PULSAR Extension: Sustained clinical outcomes with reduced treatment burden after switching from aflibercept 2 mg to 8 mg in patients with neovascular age-related macular degeneration

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on behalf of the PULSAR study investigators

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PULSAR Extension Design

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PULSAR (BL–W96)
(Masked)

Patients with treatment-naïve nAMD

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

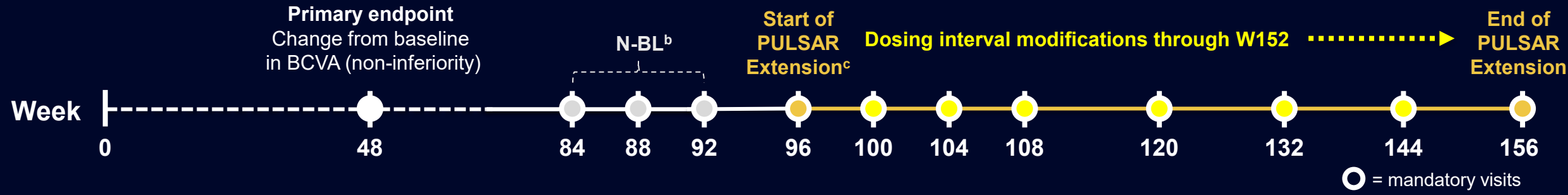
8q12 group (n=335)
Aflibercept 8 mg every 12 weeks after 3 initial monthly injections

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

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

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

8mg group (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 were required 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, W88, and W92. [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.

2q8→8mg: Mean BCVA[a] Through Week 156

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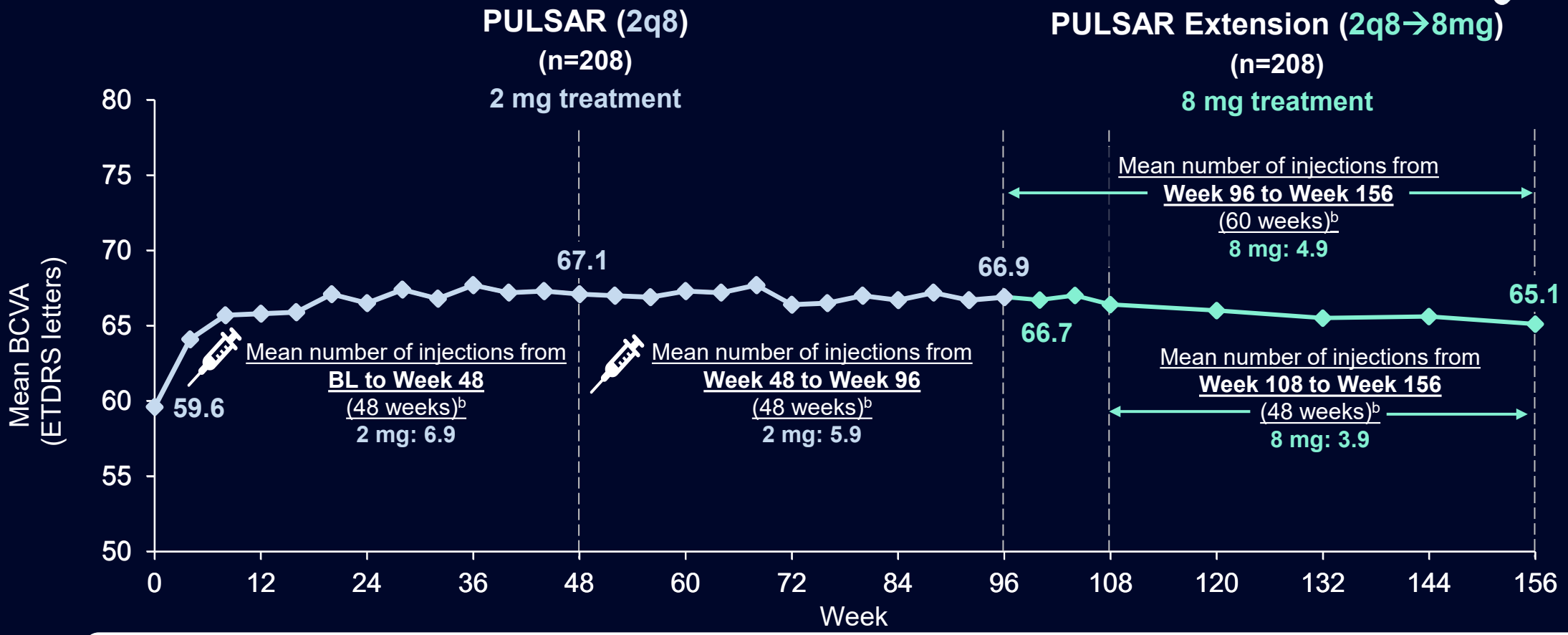

