| Use Case | PPT slides | PDF file | Notes |
|---|---|---|---|
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| Presentation at local symposia or other large audience meetings (proactive communication) | ? | ? | Seek guidance from local compliance and follow guidance regarding unpublished data |
| Presentation during an Advisory Board | ✓ | ✓ | Under confidentiality |
| Internal medical training | ✓ | ✓ | In accordance with local rules / regulations; distribute PDF only |
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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

- **Richard Gale:** Consultant for AbbVie, Allergan, Apellis, Bayer, Biogen, Boehringer Ingelheim, Notal, Novartis, Roche, and Santen; and receives funding from Bayer, Novartis, and Roche.
  - **MRM:** Consulting fees from AbbVie, Allergan, Apellis, Bayer, Dandelion, Eyepoint, Gensight, Iveric Bio, Kubota, Lumithera, Novartis, Ocuterra, RetinAI, Roche, and Zeiss. **RG:** Consultant for AbbVie, Allergan, Apellis, Bayer, Biogen, Boehringer Ingelheim, Notal, Novartis, Roche, and Santen; and receives funding from Bayer, Novartis, and Roche. **AA:** Consultant for Apellis, Bayer, Novartis, and Roche. **PJP:** Honoraria/attendance at advisory boards for Bayer, Boehringer Ingelheim, and Roche; and speaker fees and educational travel grants from Bayer and Roche. **PL:** Consultant for Aerie Pharmaceuticals, Allergan, Apellis, Bausch + Lomb, Bayer, Biogen, Boehringer Ingelheim, I-Care, Genentech, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche. **J-FK:** Consultant for AbbVie, Apellis, Bayer, Eyepoint Pharma, Ocuphire, Roche, Théa Pharmaceuticals, and Carl Zeiss Meditec AG; and member of a data safety monitoring board or advisory board for Alexion, Novo Nordisk, and Opthea. **SS:** Receives funding/fees from Allergan, Apellis, Bayer, Biogen, Boehringer Ingelheim, EyeBiotech, Novartis, Optos, and Roche. **SL** and **XZ**: Employees of Bayer Consumer Care AG. **TM**: Employee of Bayer AG
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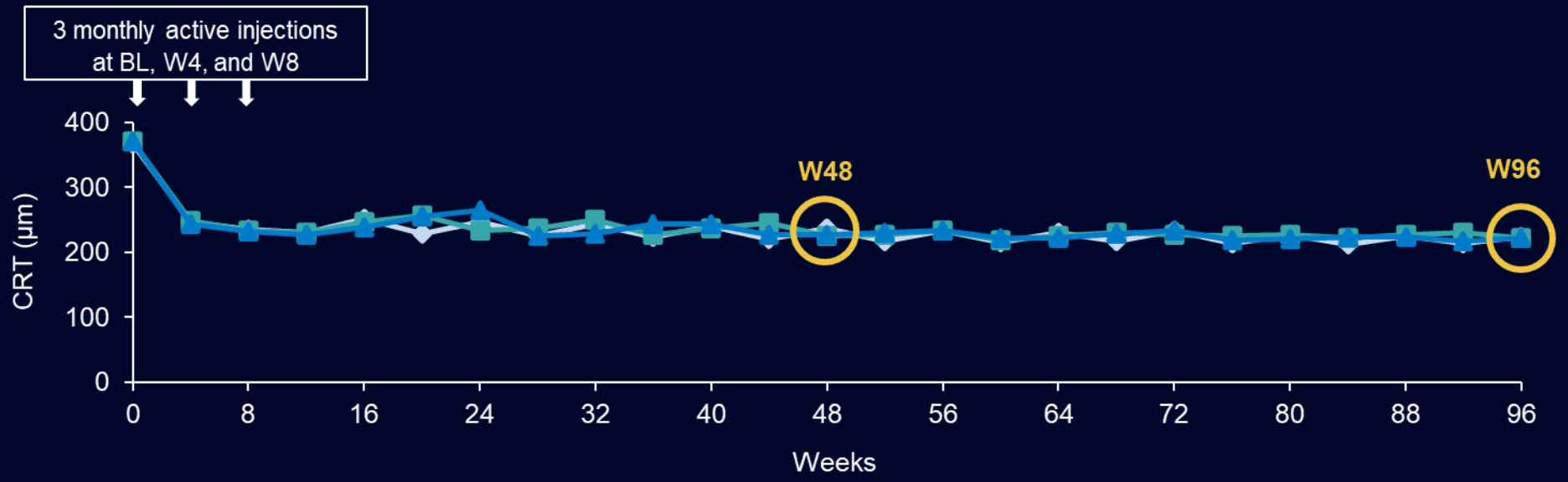
# PULSAR: 96-Week, Multicenter, Double-Masked Study in Patients with Treatment-Naïve nAMD

