

# Early clinical results in Spain of the global real-world SPECTRUM study of aflibercept 8 mg in patients with naïve and previously treated neovascular age-related macular degeneration

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## Purpose

- The CANDELA (Phase 2),<sup>1</sup> PHOTON (Phase 2/3)<sup>2</sup> and PULSAR (Phase 3)<sup>3</sup> clinical trials led to the regulatory approval of the aflibercept 8 mg formulation in patients with diabetic macular edema (DME) and **neovascular age-related macular degeneration (nAMD)**.<sup>4,5</sup>
- SPECTRUM is the first global study to assess the real-world effectiveness and safety of aflibercept 8 mg for these indications
- Here we present the 6 months data of the Spanish cohort of treatment-naïve (TN) and previously treated (PT) patients with nAMD from the SPECTRUM study

## Conclusions

At Month 6, aflibercept 8 mg demonstrated **early effectiveness** in the Spanish cohort of clinically heterogenous patients with nAMD in diverse real-world settings.

- Treatment-naïve patients achieved VA gains (+ 7.6 letters) and marked reduction in CRT**, especially in those with thick retina CRT ( $\geq 400 \mu\text{m}$ ) at baseline
- Previously treated patients maintained visual outcomes with additional anatomical improvement**
- A high rate of fluid resolution was observed (82% of TN and 66% of PT without IRF)**, with no new safety signals identified
- Results are consistent with the global SPECTRUM cohort

### Disclosures

Javier Muñoz-Solano: Received honoraria from Abbvie, Bayer and Roche for educational lectures.

### Acknowledgments

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### References

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## Methods

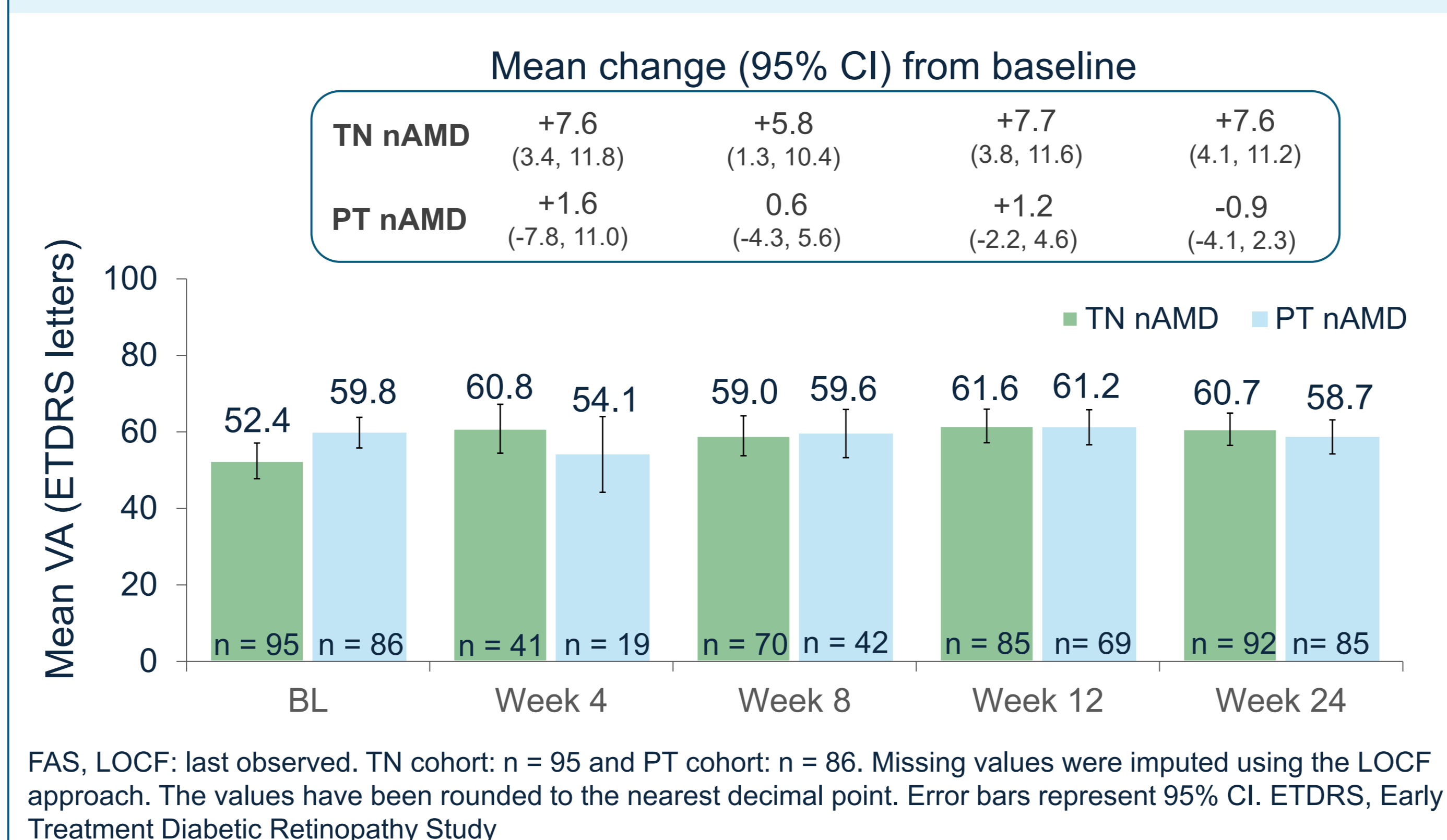
- Treatment-naïve and previously treated patients with DME aged  $\geq 18$  years or with nAMD aged  $\geq 50$  years, who have been prescribed aflibercept 8 mg by their attending physician, are eligible for enrollment.
- Data are being collected from medical records and imaging during routine visits from February 2024 to September 2027, with a follow-up period of up to 24 months per patient.
- In Spain, **101 patients** have been enrolled in the **TN nAMD** cohort, while **100 patients** have been included in the **PT nAMD** cohort across 20 participating sites

