Aflibercept 8 mg in macular edema following retinal vein occlusion: Week 64 results from the QUASAR trial

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Disclosures

- **Varun Chaudhary** is a consultant for EyePoint Pharmaceuticals; grants from Bayer, Novartis, and Roche; and serves on advisory boards for Apellis, Bayer, Boehringer Ingelheim, EyePoint Pharmaceuticals, Novartis, and Roche
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- This study included research conducted on human patients. Institutional Review Board/Institutional Ethics Committee approval was obtained prior to study initiation
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QUASAR: Study Design

A multicenter, randomized, double-masked, Phase 3 study in patients with treatment-naïve macular edema secondary to RVO
Randomly assigned at baseline 1 (2q4) : 1 (8q8/3) : 1 (8q8/5)

2q4
Aflibercept 2 mg initiated with 9 monthly injections followed by T&E[a]
n=301

8q8/3
Aflibercept 8 mg initiated with 3 monthly injections, followed by Q8 and T&E[a]
n=293

8q8/5
Aflibercept 8 mg initiated with 5 monthly injections, followed by Q8 and T&E[a]
n=298

	Day 1	W4	W8	W12	W16	W20	W24	W28	W32	W36 (Primary endpoint)	W40	W44	W48	W52	W56	W60	W64 (EOS Key secondary endpoint)
2q4	X	X	X	X	X	X	X	X	X	T&E	T&E	T&E	T&E	T&E	T&E	T&E	
8q8/3	X	X	X	o	X	o[b]	X	o[c]	X	T&E	T&E	T&E	T&E	T&E	T&E	T&E	
8q8/5	X	X	X	X	X	o	X	o[c]	X	o[d]	X	T&E	T&E	T&E	T&E	T&E	

DRM for interval shortening

Dosing interval shortened by 4 weeks if the last dosing interval was >4 weeks and both the following criteria were met at a dosing visit:

- BCVA loss of >5 letters from the reference visit, AND
- >50 µm increase in CRT from the reference visit[e]

DRM for interval extension

Dosing interval extended by 4 weeks starting at Week 32 for 8q8/3 and 2q4 and at Week 40 for 8q8/5 if both the following criteria were met at a dosing visit:

- BCVA loss of <5 letters from the reference visit[e], AND
- CRT <320 µm Heidelberg/<300 µm Cirrus or Topcon SD-OCT

