PULSAR Extension: Comparable Clinical Outcomes with Lower Treatment Burden over 156 Weeks in Patients with Neovascular Age-related Macular Degeneration who Switch from Aflibercept 2 mg to Aflibercept 8 mg

Sandrine Zweifel,[1] Sergio Leal,[2] Andrea Schulze,[3] Xin Zhang,[2]
on behalf of the PULSAR Extension investigators

[1]Department of Ophthalmology, University Hospital Zurich, University of Zurich, Zurich, Switzerland;
[2]Bayer Consumer Care AG, Basel, Switzerland;
[3]Bayer AG, Berlin, Germany

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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

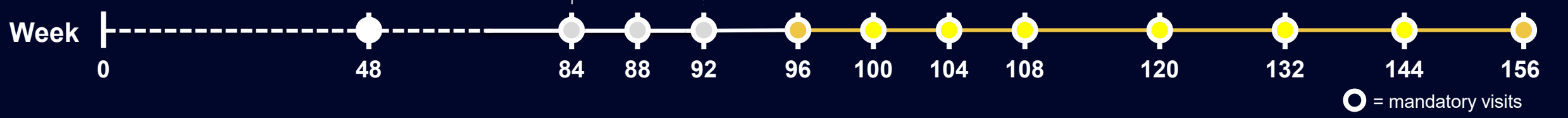
Primary endpoint
Change from baseline in BCVA (non-inferiority)

N-BL[b]

Start of PULSAR Extension[c]

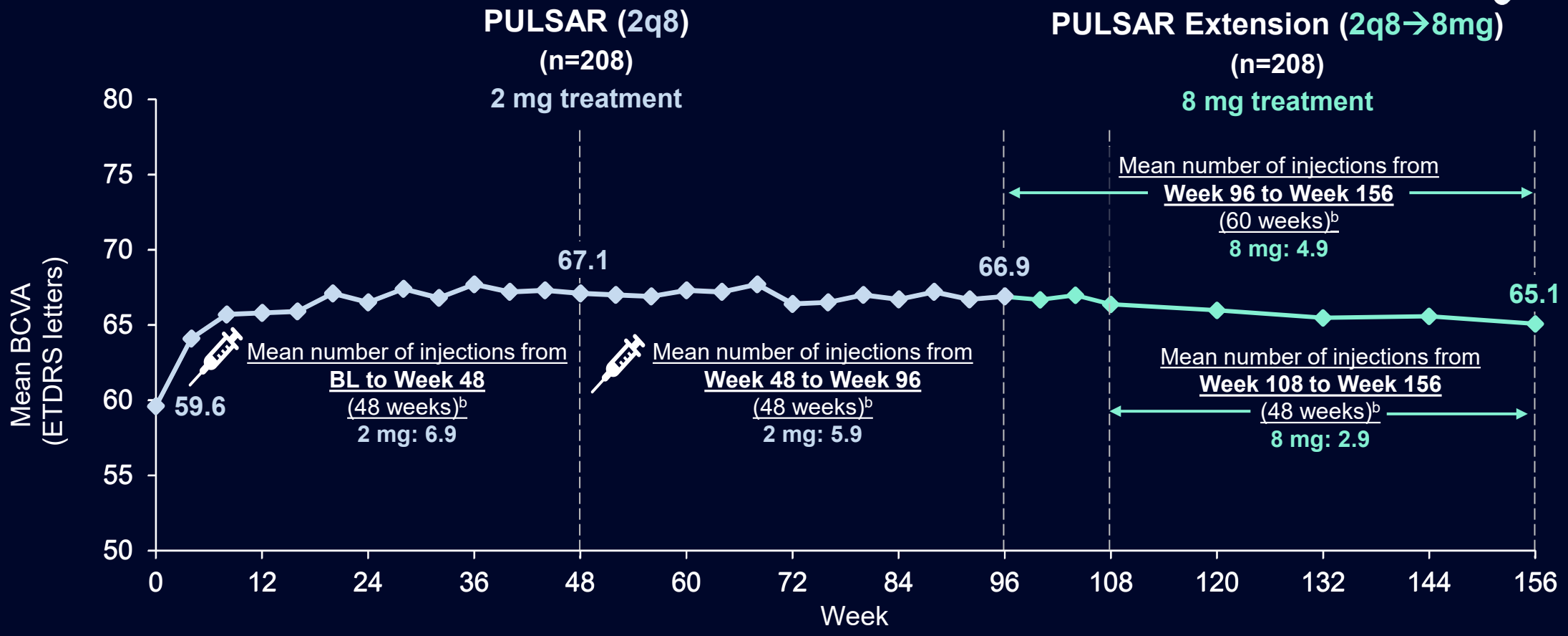
Dosing interval modifications through W152

