

Pooled Safety Analysis of Aflibercept 8 mg for up to 96 Weeks in the CANDELA, PHOTON, and PULSAR Trials

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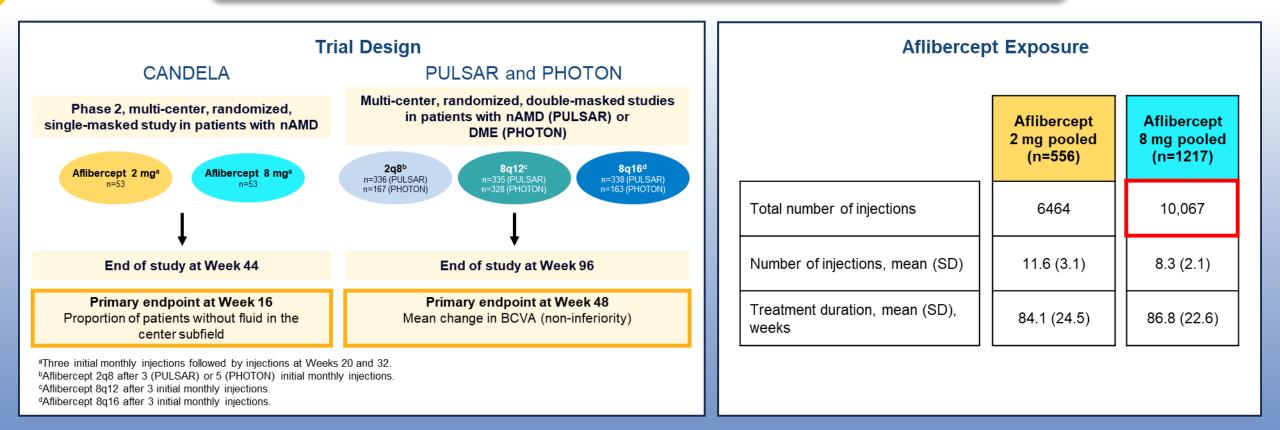
Financial Disclosures:

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METHODS

Objective: This analysis evaluated the pooled safety of aflibercept 8 mg and 2 mg for up to 96 weeks across the CANDELA, PULSAR, and PHOTON trials





RESULTS

Ocular and Serious TEAEs Through Week 96	Aflibercept 2 mg pooled (n=556)	Aflibercept 8 mg pooled (n=1217)
Any ocular TEAEs, n (%)	263 (47.3)	583 (47.9)
Any ocular TEAEs in ≥5% of patients in any treatment group, n (%)		
Cataract ^a	53 (9.5)	140 (11.5)
Visual acuity reduced	30 (5.4)	53 (4.4)
Any serious ocular TEAEs, n (%)	7 (1.3)	28 (2.3)
Any serious ocular TEAEs in ≥3 patients in any treatment group, n (%)		
Cataract ^b	1 (0.2)	7 (0.6)
Retinal detachment	1 (0.2)	6 (0.5)
Retinal hemorrhage	1 (0.2)	4 (0.3)
Intraocular pressure increased	0	3 (0.2)
Vitreous hemorrhage	0	3 (0.2)

 No cases of ION were reported with aflibercept 8 mg, and 1 case of ION was reported with aflibercept 2 mg

^aIncludes cataract, cataract cortical, cataract nuclear, cataract operation, cataract subcapsular, lenticular opacities, and posterior capsule opacification although not all terms met the \geq 5% threshold.

^bIncludes cataract, cataract nuclear, and cataract subcapsular although these terms did not meet the 3-patient threshold.

OI Through Week 96	Aflibercept 2 mg pooled (n=556)	Aflibercept 8 mg pooled (n=1217)
Any intraocular inflammation, n (%)	11 (2.0)	16 (1.3)
Iridocyclitis	2 (0.4)	4 (0.3)
Iritis	0	3 (0.2)
Anterior chamber cell	1 (0.2)	2 (0.2)
Uveitis	2 (0.4)	2 (0.2)
Vitreal cells	2 (0.4)	2 (0.2)
Vitritis	0	2 (0.2)
Chorioretinitis	0	1 (<0.1)
Endophthalmitis	2 (0.4)	0
Eye inflammation	1 (0.2)	0
Hypopyon	1 (0.2)	0

Most IOI cases were non-serious and mild or moderate in severity

 No cases of endophthalmitis were reported with aflibercept 8 mg, and 2 cases of endophthalmitis were reported with aflibercept 2 mg

No cases of occlusive retinal vasculitis were reported in the trials

Non-ocular TEAEs, APTC events, and Deaths Through Week 96	Aflibercept 2 mg pooled (n=556)	Aflibercept 8 mg pooled (n=1217)
Any non-ocular TEAEs, n (%)	396 (71.2)	884 (72.6)
Any serious non-ocular TEAEs, n (%)	112 (20.1)	256 (21.0)
APTC events, ^c n (%)	23 (4.1)	45 (3.7)
Any death, ^c n (%)	17 (3.1)	33 (2.7)

°Treatment-emergent.



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SUMMARY POINTS

- In this pooled analysis, aflibercept 8 mg demonstrated comparable safety to aflibercept 2 mg for up to 96 weeks across the CANDELA, PULSAR, and PHOTON trials
 - Incidence of IOI was low and similar between aflibercept 8 mg and 2 mg
 - No cases of endophthalmitis were reported with aflibercept 8 mg; 2 cases of endophthalmitis were reported with aflibercept 2 mg
 - No cases of ION were reported with aflibercept 8 mg; 1 case of ION was reported with aflibercept 2 mg
 - Incidence of non-ocular TEAEs, including serious TEAEs, APTC events, and deaths, was similar between aflibercept 8 mg and 2 mg