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Greater and more durable fluid resolution with aflibercept 8 mg versus aflibercept 2 mg in the PULSAR trial: A 96-week post-hoc analysis

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Disclosures

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nAMD

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PULSAR: 96-Week, Multicenter, Double-Masked Study in Patients With Treatment-Naïve nAMD

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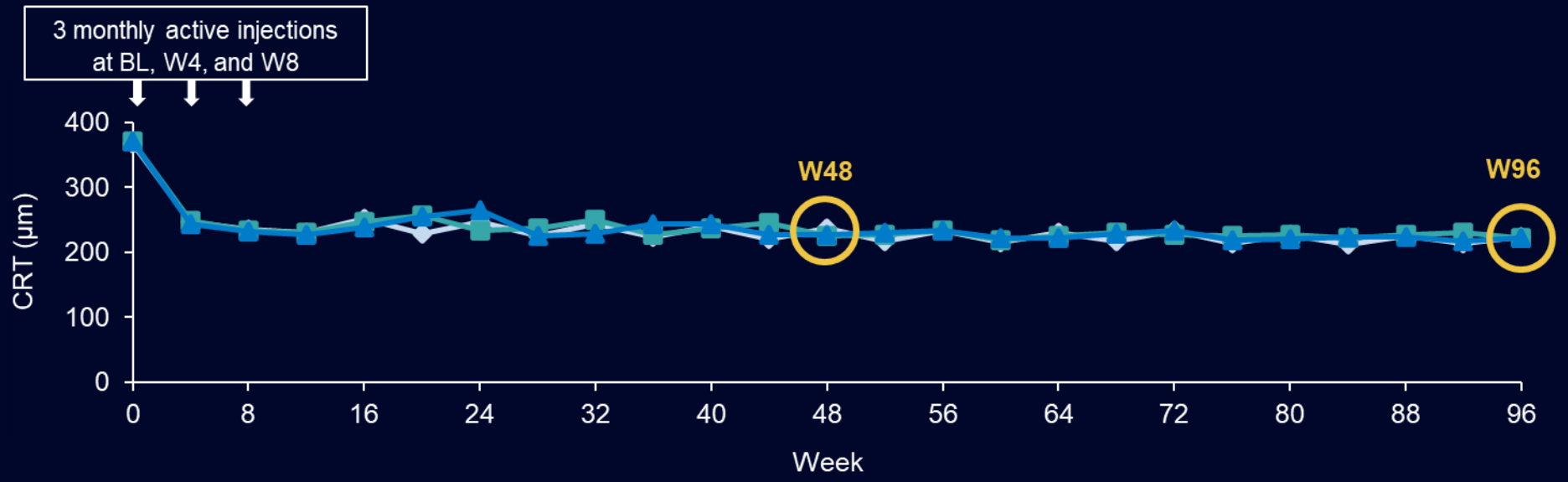
Patients were randomly assigned (1:1:1) to receive aflibercept 8q12 (n=335), 8q16 (n=338), or 2q8 (n=336), each after 3 monthly injections

At W48, treatment with aflibercept 8 mg demonstrated non-inferior BCVA gains with extended dosing intervals versus aflibercept 2 mg in patients with nAMD,[1] with no new safety signals
At W96, treatment with aflibercept 8 mg maintained improvements in visual and anatomic outcomes with extended dosing intervals, demonstrating long-term efficacy with no new safety signals

Absolute CRT (observed values)



LS means CRT (µm) change from BL[a,b]

	W48	W96
2q8	–136	–147
8q12	–147	–152
8q16	–147	–149

FAS: 2q8 n=336; 8q12 n=335; 8q16 n=338 (at BL). [a]LS mean values (data post-ICE were censored). [b]LS means were generated using MRMM, with BL CRT measurement as a covariate, and treatment group (aflibercept 2q8, 8q12, 8q16), visit, and stratification variables (geographic region [Japan vs Rest of World] and BL BCVA [<60 vs ≥60]) as fixed factors, and interaction terms for BL and visit and for treatment and visit. **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; **BL**, baseline; **CRT**, central subfield retinal thickness; **FAS**, full analysis set; **ICE**, intercurrent event; **LS**, least squares; **MMRM**, mixed model for repeated measures; **nAMD**, neovascular age-related macular degeneration; **W**, week.

[1]Lanzetta P, et al. Lancet. 2024;403:1141–1152.

