pulsar Extension

Similar Visual and Anatomic Outcomes with Aflibercept 8 mg in Patients with Neovascular Age-related Macular Degeneration by Baseline BCVA and CRT: A 156-Week PULSAR Subgroup Analysis

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Disclosures

pulsar
nAMD
Extension

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PULSAR Extension Design

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PULSAR (BL–W96)
(Masked)

Patients with treatment-naïve nAMD

2q8 arm (n=336)
Aflibercept 2 mg every 8 weeks after 3 initial monthly injections

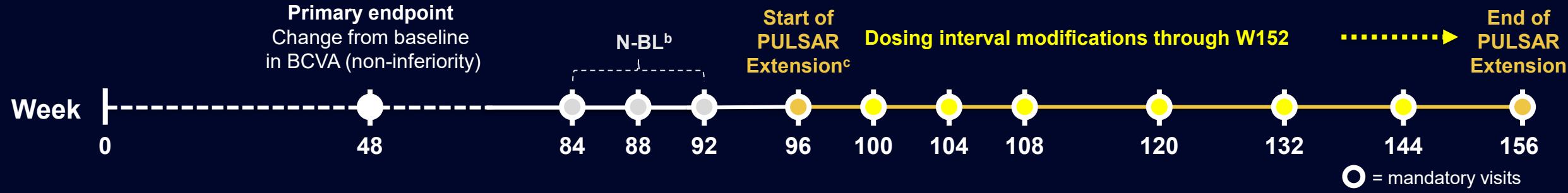
8q12 arm (n=335)
Aflibercept 8 mg every 12 weeks after 3 initial monthly injections

8q16 arm (n=338)
Aflibercept 8 mg every 16 weeks after 3 initial monthly injections

PULSAR Extension (W96–W156)
(Open-label and optional)[a]

2q8→8mg arm (n=208)
Patients originally assigned to 2q8 switched to aflibercept 8 mg every 12 weeks

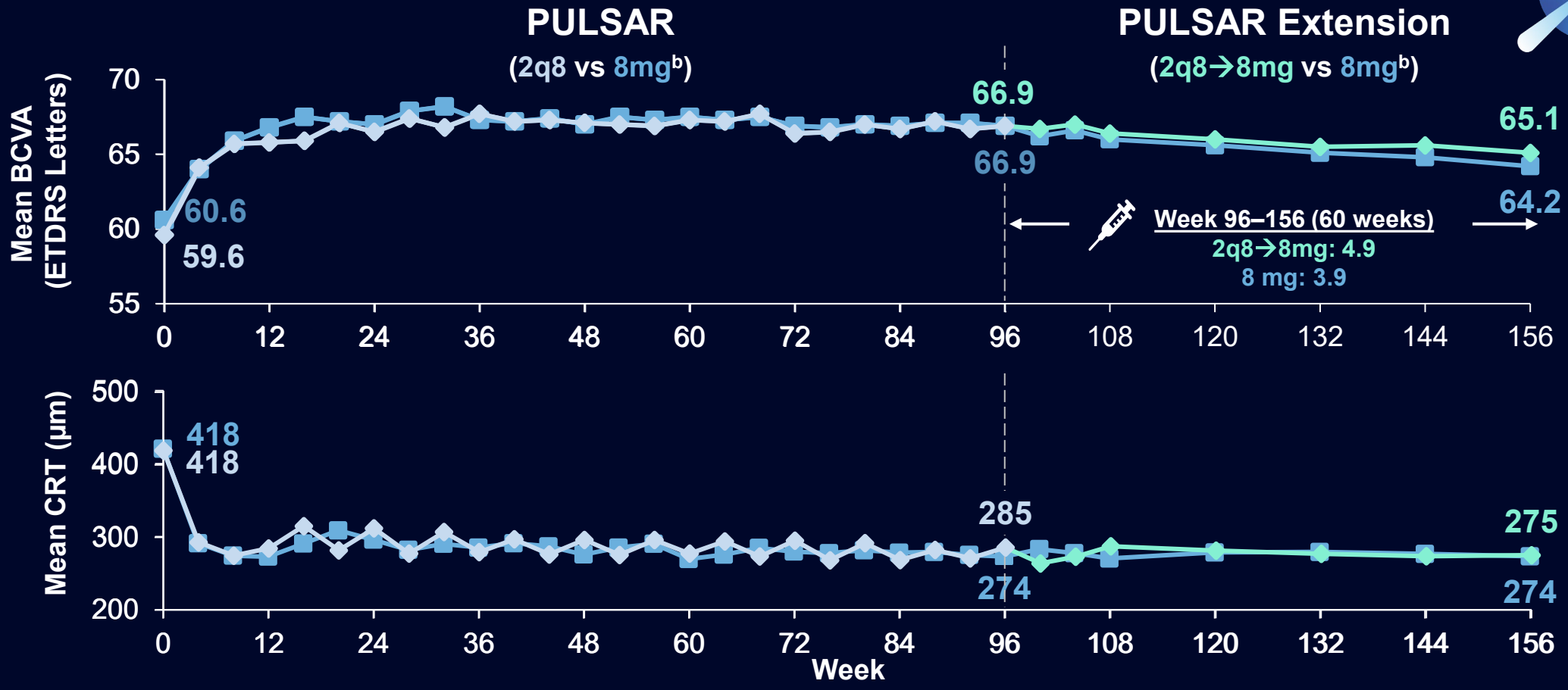
8mg arm (n=417)
Patients originally assigned to 8q12 or 8q16 continued aflibercept 8 mg on last assigned dosing interval



