

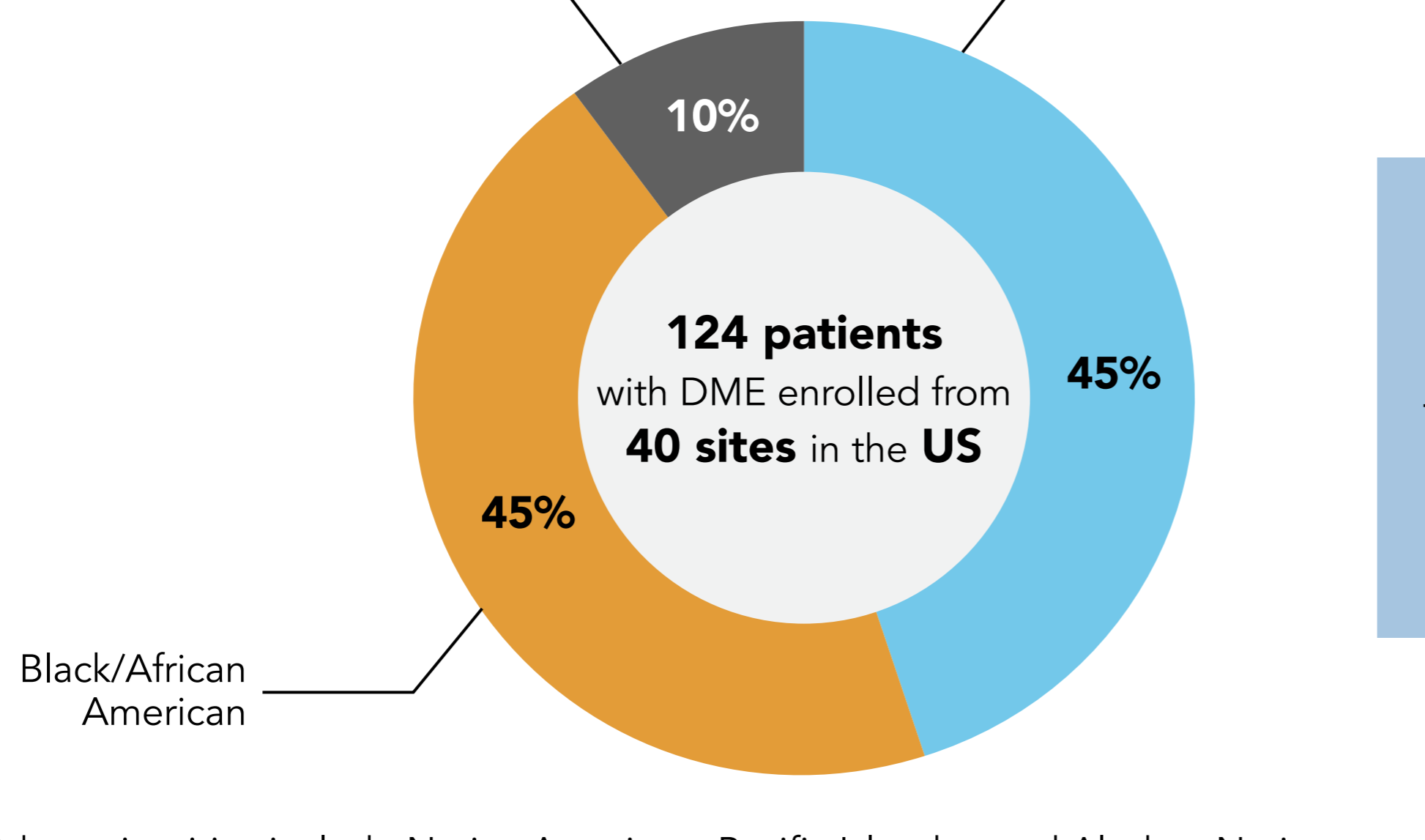
Baseline Biomarker Levels in Underrepresented Patients With DME: A Post Hoc Exploratory Analysis of ELEVATUM

Brown J, Dinah C, Lim JI, et al. Presented at: Hawaiian Eye and Retina; January 18-24, 2026; Waikoloa Village, Hawaii.

