



A 96-week PULSAR Subgroup Analysis: Similar Visual and Anatomic Improvements with Aflibercept 8 mg Every 12 Weeks or Longer and 2 mg Every 8 Weeks, as Defined by Baseline BCVA, CRT, CNV Type, and Race

Jean-François Korobelnik,^{1,2} Richard Gale,³ Oliver Zeitz,⁴ Sobha Sivaprasad,⁵ Sergio Leal,⁶ Tobias Machewitz,⁷ Xin Zhang,⁶ on behalf of the PULSAR study investigators

¹CHU Bordeaux GH Pellegrin, Service d'Ophthalmologie, Bordeaux, France; ²University of Bordeaux, INSERM, Bordeaux Population Health Research Center, Bordeaux, France; ³York and Scarborough Teaching Hospital NHS Foundation Trust, York, UK;

⁴Department of Ophthalmology, Charité Universitätsmedizin, Berlin, Germany; ⁵Moorfields Eye Hospital, London, UK; ⁶Bayer Consumer Care AG, Basel, Switzerland;

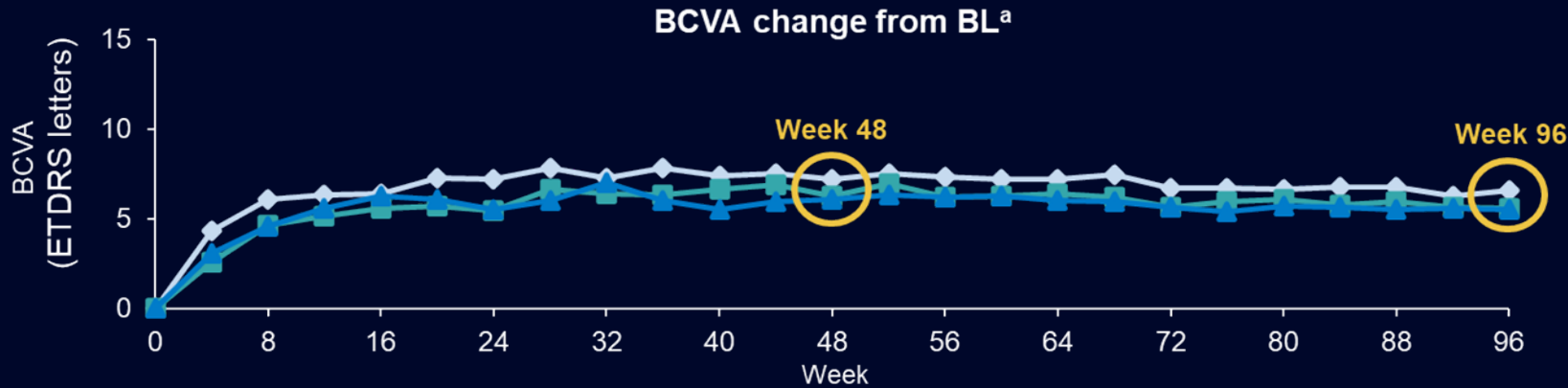
⁷Bayer AG, Berlin, Germany

Disclosures



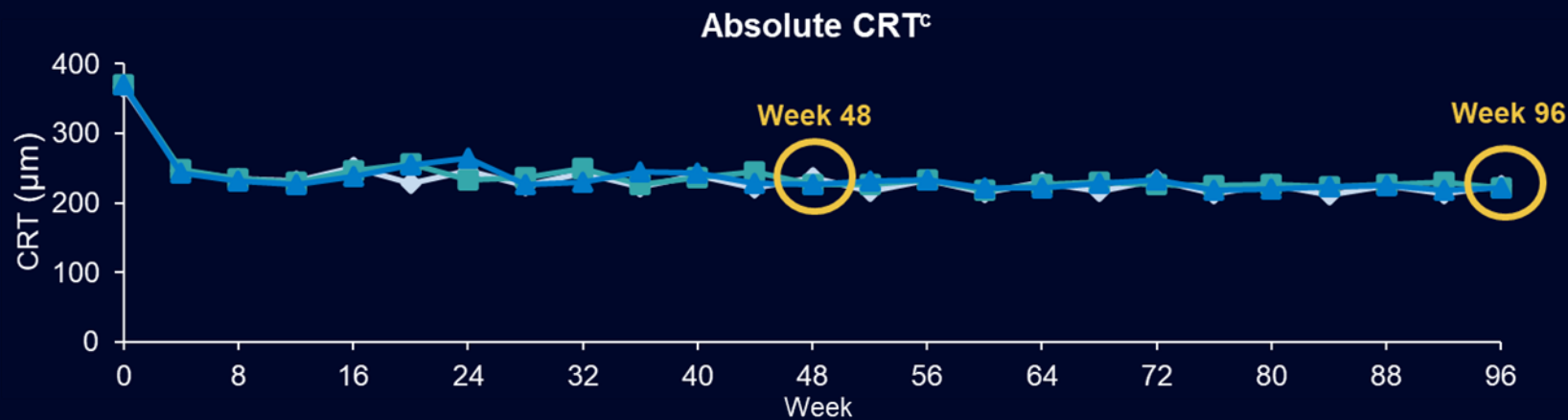
- **Jean-François Korobelnik:** Consultant: AbbVie, Apellis, Bayer, Carl Zeiss Meditec AG, Janssen, Nano Retina, Roche, and Théa Pharmaceuticals; Data safety monitoring/advisory board: Alexion, Novo Nordisk, and Oxular
 - **RG:** Consultant: AbbVie, Allergan, Apellis, Bayer, Biogen, Boehringer Ingelheim, Notal, Novartis, Roche, and Santen; Research: Bayer, Novartis, and Roche. **OZ:** Consultant and speaker: Allergan, Bayer, Boehringer Ingelheim, and Novartis; Consultant: Omeicos and Oxular; Research: Bayer, Boehringer-Ingelheim, and Novartis. Employment with Bayer ended September 30, 2016. **SS:** Funding/fees: Allergan, Apellis, Bayer, Biogen, Boehringer Ingelheim, EyeBiotech, Novartis, Optos, and Roche. **SL, TM, and XZ:** Employees of Bayer
- The PULSAR study (NCT04423718) was sponsored by Bayer AG (Leverkusen, Germany) and co-funded by Regeneron Pharmaceuticals, Inc. (Tarrytown, NY, USA). The sponsor participated in the design and conduct of the study, analysis of the data, and preparation of this presentation
- Study disclosures: This study includes research conducted on human patients. Institutional Review Board approval was obtained prior to study initiation
- 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;175:1298–1304)
- The data in this presentation were originally presented at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, Seattle, WA, USA, May 5–9, 2024