In the **2q8→8mg group**, the **mean number of injections** over a 48-week period was **reduced** from **5.9** to **3.9** after **switching from aflibercept 2 mg to 8mg**, while **maintaining BCVA gains**

Note: At Week 156, the 2q8→8mg group (n=208) reported a LS mean (95% CI) change (MMRM) from baseline in BCVA of +4.6 (2.6, 6.6) letters, MMRM was used to generate LS means for the eFAS with baseline BCVA as a covariate; treatment group (aflibercept 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 and the interaction between visit and treatment. [a]eFAS (OC). [b]eSAF.

CI, confidence interval; **eFAS**, full analysis set in the PULSAR Extension; **eSAF**, safety analysis set in the PULSAR Extension; ETDRS, Early Treatment Diabetic Retinopathy Study; **LS**, least squares; **MMRM**, mixed model for repeated measures; **OC**, observed cases.

2q8→8mg: Proportion of Patients who Achieved BCVA Score of ≥69 ETDRS Letters[a]

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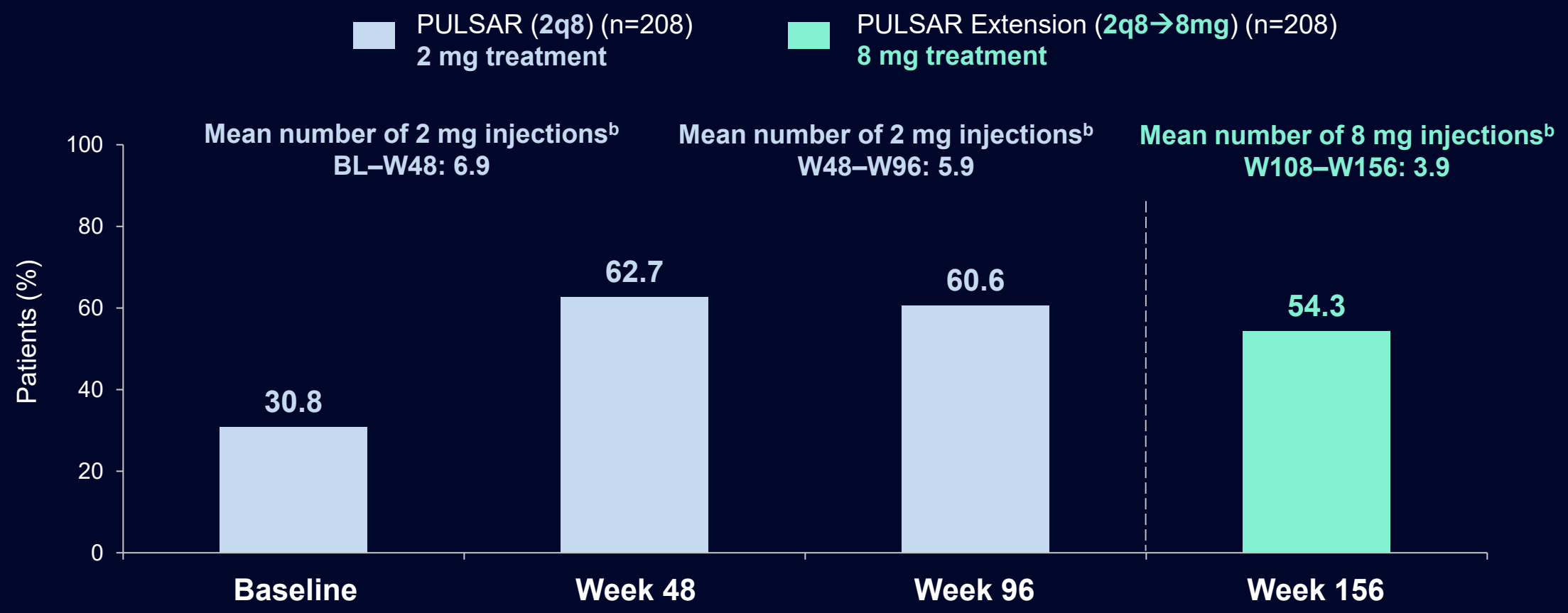