End of PULSAR Extension



[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[a] Through Week 156



Injection number over 48-week periods was reduced from 5.9 to 2.9 following the switch from aflibercept 2 mg to aflibercept 8 mg, 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; **eSAF**, safety analysis set in the PULSAR Extension; EXT, Extension; **LS**, least squares; **MMRM,** mixed model for repeated measures; **OC**, observed cases.

Proportion of Patients who Achieved ≥69 ETDRS Letter Score

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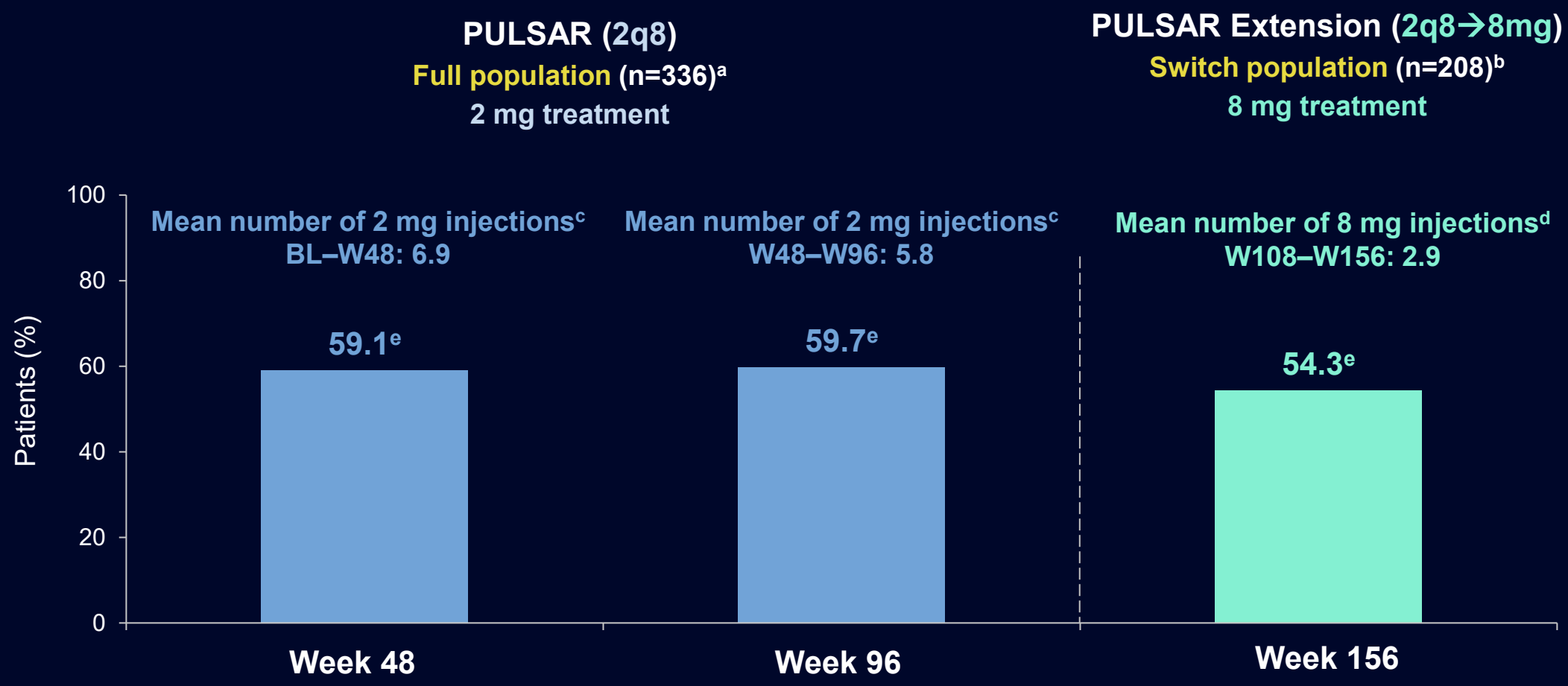
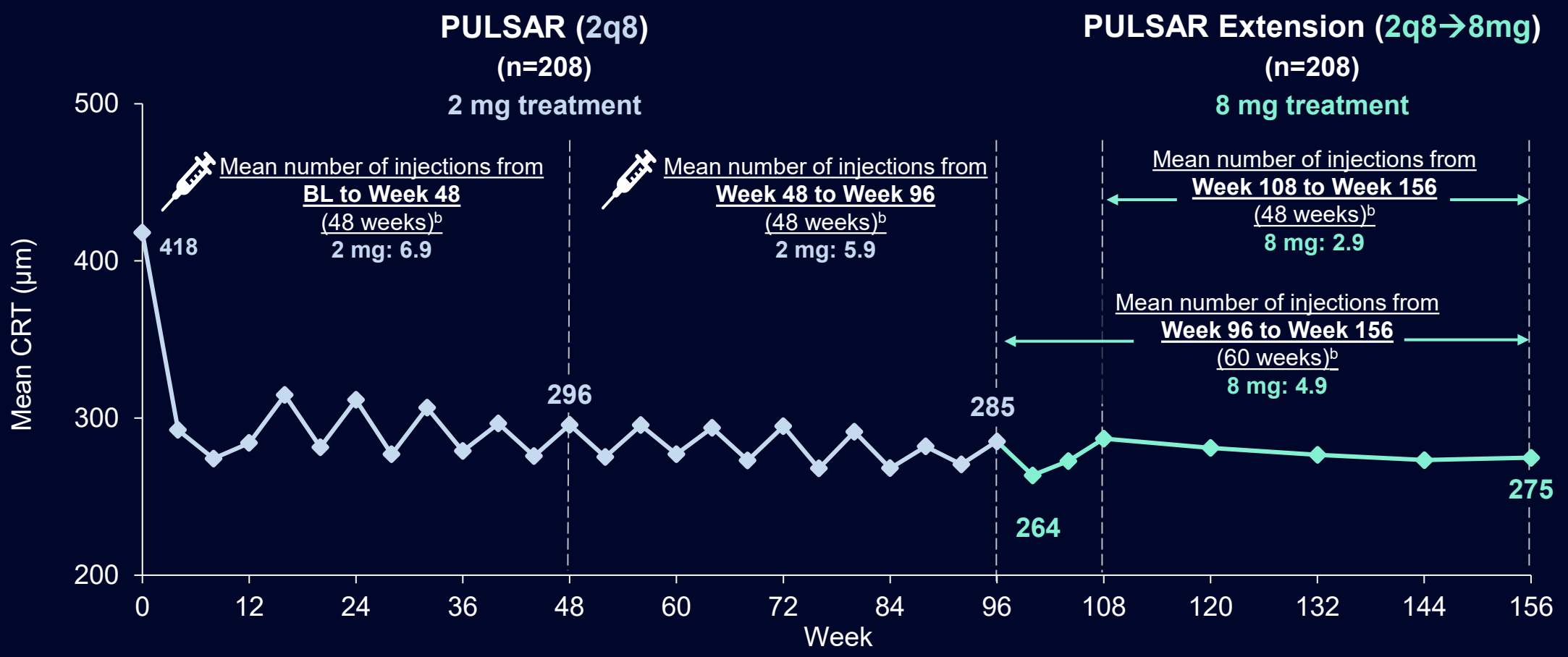


[a]FAS (OC; PULSAR). [b]eFAS (OC; PULSAR EXT). [c]SAF (PULSAR).[d]eSAF (PULSAR EXT).eEvaluable population; Week 48 (n=286), Week 96 (n=243), Week 156 (n=186).

Mean CRT[a] Through Week 156



Injection number over 48-week periods was reduced from 5.9 to 2.9 following the switch from aflibercept 2 mg to aflibercept 8 mg, while maintaining CRT gains

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.