ELEVATUM (NCT05224102) is a phase 4, multicenter, open-label, single-arm, 1-year trial of faricimab that focuses on historically underrepresented minorities in clinical trials. Before the study, trial participants have not been treated with an anti-vascular endothelial growth factor.

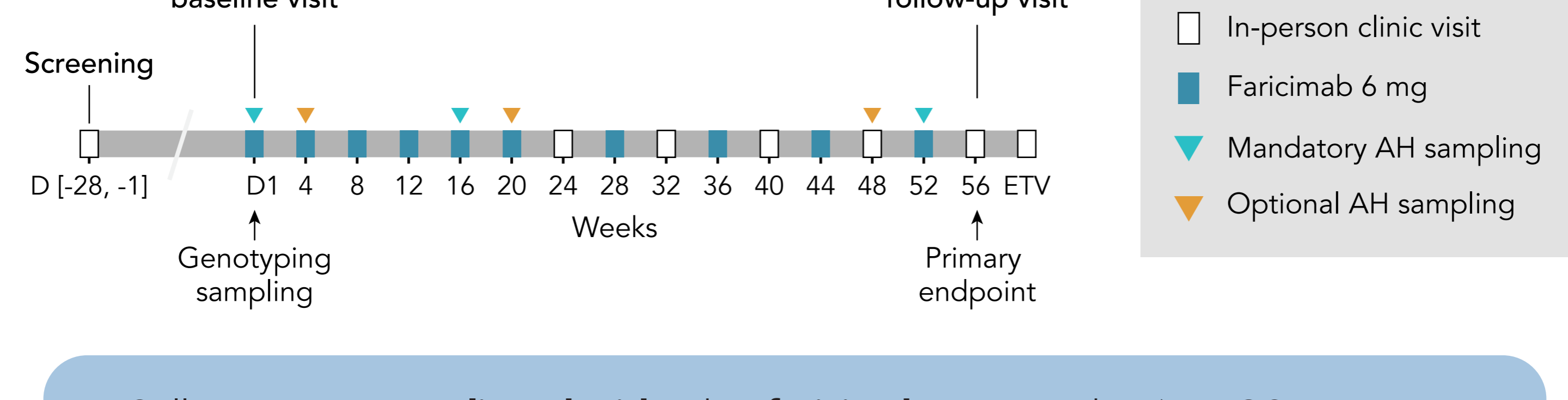
The primary endpoint is change in BCVA from baseline at week 56 and the secondary endpoints include safety and change in central subfield thickness from baseline over time. Results from the ELEVATUM trial were consistent with the pivotal phase 3 YOSEMITE and RHINE studies.

ELEVATUM is the first industry-sponsored clinical trial focused on historically underrepresented minorities in retina



This biomarker analysis includes **Hispanic/Latino** and **Black/African American** patients from the US.

