# Intraocular Pressure Outcomes With Aflibercept 8 mg and 2 mg in Patients With Diabetic Macular Edema Through Week 48 of the Phase 2/3 PHOTON Trial

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**Financial Disclosures:**
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# METHODS

**Objective:** As aflibercept 8 mg is administered in a 70-µL injection volume versus a 50-µL injection volume for aflibercept 2 mg, this post hoc analysis of the PHOTON trial evaluated the potential effect of a higher injection volume on IOP outcomes through Week 48

## IOP Assessment in the PHOTON Trial

- Bilateral IOP was measured at all study visits; the same method of measurement was used in each patient throughout the study[a]
  - On days when the study drug was administered, sites were permitted to follow their usual post-injection monitoring routine. The study protocol recommended that IOP be measured at approximately 30 minutes post-dose

## Fellow Eye Treatment in the PHOTON Trial

- In the trial, fellow eyes could receive aflibercept 2 mg for DME or any other approved indication, at the discretion of the study investigator. Patients were not allowed to receive any other anti-VEGF agent in the fellow eye
  - Through Week 48, fellow eye injections with aflibercept 2 mg were reported in 61.7%, 61.0%, and 62.0% of patients in the aflibercept 2q8, 8q12, and 8q16 groups, respectively

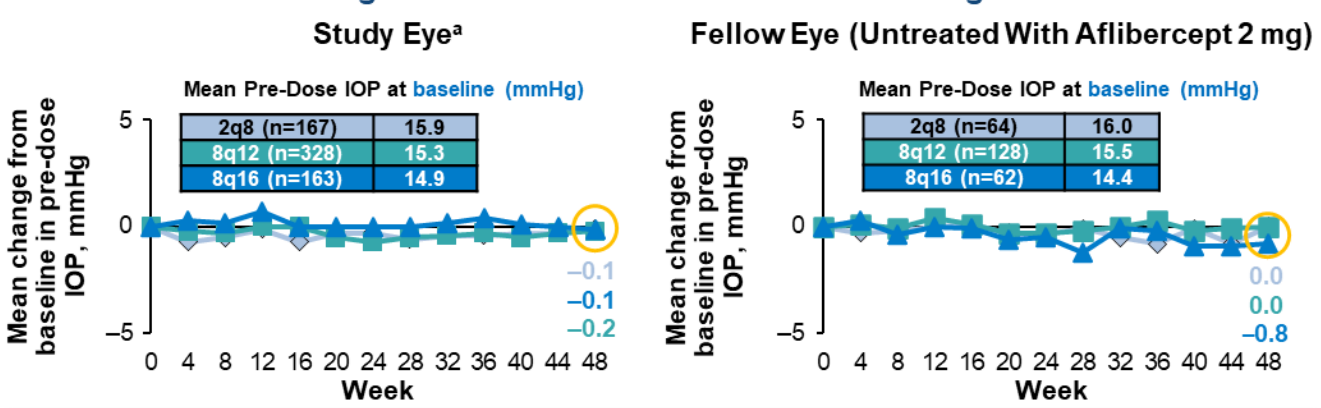
## Outcomes Assessed Post Hoc

- Mean change in pre-dose IOP from baseline in study eyes receiving aflibercept 8 mg or 2 mg and untreated fellow eyes[b] through Week 48
- The proportion of patients requiring new or additional IOP-lowering agent(s) and IOP-lowering procedures was evaluated for those with and without glaucoma-related history

[a]IOP was measured using either Goldmann applanation tonometry or Tono-pen™.
[b]In this analysis, fellow eyes were grouped based on study eye randomization. Untreated fellow eyes which did not receive aflibercept 2 mg were included
2q8, aflibercept 2 mg administered every 8 weeks after 5 initial monthly injections; 8q12, aflibercept 8 mg administered every 12 weeks after 3 initial monthly injections; 8q16, aflibercept 8 mg administered every 16 weeks after 3 initial monthly injections; DME, diabetic macular edema; IOP, intraocular pressure; VEGF, vascular endothelial growth factor.