## Results

### VISUAL ACUITY (VA) UP TO MONTH 6

Mean change in VA at month 6 was **+ 7.6** and **- 0.9** ETDRS letters for TN and PT patients with nAMD, respectively.

Figure 2: Visual Acuity (VA) from baseline to Month 6 in TN and PT patients with nAMD



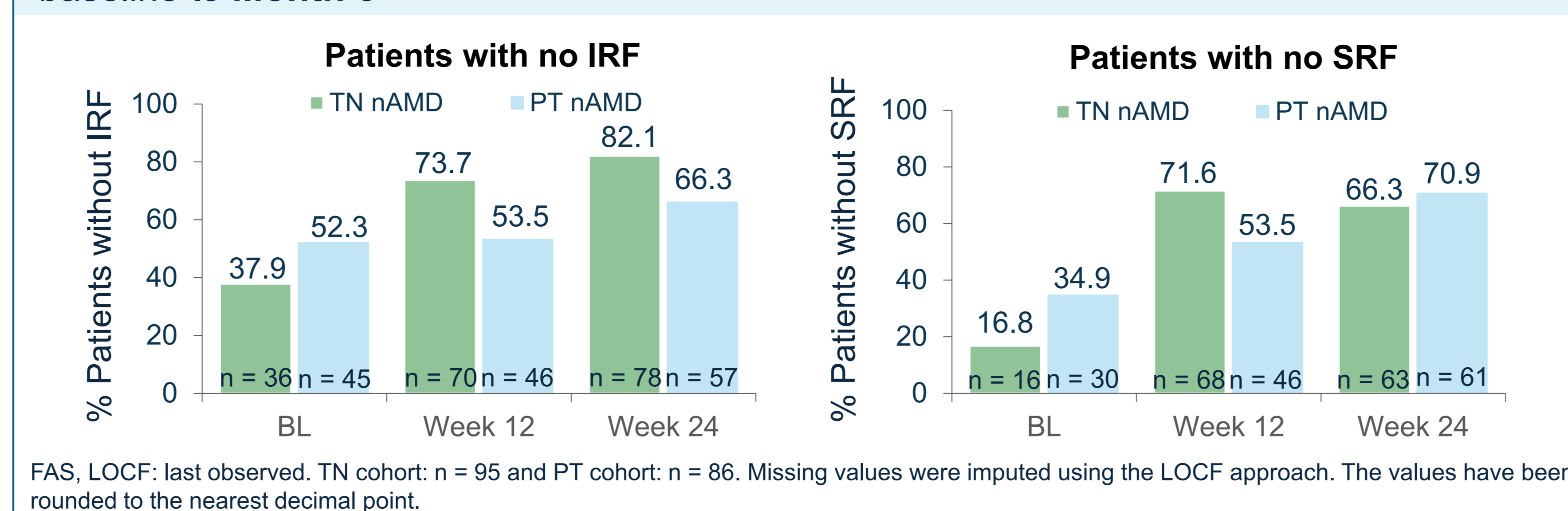
FAS, LOCF: last observed. TN cohort: n = 95 and PT cohort: n = 86. Missing values were imputed using the LOCF approach. The values have been rounded to the nearest decimal point. Error bars represent 95% CI. ETDRS, Early Treatment Diabetic Retinopathy Study