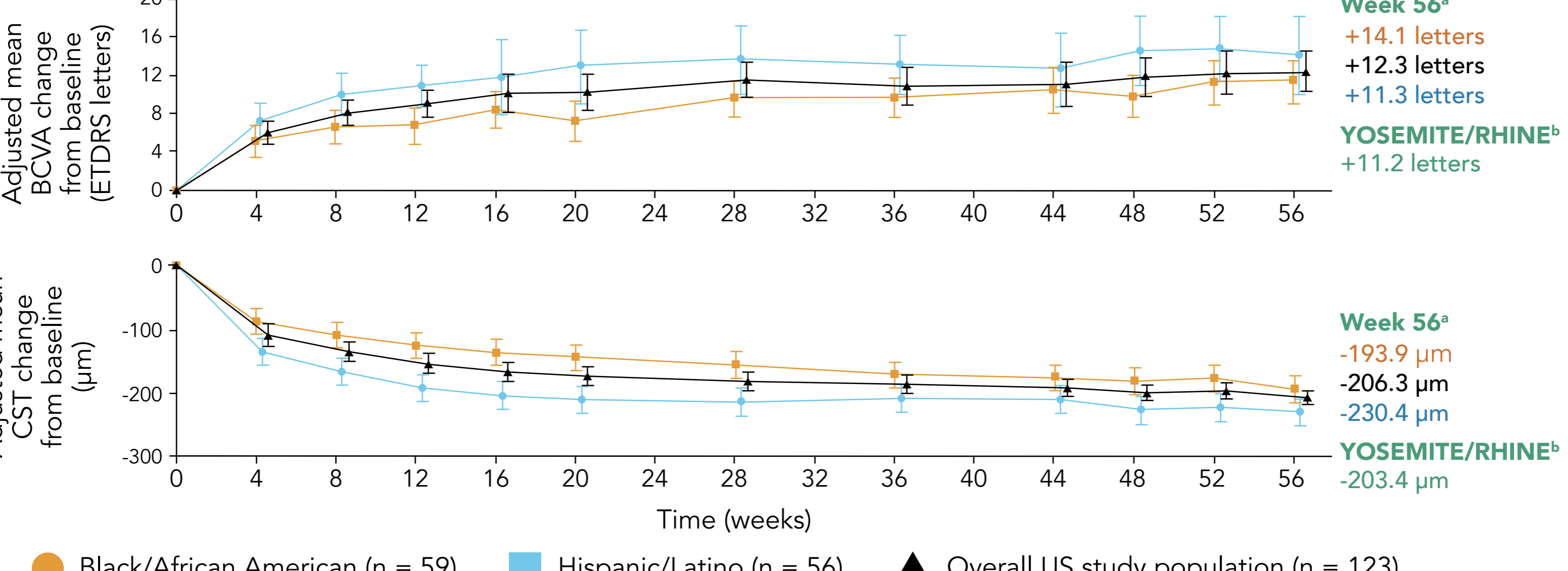
^aOther minorities include Native American, Pacific Islander, and Alaskan Native. DME = diabetic macular edema.



Collection visits are **aligned with other faricimab DME studies** (ie, YOSEMITE, RHINE, and ALTIMETER) to enable **biomarker comparisons** across studies. AH samples were measured for VEGF and Ang-2 via immunoassay, and post hoc analysis was performed, comparing baseline concentrations across ethnicities.

YOSEMITE (NCT03622580); RHINE (NCT03622593); ALTIMETER (NCT04597918). AH = aqueous humor; Ang-2 = angiopoietin-2; D = day; DME = diabetic macular edema; ETV = early termination visit; VEGF = vascular endothelial growth factor.

Patients treated with faricimab achieved robust vision gains and improved CST across racial/ethnic subgroups and the overall study population

