BCVA Gains With Aflibercept 8 mg Maintained Through Week 96 in the PULSAR Phase 3 Trial With Extended Treatment Intervals in Patients With nAMD

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METHODS

PULSAR: a 2-year, 3-arm, randomized, double-masked study (NCT04423718)

Patients with treatment-naïve nAMD, randomized at baseline
1 (2q8) : 1 (8q12) : 1 (8q16)

	YEAR 1													YEAR 2											
	Day 1	W4	W8	W12	W16	W20	W24	W28	W32	W36	W40	W44	W48	W52	W56	W60	W64	W68	W72	W76	W80	W84	W88	W92	W96
2q8[a] (n=336)	X	X	X		X	o	X	o	X	o	X	o	X	o	X	o	X	o	X	o	X	o	X	o	–
8q12[a] (n=335)	X	X	X		o[b]	X[b]	o	o	X[b]	o	o	X[b]	o	o	X[b,c]	o	o	X[b,c]	o	o	X[b,c]	o	o	X[b,c]	–
8q16[a] (n=338)	X	X	X		o[b]	o[b]	X[b]	o	o	o	X[b]	o	o	o	X[b,c]	o	o	o	X[b,c]	o	o	o	X[b,c]	o	–

Primary endpoint at W48:
Mean change in BCVA (non-inferiority)

[b]DRM: Interval Shortening During Years 1 and 2

Criteria for interval shortening
- >5-letter loss in BCVA compared with Week 12 due to persistent or worsening nAMD **AND**
- >25 µm increase in CRT compared with Week 12, **OR** new foveal neovascularization, **OR** new foveal hemorrhage

[c]DRM: Interval Extension During Year 2

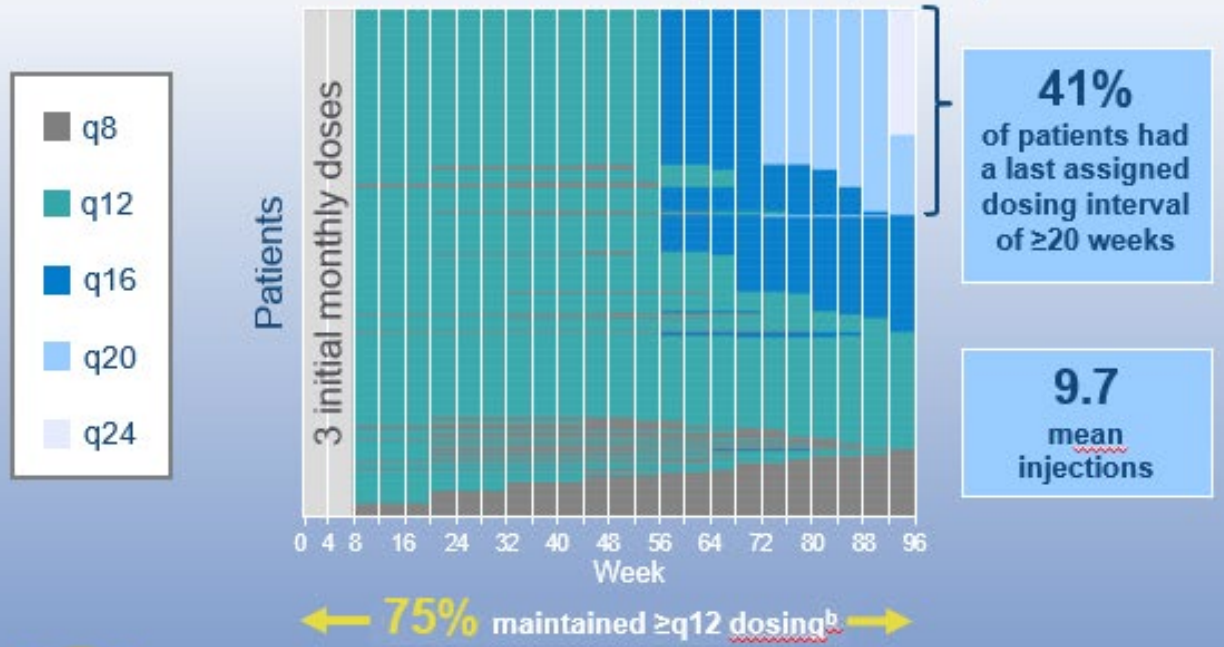
Criteria for interval extension
- <5-letter loss in BCVA compared with Week 12 **AND**
- No fluid at the central subfield on OCT **AND**
- No new foveal hemorrhage or foveal neovascularization