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 noninferior BCVA gains with extended dosing intervals compared with 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)



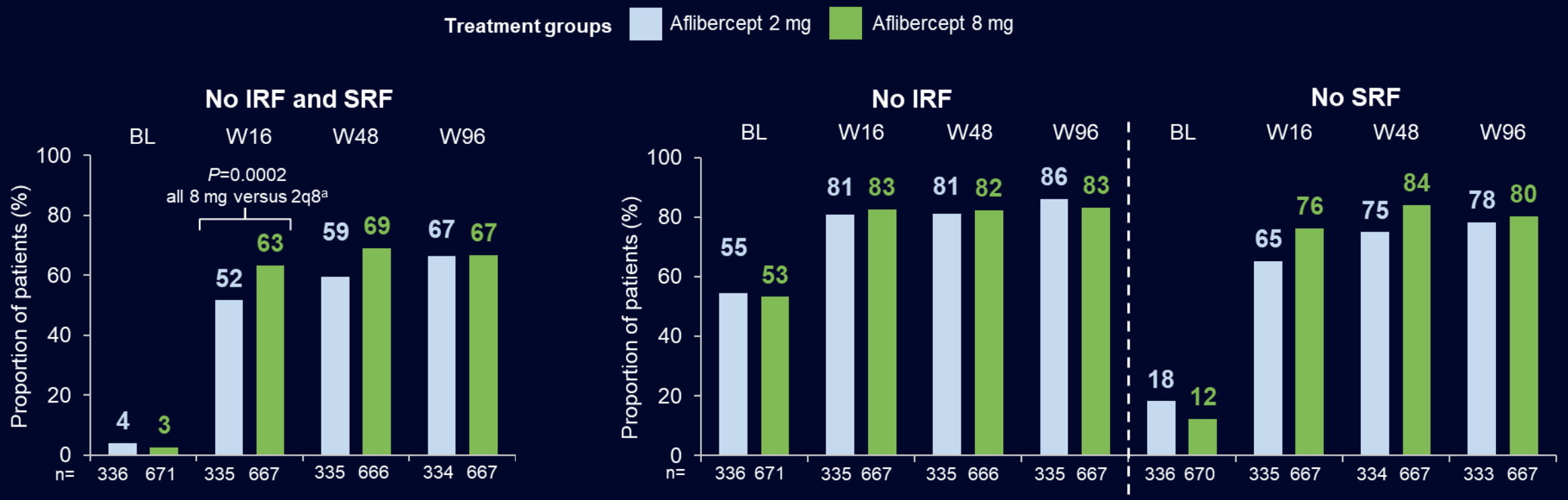

**LS means CRT (µm) change from BL[a,b]**

| | 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 (post-ICE data 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