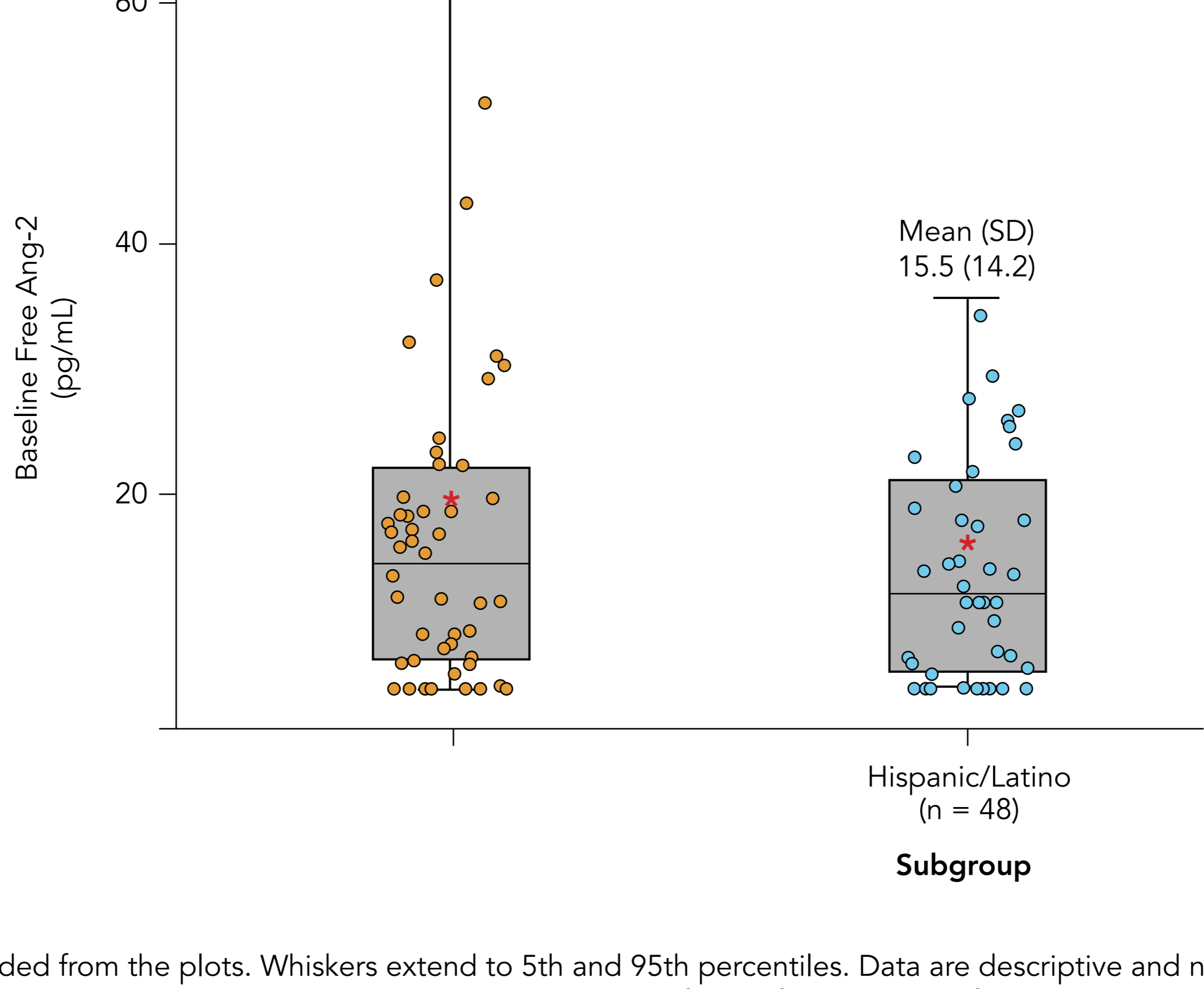


^aAdjusted mean change from baseline at week 56. ^bTreatment-naïve faricimab Q8W arm in YOSEMITE/RHINE. Patients who self-identify to >1 such grouping are only represented once in the overall US study population. MMRM was adjusted for visit and baseline BCVA (continuous) or baseline CST (continuous) as applicable. 124 patients were enrolled; however, 1 patient, who did not belong to a racial/ethnic group of focus in this trial, received treatment and was included in the safety population but not in the modified intention-to-treat population. 95% CI error bars are shown.

BCVA = best-corrected visual acuity; CI = confidence interval; CST = central subfield thickness; ETDRS = Early Treatment Diabetic Retinopathy Study; MMRM = mixed-effect model with repeated measures; Q8W = every 8 weeks.

Baseline aqueous humor Ang-2 concentrations were numerically higher on average in Black/African American patients vs Hispanic/Latino patients