[a]eFAS (OC). [b]eSAF.

2q8→8mg: Mean CRT[a] Through Week 156

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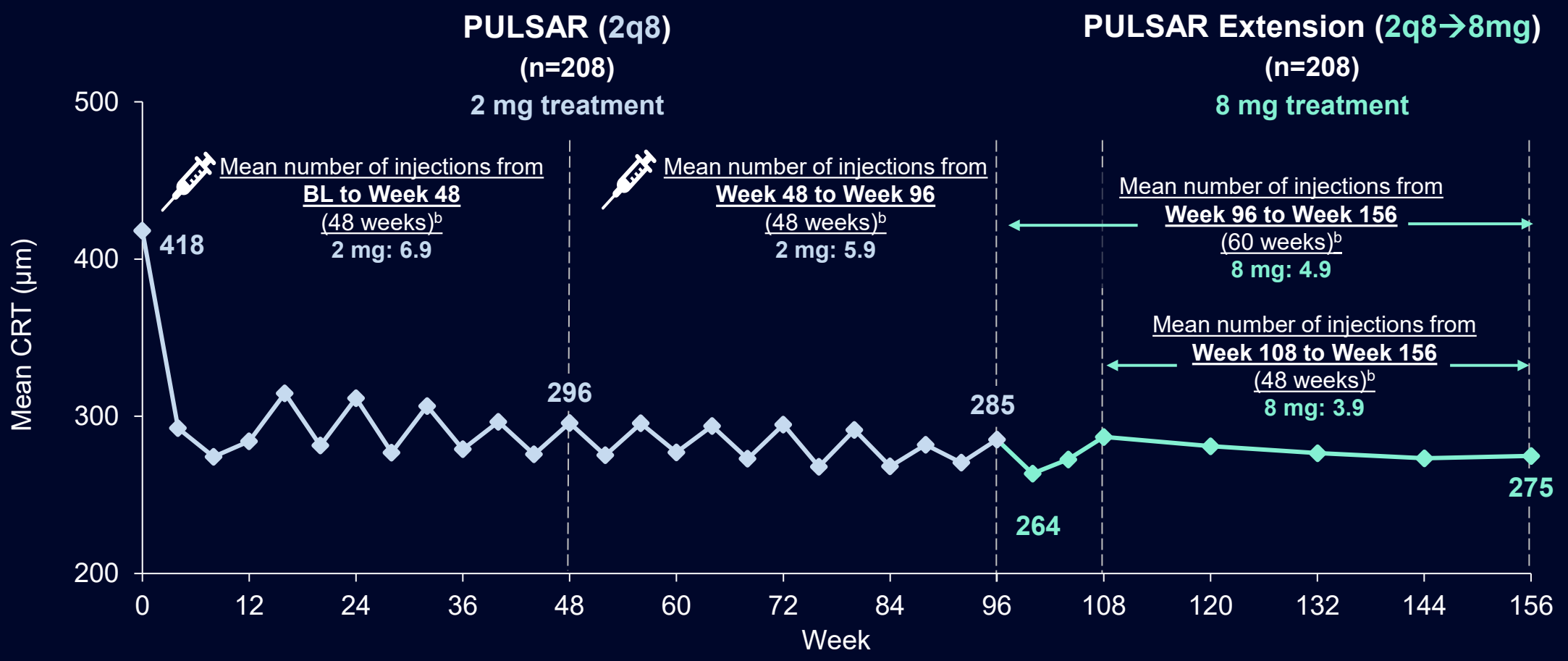