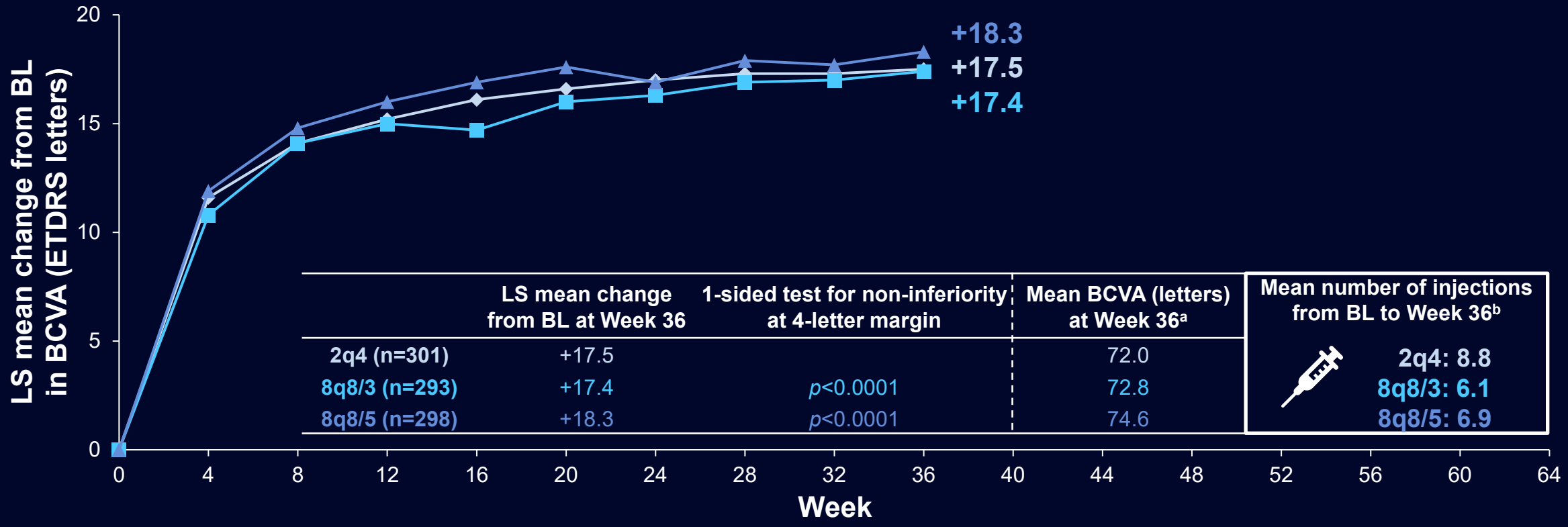
The primary efficacy endpoint was change from baseline in BCVA at Week 36, with a non-inferiority margin of 4 letters. Stippled boxes = initial treatment phase; X = active injection; o = sham injection. Note: Table does not reflect all dosing options once a patient's dosing interval is shortened. [a]With opportunity for extension per DRM. [b]Active injection for patients meeting DRM criteria at Week 16. [c]Active injection for patients meeting DRM criteria at Week 16 or 24. [d]Active injection for patients meeting DRM at Weeks 16, 24, or 32. [e]Reference is Week 12 for 8q8/3 and Week 20 for 8q8/5 and 2q4 (denoted by green boxes on table).
2q4, aflibercept 2 mg administered every 4 weeks; **8q8/3**, aflibercept 8 mg administered every 8 weeks, after 3 initial injections at 4-week intervals; **8q8/5**, aflibercept 8 mg administered every 8 weeks, after 5 initial injections at 4-week intervals; **BCVA**, best-corrected visual acuity; **CRT**, central subfield retinal thickness; **DRM**, dose-regimen modification; **EOS**, end of study; Q8, every 8 weeks; **RVO**, retinal vein occlusion; **SD-OCT**, spectral-domain optical coherence tomography; **T&E**, treat and extend; **W**, week.

Patient Disposition and Baseline Characteristics

	2q4 (n=301)	8q8/3 (n=293)	8q8/5 (n=298)	Total (n=892)
Patients completing Week 36, n (%)	287 (95.0)	278 (94.6)	273 (91.6)	838 (93.7)
Patients completing Week 64, n (%)	270 (89.4)	269 (91.5)	256 (85.9)	795 (88.9)
Age, years	65.9 (11.7)	65.8 (11.5)	65.8 (11.5)	65.9 (11.6)
Female, n (%)	144 (47.8)	136 (46.4)	146 (49.0)	426 (47.8)
RVO type, n (%)[a]				
BRVO	149 (49.5)	159 (54.3)	159 (53.4)	467 (52.4)
CRVO	117 (38.9)	99 (33.8)	102 (34.2)	318 (35.7)
HRVO	35 (11.6)	35 (11.9)	37 (12.4)	107 (12.0)
BCVA, ETDRS letters	54.1 (14.3)	55.2 (13.6)	55.4 (13.4)	54.9 (13.8)
CRT, µm	651 (240)	626 (230)	609 (213)	629 (229)

Full analysis set. Data are mean (SD) unless otherwise indicated. [a]Reading center assessed.
BRVO, branch retinal vein occlusion; **CRVO**, central retinal vein occlusion; **ETDRS**, Early Treatment Diabetic Retinopathy Study; **HRVO**, hemiretinal vein occlusion; **SD**, standard deviation.