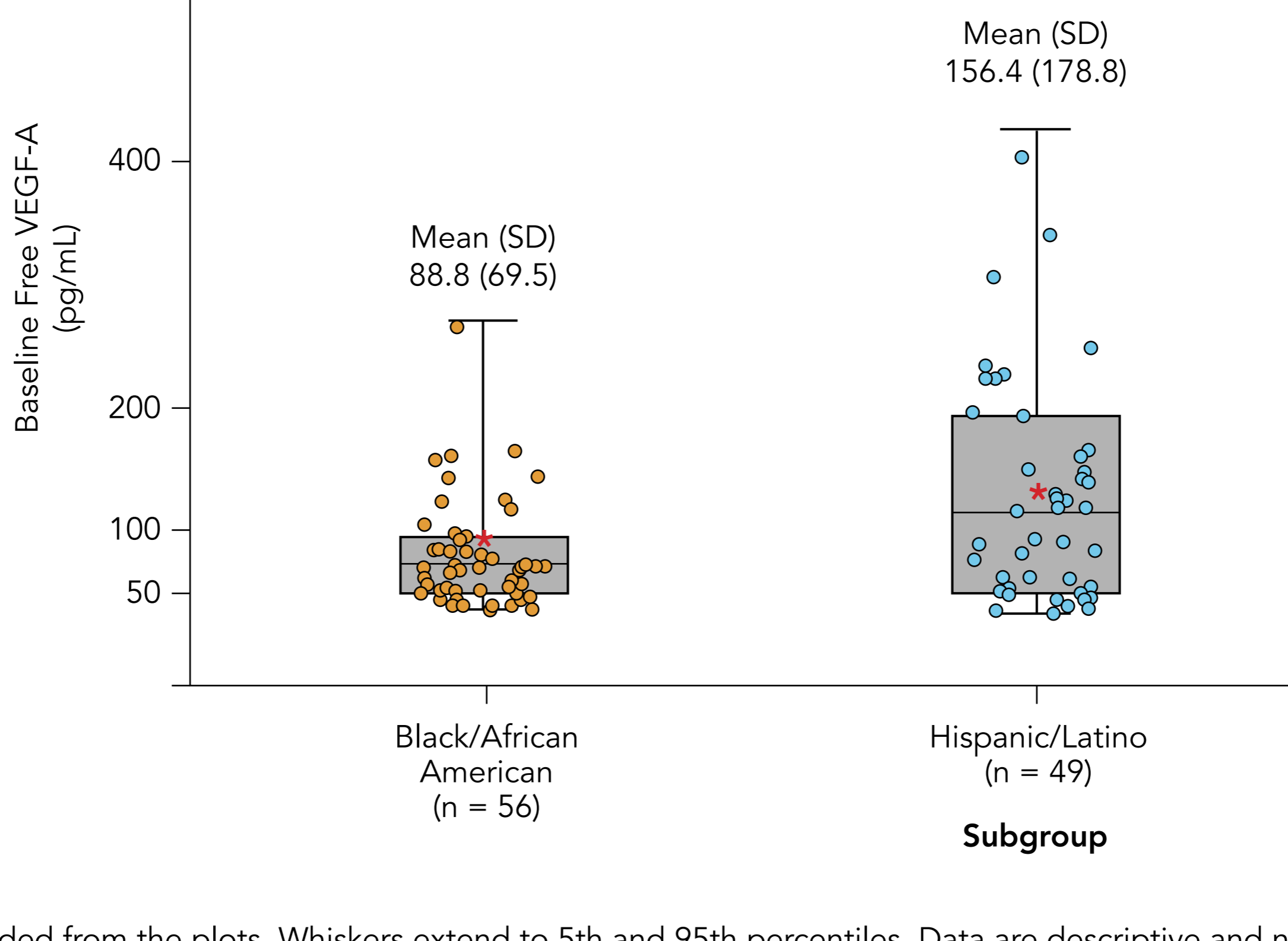
ELEVATUM: Post Hoc Analysis Aqueous Humor Levels



Outliers are excluded from the plots. Whiskers extend to 5th and 95th percentiles. Data are descriptive and no formal testing was performed. Does not include the Hispanic/Latino patient who self-identified as Black/African American. Ang-2 = angiopoietin-2; SD = standard deviation.