# RESULTS

## Mean Change in Pre-Dose IOP from Baseline Through Week 48




**Mean change in pre-dose IOP from baseline through Week 48 was less than ±1 mmHg and similar in study and untreated fellow eyes, suggesting no drift toward increased IOP over time**

Safety analysis set.
[a]Study eyes in 2q8, 8q12, and 8q16 groups received a mean of 7.7, 5.7, and 4.9 injections, respectively, through Week 48.

## Eyes Requiring IOP-Lowering Procedures[a] Through Week 48

| | Study Eye | | | | Fellow Eye[b] |
|---|---|---|---|---|---|
| | 2q8 (n=167) | 8q12 (n=328) | 8q16 (n=163) | All 8 mg (n=491) | All eyes (n=658) |
| Eyes receiving anterior chamber paracentesis, Week 48, n (%) | 0 (0.0) | 2 (0.6) | 0 (0.0) | 2 (0.4) | 1 (0.2) |

**Only 3 eyes required anterior chamber paracentesis, the only reported IOP-lowering procedure through Week 48**

Safety analysis set.
[a]Ocular treatment-emergent surgeries in study/fellow eye related to IOP lowering. [b]Treated and untreated fellow eyes.

## Glaucoma-Related History at Baseline

| | Study Eye | | | | Fellow Eye[a] |
|---|---|---|---|---|---|
| | 2q8 (n=167) | 8q12 (n=328) | 8q16 (n=163) | All 8 mg (n=491) | All eyes (n=658) |
| Eyes with medical history of glaucoma/glaucoma suspect[b] AND/OR receiving ≥1 IOP-lowering agent[c] at baseline, n (%) | 12 (7.2) | 26 (7.9) | 13 (8.0) | 39 (7.9) | 60 (9.1) |
| Eyes with no glaucoma-related history at baseline, n (%)[b] | 155 (92.8) | 302 (92.1) | 150 (92.0) | 452 (92.1) | 598 (90.9) |

Safety analysis set.
Glaucoma-related history was defined as a medical history of glaucoma/glaucoma suspect and/or receiving an IOP-lowering agent(s) at baseline in study and/or fellow eyes.
[a]Treated and untreated fellow eyes.
[b]Medical history of glaucoma/glaucoma suspect or on an IOP-lowering agent(s) at baseline: glaucoma/glaucoma suspect terms- glaucoma, open angle glaucoma, borderline glaucoma, ocular hypertension, angle closure glaucoma, glaucomatous optic disc atrophy, optic nerve cupping, trabeculoplasty, intraocular pressure increased.
[c]IOP-lowering agents: beta blocking agents, prostaglandin analogues, carbonic anhydrase inhibitors, or other anti-glaucoma preparations.

## IOP-Lowering Agents in Eyes With/Without Glaucoma-Related History

| | Study Eye | | | | Fellow Eye[a] |
|---|---|---|---|---|---|
| | 2q8 | 8q12 | 8q16 | All 8 mg | All eyes |
| Eyes with glaucoma-related history who were started on or received a new IOP-lowering agent(s) through Week 48, n (%) | 2/12 (16.7) | 3/26 (11.5) | 0/13 (0.0) | 3/39 (7.7) | 3/60 (5.0) |
| Eyes with no glaucoma-related history who were started on an IOP-lowering agent(s) through Week 48, n (%) | 3/155 (1.9) | 4/302 (1.3) | 1/150 (0.7) | 5/452 (1.1) | 5/598 (0.8) |

**Proportions of study and fellow eyes requiring IOP-lowering agent(s) were low across all treatment groups, regardless of glaucoma-related history**

Safety analysis set.
[a]Treated and untreated fellow eyes.

# DISCUSSION

- Through Week 48, mean changes in pre-dose IOP from baseline did not exceed ±1 mmHg in study eyes receiving aflibercept 8 mg or 2 mg and in untreated fellow eyes, suggesting no drift toward increased IOP over time
- Proportions of study and fellow eyes requiring addition of IOP-lowering agent(s) were low across all treatment groups, regardless of glaucoma-related history
- Only 3 eyes required anterior chamber paracentesis, the only reported IOP-lowering procedure through Week 48

**Despite a 70-µL injection volume, no long-term IOP adverse effects were seen through Week 48 with aflibercept 8 mg versus 2 mg (50 µL)**