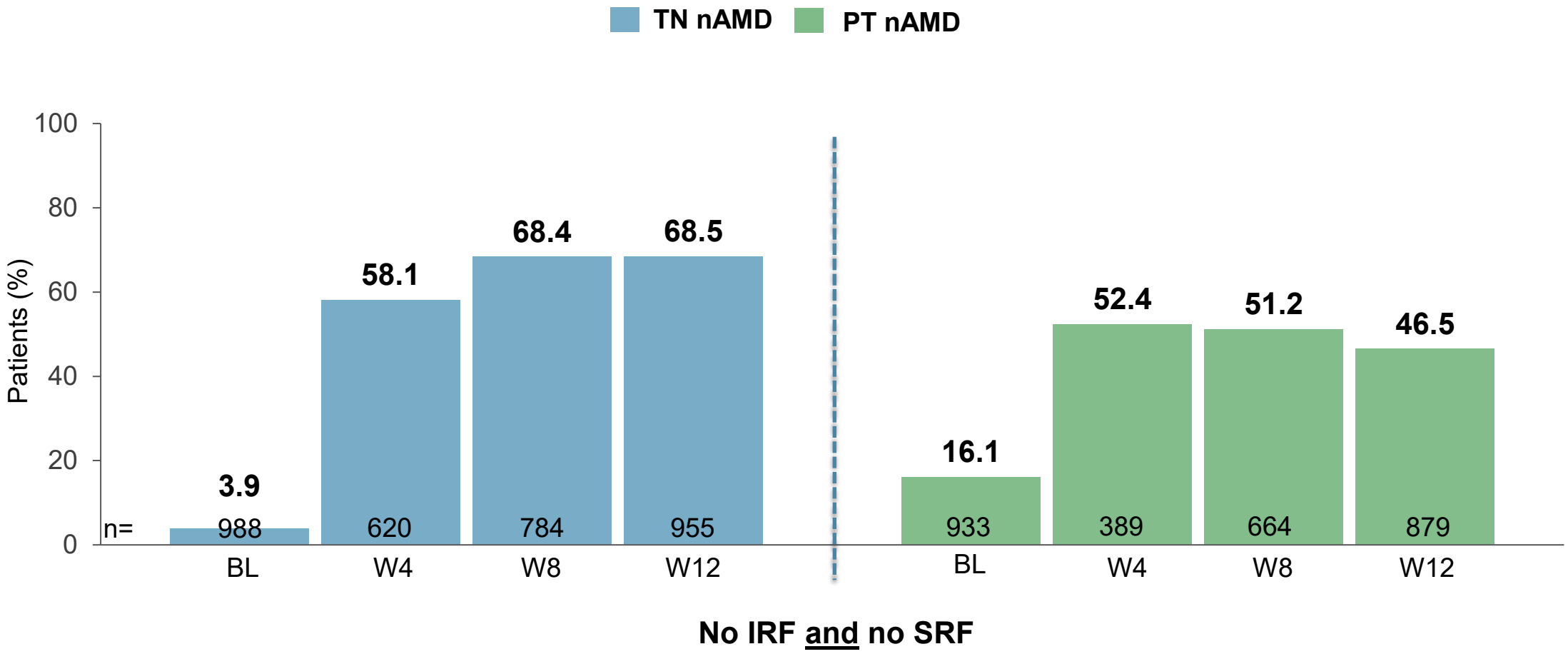
FAS, LOCF (TN nAMD: n=1043; PT nAMD: n=963). Missing values were imputed using the LOCF approach. Error bars represent 95% CI. [a]CRT was assessed by either CRT or CST, per investigator discretion; the parameter assessed at baseline (CRT or CST) for each individual patient was included through Week 12 for this analysis, or CST thereafter if no baseline value was available.

