

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

Niro Narendran^{1,2}, Andreas Stahl³, Hassiba Oubraham⁴, Varun Chaudhary⁵, Marion R. Munk⁶⁻⁸, Clare Bailey⁸, Paolo Lanzetta^{10,11}, Tobias Machewitz¹², Susanne Oesch¹³, Peter Morgan-Warren¹³, Clemens Lange^{14,15} on behalf of the SPECTRUM study investigators
niro.narendran@nhs.net

¹Eye Infirmary, Royal Wolverhampton NHS Trust, Wolverhampton, UK; ²Paragon Clinic, Shrewsbury, UK; ³Department of Ophthalmology, University Medicine Greifswald, Greifswald, Germany ⁴Centre OPHTA-45, Montargis, France; ⁵Department of Surgery, McMaster University, Hamilton, ON, Canada; ⁶Augenarzt Praxisgemeinschaft Gutblick AG, Pfäffikon, Switzerland; ⁷Department of Ophthalmology, University Hospital Bern, Bern, Switzerland; ⁸Northwestern University, Feinberg School of Medicine, Chicago, IL, USA; ⁹Department of Ophthalmology, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK; ¹⁰Department of Medicine – Ophthalmology, University of Udine, Udine, Italy; ¹¹Istituto Europeo di Microchirurgia Oculare (IEMO), Udine, Italy; ¹²Bayer AG, Berlin, Germany; ¹³Bayer Consumer Care AG, Basel, Switzerland; ¹⁴Eye Center, Faculty of Medicine, Albert-Ludwig University Freiburg, Freiburg, Germany; ¹⁵Department of Ophthalmology, St Franziskus Hospital, Münster, Germany

Purpose

- Aflibercept 8 mg is approved for the treatment of neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME), and visual impairment due to macular edema secondary to retinal vein occlusion (RVO)¹
- SPECTRUM is a global study evaluating the real-world effectiveness and safety profile of aflibercept 8 mg in patients with treatment-naïve (TN) and previously treated (PT) nAMD or DME²

Conclusions

This Week 12 analysis of the SPECTRUM global DME cohorts shows **improved VA** and **CRT** in both **TN** and **PT** patients, and **no IRF** or **SRF** for the **majority of TN and PT patients**.

Disclosures
Niro Narendran: Honoraria and travel grants from Advanz Pharma, Bayer, Novartis, and Roche.
Acknowledgments
The SPECTRUM study was sponsored by Bayer Consumer Care AG (Basel, Switzerland). The sponsor participated in the design and conduct of the study, analysis of the data, and preparation of this abstract. Medical writing support, under the direction of the authors, was provided by ApotheCom and funded by Bayer Consumer Care AG, Basel, Switzerland, in accordance with Good Publication Practice (GPP) guidelines (*Ann Intern Med* 2022; 175 (9): 1298–1304).
References
1. Bayer plc. Aflibercept 8 mg – summary of product characteristics.
2. Lobo A *et al.* Presentation at ARVO 2025; Salt Lake City, UT, USA, May 4–8, 2025.
3. Bailey C *et al.* Presentation at FLORetina 2024; Florence, Italy, December 5–8, 2024.
4. ClinicalTrials.gov NCT06075147. Available at: <https://clinicaltrials.gov/study/NCT06075147>. Accessed April 2026.