Proportion of Patients With IRF and SRF Resolution Through Week 96

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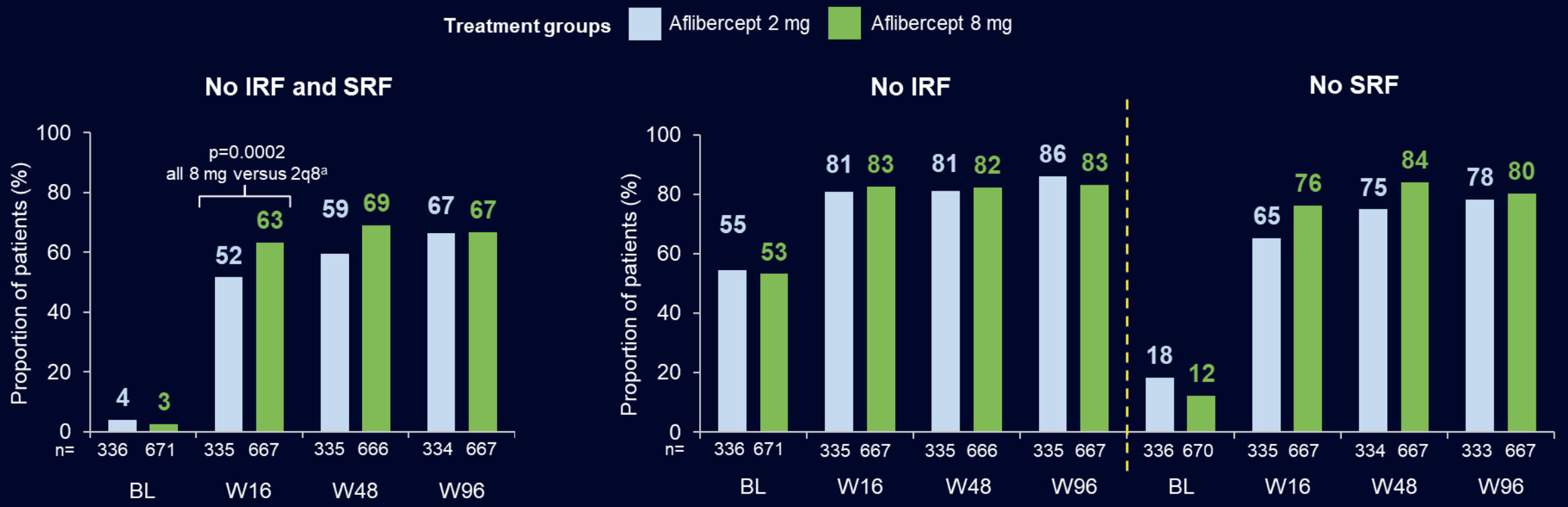

	W48[b]		W96[c]	
	2 mg	**8 mg**	**2 mg**	**8 mg**
Completers, n	309	628	292	583
Mean active injections	**6.9**	**5.6**	**12.8**	**9.0**

- Fluid control was sustained from W16 to W96 for IRF and SRF combined, and IRF and SRF separately
- Resilient fluid control at 1 and 2 years was achieved with fewer injections in the aflibercept 8 mg group versus the aflibercept 2 mg group

FAS, LOCF (censoring data post ICE); FAS: 2q8 n=336; 8q12 n=335; 8q16 n=338; all 8 mg n=673. [a]One-sided superiority, p-value: 1-sided CMH; weighting scheme adjusted by geographic region and BL BCVA (<60 vs ≥60). [b]Patients completing Week 48. [c]Patients completing Week 96. **2q8**, aflibercept 2 mg every 8 weeks; **CMH**, Cochran-Mantel-Haenszel; **IRF**, intraretinal fluid; **LOCF**, last observation carried forward; **SRF**, subretinal fluid.