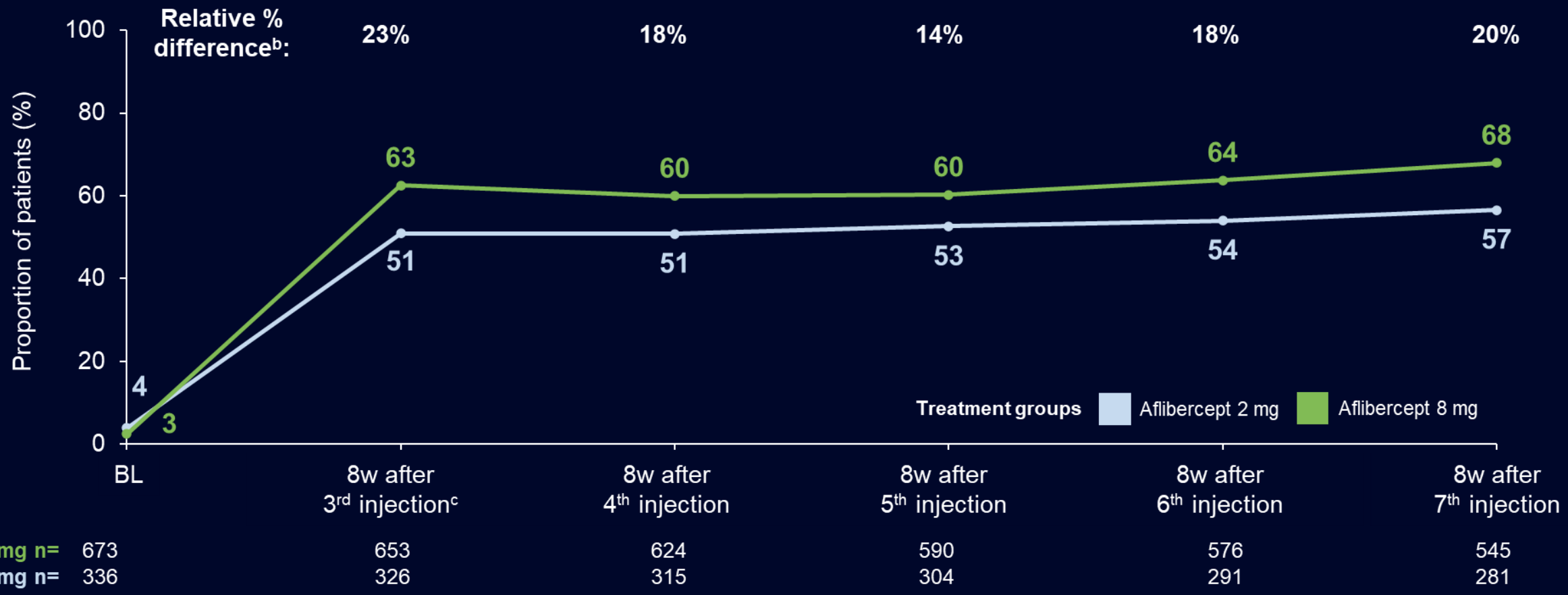

| | W48[b] | | W96[c] | |
|---|---|---|---|---|
| | **2 mg** | **8 mg** | **2 mg** | **8 mg** |
| Completers, n | 309 | 628 | 286 | 583 |
| **Mean number of active injections** | **6.9** | **5.6** | **12.8** | **9.0** |

- The proportion of patients who had fluid resolution at W16 was maintained at W48 and 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 compared with 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 test; weighting scheme adjusted by geographic region and BL BCVA (<60 vs ≥60 ETDRS letters). [b]Patients completing Week 48. [c]Patients completing Week 96. **CMH**, Cochran-Mantel-Haenszel; **IRF**, intraretinal fluid; **LOCF,** last observation carried forward; **SRF**, subretinal fluid.