BCVA and CRT through Week 96: Comparable outcomes with aflibercept 8 mg and 2 mg overall



LS means^{a,b}

	Week 48	Week 96
2q8	+7.0	+6.6
8q12	+6.1	+5.6
8q16	+5.9	+5.5



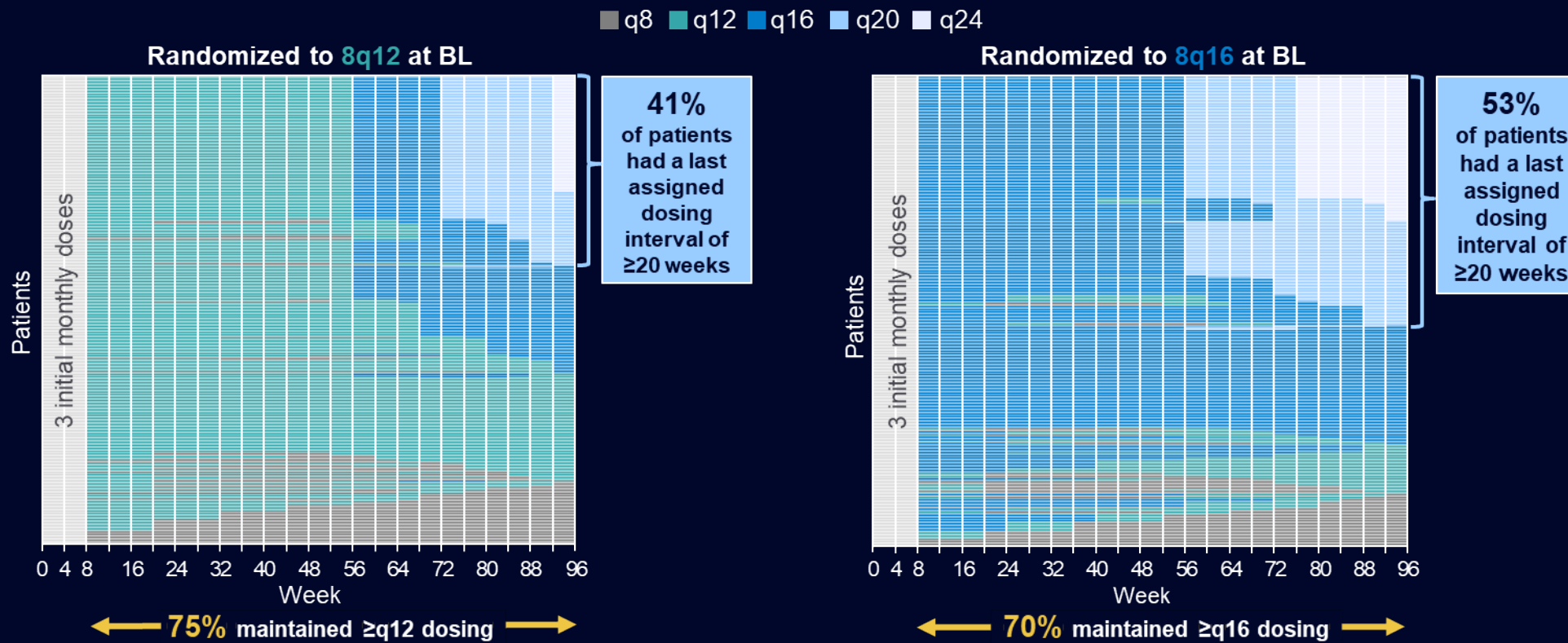
LS means^{a,b}

	Week 48	Week 96
2q8	-136	-147
8q12	-147	-152
8q16	-147	-149

In the PULSAR trial, aflibercept 8 mg demonstrated non-inferior BCVA gains with extended dosing intervals versus aflibercept 2 mg in patients with nAMD, with no new safety signals through Week 48¹