Baseline aqueous humor VEGF-A concentrations were numerically higher on average in Hispanic/Latino vs Black/African American patients

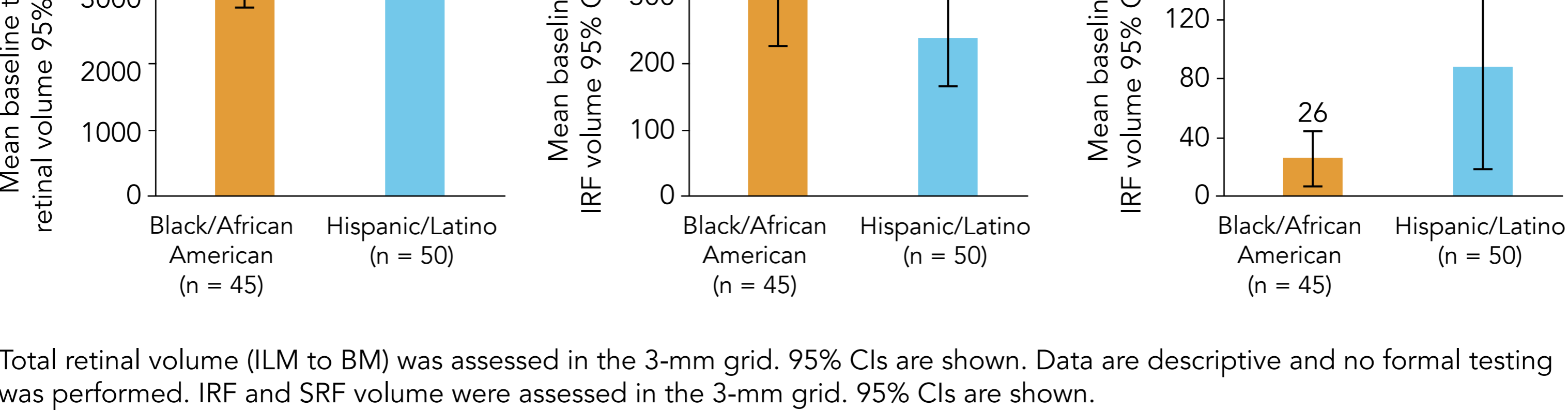
ELEVATUM: Post Hoc Analysis Aqueous Humor Levels



Outliers are excluded from the plots. Whiskers extend to 5th and 95th percentiles. Data are descriptive and no formal testing was performed. Does not include the Hispanic/Latino patient who self-identified as Black/African American. SD = standard deviation; VEGF-A = vascular endothelial growth factor A.

Mean baseline retinal volumes differed between Black/African American and Hispanic/Latino patients

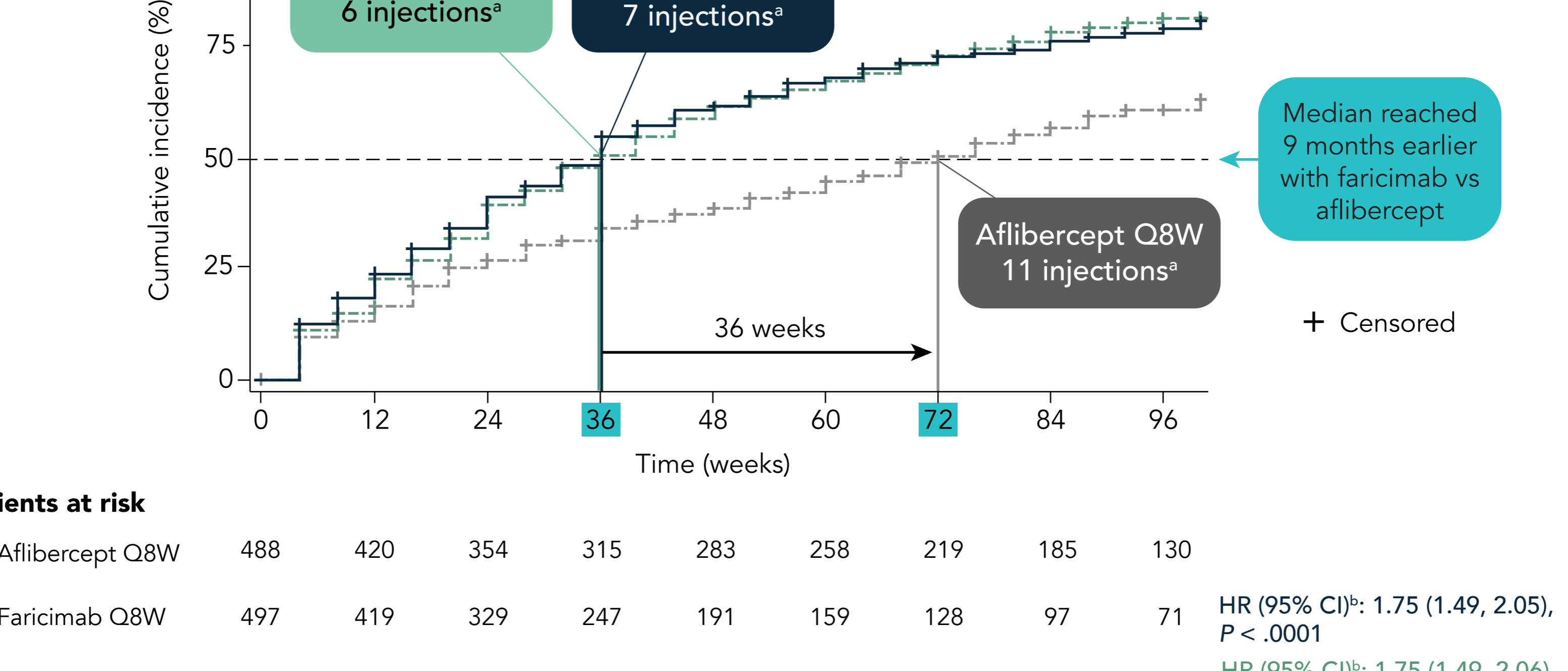
ELEVATUM: Post Hoc Analysis 3-mm Diameter