Proportion of Patients who were fluid-free (no IRF and no SRF) in Center Subfield[a] Through Week 156

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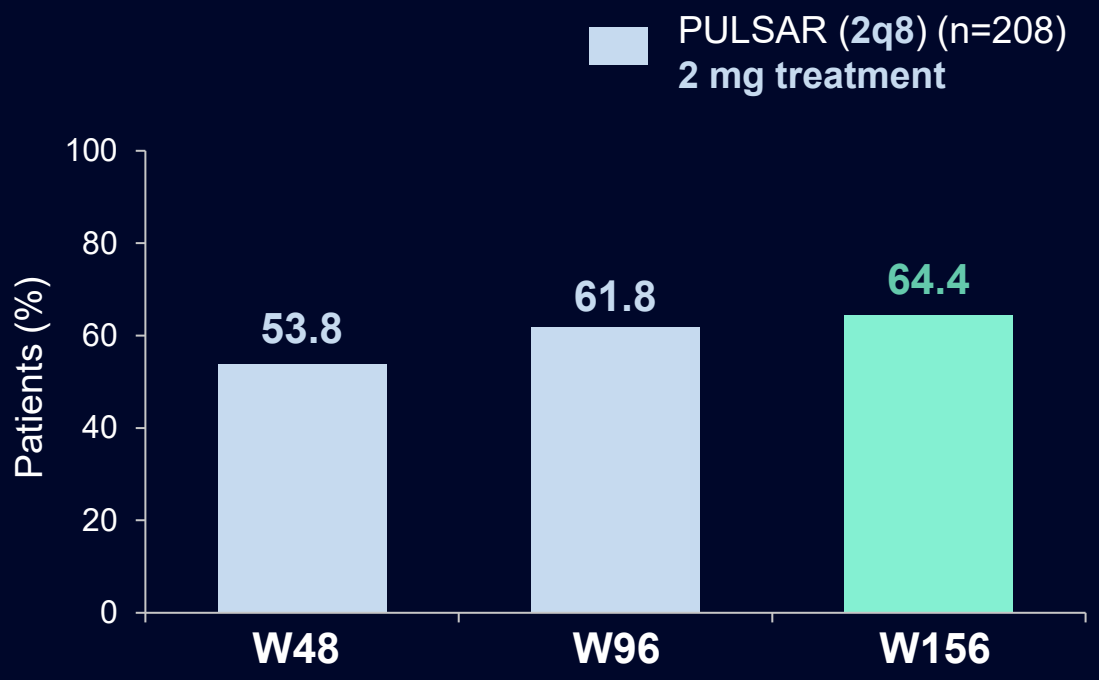
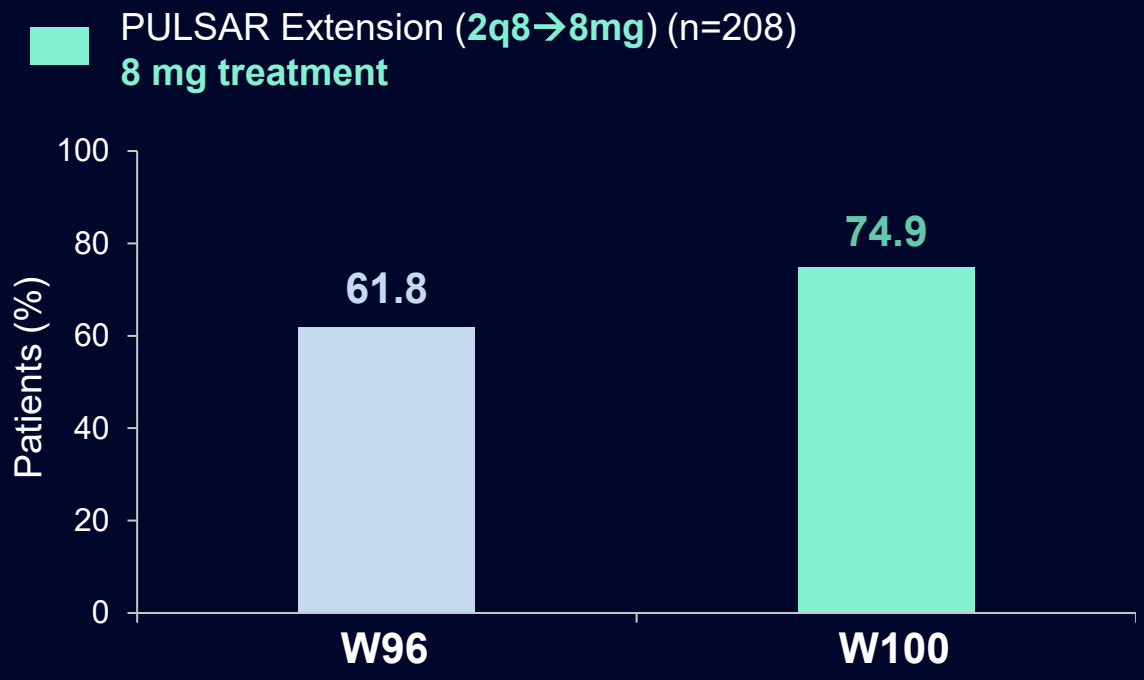
Long-term efficacy