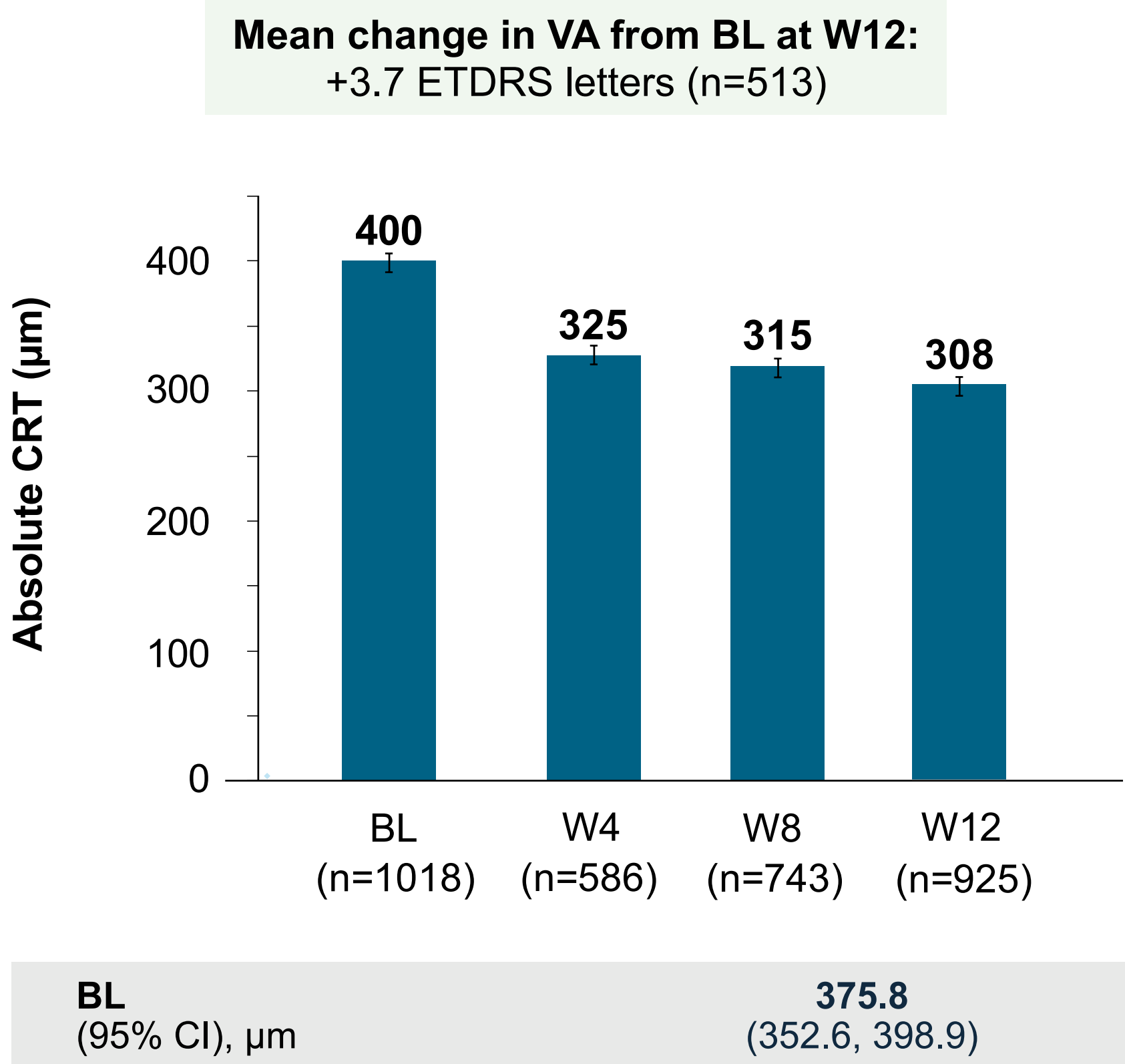
Methods

- SPECTRUM (NCT06075147) is an ongoing, 24-month, prospective observational study being conducted in 18 countries, including the UK^{3,4}
- Patients (TN and PT) with nAMD aged ≥50 years or DME aged ≥18 years, who have been prescribed aflibercept 8 mg by their physician, were eligible for enrollment⁴
- Decisions regarding monitoring, retreatment, and treatment schedules are made by each patient’s attending physician in accordance with local clinical practice⁴
- Data are being collected during routine clinical visits (February 2024 to September 2027)³

Results

- In the Global TN (n=1043) and PT (n=963) DME cohorts, the mean age was 64.6 and 66.2 years, respectively, and the median (min, max) time from DME diagnosis in the TN cohort was 0.3 (0.0, 115.1) months.
- In the PT cohort, the median time from DME diagnosis was 41.8 (0.0, 331.2) months, with 65.0% receiving aflibercept 2mg, 16.5% receiving faricimab 6mg, and 6.1% receiving ranubizumab 0.5mg as previous treatment.
- The mean (95)% confidence interval [CI] change in VA at Week (W) 12 was +3.7(2.6 to 4.9) letters and 1.7 (0.9 to 2.6) letters in the global TN and PT cohorts, from a BL of 63.6 letters and 66.8 letters, respectively (Figures 1 and 2).
- The mean (95% CI) change in CRT at W12 was -91 (-101 to -82) µm and -50 (-59 to -41) µm in the global TN and PT cohorts, from a BL of 371µm and 300µm respectively (Figure 1 and 2)
- The proportion of in the TN and PT cohorts without subretinal fluid (SRF) through week 12 were 91.8% and 94.5% respectively.

Figure 1: VA and CRT outcomes with aflibercept 8mg in TN patients with DME.