[a]To be eligible for PULSAR Extension, patients had to have ≥1 BCVA and CRT assessments between Week 84 and Week 92. Masked transition period (W96–108) was followed by open-label part (W108–W156). [b]N-BL was an average of values from W84, 88, and 92. [c]Optional phase added while PULSAR was ongoing; therefore, not all patients were able to enroll due to time constraints.

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 subfield retinal thickness; **nAMD**, neovascular age-related macular degeneration; **N-BL**, new baseline; **W**, week.

Mean BCVA and CRT Through Week 156[a]



Mean number of active injections over 48-week periods:[c]

BL–Week 48
2 mg: 6.9
8q12: 6.1
8q16: 5.2

Week 48–96
2 mg: 5.9
8q12: 3.6
8q16: 3.1

Week 108–156
8 mg: 2.9
8 mg: 2.9

Note: At Week 156, the 2q8→8mg group (n=208) and 8mg group (n=417) reported LS mean (95% CI) changes from baseline (MMRM) in BCVA of +4.6 (2.6, 6.6) letters and +3.4 (1.9, 4.9) letters, respectively, and in CRT of −145 (−155, −136) µm and −148 (−156, −140) µm, respectively. MMRM was used to generate BCVA/CRT LS means for the eFAS with baseline BCVA/CRT as a covariate; treatment group (aflibercept 8q12, 8q16, 2q8), visit, and stratification variables (geographic region [Japan vs rest of the world] and baseline BCVA [<60 vs ≥60 letters]) as fixed factors; and terms for the interaction between visit and baseline BCVA/CRT and the interaction between visit and treatment. [a]eFAS (observed cases). [b]Patients who were randomly assigned to the 8q12 or 8q16 groups at the beginning of the PULSAR study and continued treatment with aflibercept 8 mg through the PULSAR Extension. [c]eSAF (156-week completers; 2q8→8mg, n=186; 8q12, n=185; 8q16, n=190; 8mg, n=375). **BL**, baseline; **CI,** confidence interval; **eSAF**, safety analysis set in the PULSAR Extension; **LS**, least squares; **MMRM,** mixed model for repeated measures.

BCVA and CRT Outcomes Sustained Across Treatment Groups Stratified by Baseline BCVA Categories