In the **2q8→8mg group, the lowest mean CRT** was achieved at Week 100 **following the first aflibercept 8 mg injection**, and **CRT remained stable** through **Week 156**

Note: At Week 156, the 2q8→8mg group (n=208) reported a LS mean (95% CI) change (MMRM)[c] from baseline in CRT of −145 (−155, −136) µm.
[a]eFAS (OC). [b]eSAF. [c]LS means were generated for the eFAS using MMRM with baseline CRT as a covariate; treatment group (aflibercept 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 CRT and the interaction between visit and treatment.

2q8→8mg: Mean CNV Lesion Area[a] Through Week 156

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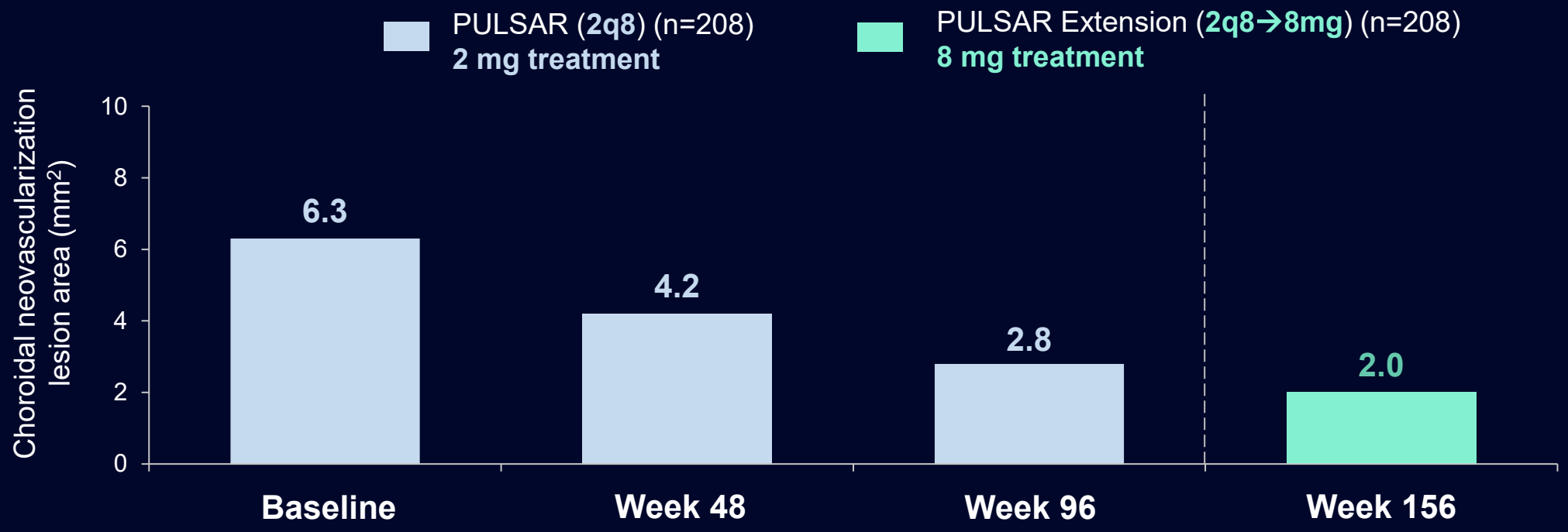

A **decrease in the CNV lesion area** was observed from baseline through **Week 96,** and a **further decrease** was observed through **Week 156** following **switch** to **aflibercept 8 mg**, indicating **continued improvement** with **aflibercept 8 mg** at **extended dosing intervals**

[a]eFAS (OC). CNV was measured using FA/FP.
CNV, choroidal neovascularization**; FA**, fluorescein angiography; **FP**, fundus photography.