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



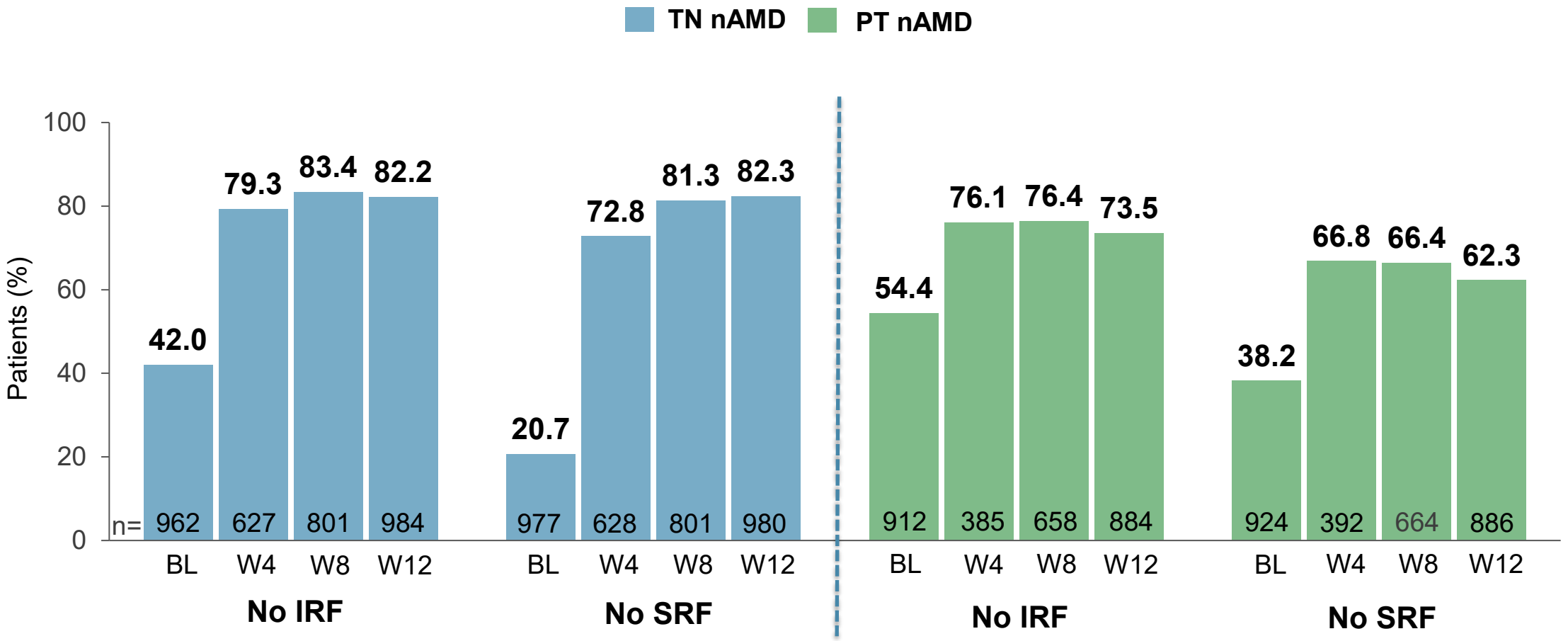
FAS, LOCF (TN nAMD: n=1043; PT nAMD: n=963). Missing values were imputed using the LOCF approach. Error bars represent 95% CI. [a]In patients with a CRT assessment at Week 4 and Week 8, the mean change in CRT at Week 4 and Week 8 grouped by baseline CRT was −65 and −69 (TN nAMD) and −26 and −17 (PT nAMD) µm for those with a baseline CRT of <400 µm, and −218 and −254 (TN nAMD) and −152 and −143 (PT nAMD) µm 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 −54, −61, and −59 (TN nAMD) and −28, −19, and −17 (PT nAMD) µm for those with a baseline CST of <400 µm, and −188, −215, and −218 (TN nAMD) and −131, −128, and −108 (PT nAMD) µm for those with a baseline CST of ≥400 µm, respectively.

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



FAS, LOCF (TN nAMD: n=1043; PT nAMD: n=963). 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; W, week.

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



FAS, LOCF (TN nAMD: n=1043; PT nAMD: n=963). Missing values were imputed using the LOCF approach. [a]The presence of intraretinal fluid and subretinal fluid 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.

Week 12 treatment exposure and safety outcomes

Patients received a mean±SD of **3.4±0.7 and 3.0±1.0 injections** from **baseline** up to **Day 118** in the TN and PT nAMD cohorts

	TN nAMD (n=1158)	PT nAMD (n=1113)
Ocular TEAEs, n (%)		
Any ocular TEAEs in the study eye[a]	75 (6.5)	79 (7.1)
Any serious ocular TEAEs	10 (0.9)	10 (0.9)
Most frequent ocular TEAEs in the study eye, n (%)[b]		
Intraocular pressure increased	7 (0.6)	9 (0.8)
Cataract	3 (0.3)	4 (0.4)
Vitreous floaters	4 (0.4)	3 (0.3)
Non-ocular TEAEs, n (%)		
Any non-ocular TEAEs	54 (4.7)	55 (4.9)
Any serious non-ocular TEAEs	21 (1.8)	20 (1.8)
Most frequent non-ocular TEAEs, n (%)[b]		
Arthralgia	2 (0.2)	3 (0.3)
Hypertension	3 (0.3)	2 (0.2)
Cough	3 (0.3)	1 (0.1)
Pneumonia	1 (0.1)	3 (0.3)

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

SAF. Week 24 = visits closest to 180 (150–210) days after BL. [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. [b]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 nAMD

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

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

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

- Improved VA and CRT from baseline
- Increased proportions of patients with fluid-free status
- Outcomes achieved with a mean of 3.4 injections up to Day 118
- No safety concerns identified

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

- Stable VA and improved CRT from baseline
- Increased proportions of patients with fluid-free status
- Outcomes achieved with a mean of 3.0 injections up to Day 118
- No safety concerns identified

SPECTRUM data on **treatment patterns** and **intraocular pressure 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 DME

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

Additional analyses up to Month 24 are ongoing