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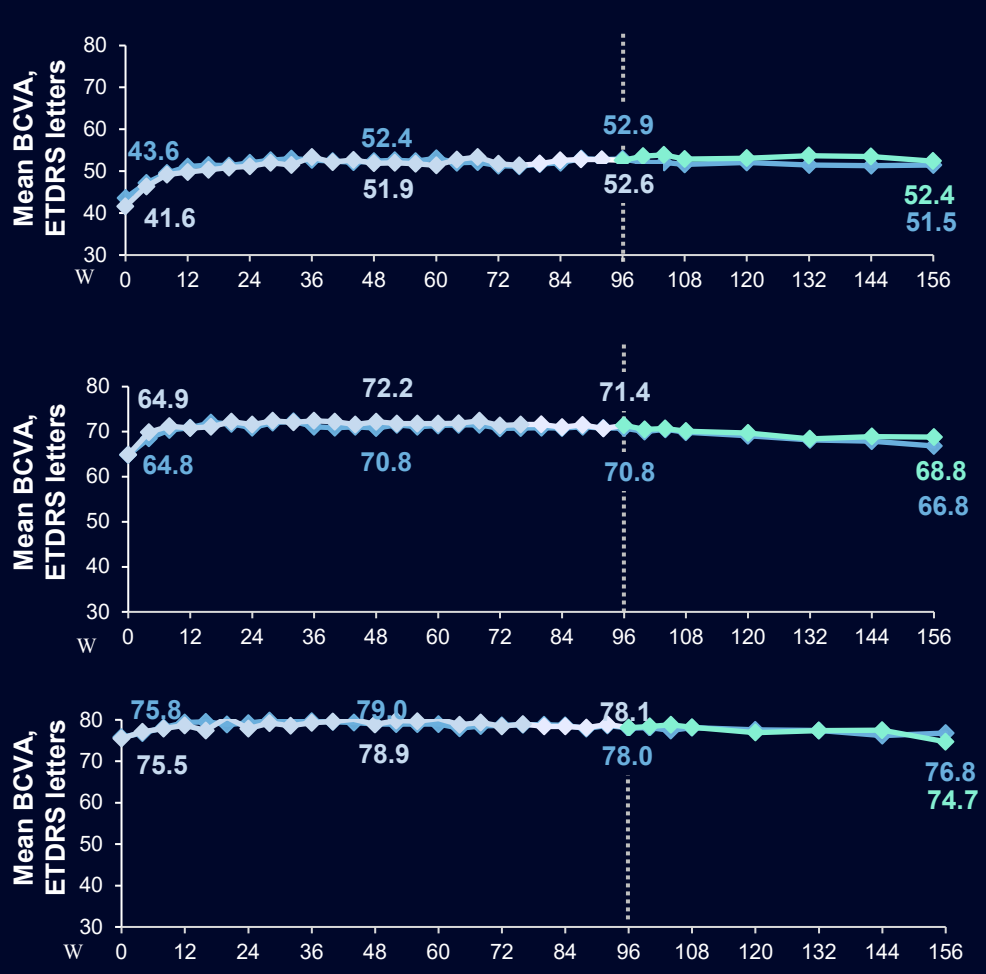
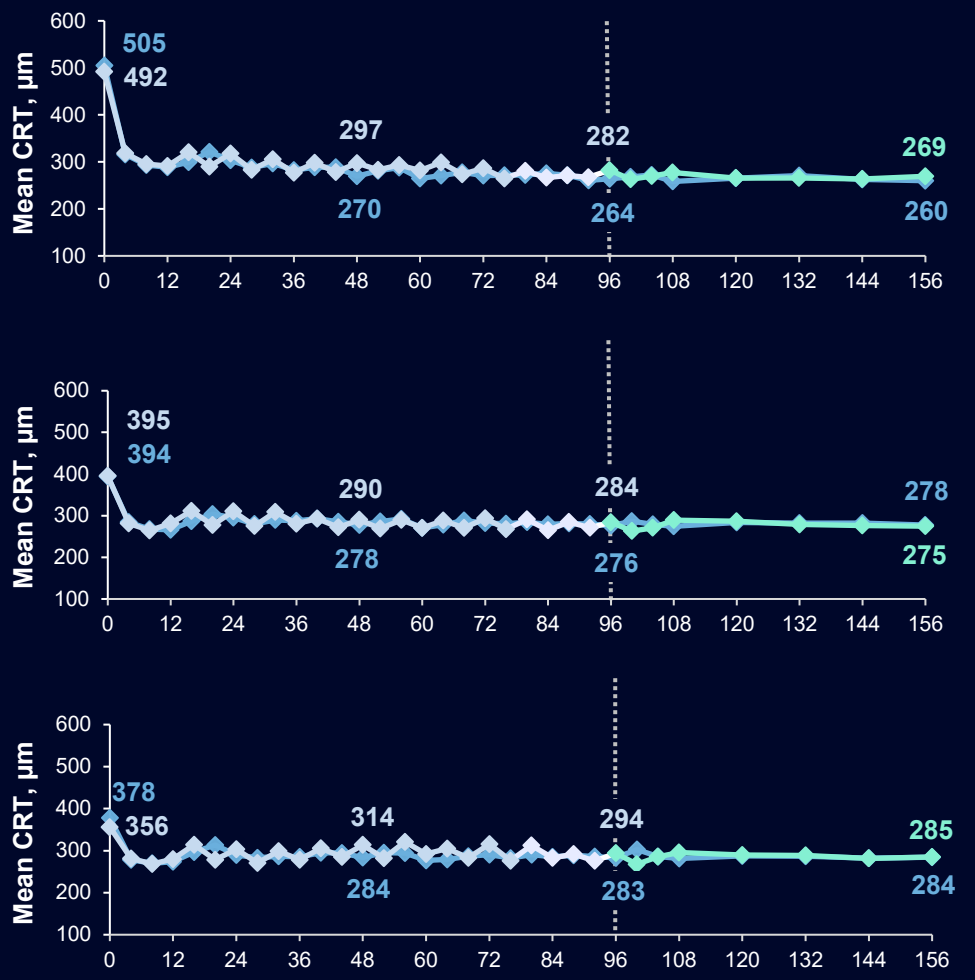
BCVA outcomes