2q8→8mg: Proportion of Retinal Fluid-free Patients (no IRF and no SRF) in the Center Subfield[a] Through Week 156

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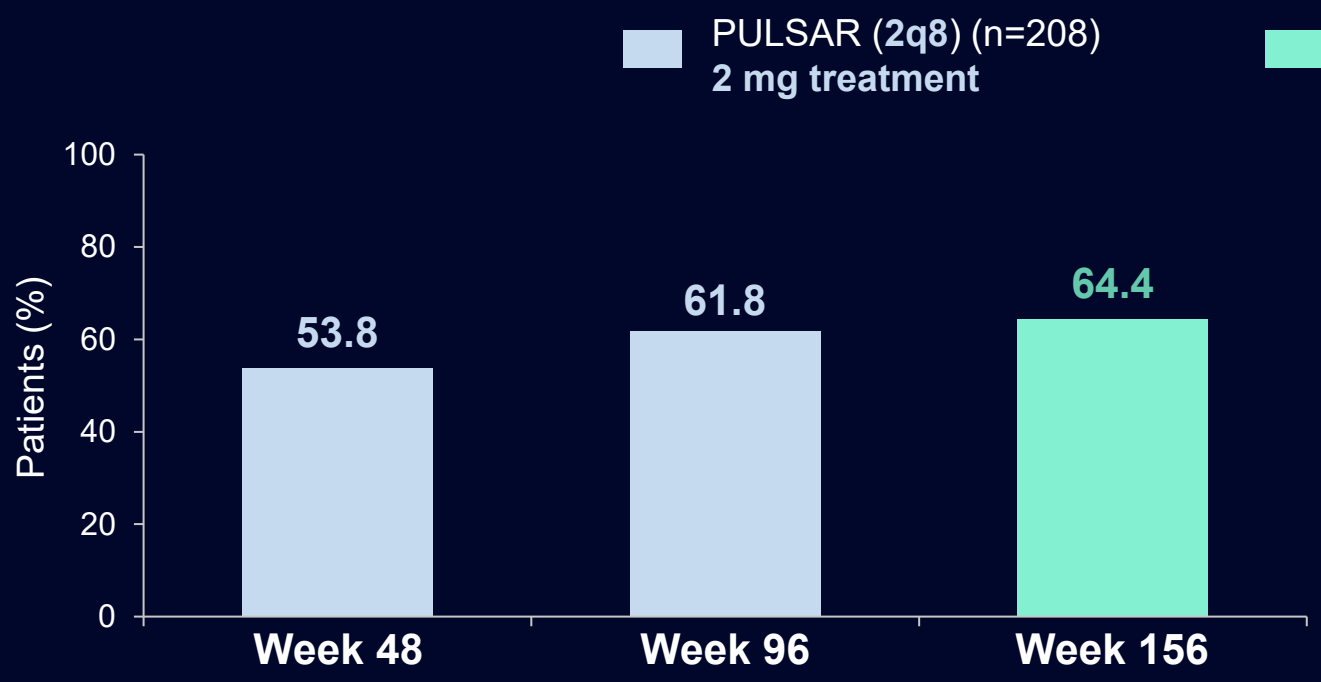
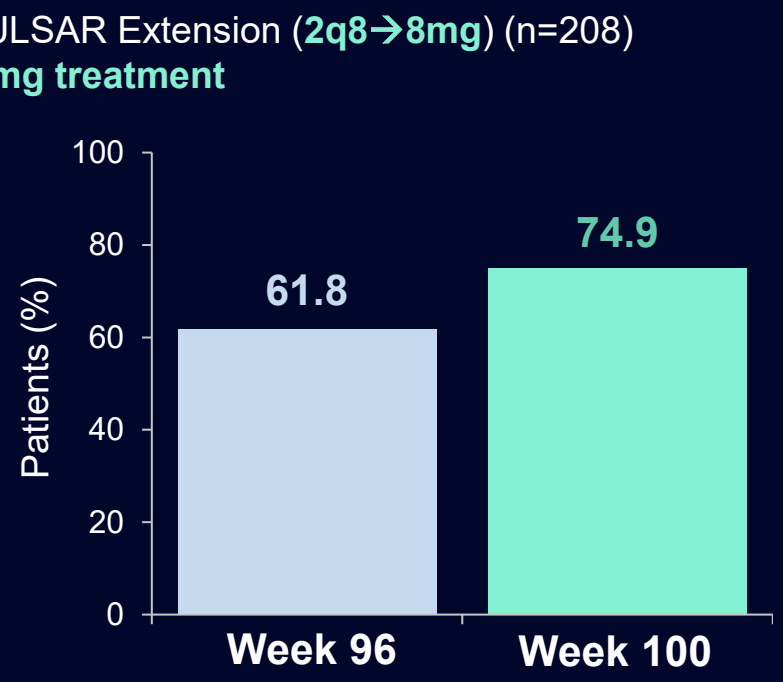
Long-term efficacy

