Intraocular Pressure Outcomes With Aflibercept 8 mg and 2 mg in Patients With Diabetic Macular Edema: 156-Week Results From the PHOTON Extension Study

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Disclosures

- Dilraj S Grewal is a consultant at Apellis, EyePoint, DORC. Priovant, Zeiss, Astellas, Regeneron Pharmaceuticals, Inc., and Roche
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Background

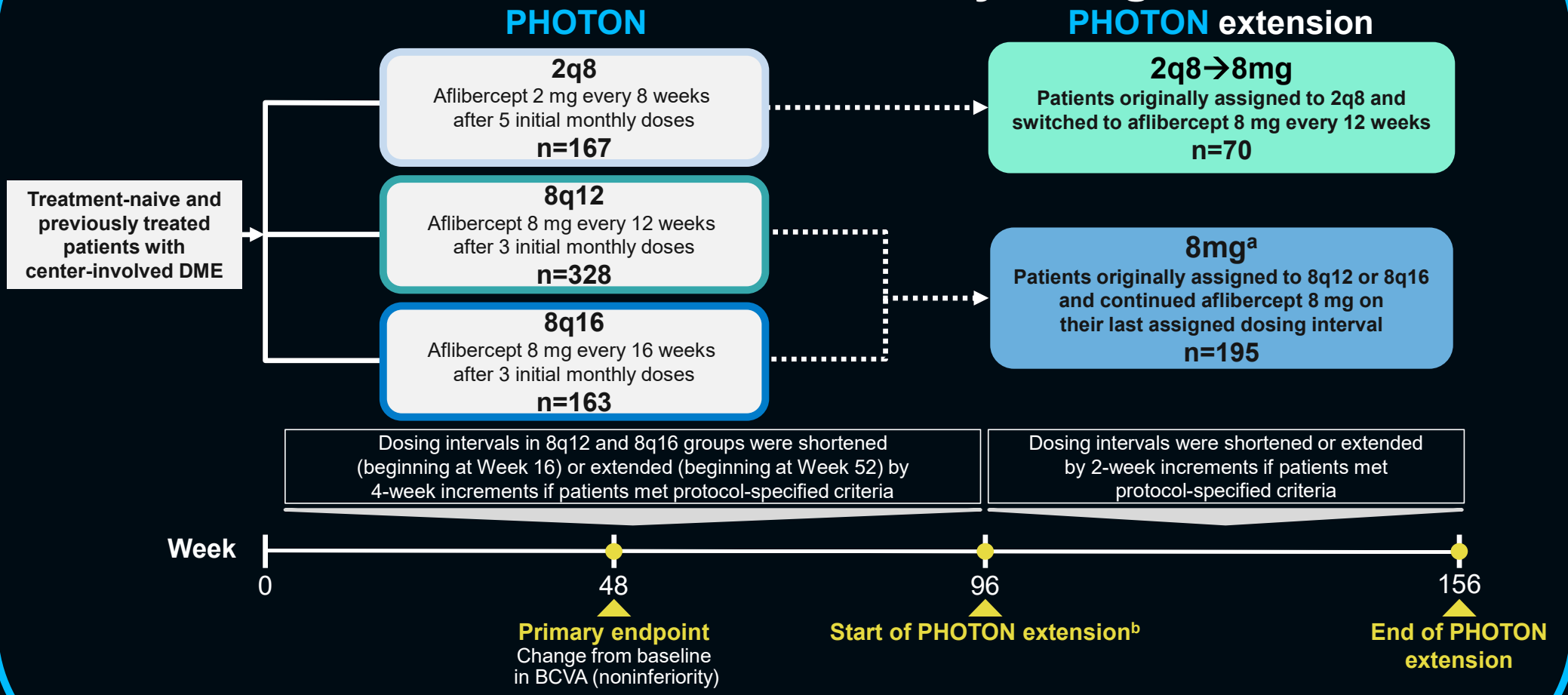
- Aflibercept 8 mg has demonstrated comparable efficacy and safety with fewer injections compared to aflibercept 2 mg in the pivotal PHOTON trial in DME through 96 weeks[1]
- While no long-term IOP-related adverse effects were seen through Week 96 with aflibercept 8 mg versus 2 mg, longer-term outcomes should be explored

As the injection volume for aflibercept 8 mg is 70 µL compared with 50 µL for aflibercept 2 mg, the potential effect of a higher injection volume on IOP and glaucoma-related outcomes was explored in the PHOTON extension study through Week 156

DME, diabetic macular edema; IOP, intraocular pressure.

