Intraocular Pressure Outcomes with Intravitreal Aflibercept 8 mg and 2 mg in Patients with Neovascular Age-Related Macular Degeneration and Diabetic Macular Edema in Phase 3 Trials

Paolo Lanzetta,[1] Ramin Khoramnia,[2] Anat Loewenstein,[3] Michael W. Stewart,[4] Richard Gale,[5] Marion Munk,[6] Ursula Schmidt-Ott,[7] April McCullough,[8] Claudia Tueckmantel,[9] Alyson Berliner,[8] Sergio Leal,[10] Tobias Machewitz,[7] Karen Chu,[8] Peter Morgan-Warren,[10] and Xin Zhang,[10] on behalf of the PULSAR and PHOTON study investigators

[1]Department of Medicine – Ophthalmology, University of Udine, and Istituto Europeo di Microchirurgia Oculare – IEMO, Udine-Milan, Italy, [2]University Eye Clinic Heidelberg, Heidelburg, Germany; [3]Ophthalmology Division, Tel Aviv Medical Center, affiliated with Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel; [4]Mayo Clinic College of Medicine and Department of Ophthalmology, Mayo Clinic, Jacksonville, FL, USA; [5]York and Scarborough Teaching Hospital NHS Foundation Trust, York, UK; [6]Augenarzt-Praxisgemeinschaft Gutblick AG, Pfäffikon, Switzerland; [7]Bayer AG, Berlin, Germany; [8]Regneron Pharmaceuticals, Inc., Tarrytown, NY, USA; [9]Bayer AG, Wuppertal, Germany; [10]Bayer Consumer Care AG, Basel, Switzerland

Presented at the FLORetina ICOOR Meeting 2024, Florence, Italy, December 05–08, 2024

Disclosures

- **Paolo Lanzetta:** Consultant: Aerie, Allergan, Apellis, Bausch & Lomb, Bayer, Biogen, Boehringer Ingelheim, Genentech, I-Care, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche
  - **RK:** Alimera, Bayer, Chengdu Kanghong, Novartis, Opthea, Roche; Speaker Activity: Abbvie, Alimera, Apellis, Bayer, Heidelberg Engineering, Novartis, Roche**. AL:** Consultant: 4DMT, AbbVie, Alkeus, Annexon, Apellis, Astellas, Bayer Health Care, Beyeonics, Eyepoint, J&J, NotalVision, Novartis, Ocular Therapeutics, Ocuphire Pharma, Ocuterra, Oculis, Opthea, Oxurion, Roche, and Syneos. **MS:** Consultant: Alkahest and Bayer; Receives funding: Allergan, Kanghong, and Regeneron. **RG:** Consultant: AbbVie, Allergan, Apellis, Bayer, Biogen, Boehringer Ingelheim, Notal, Novartis, Roche, and Santen; Receives funding: Bayer, Novartis, and Roche. **MM:** Consultant: AbbVie, Allergan, Apellis, Bayer, Dandelione, Eyepoint, Isarna, Kubota, Lumithera, Novartis, Oculis, Ocuterra, RetinAI, Roche, and Zeiss. **USO**, **CT**, and **TM:** Employees of Bayer AG. **AM**, **AB**, and **KC:** Employees of Regeneron Pharmaceuticals, Inc. **SL**, **PMW**, and **XZ:** Employees of Bayer Consumer Care AG
- The PULSAR study was sponsored by Bayer AG (Leverkusen, Germany) and co-funded by Regeneron Pharmaceuticals, Inc. (Tarrytown, NY, USA). The PHOTON study was sponsored by Regeneron Pharmaceuticals, Inc. (Tarrytown, NY, USA) and co-funded by Bayer AG (Leverkusen, Germany). The study sponsors participated in the design and conduct of the respective studies, analysis of the data, and preparation of this presentation. Both studies included research conducted on human patients. Institutional Review Board approval was obtained prior to study initiation.
- Study disclosures: These studies include research conducted on human patients; Institutional Review Board approval was obtained prior to study initiation
- The data presented here were previously presented at the The Deutsche Ophthalmologische Gesellschaft (DOG) 2024 Congress, Estrel, Berlin, Germany, October 10–13, 2024
- Medical writing support, under the direction of the authors, was provided by ApotheCom and funded by Bayer Consumer Care AG (Basel, Switzerland), in accordance with Good Publication Practice (GPP) guidance (Ann Intern Med. 2022;175:1298–1304