PULSAR 2q8 vs 8mg | PULSAR Extension 2q8→8mg vs 8mg



CRT outcomes

PULSAR 2q8 vs 8 mg | PULSAR Extension 2q8→8mg vs 8mg



Mean no. of injections[a]

	BL–W96	W96–W156
≤54 ETDRS letters	12.9 vs 9.2	4.7 vs 3.8
55–73 ETDRS letters	12.8 vs 9.0	4.9 vs 3.9
≥74 ETDRS letters	13.0 vs 9.0	5.1 vs 3.9

eFAS; observed cases. [a]eSAF. **ETDRS**, Early Treatment Diabetic Retinopathy Study.

Majority of Patients Were Assigned Extended Dosing Intervals at Week 156 Irrespective of Baseline BCVA Categories

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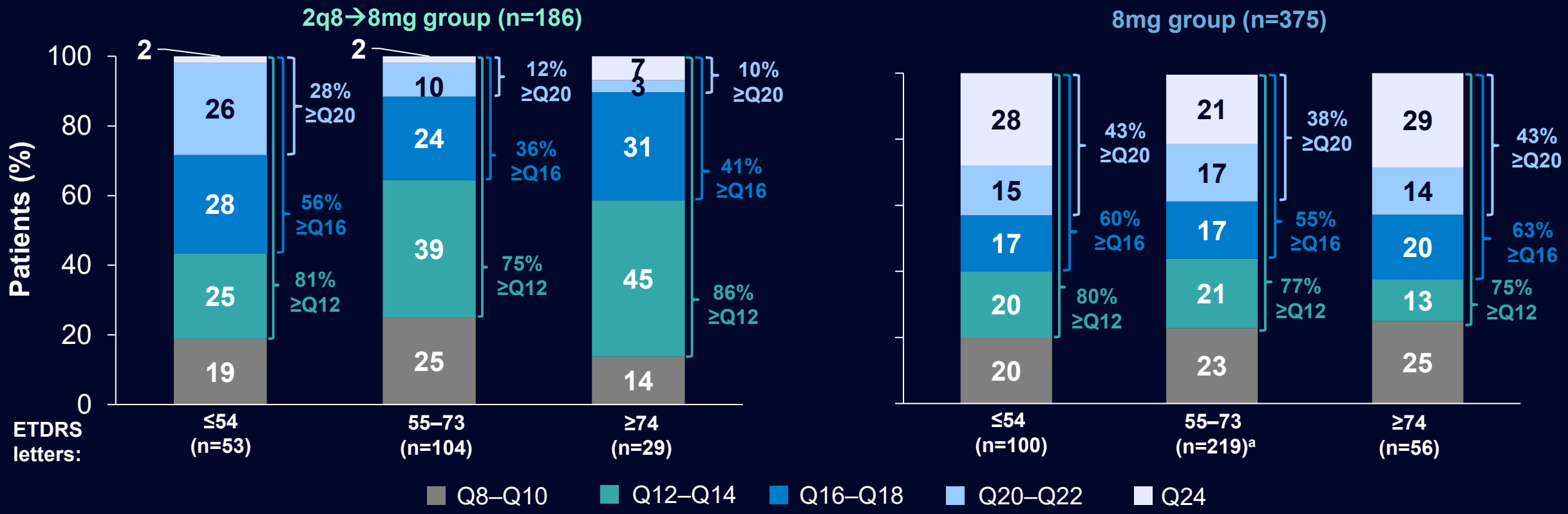
Last assigned dosing intervals at Week 156 by baseline BCVA categories



- Most patients (75%–86%) achieved ≥12-week dosing intervals at Week 156 within the BCVA categories for the **2q8→8mg** and **8mg** groups

eSAF, participants who completed 156 weeks of treatment. Values may not add up to 100% due to rounding. [a]One patient was missing from the analysis. **Qn**, n-weekly interval.

BCVA Outcomes Sustained Across Treatment Groups Stratified by Baseline CRT Quartiles

