HAWK and HARRIER: Ninety-six-week outcomes from the phase 3 trials of brolucizumab for neovascular age-related macular degeneration (nAMD)

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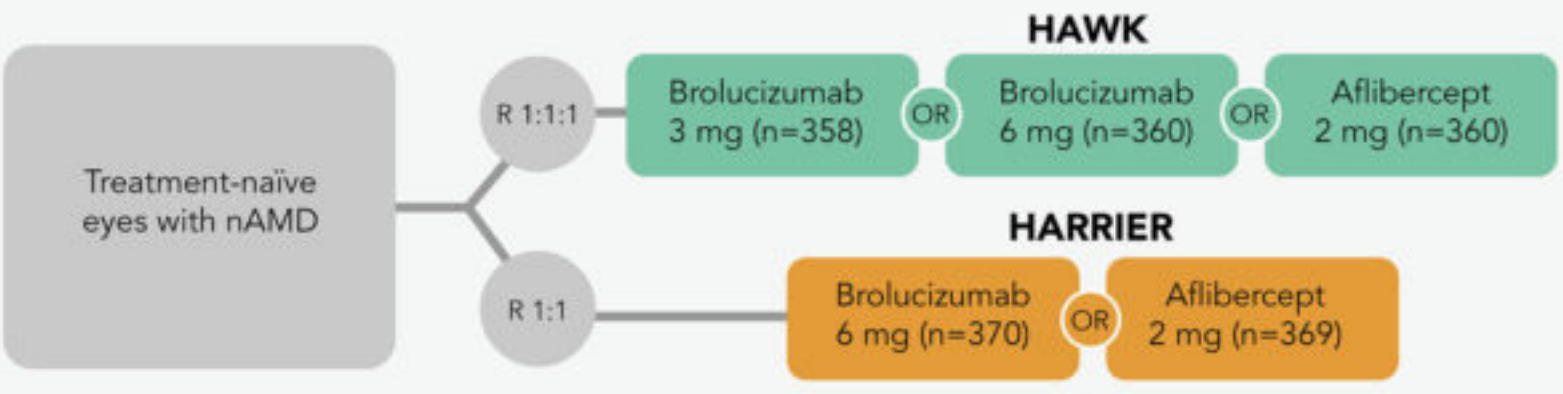
The 96-week efficacy and safety outcomes from the phase 3 HAWK and HARRIER studies are presented in this paper. The studies compared brolucizumab and aflibercept in patients with treatment-naïve nAMD.

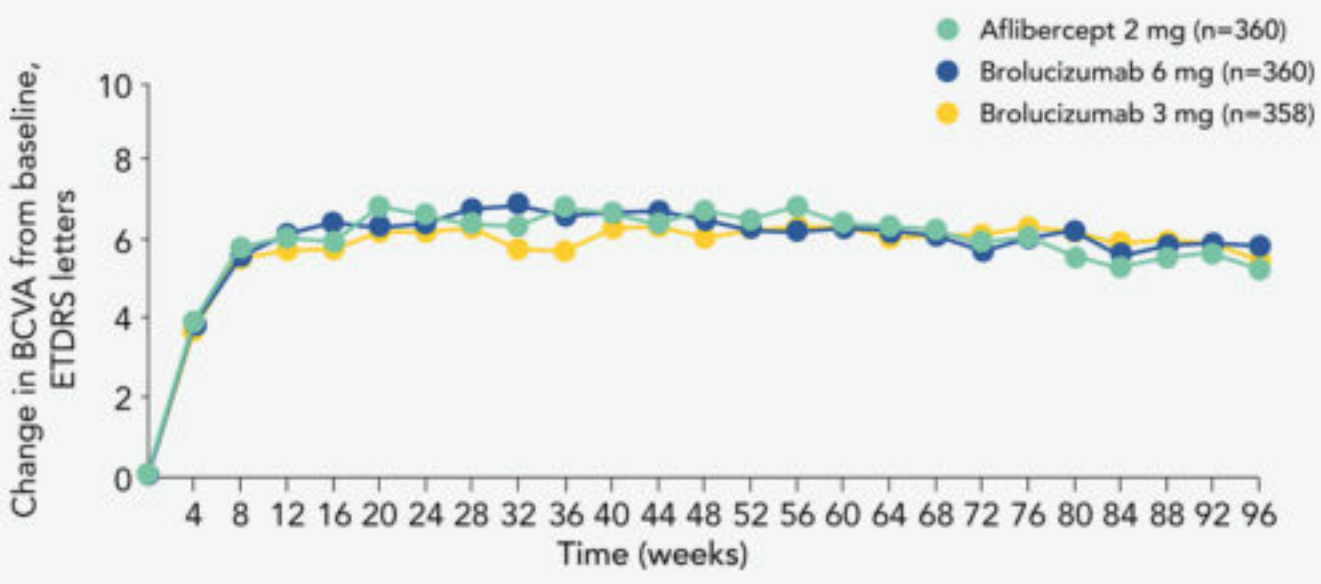
This was a phase 3, prospective, randomized, double-masked, multicenter study.