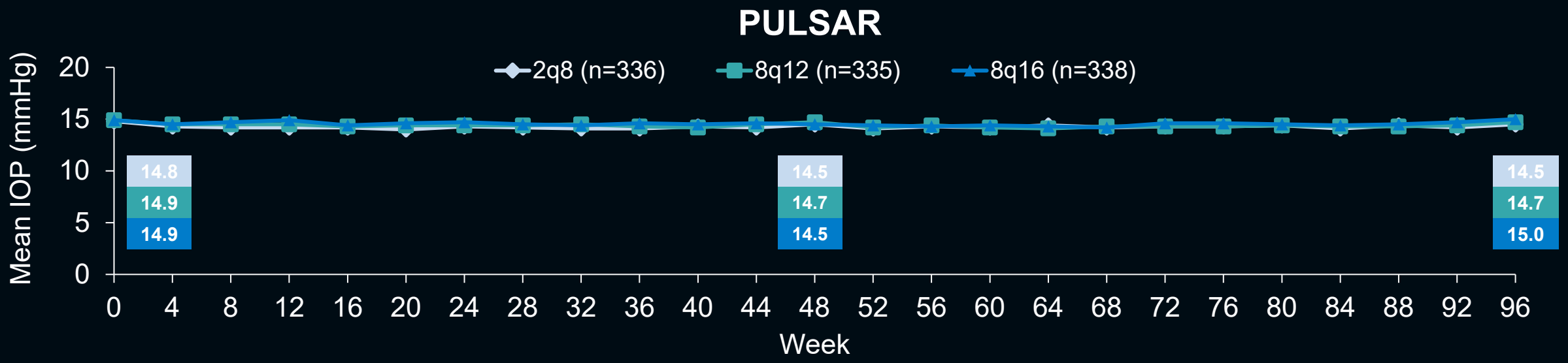
Backgrounds and Methods

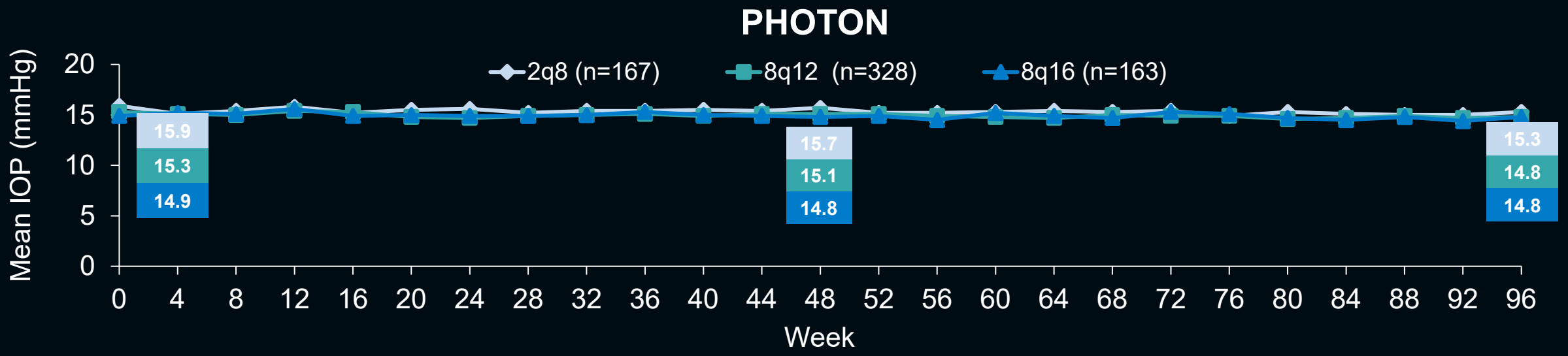
- The purpose of the current analysis was to evaluate the IOP outcomes of aflibercept 8 mg and 2 mg up to 96 weeks

- Data from 2 multicenter, randomized clinical trials comparing the efficacy and safety of aflibercept 8 mg versus aflibercept 2 mg were analyzed:
  - Phase 3 PULSAR trial in treatment-naïve patients with nAMD
  - Phase 2/3 PHOTON trial in treatment-naïve and previously treated patients with DME

[a]Three initial monthly injections followed by injections at Weeks 20 and 32.
DME, diabetic macular edema; **IOP**, intraocular pressure; **nAMD**, neovascular age-related macular degeneration.

An Analysis of the PHOTON and PULSAR Trials Demonstrated That Pre-injection IOP Outcomes Were Comparable Between Aflibercept 8 mg and 2 mg





Safety analysis set. **IOP**, intraocular pressure.

An Analysis of the PHOTON and PULSAR Trials Demonstrated That IOP Outcomes Were Comparable Between Aflibercept 8 mg and 2 mg

	2q8 (n=503)	8q12 (n=663)	8q16 (n=501)	All 8 mg (n=1164)
Mean change (SD) in pre- to post-injection IOP, mmHg	2.9 (3.9)	3.7 (4.2)	3.7 (4.0)	3.7 (4.1)

	PULSAR			PHOTON		
	2q8 (n=336)	8q12 (n=335)	8q16 (n=338)	2q8 (n=167)	8q12 (n=328)	8q16 (n=163)
Pre- or post-injection IOP ≥35 mmHg, n (%)	2 (0.6)	3 (0.9)	1 (0.3)	2 (1.2)	2 (0.6)	0
Patients requiring paracentesis or anterior chamber puncture in the study eye, n (%)	0 (0)	1 (0.3)	0 (0)	0 (0)	3 (0.9)	1 (0.6)
Patients requiring paracentesis or anterior chamber puncture in the fellow eye, n (%)	0 (0)	0 (0)	0 (0)	1 (0.6)	1 (0.3)	0 (0)

Safety analysis set. **IOP**, intraocular pressure.

Conclusion

- Overall, IOP outcomes through Week 96 were comparable with intravitreal aflibercept 8 mg and 2 mg in both patients with nAMD and patients with DME