Total retinal volume (ILM to BM) was assessed in the 3-mm grid. 95% CIs are shown. Data are descriptive and no formal testing was performed. IRF and SRF volume were assessed in the 3-mm grid. 95% CIs are shown. BM = Bruch's membrane; CI = confidence interval; ILM, internal limiting membrane; IRF = intraretinal fluid; SRF = subretinal fluid.

Median time to first achievement of IRF volume <5 nL faster and with fewer injections with faricimab vs aflibercept 2 mg

YOSEMITE/RHINE Pooled: Post-Hoc Analysis 3-mm Diameter



Patients at risk	0	12	24	36	48	60	72	84	96
--- Aflibercept Q8W	488	420	354	315	283	258	219	185	130
— Faricimab Q8W	497	419	329	247	191	159	128	97	71
--- Faricimab T&E	503	408	321	249	186	153	129	112	79

Summaries of time to first achievement of IRF <5 nL are Kaplan-Meier estimates. Patients with IRF <5 nL at baseline and patients with no data at baseline were excluded from the analysis. P values are nominal and not adjusted for multiplicity; no formal statistical conclusion should be made based on the P values. Statistics for pairwise comparisons were calculated using a separate model for each comparison. HRs were estimated by Cox regression. Statistical analyses were stratified by baseline BCVA (<64 vs ≥64 letters), prior intravitreal anti-VEGF therapy (yes vs no), region (US and Canada, Asia and the rest of the world) and study (YOSEMITE vs RHINE). ^aThe median number of injections includes any active drug administered (faricimab or aflibercept), including medication errors. ^bResults from stratified analyses are presented for HR and log-rank test vs aflibercept. An HR >1 favors faricimab over aflibercept.

BCVA = best-corrected visual acuity; CI = confidence interval; ETDRS = Early Treatment Diabetic Retinopathy Study; HR = hazard ratio; IRF = intraretinal fluid; Q8W = every 8 weeks; T&E = treat-and-extend; VEGF = vascular endothelial growth factor.

Conclusion

- **Ang-2 and VEGF biomarker levels differed across racial/ethnic subgroups in patients with DME who are historically underrepresented in ophthalmology trials**
- **Patients treated with faricimab achieved robust vision gains and improved CST across racial/ethnic subgroups and the overall study population**
- **Support ongoing efforts toward precision medicine by exploring associations between:**
 - Baseline biomarkers and disease pathophysiology
 - Ang-2 and exudates
 - Change in biomarkers over time and disease resolution
- **Faricimab was well tolerated, with a safety profile that was consistent with YOSEMITE/RHINE**