All treatment groups received 3 initial monthly doses. FAS: 2q8 n=336; 8q12 n=335; 8q16 n=338 (at BL). ^aLS mean values (data post-ICE were censored); ^bLS means were generated using MMRM, with baseline BCVA measurement (for BCVA analysis) or BL CRT measurement (for CRT analysis) as a covariate, and treatment group (aflibercept 2q8, 8q12, 8q16), visit, and stratification variables (geographic region [Japan vs. Rest of World] and BL BCVA [<60 vs. ≥ 60]) as fixed factors, and interaction terms for BL and visit and for treatment and visit. ^cObserved values. **2q8**, aflibercept 2 mg every 8 weeks; **8q12**, aflibercept 8 mg every 12 weeks; **8q16**, aflibercept 8 mg every 16 weeks; **BCVA**, best-corrected visual acuity; **BL**, baseline; **CRT**, central retinal thickness; **ETDRS**, Early Treatment of Diabetic Retinopathy Study; **FAS**, full analysis set; **ICE**, intercurrent event; **LS**, least squares; **MMRM**, mixed model for repeated measures. 1. Lanzetta P, et al. Lancet. 2024;403:1141–1152.

Dosing Intervals \geq q20 Were Assigned to ~50% of Patients Receiving Aflibercept 8 mg by Week 96



Mean number (SD) of active injections through Week 96

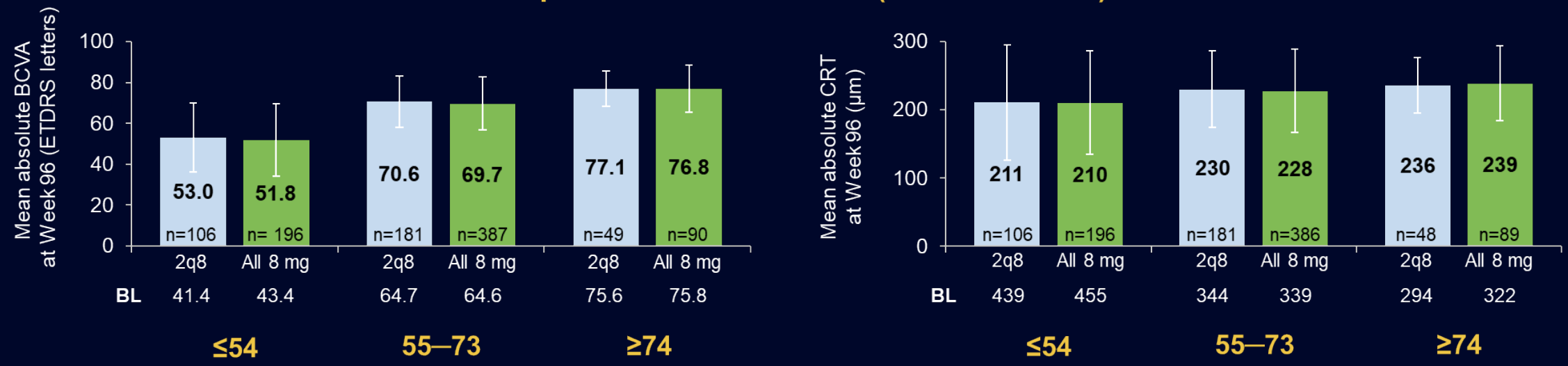
2q8	8q12	8q16
12.8 (0.6)	9.7 (1.2)	8.2 (1.6)

This analysis assessed whether visual improvements achieved with aflibercept 8 mg versus aflibercept 2 mg at Week 96 in patients with nAMD in PULSAR were comparable across several patient subgroups

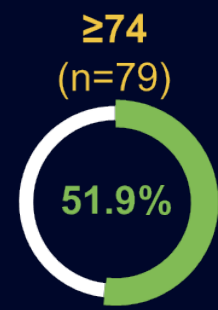
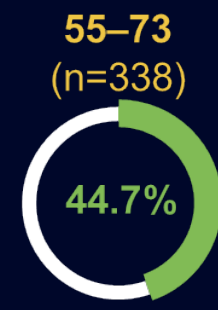
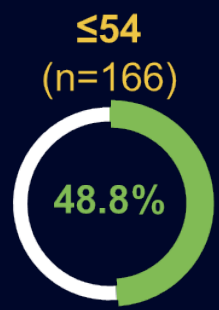
SAF, data are for Week 96 completers.
 q8, every 8 weeks; q12, every 12 weeks; q16, every 16 weeks; q20, every 20 weeks; q24, every 24 weeks; SAF, safety analysis set; SD, standard deviation.