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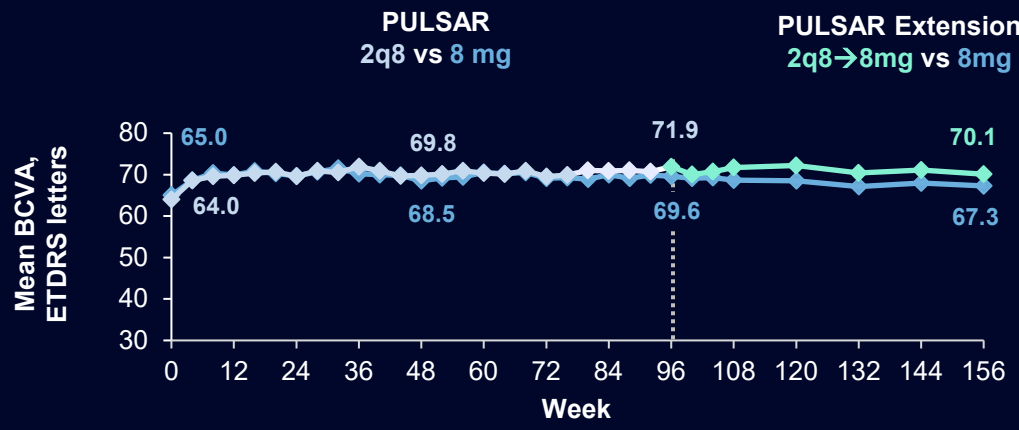
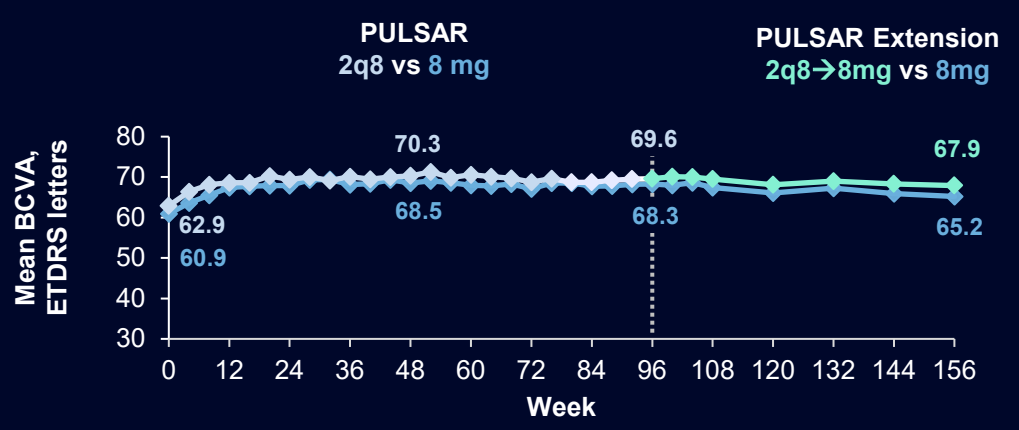
CRT, <326 µm (n=48,n=108)



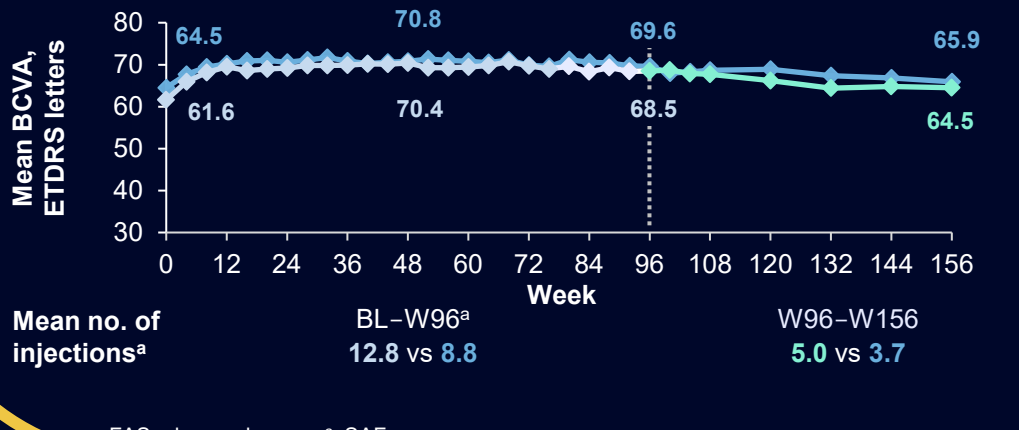
Mean no. of injections[a]	BL–W96[a]	W96–W156
	12.9 vs 8.6	4.8 vs 3.6

CRT, ≥396 to <483 µm (n=56, n=100)