TN and PT nAMD patients received an average of **4.8** and **3.7** injections, respectively, up to day 210 from baseline (BL)

### INTRARETINAL FLUID (IRF) OR SUBRETINAL FLUID (SRF) UP TO MONTH 6

Figure 5: Proportion of patients in the TN and PT cohorts with no IRF or SRF from baseline to Month 6



FAS, LOCF: last observed. TN cohort: n = 95 and PT cohort: n = 86. Missing values were imputed using the LOCF approach. The values have been rounded to the nearest decimal point.

## Baseline characteristics

Table 1: Baseline characteristics of the Spanish cohort of TN and PT patients with nAMD

	TN nAMD (n = 95)	PT nAMD (n=86)
Age $\pm$ SD (years)	78.9 $\pm$ 8.4	80.8 $\pm$ 7.1
Median (min., max.) time since nAMD diagnosis (months)	0.1 (0.0, 1.7)	28.1 (0.8, 153.6)
Initial VA $\pm$ SD (ETDRS letters)	52.4 $\pm$ 22.9	59.8 $\pm$ 18.7
Initial CRT $\pm$ SD ( $\mu\text{m}$ )	400.6 $\pm$ 159.9	288.2 $\pm$ 84.3
Sex		
Male, n (%)	45 (47.4)	41 (47.7)
Female, n (%)	50 (52.6)	45 (52.3)