Matched Timepoints: Proportion of Patients With Fluid Resolution

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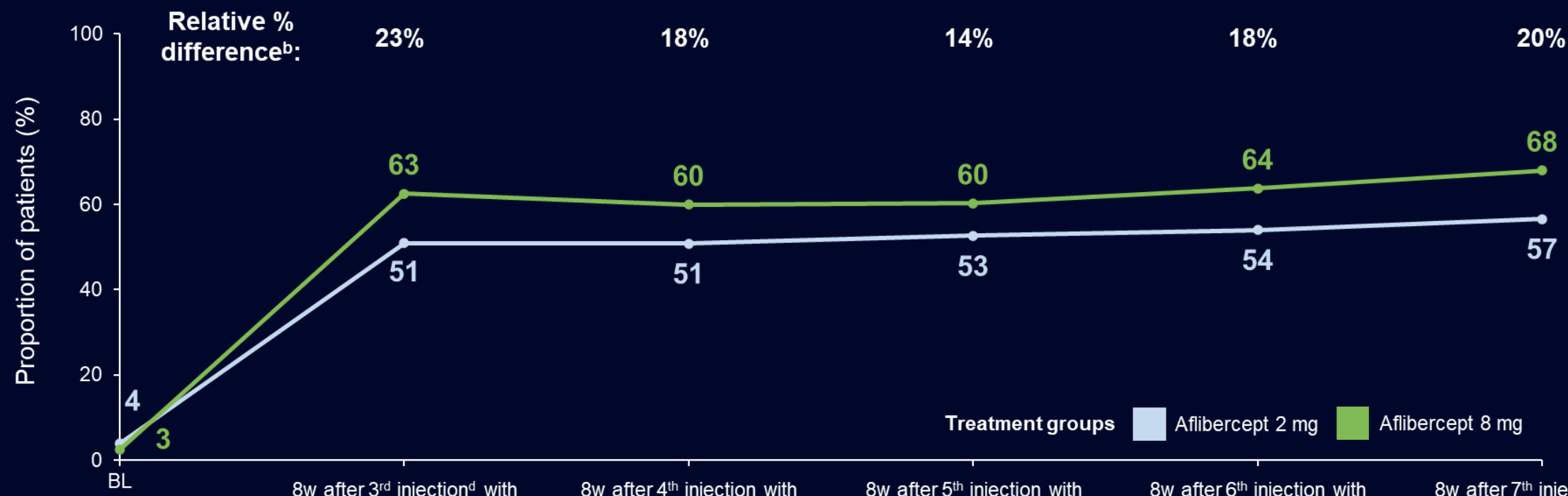
14–23% higher fluid resolution 8 weeks after each active injection of aflibercept 8 mg versus aflibercept 2 mg[a,b,c]



	BL	8w after 3rd injection[d] with an injection interval of ≥8w afterwards	8w after 4th injection with an injection interval of ≥8w afterwards	8w after 5th injection with an injection interval of ≥8w afterwards	8w after 6th injection with an injection interval of ≥8w afterwards	8w after 7th injection with an injection interval of ≥8w afterwards
8 mg n=	673	653	624	590	576	545
2 mg n=	336	326	315	304	291	281

OC, FAS. OC prior to ICE adjusted by geographic region and BL BCVA (<60 vs ≥60). Visits were matched such that patients in any treatment group received the same number of active injections.
[a]Fluid resolution defined as no IRF and no SRF in center subfield. [b]Relative difference between absolute percentages in the aflibercept 8 mg and 2 mg group divided by the percentages in the aflibercept 2 mg group. [c]8w after each injection with an injection interval of ≥8w afterwards. [d]Third injection is at Week 8 for all treatment groups. **OC**, observed cases; **w**, weeks.

Matched Timepoints: CRT Change from BL

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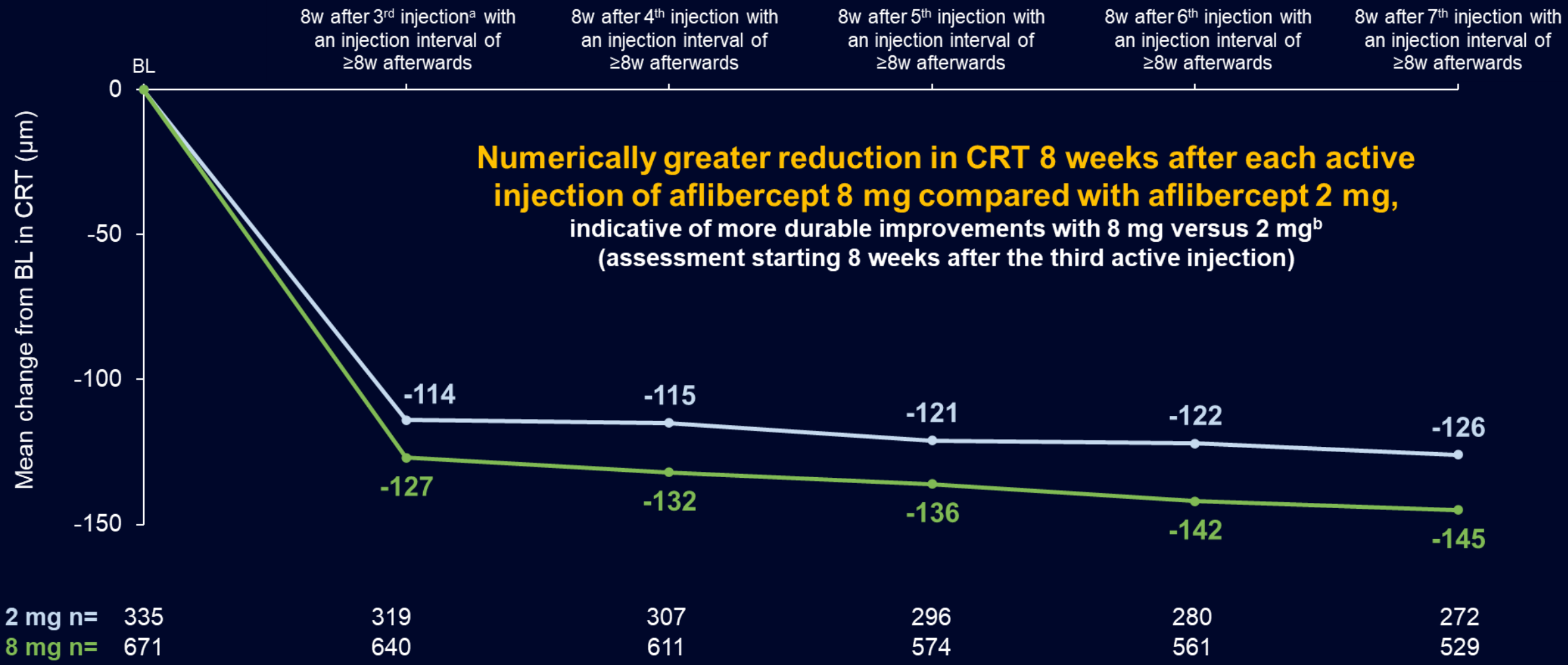