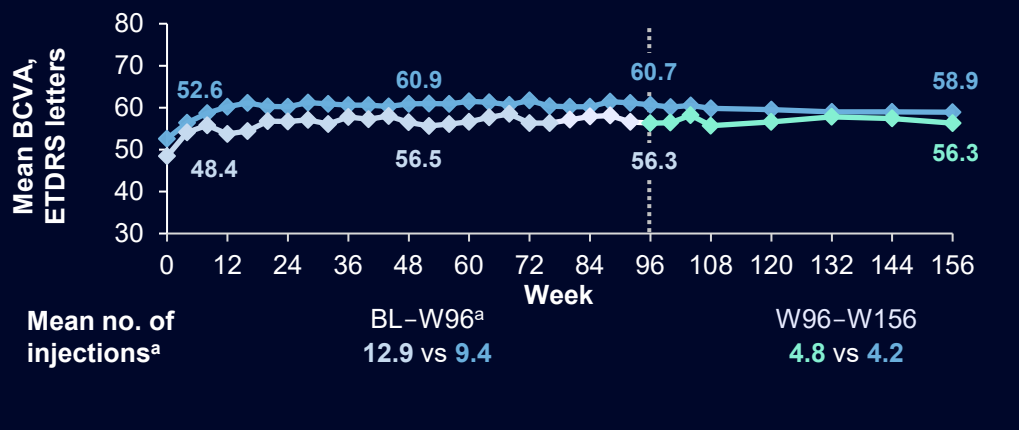
Mean no. of injections[a]	BL–W96[a]	W96–W156
	12.8 vs 9.2	4.9 vs 3.9

CRT, ≥326 to <396 µm (n=58, n=98)



Mean no. of injections[a]	BL–W96[a]	W96–W156
	12.8 vs 8.8	5.0 vs 3.7

CRT, ≥483 µm (n=46, n=111)



Mean no. of injections[a]	BL–W96[a]	W96–W156
	12.9 vs 9.4	4.8 vs 4.2

eFAS; observed cases. [a]eSAF.

CRT Outcomes Sustained Across Treatment Groups Stratified by Baseline CRT Quartiles

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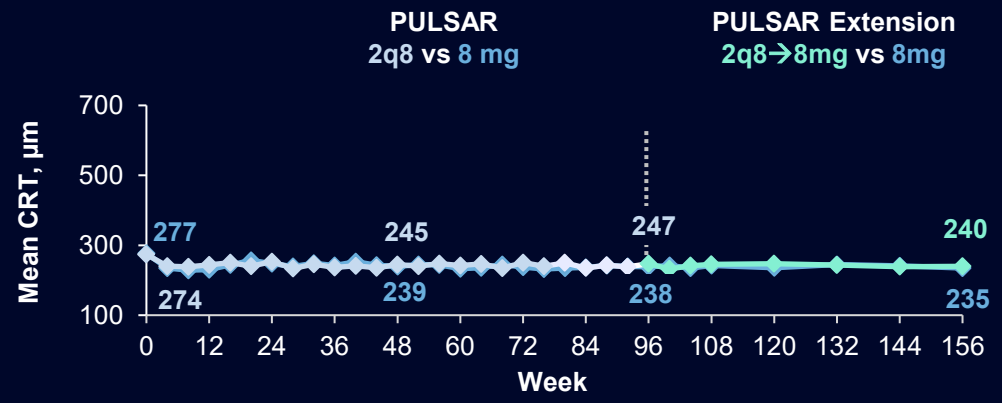
CRT, <326 µm (n=48, n=108)



Mean no. of injections[a]	BL–W96[a]	W96–W156
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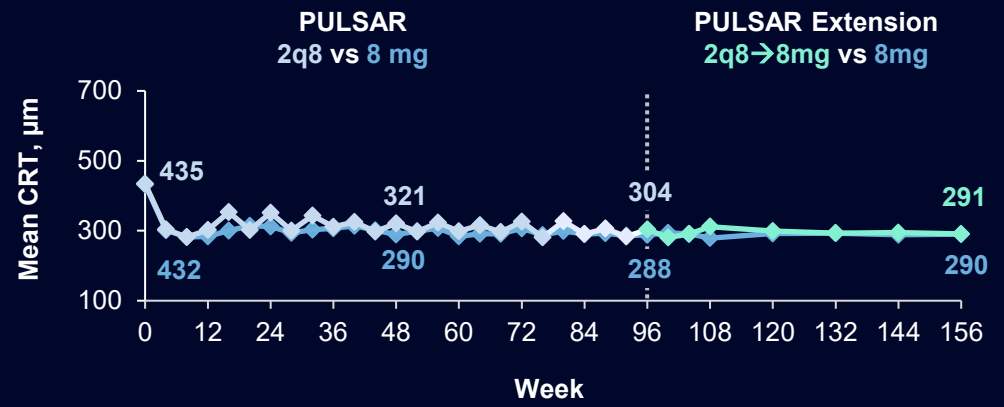
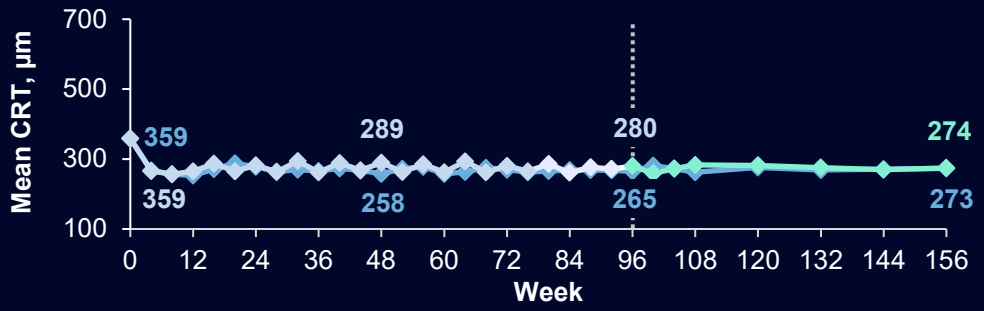