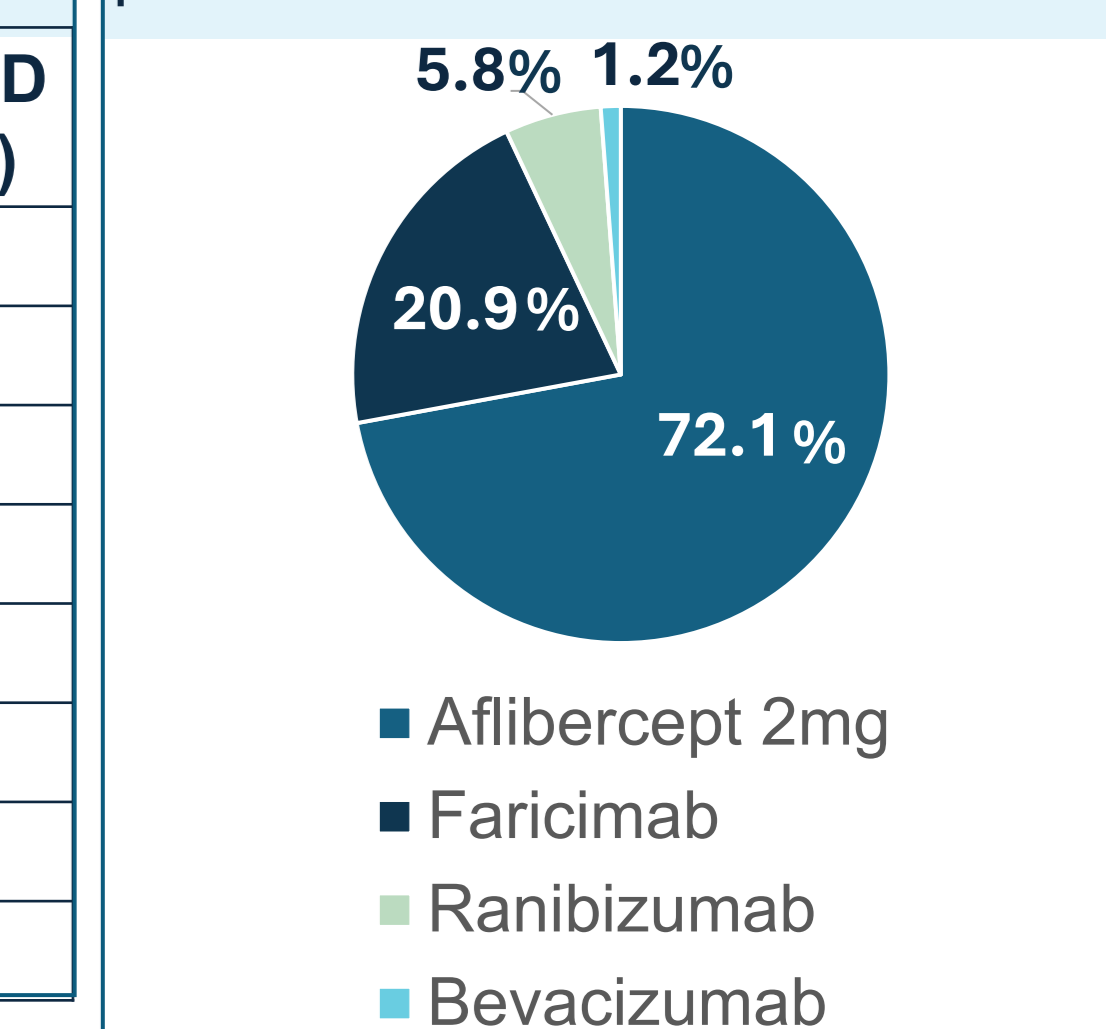
FAS (Full Analysis Set) = 95 (TN), 86 (PT); SD: Standard deviation; Min: minimum; Max: maximum

Table 2: MNV type in the Spanish cohort of TN and PT patients with nAMD

	TN nAMD (n = 95)	PT nAMD (n = 86)
MNV type (%)		
1	40.0	54.7
2	28.4	20.9
1 and 2	12.6	3.5
3	13.7	3.5
Cannot Grade	1.1	4.7
Unknown	3.2	12.8
Not Applicable	1.1	0.0