2 mg n=	335	319	307	296	280	272
8 mg n=	671	640	611	574	561	529

OC, FAS. OC prior to ICE adjusted by geographic region and BL BCVA (<60 vs ≥60). Visits were matched such that patients in any treatment group received the same number of active injections.
[a]Third injection is at W8 for all treatment groups. [b]8w after each injection with an injection interval of ≥8w afterwards.

Conclusions

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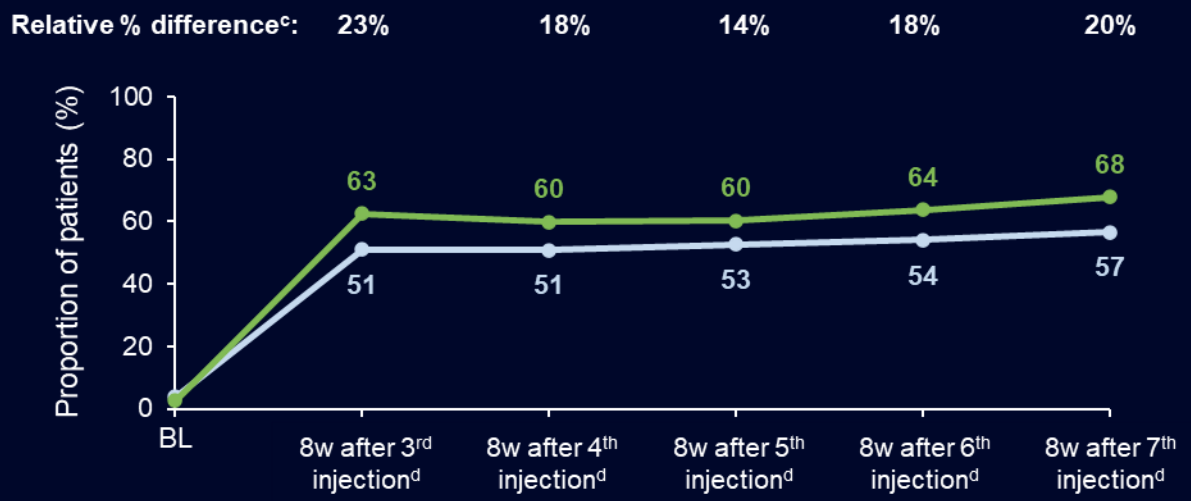
- **Greater fluid resolution and improvement in CRT** was observed with aflibercept 8 mg versus aflibercept 2 mg at matched time points after each active injection, starting with the third injection[a]
- Aflibercept 8 mg achieved **durable fluid control** versus aflibercept 2 mg through Week 96 with extended dosing and fewer injections[b] in a substantial proportion of treatment-naïve patients with nAMD

Matched timepoints: Proportion of patients without retinal fluid



Matched timepoints: CRT change from baseline

Treatment groups 2 mg 8 mg

OC, FAS. OC prior to ICE adjusted by geographic region and BL BCVA (<60 vs ≥60). [a]Visits were matched such that patients in any treatment group received the same number of active injections. Assessment started 8w after the third active injection (at W8) for all groups with an injection interval of ≥8w afterwards. [b]6.9 versus 5.6 injections at W48, and 12.8 versus 9.0 injections at W96 in the aflibercept 8 mg versus 2 mg groups, respectively; [c]Difference between absolute percentages in the 8 mg and 2 mg group divided by the percentages in the 2 mg group. [d]With an injection interval of ≥8w afterwards.