# Proportion of Patients with Fluid Resolution 8 Weeks After Each Matched Number of Active Injections

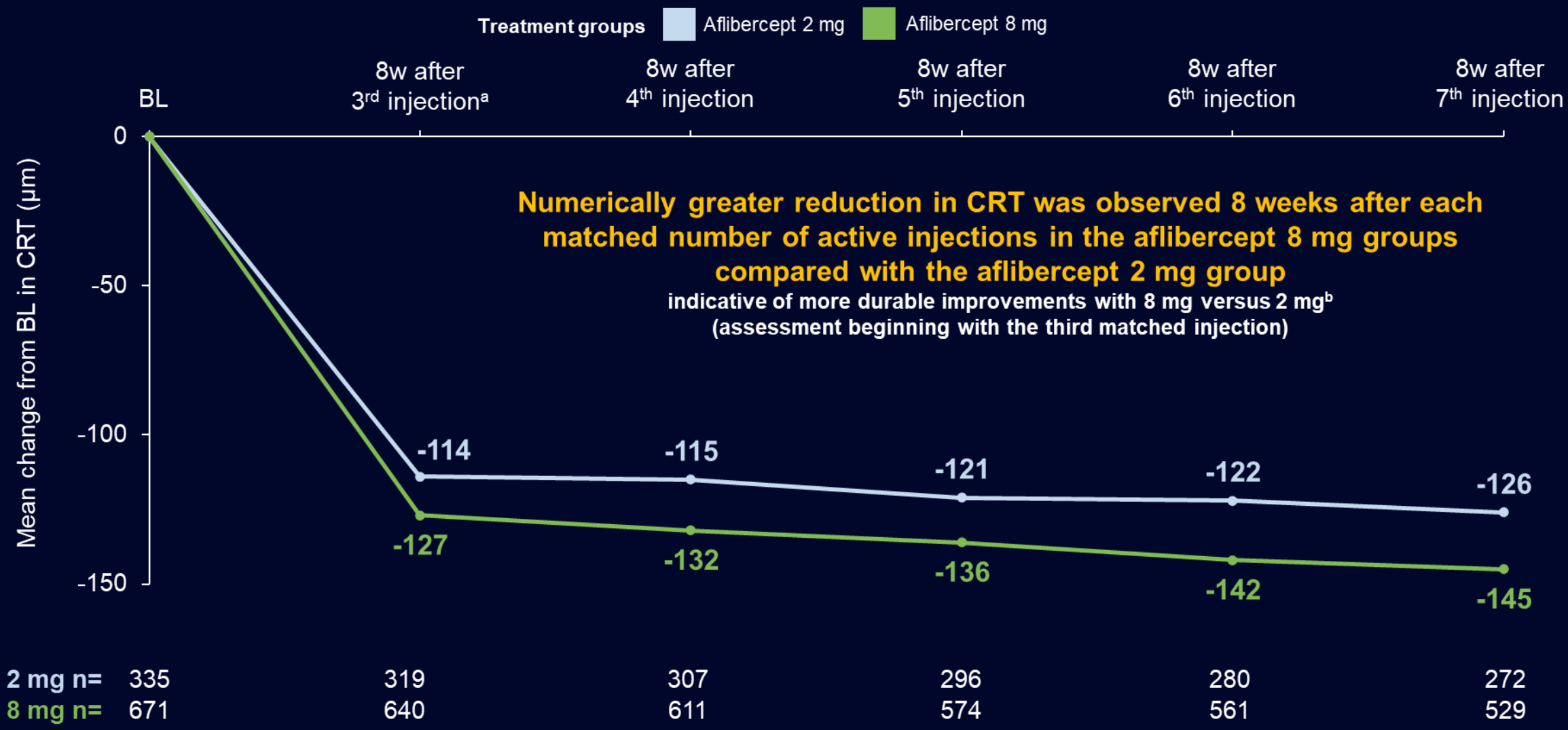
## More patients achieved fluid resolution with aflibercept 8 mg compared with aflibercept 2 mg (14–23% relative difference)[a,b]




| | BL | 8w after 3rd injection[c] | 8w after 4th injection | 8w after 5th injection | 8w after 6th injection | 8w after 7th injection |
|---|---|---|---|---|---|---|
| 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 ETDRS letters). 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 the central subfield. [b]The relative difference in the proportion of patients with fluid resolution was calculated by the difference in the aflibercept 8 mg and 2 mg groups, divided by the percentage in the aflibercept 2 mg group. [c]The third injection occurred at Week 8 for all treatment groups. **OC**, observed cases.