1. Do DV et al. *Ophthalmology*. 2025;S0161-6420(25)00707–9.

PHOTON Extension Study Design



[a]Patients who were randomized to the 8q12 or 8q16 groups at the beginning of the PHOTON study and continued treatment with aflibercept 8 mg through the PHOTON extension study.
[b]Optional extension phase was added while the pivotal study was ongoing; therefore, not all patients were able to enroll due to time constraints.
2q8, aflibercept 2 mg every 8 weeks after 5 initial monthly doses; 2q8→8mg, patients originally assigned to 2q8 and switched to aflibercept 8 mg every 12 weeks; 8mg, Patients originally assigned to 8q12 or 8q16 and continued aflibercept 8 mg on their last assigned dosing interval; 8q12, aflibercept 8 mg every 12 weeks after 3 initial monthly doses; 8q16, aflibercept 8 mg every 16 weeks after 3 initial monthly doses.

Methods

IOP Assessment in the PHOTON Trial

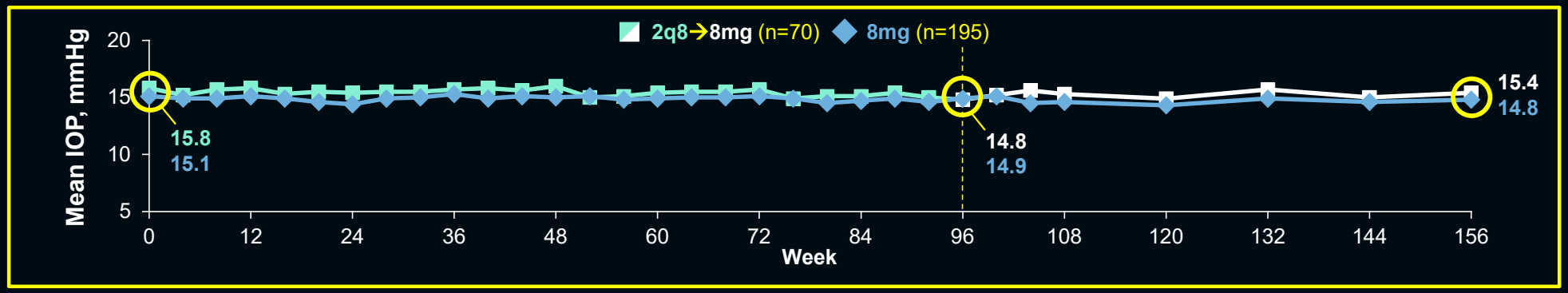
- Bilateral IOP was measured at all study visits using either Goldmann applanation tonometry or Tono-pen™. The same method of measurement was used in each patient throughout the study
  - On days when the study drug was administered, sites were permitted to follow their usual post-injection monitoring routine. The study protocol recommended IOP be measured at approximately 30 minutes post-dose

Post Hoc Analysis

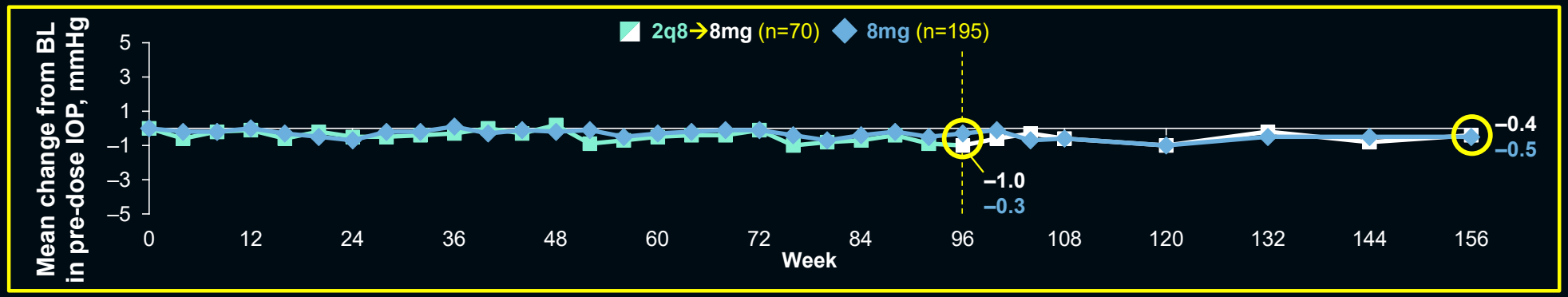
- IOP outcomes for study and fellow eyes in the extension safety analysis set were evaluated through Week 156
  - In this analysis, fellow eyes were grouped based on study eye randomization in PHOTON. Both untreated and treated (only aflibercept was permitted) fellow eyes were included
  - Through Week 156, fellow eye injections with aflibercept 2 mg or 8 mg were reported in ~73% of participants (75.7% in the 2q8→8mg group and 71.8% in the 8mg group)