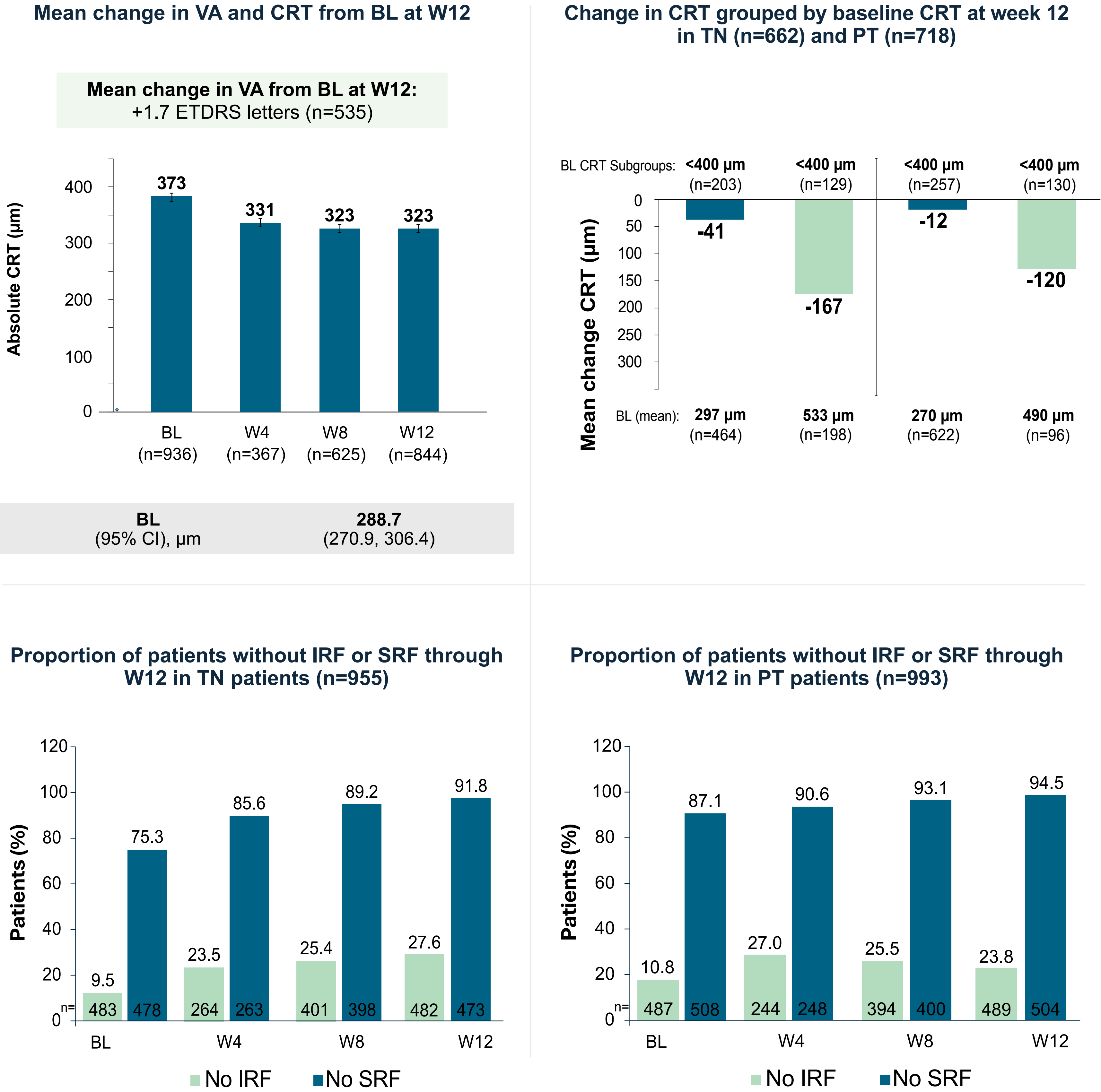
LOCF. Missing values are imputed with the LOCF approach. Error bars indicate 95% CI. BL, baseline; CI, confidence interval; CRT, central retinal thickness; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; LOCF, last observation carried forward; nAMD, neovascular age-related macular degeneration; TN, treatment-naïve; VA, visual acuity; W, Week. SRF, subretinal fluid, IRF, intraretinal fluid



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



Figure 2: VA, CRT, change in CRT grouped by baseline CRT, and proportion of patients without IRF or SRF in TN and PT patients with DME.



LOCF. Missing values are imputed with the LOCF approach. Error bars indicate 95% CI. BL, baseline; CI, confidence interval; CRT, central retinal thickness; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; LOCF, last observation carried forward; nAMD, neovascular age-related macular degeneration; PT, previously treated; qX, every X weeks; VA, visual acuity; W, Week.