# Intraocular Pressure Outcomes with Intravitreal Aflibercept 8 mg and 2 mg in Patients with Neovascular Age-related Macular Degeneration Through Week 96 of the PULSAR Trial

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# Disclosures

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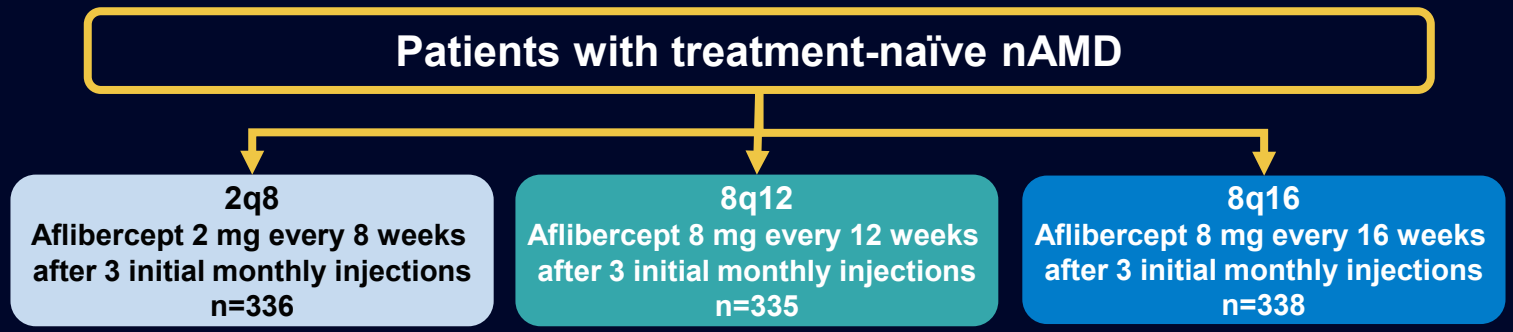
# PULSAR: Multicenter, Randomized, Double-masked 96-week Study




| | Injection volume | Mean (SD) number of active injections of aflibercept 8 mg or 2 mg through Week 96[a] |
|---|---|---|
| 2q8 | 50 µL | 11.9 (2.4) |
| 8q12 | 70 µL | 9.2 (1.9) |
| 8q16 | | 7.8 (2.0) |

**This post hoc analysis evaluated the potential effect of the higher injection volume of aflibercept 8 mg versus 2 mg on IOP outcomes for study eyes in patients with nAMD through to 96 weeks**

Safety analysis set.
**2q8**, aflibercept 2 mg every 8 weeks; **8q12**, aflibercept 8 mg every 12 weeks; **8q16**, aflibercept 8 mg every 16 weeks; **IOP**, intraocular pressure; **nAMD**, neovascular age-related macular degeneration.

# Pre- and Post-injection IOP Assessment

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**Pre-injection IOP assessment (bilaterally)**

Measured at active and sham injection visits

**Post-injection IOP assessment (study eye only)**

Measured at active and sham injection visits

IOP was measured ~30 to 60 minutes after administration (study eye only)

Symptoms indicative of a **higher IOP increase prior to 30 minutes post-injection**

- IOP measured sooner
- Managed at investigator's discretion

Reported post-injection IOP was the last measurement recorded before the patient left the study site[a]

The same method of measurement was used in each patient throughout the study (e.g., Goldmann applanation tonometry, rebound tonometry Icare, or Tono-pen™)

Patients with uncontrolled glaucoma (defined as IOP >25 mmHg despite treatment with antiglaucoma medication) in the study eye at screening or baseline were excluded from the study.
[a]Any clinically meaningful injection-related increase in IOP was documented as an adverse event at the discretion of the investigator in a masked fashion.