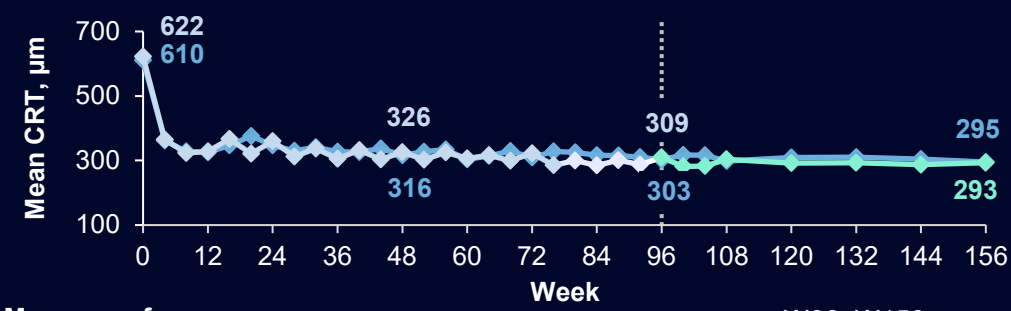
Mean no. of injections[a]	BL–W96[a]	W96–W156
	12.8 vs 9.2	4.9 vs 3.9

CRT, ≥326 to <396 µm (n=58, n=98)



Mean no. of injections[a]	BL–W96[a]	W96–W156
	12.8 vs 8.8	5.0 vs 3.7

CRT, ≥483 µm (n=46, n=111)



Mean no. of injections[a]	BL–W96[a]	W96–W156
	12.9 vs 9.4	4.8 vs 4.2

eFAS; observed cases. [a]eSAF.

Majority of Patients Were Assigned Extended Dosing Intervals at Week 156 Irrespective of Baseline CRT Quartiles

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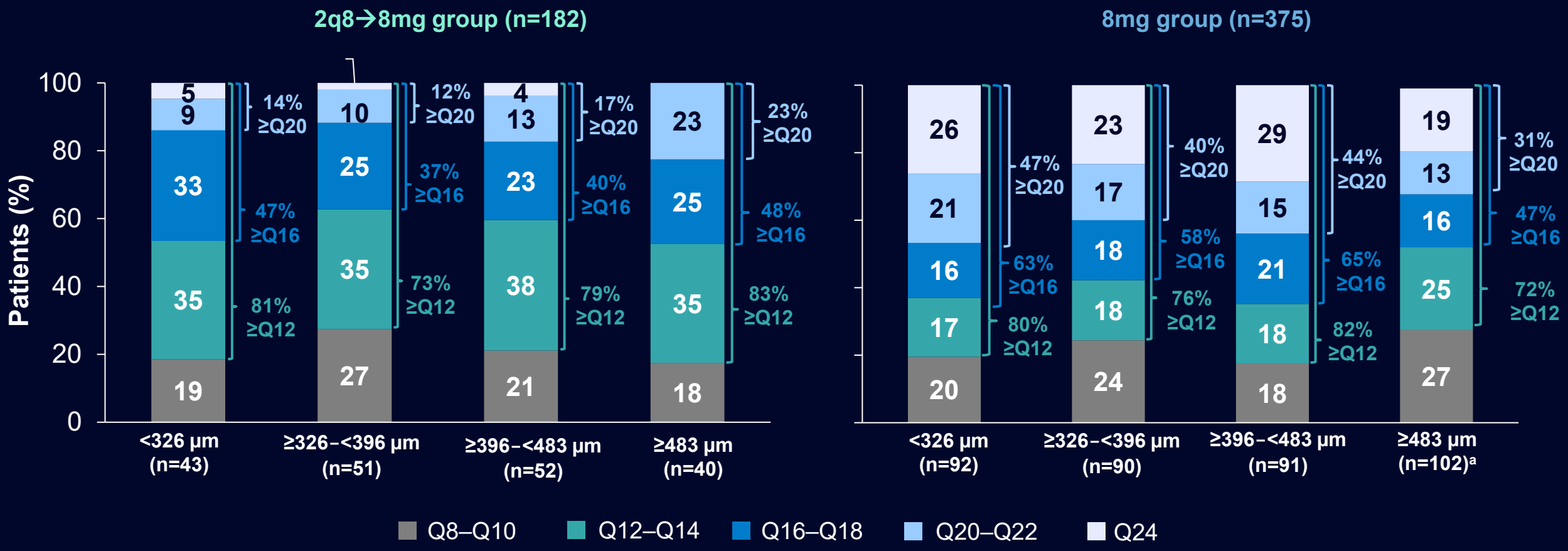
Last assigned dosing intervals at Week 156 by baseline CRT quartiles