BCVA and CRT Outcomes at Week 96 Are Similar with Aflibercept 8 mg and 2 mg Independent of BL BCVA

Groups based on BL BCVA (ETDRS letters)



Proportion of patients receiving all 8 mg with ≥q20 last assigned dosing interval at Week 96^a

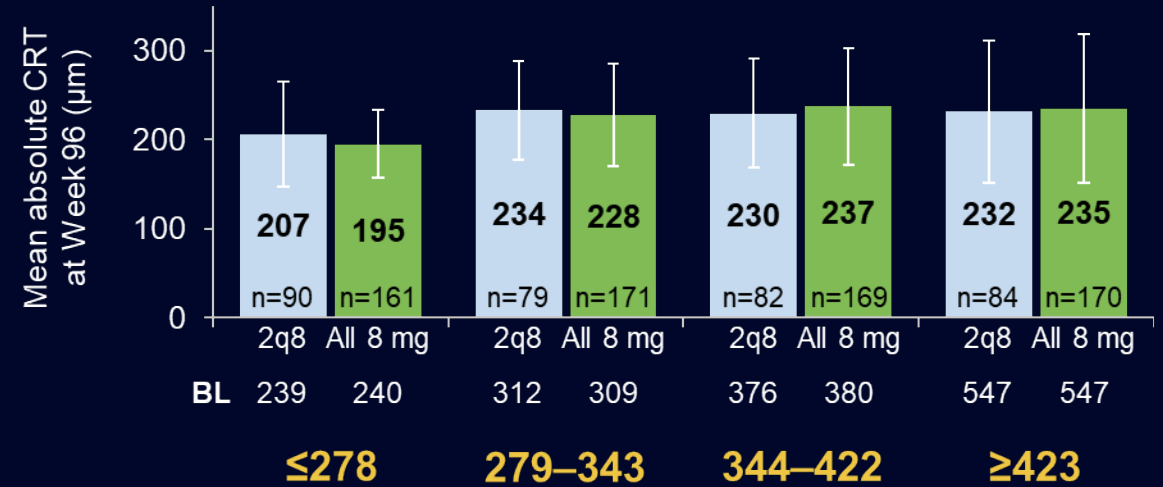
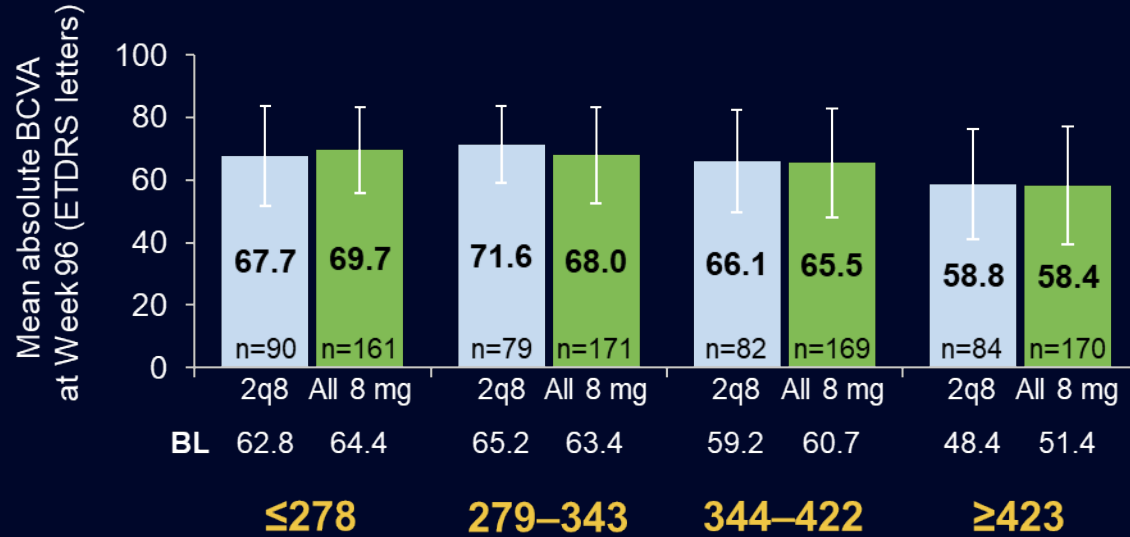


FAS, LOCF unless otherwise noted. Error bars show SD. N values for BL. Analyses were not adjusted for multiplicity or to allow for differences in BL BCVA or BL CRT.
^aData shown for patients who completed 96 weeks of treatment. LOCF, last observation carried forward.