Pre-Dose IOP Values in Study Eyes[a] Through Week 156

Mean Pre-Dose IOP



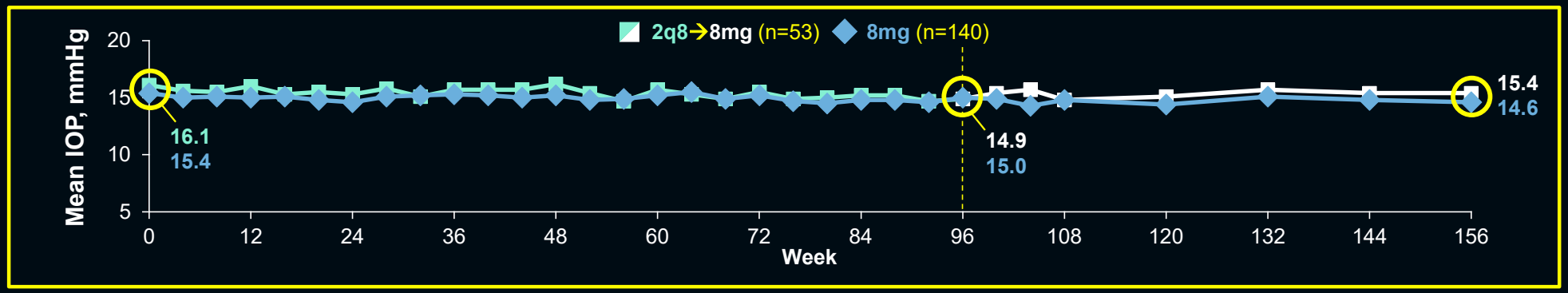
Mean Change From BL in Pre-Dose IOP



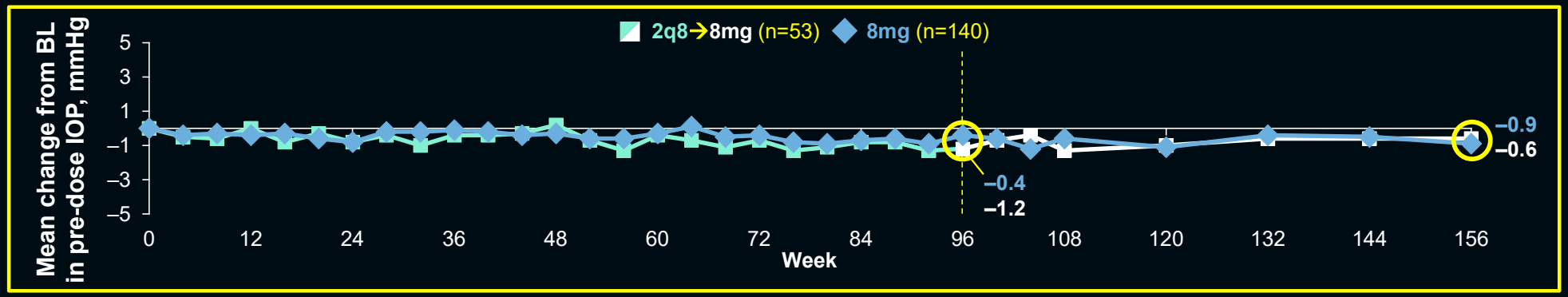
Extension safety analysis set. Dashed lines at Week 96 indicate the end of the PHOTON trial and the beginning of the PHOTON extension.
[a]Study eyes in the 2q8→8mg and 8mg groups received a mean of 18.6 and 12.6 injections, respectively.
BL, baseline.