The proportion of patients who were **fluid-free** was **maintained** from **Week 96 to Week 156** following **switch to aflibercept 8 mg,** with **extended dosing intervals**

Immediate improvement

13.1% increase in the proportion of patients who were **fluid-free** from **Week 96 to Week 100** following **switch to aflibercept 8 mg**





[a]eFAS (LOCF).
IRF, intraretinal fluid; **LOCF**, last observation carried forward; **SRF**, subretinal fluid.

2q8→8mg: Proportion of Patients with no IRF and no SRF in the Center Subfield[a] Through Week 156

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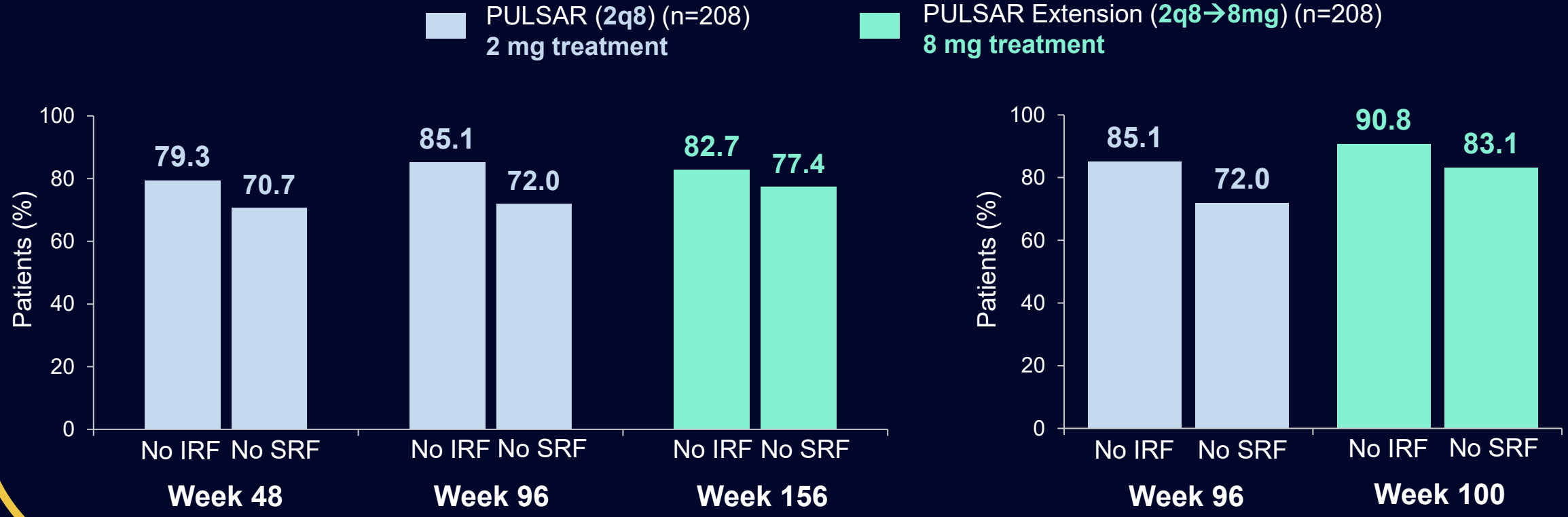
Long-term efficacy