BCVA and CRT Outcomes at Week 96 are Similar with Aflibercept 8 mg and 2 mg Independent of BL CRT



Groups based on BL CRT (μm)



≤278

279-343

344-422

≥423

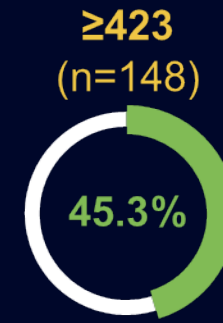
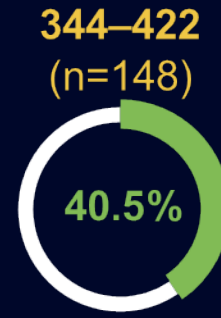
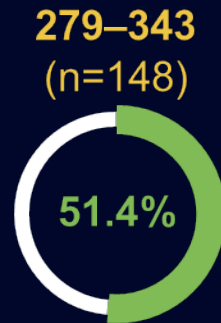
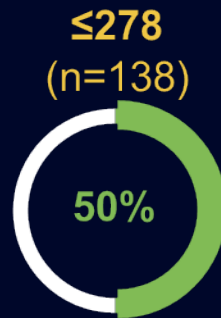
≤278

279-343

344-422

≥423

Proportion of patients receiving all 8 mg with $\geq\text{q}20$ last assigned dosing interval at Week 96^a

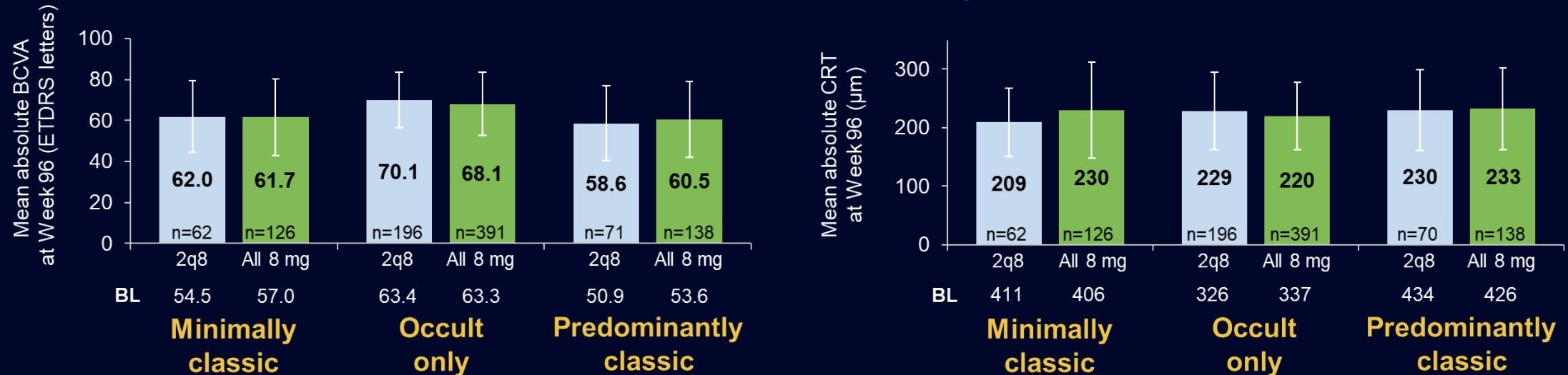


FAS, LOCF unless otherwise noted. Error bars show SD. N values for BL. Analyses were not adjusted for multiplicity or to allow for differences in BL BCVA or BL CRT.

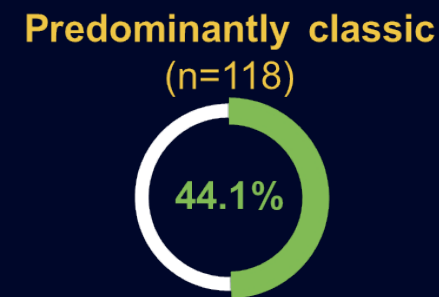
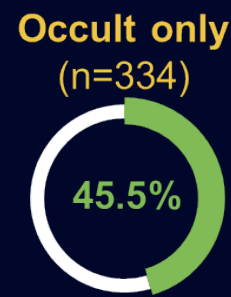
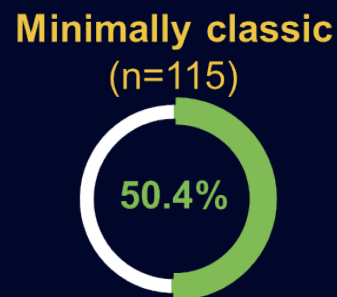
^aData shown for patients who completed 96 weeks of treatment.