The proportion of patients who were **fluid-free** was **maintained** from **W96 to W156 following switch to aflibercept 8 mg**

Immediate improvement

13.1% increase in proportion of patients who were **fluid-free** from **W96 to W100** following **switch to aflibercept 8 mg**





[a]eFAS (LOCF). **IFR**, intraretinal fluid; **SRF**, subretinal fluid.

Proportion of Patients with no IRF and no SRF in Center Subfield[a] Through Week 156

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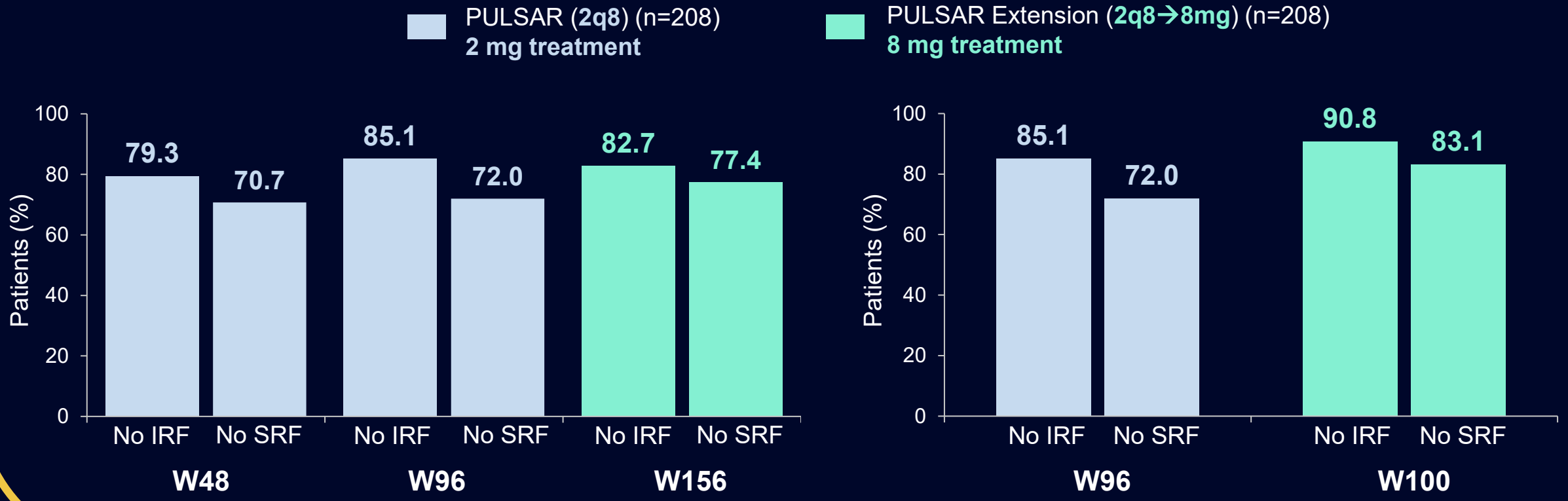
Long-term efficacy

The proportion of patients who were **IRF-free and SRF-free** was **maintained from W96 to W156** following switch to **aflibercept 8 mg**

Immediate improvement

5.7% and 11.1% increase in the proportion of patients who were **IRF-free and SRF-free** from **W96 to W100** following **switch to aflibercept 8 mg**



[a]eFAS (LOCF).