# Mean Pre-injection IOP Values in Study Eyes Were Similar Through Week 96

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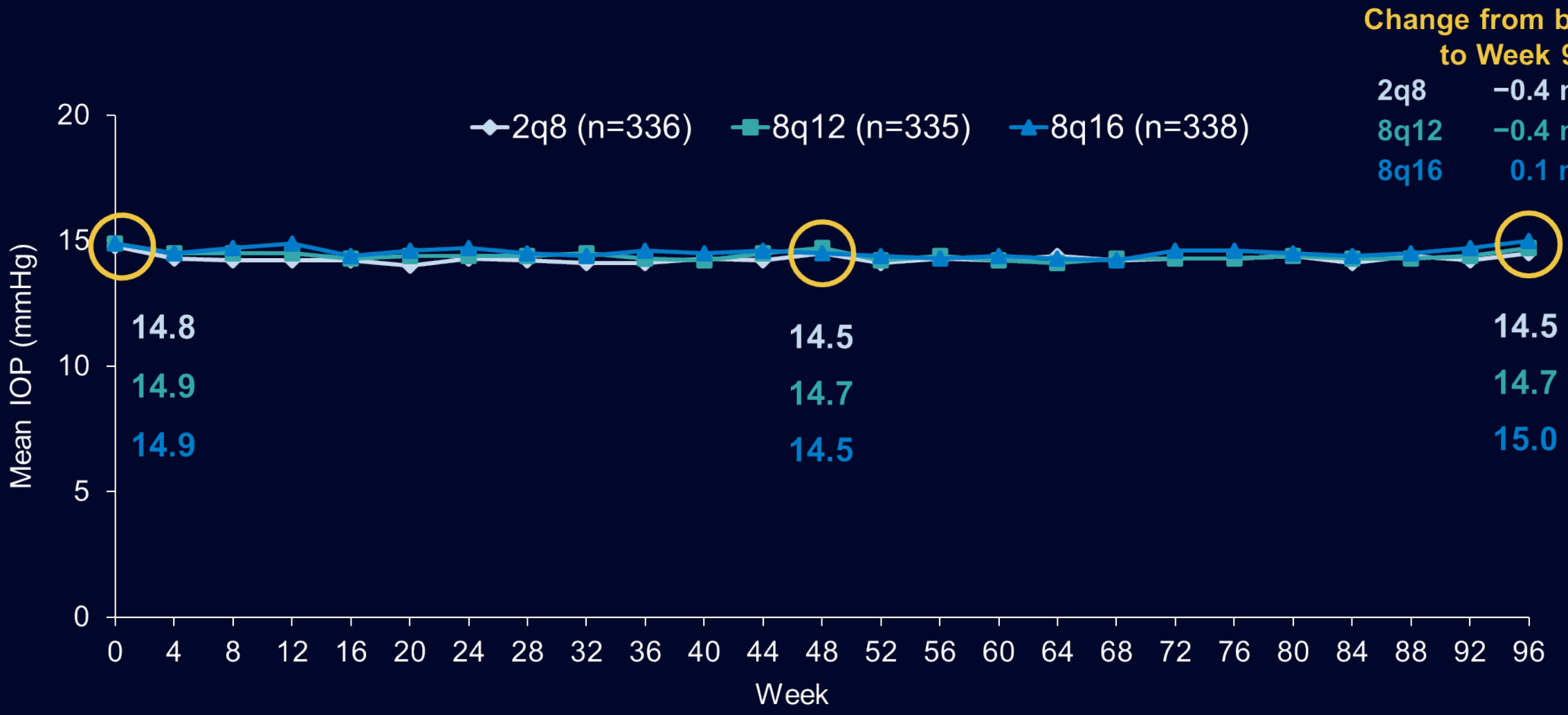


Safety analysis set through Week 96.
Study eyes in the safety analysis set in 2q8, 8q12, and 8q16, received a mean of 11.9, 9.2, and 7.8 injections, respectively, through Week 96.

# Pre-injection IOP in the Study Eye Through Week 96

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| | 2q8 | 8q12 | 8q16 | All 8 mg |
|---|---|---|---|---|
| Safety analysis set, n | 336 | 335 | 338 | 673 |
| Pre-injection IOP ≥25 mmHg, n (%)[a] | 6 (1.8) | 9 (2.7) | 7 (2.1) | 16 (2.4) |
| Pre-injection IOP ≥35 mmHg, n (%)[a] | 1 (0.3) | 1 (0.3) | 0 | 1 (0.1) |

**Proportion of patients with pre-injection IOP ≥25 or ≥35 mmHg at any visit through Week 96 was comparable across the treatment groups**

[a]At any visit.