BCVA and CRT Outcomes at Week 96 are Similar with Aflibercept 8 mg and 2 mg Independent of BL CNV Type

Groups based on BL CNV type



Proportion of patients receiving all 8 mg with \geq 20 last assigned dosing interval at Week 96^a

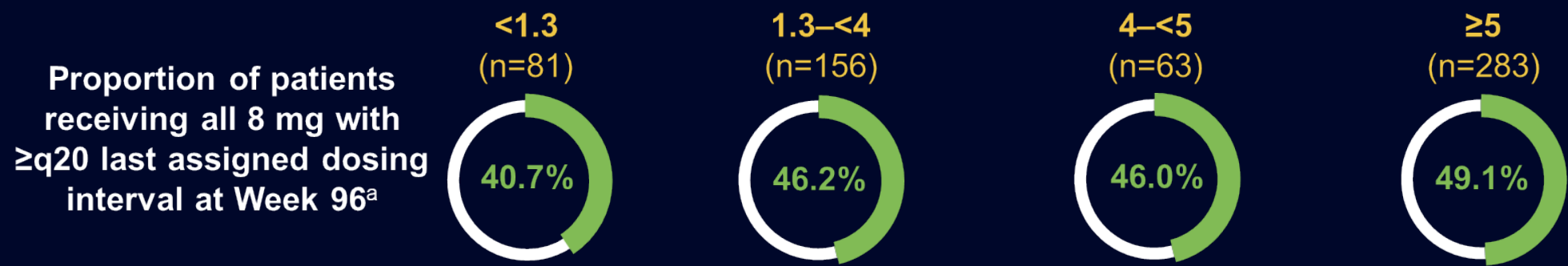
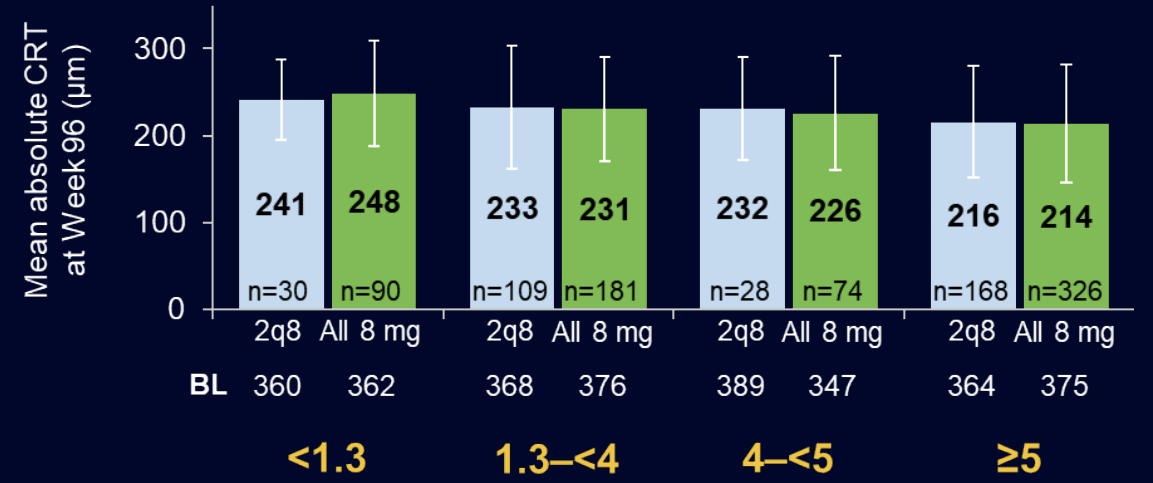
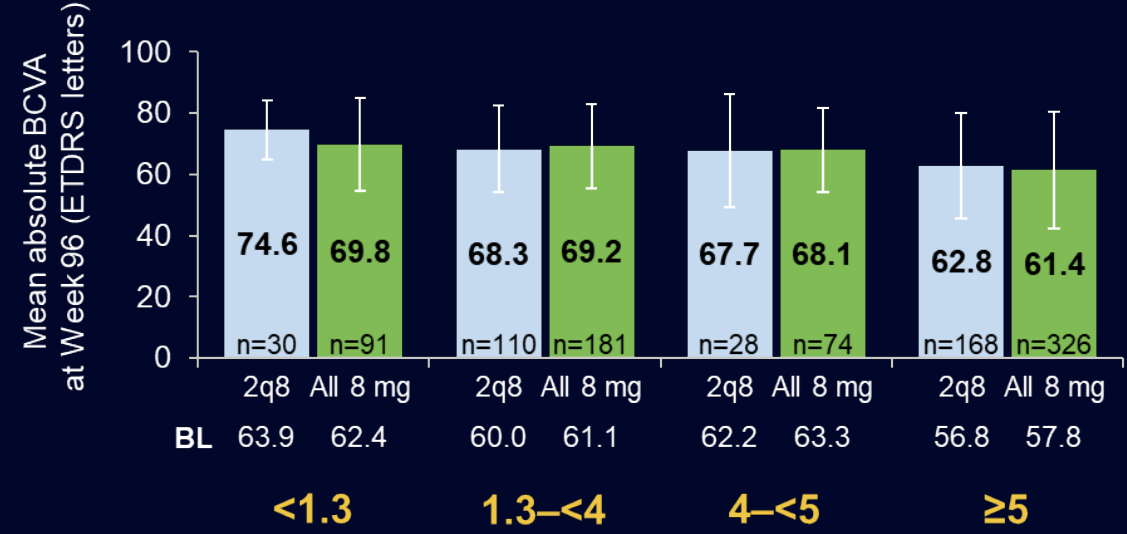


FAS, LOCF unless otherwise noted. Error bars show SD. N values for BL. Analyses were not adjusted for multiplicity or to allow for differences in BL BCVA or BL CRT.