MNV: Neovascular Membranes

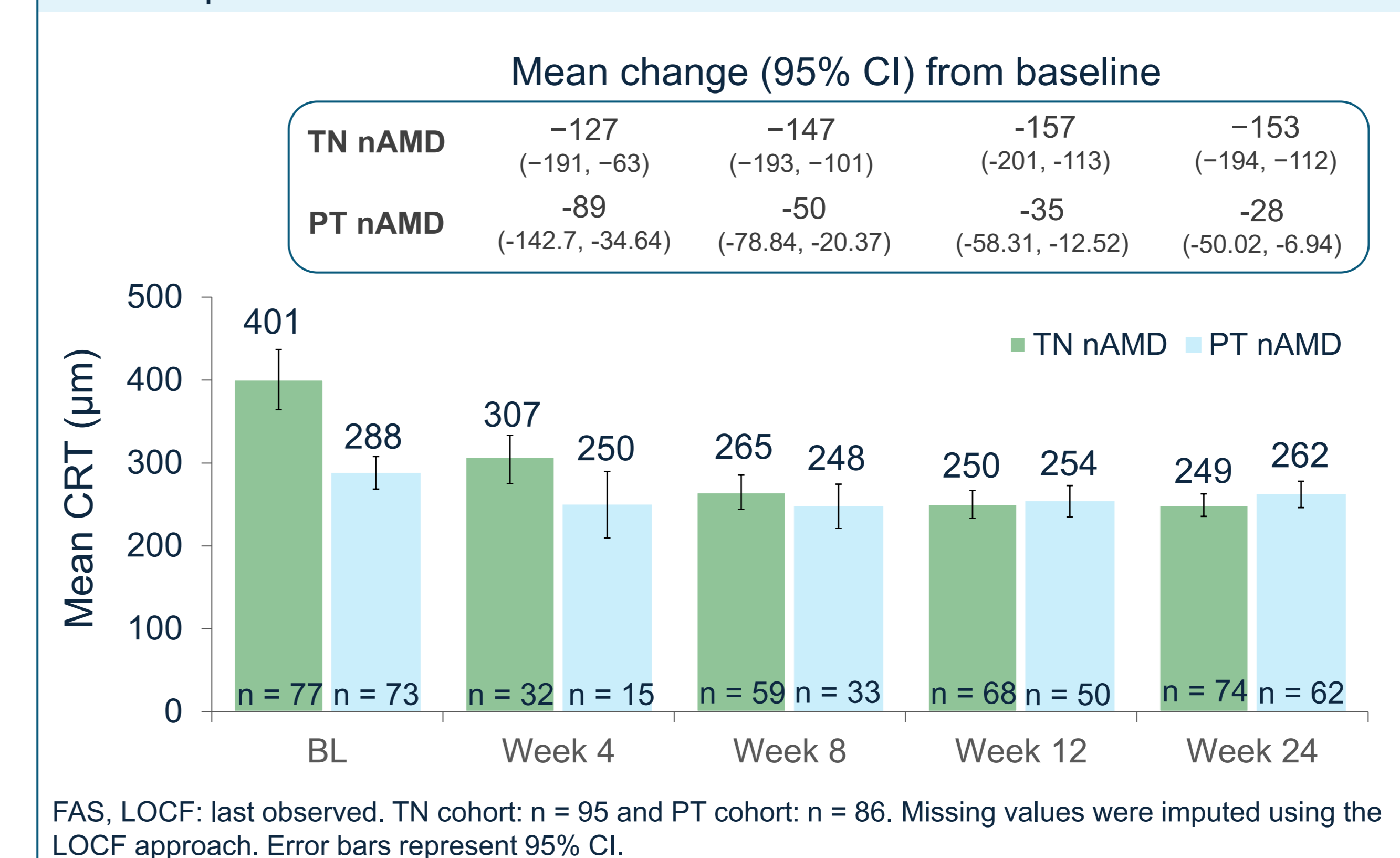
Figure 1: Previous medication in the Spanish cohort of PT patients with nAMD