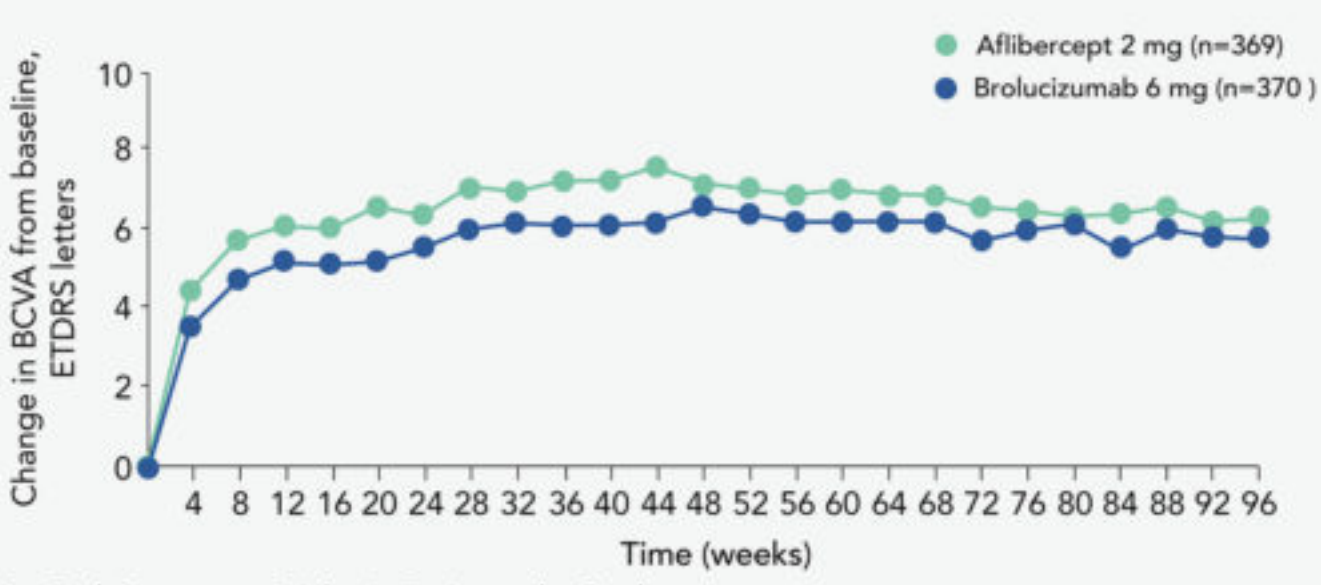
After 3 monthly loading doses, brolucizumab patients received every 12 week (Q12W) dosing, possibly adjusting to Q8W dosing if disease activity was present at predefined disease activity assessment (DAA) visits. Aflibercept was dosed in a fixed Q8W regimen. Visual and anatomic parameters were assessed throughout. The primary endpoint was assessed at week 48 and confirmed at week 96.

The mean change in best-corrected visual acuity (BCVA) from baseline at week 48 in brolucizumab-treated eyes was noninferior to that in aflibercept-treated eyes, and these visual gains were maintained to week 96.