# CRT Change from Baseline 8 Weeks After Each Matched Number of Active Injections



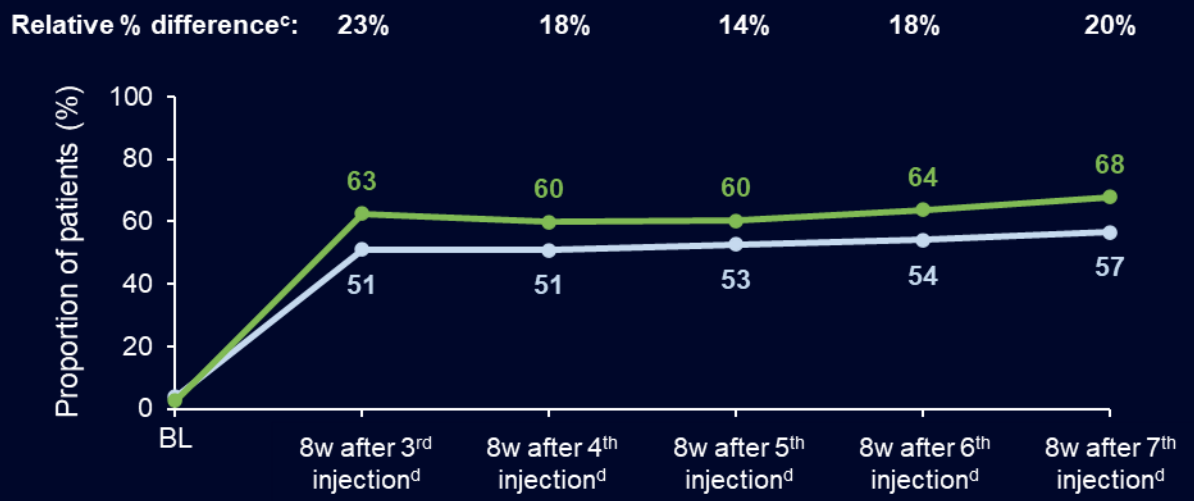

| | | | | | | |
|---|---|---|---|---|---|---|
| 2 mg n= | 335 | 319 | 307 | 296 | 280 | 272 |
| 8 mg n= | 671 | 640 | 611 | 574 | 561 | 529 |

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

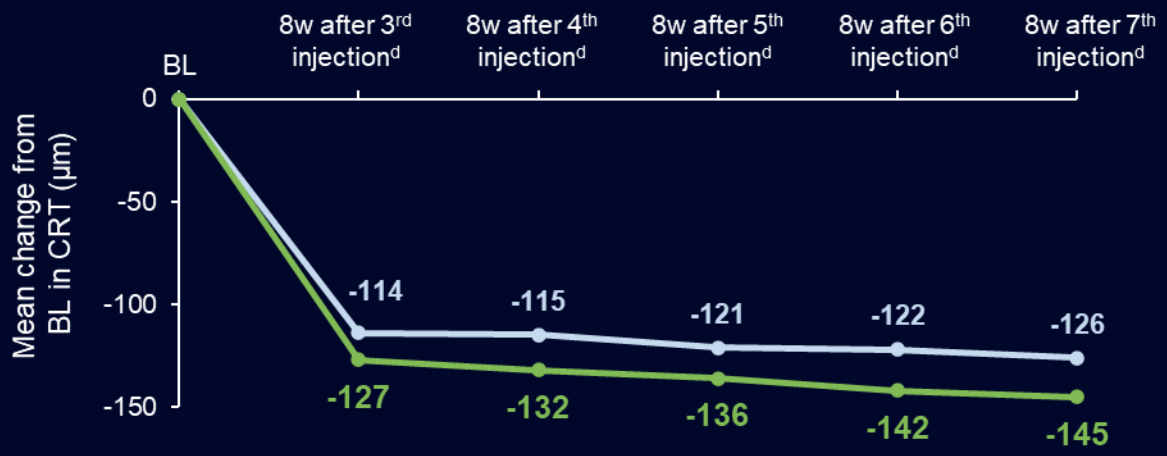
# Conclusions

- **A greater proportion of patients with fluid resolution and CRT improvements** was observed in the combined aflibercept 8 mg groups compared with the aflibercept 2 mg group 8 weeks after each matched number of active injections, beginning from the third injection[a]
- Aflibercept 8 mg achieved **durable fluid control** compared with aflibercept 2 mg through Week 96 with extended dosing and fewer injections[b] in a substantial proportion of treatment-naïve patients with nAMD

**Proportion of patients with fluid resolution 8 weeks after each matched number of active injections**




**CRT change from baseline 8 weeks after each matched number of active injections**




**Treatment groups** 2 mg 8 mg

OC, FAS. OC prior to ICE, adjusted by geographic region and BL BCVA (<60 vs ≥60 ETDRS letters). [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]The relative difference in the proportion of patients with fluid resolution was calculated by the difference in the aflibercept 8 mg and 2 mg groups divided by the percentage in the aflibercept 2 mg group. [d]With an injection interval of ≥8w afterwards.