### CENTRAL RETINAL THICKNESS (CRT) UP TO MONTH 6

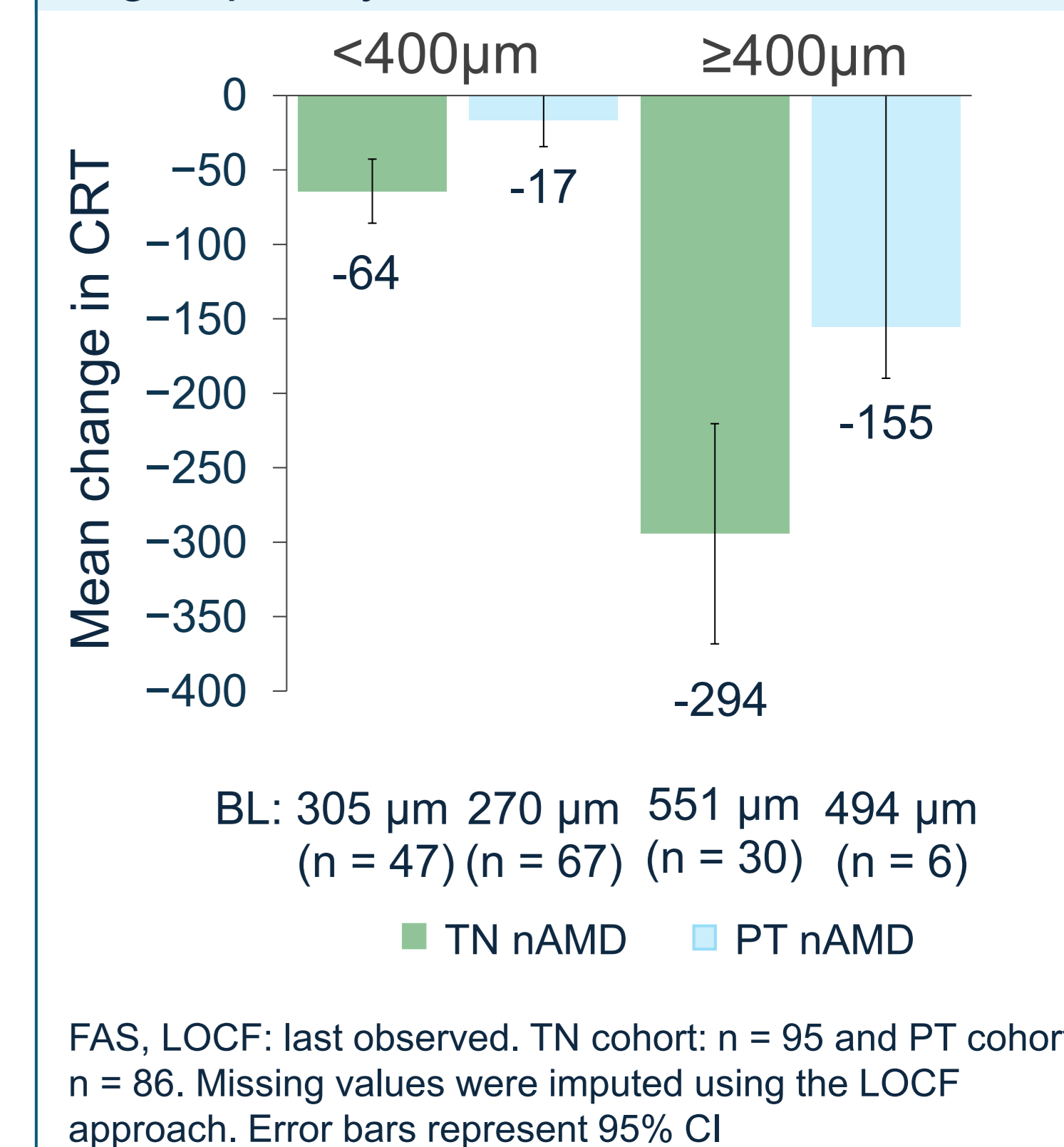
The mean change in CRT at month 6 was **-153  $\mu\text{m}$**  for the TN nAMD patients and **-28  $\mu\text{m}$**  for the PT nAMD.

Figure 3: Central Retinal Thickness (CRT) from baseline to Month 6 in TN and PT patients with nAMD



FAS, LOCF: last observed. TN cohort: n = 95 and PT cohort: n = 86. Missing values were imputed using the LOCF approach. Error bars represent 95% CI.

Figure 4: Mean change in CRT at month 6 grouped by baseline CRT



FAS, LOCF: last observed. TN cohort: n = 95 and PT cohort: n = 86. Missing values were imputed using the LOCF approach. Error bars represent 95% CI

### SAFETY

Table 3: Safety overview

	TN n = 100	PT n = 100
<b>Ocular TEAE</b>		
Any ocular TEAE in the study eye <sup>a</sup> , n (%)	8 (8)	17 (17)
Any serious ocular TEAE, n (%)	1 (1)	0 (0)
<b>Non ocular TEAE</b>		
Any non-ocular TEAE, n (%)	7 (7)	12 (12)
Any serious non-ocular TEAE, n (%)	2 (2)	3 (3)

TEAE = Treatment-Emergent Adverse Event; SAF (Safety analysis set) = 100; <sup>a</sup>The eye treated with aflibercept 8 mg was considered the study eye. If treatment with aflibercept 8 mg was decided simultaneously in both eyes, the study eye was considered to be the worst in the opinion of the treating physician.

**No cases of endophthalmitis, vitritis, or vasculitis have been reported**  
No changes in pre-injection intraocular pressure (IOP) were observed until month 6