Pre-Dose IOP Values in Treated Fellow Eyes[a] Through Week 156

Mean Pre-Dose IOP



Mean Change From BL in Pre-Dose IOP

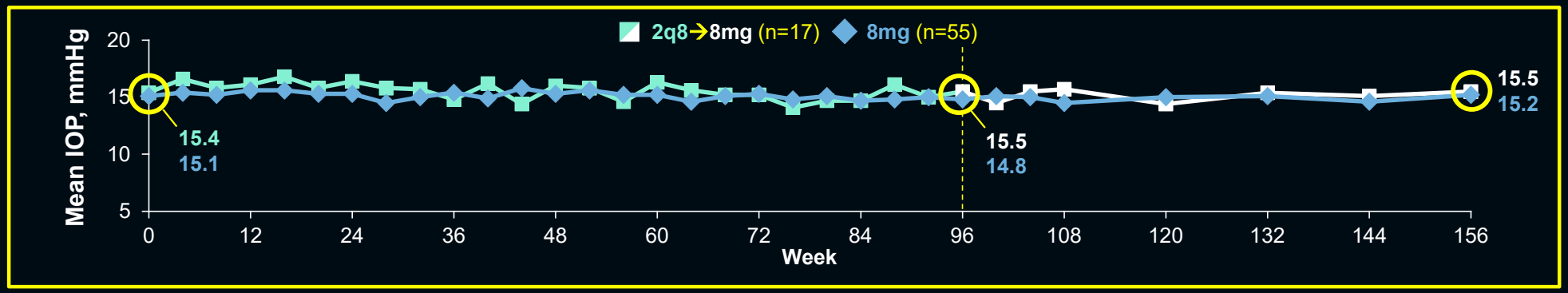


Extension safety analysis set. Dashed lines at Week 96 indicate the end of the PHOTON trial and the beginning of the PHOTON extension.

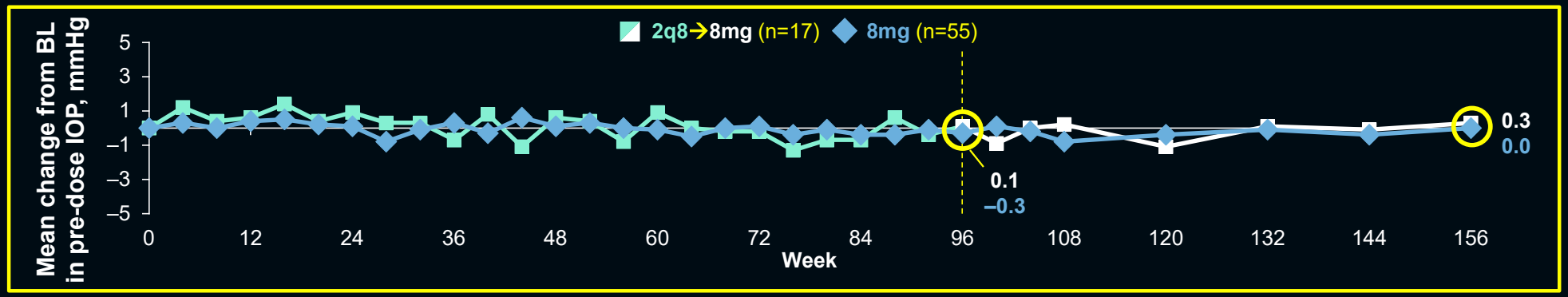
[a]Treated with aflibercept 2 mg or 8 mg. At the discretion of the investigator, 75.7% of fellow eyes in the 2q8→8mg group and 71.8% of fellow eyes in the 8mg group received a mean of 14.6 and 14.0 injections, respectively, of aflibercept 2 mg or 8 mg. Fellow eye treatment was most commonly aflibercept 2 mg (only 10 patients received a total of 12 injections of aflibercept 8 mg in the fellow eye in the PHOTON extension).

Pre-Dose IOP Values in Untreated Fellow Eyes Through Week 156

Mean Pre-Dose IOP



Mean Change From BL in Pre-Dose IOP



Extension safety analysis set. Dashed lines at Week 96 indicate the end of the PHOTON trial and the beginning of the PHOTON extension.

Cumulative Incidence of Patients Meeting Pre-Dose IOP Criteria Through Week 156

	Study eye				Fellow eye[a]			
	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)	8mg (n=195)	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)	8mg (n=195)
Pre-dose IOP ≥25 mmHg at 2 consecutive visits, %	0	0	0	0	1 (1.4)	2 (1.5)	0	2 (1.0)
Pre-dose IOP ≥30 mmHg at any visit, %	0	0	0	0	1 (1.4)	1 (0.8)	1 (1.5)	2 (1.0)

Extension safety analysis set.
Kaplan–Meier methodology was used to generate the data. If an assessment was missing at a specific visit, the visits preceding and following this visit were treated as consecutive visits. Eyes were counted only once in this analysis.
[a]Untreated or treated with aflibercept 8 mg or 2 mg.

IOP Through Week 156 in Study and Fellow Eyes

	Study eye			Fellow eye[a]		
	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)
IOP ≥35 mmHg pre- or post-injection at any visit, n (%)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Values are n (%).
[a]2-mg or 8-mg treated and untreated fellow eyes, all study eye randomization arms combined.