- Most patients (72%–83%) achieved ≥12-week dosing intervals at Week 156 within the baseline CRT quartiles for the **2q8→8mg** and **8mg** groups

eSAF, participants who completed 156 weeks of treatment. Values may not add up to 100% due to rounding. [a]One patient was missing from the analysis.

Conclusion

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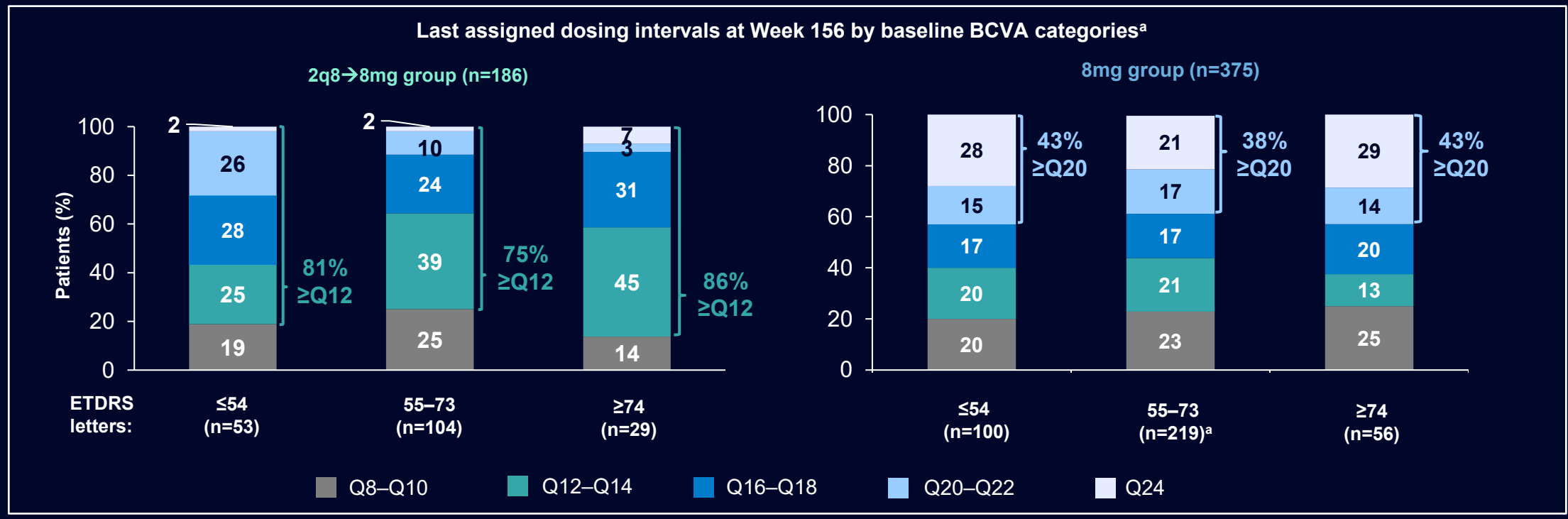
- In the PULSAR Extension, functional and anatomic improvements were sustained through Week 156 **in the 2q8→8mg and 8mg groups**
- Regardless of baseline BCVA and CRT, patients in the **2q8→8mg group maintained BCVA gains and CRT improvements through** Week 156 after switching to aflibercept 8 mg at Week 96
- The findings in the 8mg group suggest that patients with treatment-naïve nAMD can achieve **durable improvements with aflibercept 8 mg** administered over extended dosing intervals, regardless of baseline BCVA and CRT
- At Week 156, **BCVA and CRT outcomes were comparable in patient groups stratified by baseline BCVA and CRT** in the **2q8→8mg** and **8mg groups,** and the majority of patients achieved extended dosing intervals ≥Q12 weeks at Week 156



[a]eSAF, participants who completed 156 weeks of treatment. Values may not add up to 100% due to rounding.