Figure does not reflect all dosing options once a patient's dosing interval is shortened or extended. Stippled boxes = initial treatment phase; X = active injection; o = sham injections. [a]Each after 3 initial monthly injections.
2q8, aflibercept 2 mg every 8 weeks; **8q12**, aflibercept 8 mg every 12 weeks; **8q16**, aflibercept 8 mg every 16 weeks; **BCVA**, best-corrected visual acuity; **CRT**, central subfield retinal thickness; **DRM**, dose regimen modification; **nAMD**, neovascular age-related macular degeneration; **OCT**, optical coherence tomography; **W**, week.

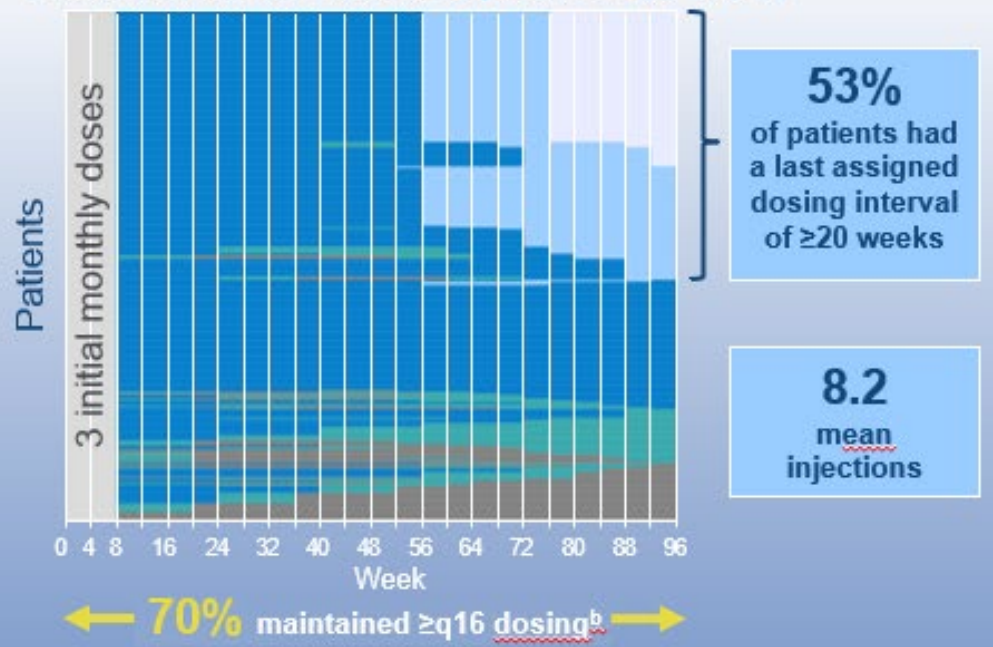
RESULTS

- There were no marked differences in baseline characteristics between groups
- Changes in BCVA and CRT from baseline through Week 96 were comparable between treatment arms

Patients randomized to 8q12 at BL (n=291[a])



Patients randomized to 8q16 at BL (n=292[a])



The safety profile of aflibercept 8 mg was comparable to that of aflibercept 2 mg and no new safety concerns were identified

SAF. [a]Data are for Week 96 completers. [b]Through Week 96.
BL, baseline; **SAF**, safety analysis set; **q8**, every 8 weeks; **q12**, every 12 weeks; **q16**, every 16 weeks; **q20**, every 20 weeks; **q24**, every 24 weeks.

DISCUSSION

- Aflibercept 8 mg groups achieved similar BCVA gains compared with the aflibercept 2 mg group at Week 96
- Anatomic improvements in PULSAR for aflibercept 8 mg were maintained over time through Week 96
- At Week 96, **75%** of patients randomized to receive aflibercept 8q12 maintained ≥q12 dosing intervals and **41%** achieved ≥q20 dosing intervals; **70%** of patients randomized to receive aflibercept 8q16 maintained ≥q16 dosing intervals and **53%** achieved ≥q20 dosing intervals
- The safety profile of aflibercept 8 mg was comparable to that of aflibercept 2 mg over 96 weeks