# Mean Change in Pre- to Post-injection IOP in Study Eyes at Active Dosing Visits Through Week 96

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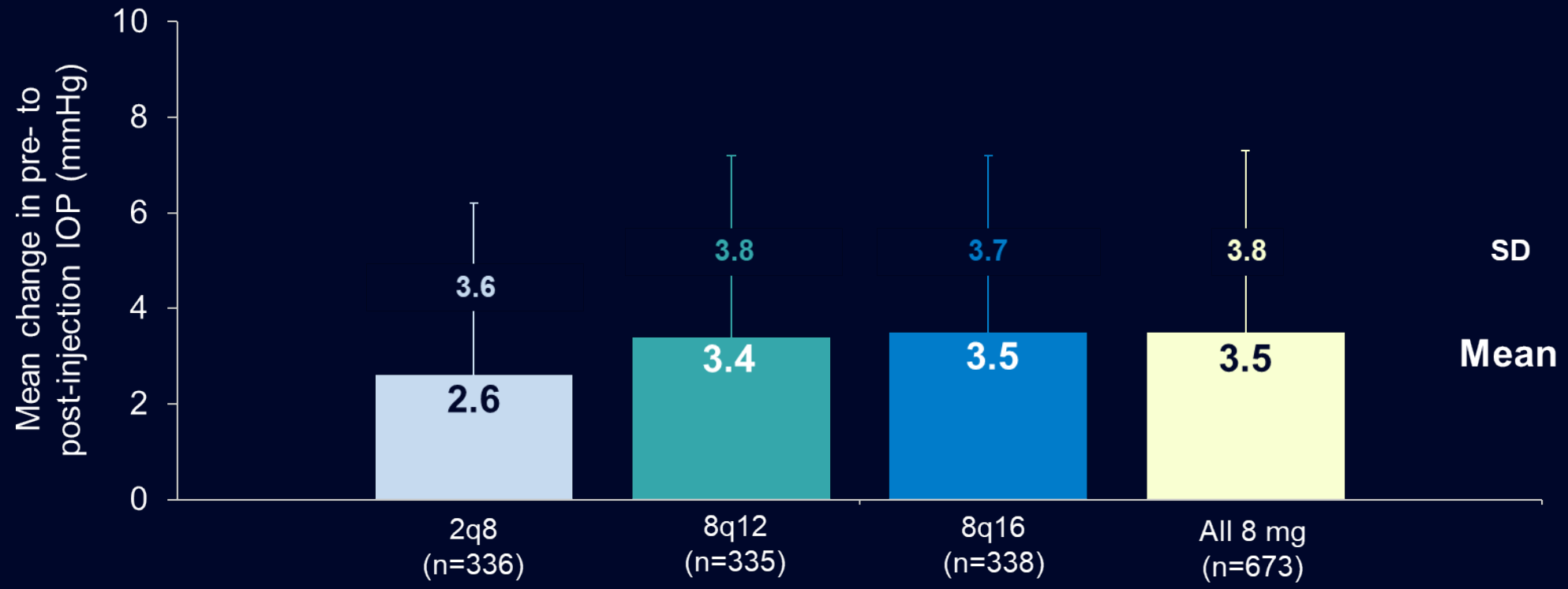
| Mean (SD) number of active injections[a] | 11.9 (2.4) | 9.2 (1.9) | 7.8 (2.0) | 8.5 (2.1) |
|---|---|---|---|---|




**The difference in mean change in pre- to post-injection IOP was <1 mmHg between treatment groups, no clinically relevant differences were observed**

Safety analysis set. Error bars show SD.

# Post-injection IOP in the Study Eye Through Week 96

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| | 2q8 | 8q12 | 8q16 | All 8 mg |
|---|---|---|---|---|
| Safety analysis set, n | 336 | 335 | 338 | 673 |
| Post-injection IOP ≥35 mmHg, n (%)[a] | 1 (0.3) | 2 (0.6) | 1 (0.3) | 3 (0.4) |

**The proportion of patients with IOP ≥35 mmHg post-injection at any visit through Week 96 was comparable across the treatment groups**

## Paracentesis or anterior chamber puncture in the study eye through Week 96[b]

| | 2q8 | 8q12 | 8q16 | All 8 mg |
|---|---|---|---|---|
| Patients requiring paracentesis or anterior chamber puncture/n (%) | 0/336 (0) | 1/335 (0.3) | 0/338 (0) | 1/673 (0.1) |
| Number of events requiring paracentesis or anterior chamber puncture/number of active study eye injections (%) | 0/4007 (0) | 2/3090 (<0.1) | 0/2621 (0) | **2/5711 (<0.1)** |

[a]At any visit. [b]Safety analysis set.

# IOP-related TEAEs Through Week 96

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| | 2q8 | 8q12 | 8q16 | All 8 mg |
|---|---|---|---|---|
| Safety analysis set, n | 336 | 335 | 338 | 673 |
| **Patients with IOP increase or glaucoma, n (%)** | **13 (3.9)** | **16 (4.8)** | **17 (5.0)** | **33 (4.9)** |
| Angle closure glaucoma | 1 (0.3) | 1 (0.3) | 1 (0.3) | 2 (0.3) |
| Glaucoma | 1 (0.3) | 1 (0.3) | 3 (0.9) | 4 (0.6) |
| Intraocular pressure increased | 10 (3.0) | 12 (3.6) | 11 (3.3) | 23 (3.4) |
| Ocular hypertension | 1 (0.3) | 4 (1.2) | 4 (1.2) | 8 (1.2) |
| Open angle glaucoma | 1 (0.3) | 0 | 0 | 0 |

TEAEs in the study eye were as assessed by the investigators. The TEAE "IOP increase or glaucoma" was defined based on the following preferred terms: "Angle closure glaucoma", "Borderline glaucoma", "Glaucoma", "Glaucomatous optic neuropathy", "Intraocular pressure increased", "Ocular hypertension", "Open angle glaucoma", "Optic nerve cupping", and "Trabeculoplasty".
**TEAE**, treatment-emergent adverse event.

# Conclusions

| | |
|---|---|
| **Pre-injection IOP** | • **Pre-injection IOP** values in study eyes were **similar across treatment groups**, and there was **no indication of sustained IOP increase** through Week 96 |
| **Pre- to post-injection IOP differences** | • The difference in mean change in pre- to post-injection IOP was **<1 mmHg between treatment groups, no clinically relevant differences** were observed<br>• Only 1 patient required paracentesis for an acute rise in post-injection IOP |
| **TEAEs** | • **Rates** of “IOP increase or glaucoma”, “IOP increased”, and “Ocular hypertension” **were comparable across treatment groups** |