PULSAR Extension: Key Week 156 Results

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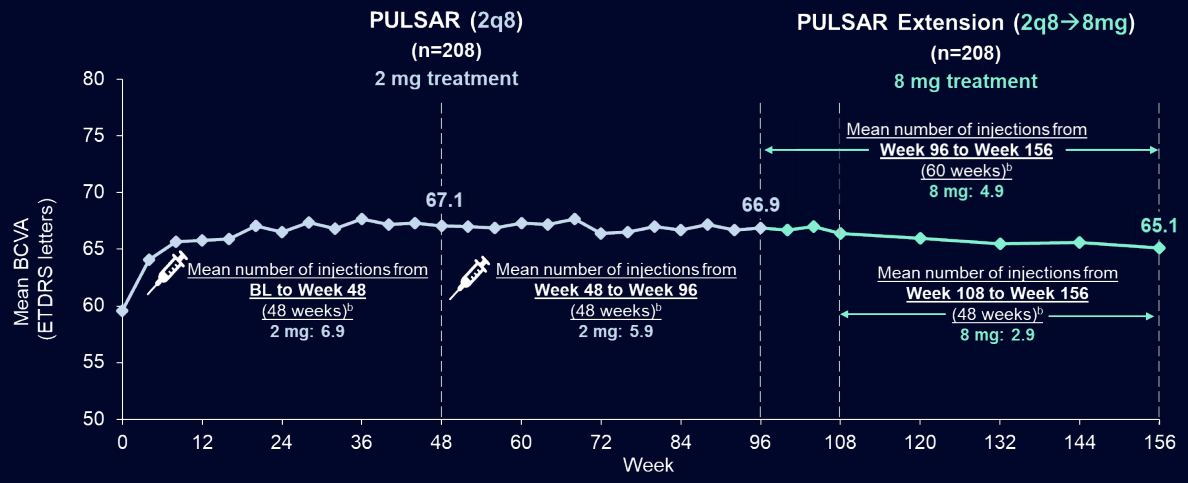
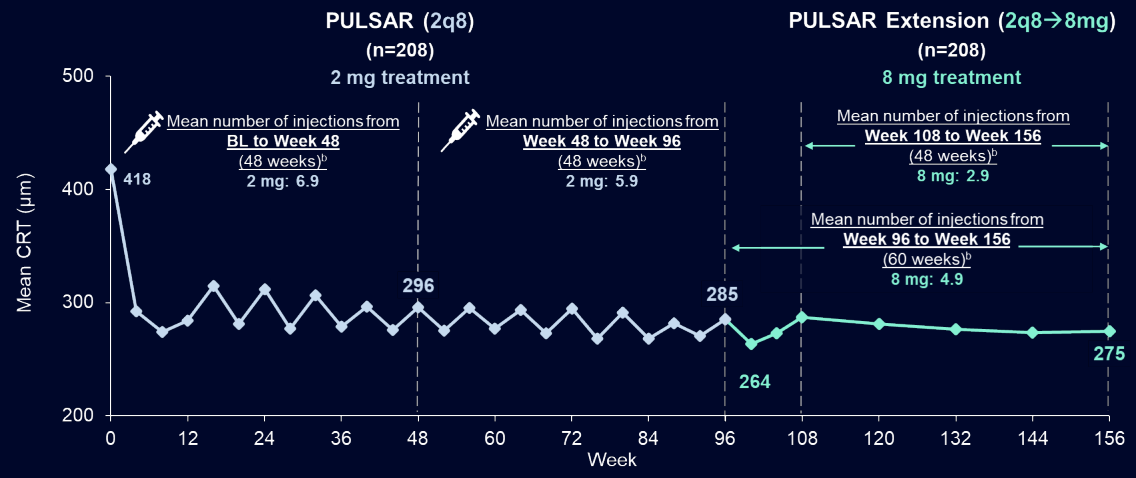
- The **mean BCVA, mean CRT, and proportion of patients who were fluid-free** in the center subfield in the aflibercept 2mg→8mg group was **generally maintained** from Week 96 to Week 156 in the PULSAR Extension **following switch to aflibercept 8 mg**
  - **Visual and anatomic outcomes were maintained with a reduced injection number** over a 48-week period following switch to aflibercept 8 mg
- 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**

Mean BCVA[a] Through Week 156



Mean CRT[a] Through Week 156



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