BCVA Change from Baseline to Week 96 - HAWK



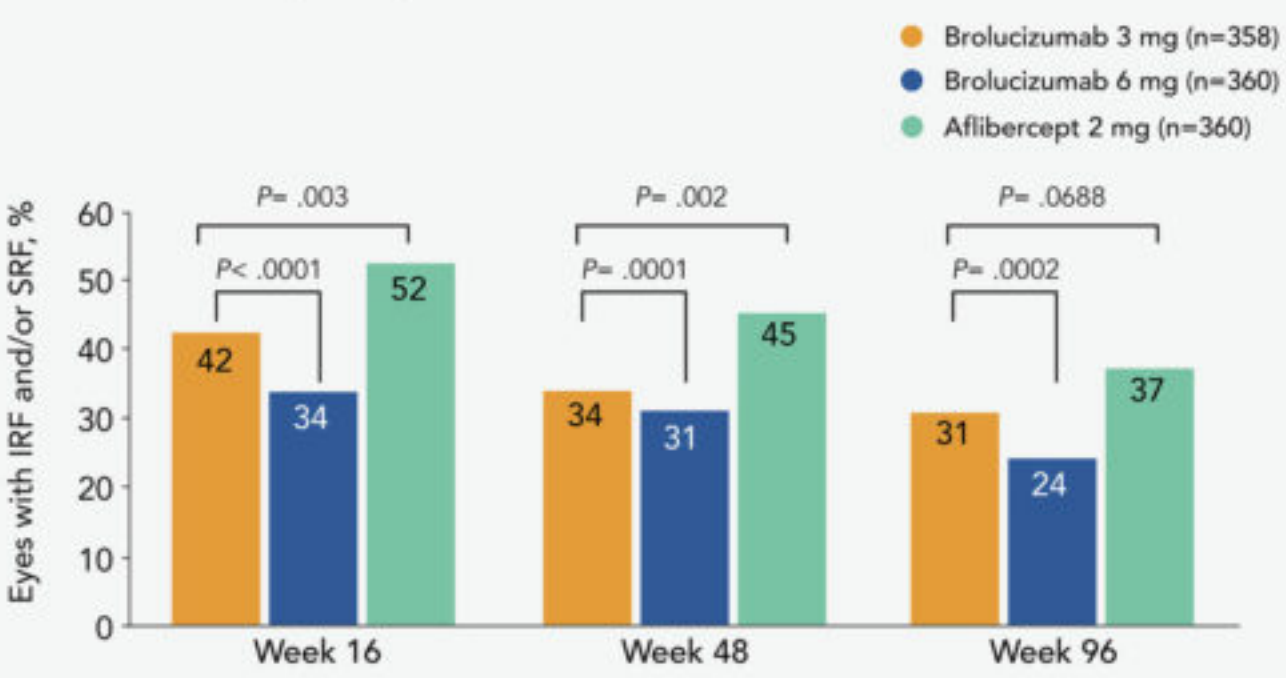
BCVA Change from Baseline to Week 96 - HARRIER



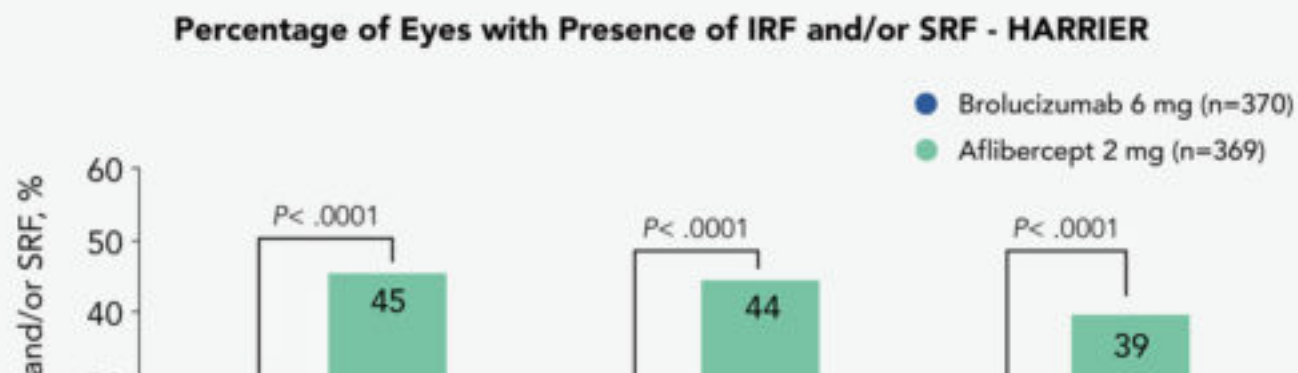
ETDRS = Early Treatment Diabetic Retinopathy Study

In both HAWK and HARRIER, significantly fewer eyes treated with brolucizumab showed intraretinal fluid (IRF) or subretinal fluid (SRF) at weeks 16 and 48, and this difference was maintained to week 96.