^aData shown for patients who completed 96 weeks of treatment. CNV, choroidal neovascularization.

BCVA and CRT Outcomes at Week 96 are Similar with Aflibercept 8 mg and 2 mg Independent of BL CNV Size

Groups based on BL CNV size (mm²)

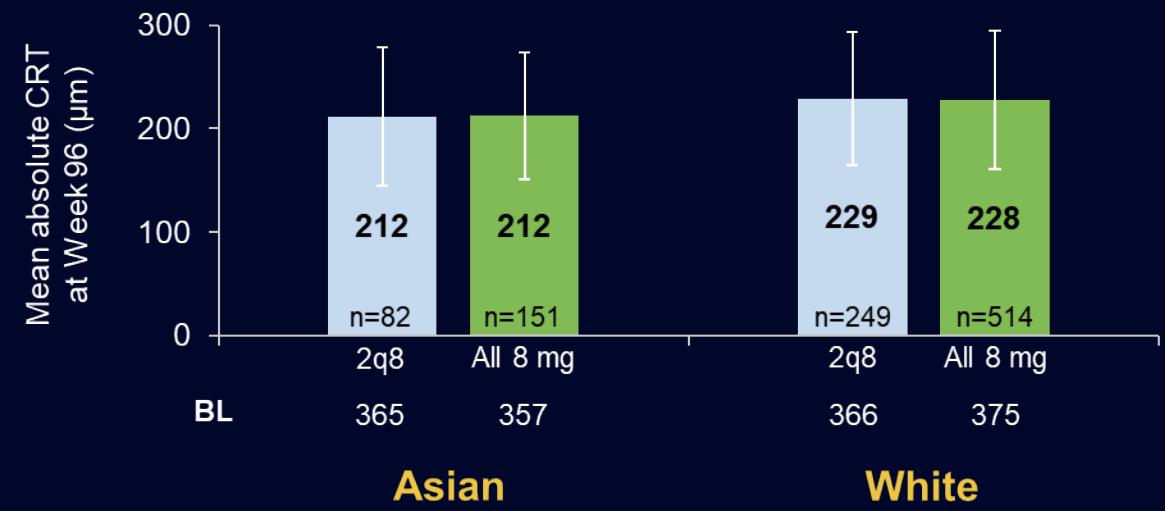
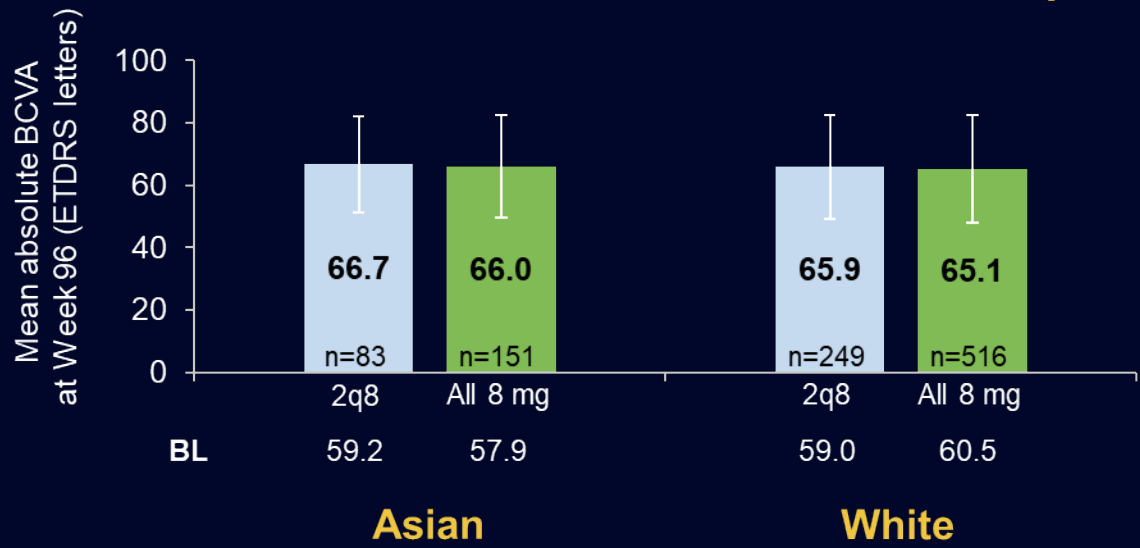


FAS, LOCF unless otherwise noted. Error bars show SD. N values for BL. Analyses were not adjusted for multiplicity or to allow for differences in BL BCVA or BL CRT.
^aData shown for patients who completed 96 weeks of treatment.