The proportion of patients who were **IRF-free and SRF-free** was **maintained from Week 96 to Week 156** following **switch to aflibercept 8 mg,** with **extended dosing intervals**

Immediate improvement

5.7% and 11.1% increase in the proportion of patients who were **IRF-free and SRF-free** from **Week 96 to Week 100** following **switch to aflibercept 8 mg**



[a]eFAS (LOCF).

Proportion of Patients who Achieved Extended Dosing Intervals at Week 156

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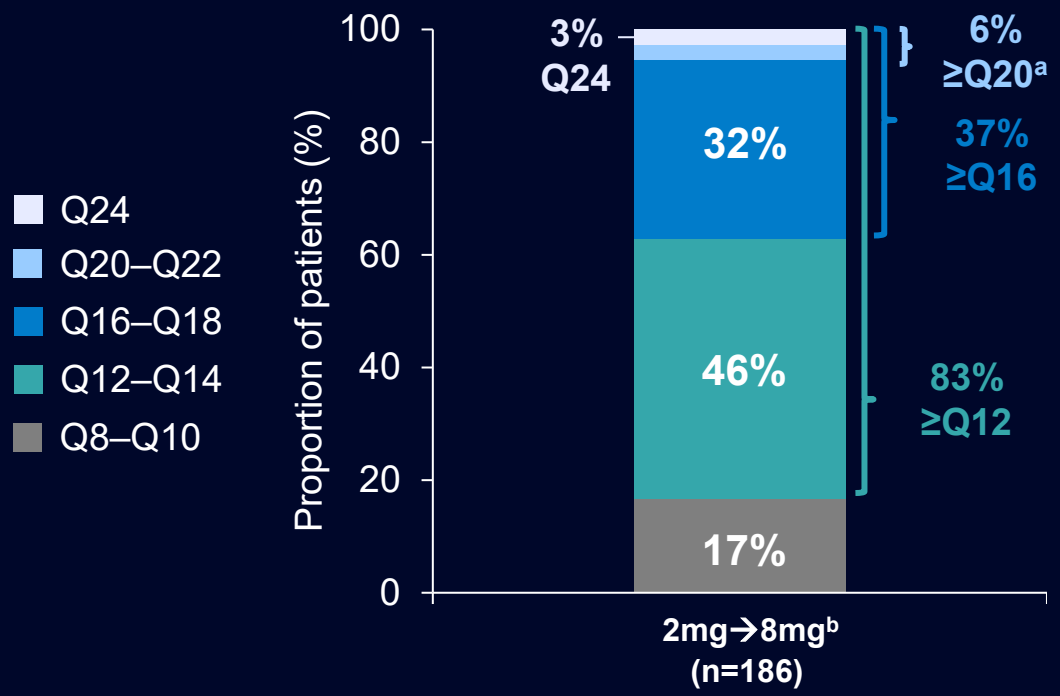
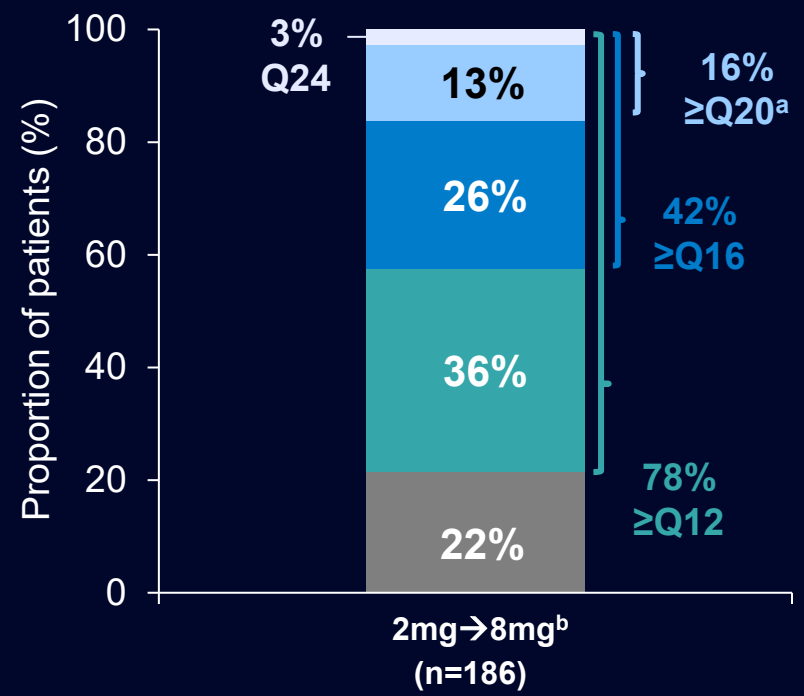
Last Completed Dosing Interval[a]