Glaucoma-Related History at Baseline

	Study eye				Fellow eye[a]			
	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)	8mg (n=195)	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)	8mg (n=195)
Medical history of glaucoma/glaucoma suspect[b] AND/OR treatment with ≥1 IOP-lowering agent[c] at BL, n (%)	4 (5.7)	12 (9.2)	9 (13.8)	21 (10.8)	4 (5.7)	13 (10.0)	10 (15.4)	23 (11.8)

The proportions of study and fellow eyes with a glaucoma-related history at baseline were slightly higher with aflibercept 8 mg versus 2 mg

Extension safety analysis set.
[a]Untreated or treated with aflibercept 8 mg or 2 mg. [b]Defined as a medical history of glaucoma/glaucoma suspect (glaucoma, open-angle glaucoma, borderline glaucoma, ocular hypertension, angle closure glaucoma, glaucomatous optic disc atrophy, optic nerve cupping, trabeculoplasty, or IOP increased) or receiving an IOP-lowering agent at BL. [c]Beta blockers, prostaglandin analogues, carbonic anhydrase inhibitors, or other antiglaucoma preparations.

IOP-Lowering Medications in Eyes Without Glaucoma-Related History Through Week 156

	Study eye				Fellow eye[a]			
	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)	8mg (n=195)	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)	8mg (n=195)
No glaucoma-related history at BL, n (%)[b]	66 (94.3)	118 (90.8)	56 (86.2)	174 (89.2)	66 (94.3)	117 (90.0)	55 (84.6)	172 (88.2)
Eyes without glaucoma-related history that received a new or additional IOP-lowering agent(s) through Week 156, n/N	3/66	4/118	1/56	5/174	2/66	6/117	0	6/172

The proportions of study and fellow eyes without a glaucoma-related history requiring an IOP-lowering agent were low and comparable across the groups

Extension safety analysis set.
[a]Untreated or treated with aflibercept 8 mg or 2 mg. [b]No medical history of glaucoma/glaucoma suspect or not receiving an IOP-lowering agent at BL.

IOP-Lowering Medications in Eyes With Glaucoma-Related History Through Week 156

	Study eye				Fellow eye[a]			
	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)	8mg (n=195)	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)	8mg (n=195)
Medical history of glaucoma/glaucoma suspect[b] AND/OR treatment with ≥1 IOP-lowering agent[c] at BL, n (%)	4 (5.7)	12 (9.2)	9 (13.8)	21 (10.8)	4 (5.7)	13 (10.0)	10 (15.4)	23 (11.8)
Eyes with glaucoma-related history that received a new or additional IOP-lowering agent(s) through Week 156, n/N	2/4	2/12	2/9	4/21	0	3/13	2/10	5/23

The proportions of study and fellow eyes with a glaucoma-related history requiring an IOP-lowering agent were low and comparable across the groups

Extension safety analysis set.
[a]Untreated or treated with aflibercept 8 mg or 2 mg. [b]Defined as a medical history of glaucoma/glaucoma suspect (glaucoma, open-angle glaucoma, borderline glaucoma, ocular hypertension, angle closure glaucoma, glaucomatous optic disc atrophy, optic nerve cupping, trabeculoplasty, or IOP increased) or receiving an IOP-lowering agent at BL. [c]Beta blockers, prostaglandin analogues, carbonic anhydrase inhibitors, or other antiglaucoma preparations.

Anterior Chamber Paracentesis Procedures[a] Through Week 156

	Study eye				Fellow eye[b]			
	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)	8mg (n=195)	2q8→8mg (n=70)	8q12 (n=130)	8q16 (n=65)	8mg (n=195)
Eyes receiving anterior chamber paracentesis, n (%)	0	1 (0.8)	1 (0.5)	2 (1.0)	0	0	0	0

- No study eyes in the 2q8→8mg group received an anterior chamber paracentesis through Week 156
- Of the 2 study eyes in the 8mg group receiving an anterior chamber paracentesis through Week 156, both were performed in Year 2 of the PHOTON trial

Extension safety analysis set.
[a]Ocular treatment-emergent surgeries in the study or fellow eye. [b]Untreated or treated with aflibercept 8 mg or 2 mg.

Conclusions

- In patients with DME, pre-dose IOP values in study and fellow eyes remained similar through Week 156 across both aflibercept 8-mg and 2-mg treatment groups, and between study eyes and fellow eyes, regardless of treatment with aflibercept 8 mg or 2 mg
- The proportions of study and fellow eyes with and without glaucoma-related history requiring IOP-lowering medications were low across all treatment groups through Week 156
- Only 2 study eyes receiving aflibercept 8 mg (1 in the 8q12 group and 1 in the 8q16 group) required anterior chamber paracentesis through Week 156

Despite a 70-µL injection volume, no long-term IOP adverse effects were seen through Week 156 with aflibercept 8 mg versus 2 mg (50 µL)