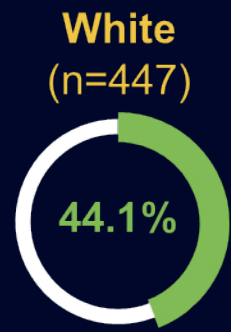
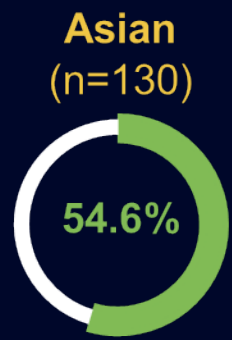
BCVA and CRT Outcomes at Week 96 are Similar with Aflibercept 8 mg and 2 mg Independent of Race



Groups based on Race



Proportion of patients receiving all 8 mg with \geq q20 last assigned dosing interval at Week 96^a

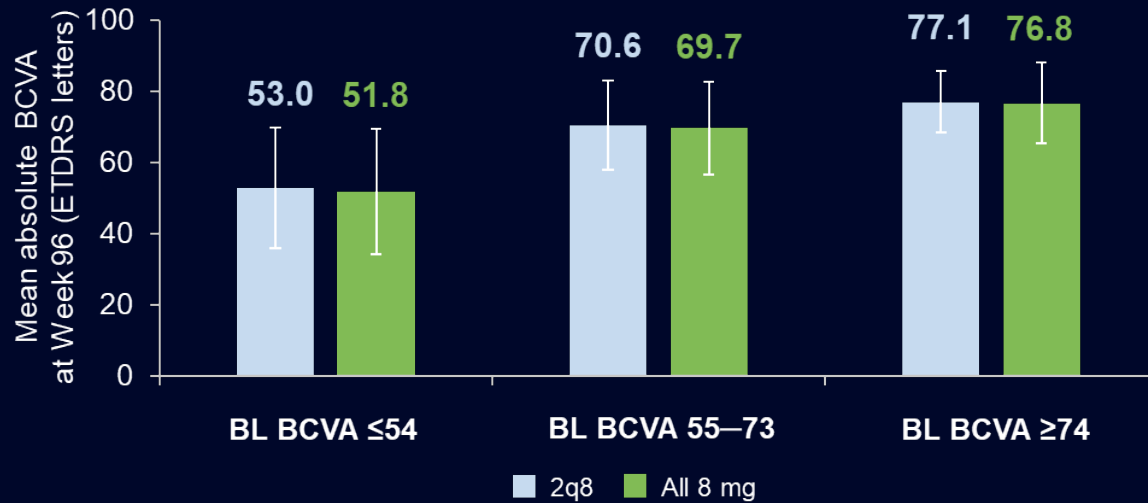


FAS, LOCF unless otherwise noted. Error bars show SD. N values for BL. Analyses were not adjusted for multiplicity or to allow for differences in BL BCVA or BL CRT.
^aData shown for patients who completed 96 weeks of treatment.

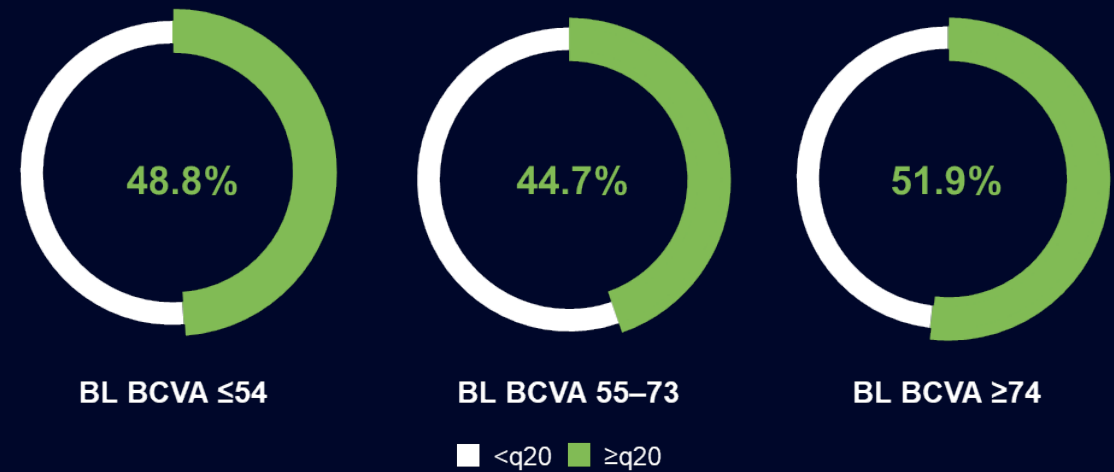
Conclusions

- At Week 96, **across all subgroups based on** baseline BCVA, CRT, CNV type, CNV size, and race:
 - Mean absolute and change in BCVA and CRT values were similar** after treatment with aflibercept 8 mg with extended dosing intervals compared with 2 mg every 8 weeks
 - Proportion of patients with last assigned dosing interval \geq q20 was similar

Week 96 BCVA Outcomes According to BL BCVA



Last Assigned Dosing Interval According to BL BCVA^a



FAS, LOCF unless otherwise noted. Error bars show SD. N values for BL. Analyses were not adjusted for multiplicity or to allow for differences in in BL BCVA or BL CRT.

^aData shown for patients who completed 96 weeks of treatment.