Last Assigned Dosing Interval[a]



eSAF, patients completing Week 156. Values may not add up to 100% due to rounding.
[a]Dosing intervals were extended if patients had less than a 5-letter loss in BCVA from new baseline AND no fluid in the central subfield on OCT AND no new onset foveal neovascularization or foveal hemorrhage.
[b]Per protocol, patients in the 2mg→8mg group did not have sufficient time to achieve a last assigned dosing interval of >Q20 by Week 156; patients misassigned to longer dosing intervals are included for completeness.
OCT, optical coherence tomography; Q24, every 24 weeks; Q20–Q22, every 20–22 weeks; Q16–Q18, every 16–18 weeks; Q12–Q14, every 12–14 weeks; Q8–Q10, every 8–20 weeks

Ocular and Non-Ocular Safety From PULSAR Baseline Through Week 156[a]

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	PULSAR[a] 2q8 (n=336) Week 0–96	PULSAR Extension[b] 2q8→8mg (n=208) Week 96–156
Ocular TEAEs, n (%)	181 (53.9)	67 (32.2)
Ocular SAEs, n (%)	4 (1.2)	4 (1.9)
Intraocular inflammation, n (n/1000 injections)	11(2.7)	3 (3.1)
Anterior chamber cell	0	0
Chorioretinitis	0	0
Endophthalmitis	2 (0.5)	1 (1.0)
Eye inflammation	2 (0.5)	0
Hypopyon	1 (0.2)	0
Iridocyclitis	2 (0.5)	1 (1.0)
Iritis	0	0
Uveitis	1 (0.2)	1 (1.0)
Vitreal cells	3 (0.7)	0
Vitritis	0	0
Occlusive vasculitis	0	0
Non-ocular SAEs, n (%)	257 (76.5)	102 (49.0)
APTC events, n (%)	11 (3.3)	4 (1.9)
Deaths, n (%)	12 (3.6)	4 (1.9)

No new safety concerns were identified with aflibercept 8 mg following switch from aflibercept 2 mg at Week 96

Additional information on safety with aflibercept 8 mg in patients with nAMD in PULSAR are presented in a later session

[a]SAF. [b]eSAF.
APTC, Anti-Platelet Trialists' Collaboration; **SAE**, serious adverse event; **TEAE**, treatment-emergent adverse event.

PULSAR Extension: Key Week 156 Results

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- The **mean BCVA, mean CRT, and proportion of patients who were fluid-free** in the center subfield in the aflibercept 2mg→8mg group were **generally maintained** from Week 96 to Week 156 in the PULSAR Extension **following switch to aflibercept 8 mg**
  - **Visual and anatomic outcomes were maintained with a reduced injection number** over a 60-week period following switch to aflibercept 8 mg
- The **majority** of patients in the **2q8→8mg group achieved ≥12-week dosing intervals** at Week 156
- **No new safety signals** were reported **following switch to aflibercept 8 mg** through Week 156
- These findings suggest that **clinical and anatomic improvements** can be **sustained** following **switch from aflibercept 2 mg to aflibercept 8 mg, with extended dosing intervals**