Percentage of Eyes with Presence of IRF and/or SRF - HAWK

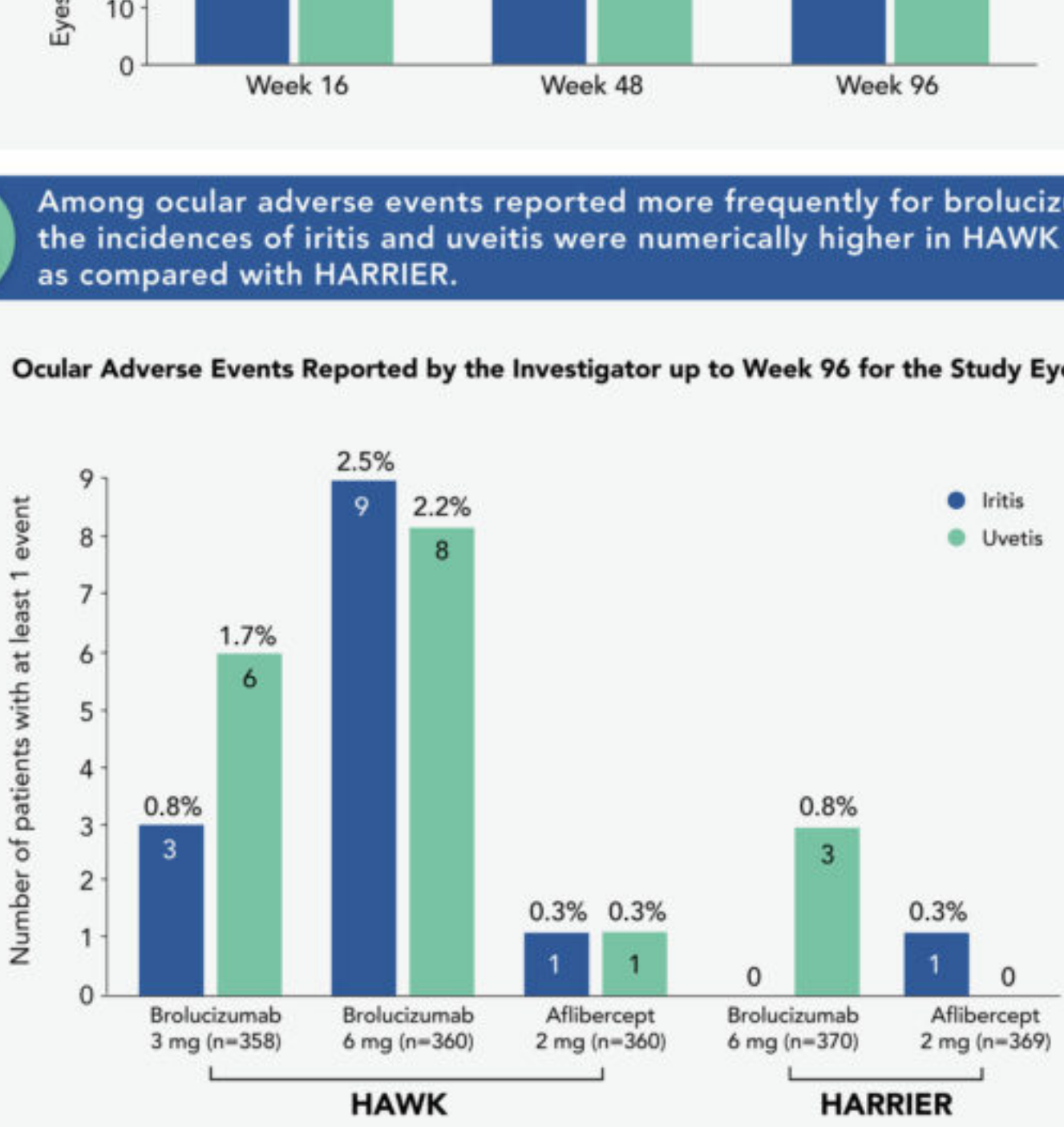


Percentage of Eyes with Presence of IRF and/or SRF - HARRIER



Among ocular adverse events reported more frequently for brolucizumab, the incidences of iritis and uveitis were numerically higher in HAWK as compared with HARRIER.

Ocular Adverse Events Reported by the Investigator up to Week 96 for the Study Eye



Conclusions

Visual outcomes from weeks 48 to 96 confirm the efficacy achieved by brolucizumab and aflibercept at week 48. Brolucizumab demonstrated greater fluid resolution compared with aflibercept. Brolucizumab-treated eyes that completed week 48 on a Q12W dosing interval successfully remained on a Q12W dosing interval until week 96.