Primary Endpoint at Week 36: Both Aflibercept 8 mg Arms Achieved Non-inferior BCVA Gains Compared with Aflibercept 2 mg at Week 36, with Fewer Injections



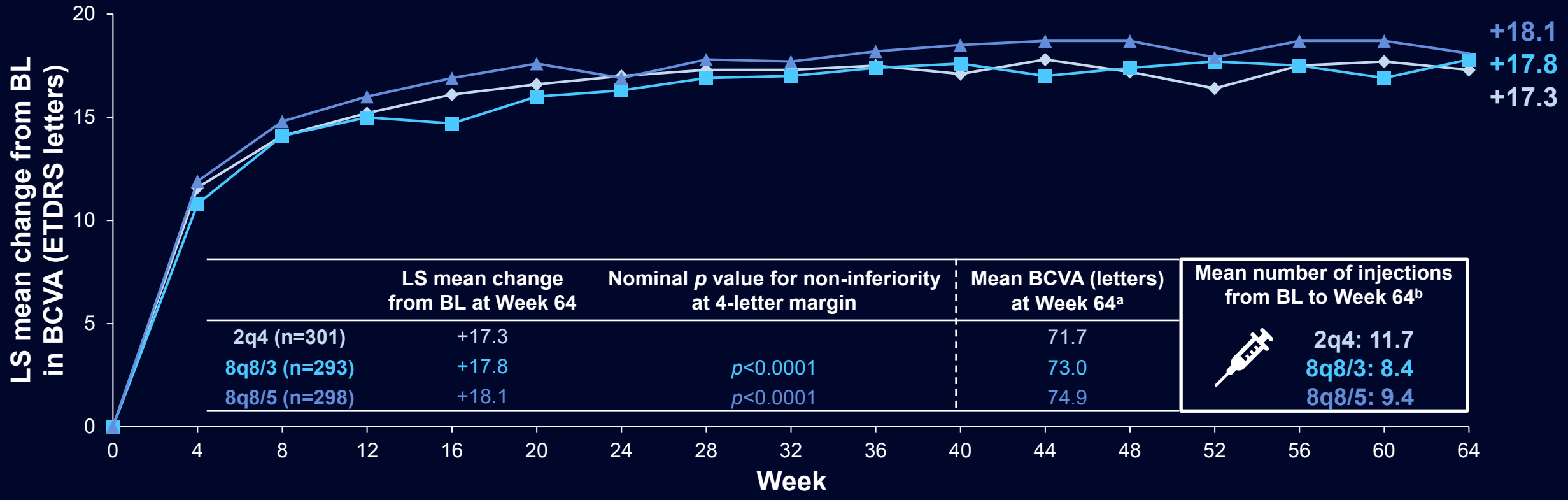
	LS mean change from BL at Week 36	1-sided test for non-inferiority at 4-letter margin	Mean BCVA (letters) at Week 36[a]
2q4 (n=301)	+17.5		72.0
8q8/3 (n=293)	+17.4	*p*<0.0001	72.8
8q8/5 (n=298)	+18.3	*p*<0.0001	74.6

Mean number of injections from BL to Week 36[b]

2q4: 8.8
8q8/3: 6.1
8q8/5: 6.9

Full analysis set. LS means were generated using a mixed model for repeated measures with baseline BCVA as a covariate. The fixed factors were treatment arm (aflibercept 8q8/3, 8q8/5, or 2q4), visit, and stratification variables: geographic region (Japan, Asian-Pacific, Europe, or America), BL BCVA (<60 vs ≥60 letters), and RVO type (CRVO/HRVO vs BRVO). The model also included terms for the interactions between BL BCVA and visit, and between treatment and visit. [a]Observed values (censoring data post intercurrent event). [b]Patients completing Week 36.
BL, baseline; **LS**, least squares.

Aflibercept 8 mg Arms Continued to Maintain Robust Improvements in BCVA Through Week 64



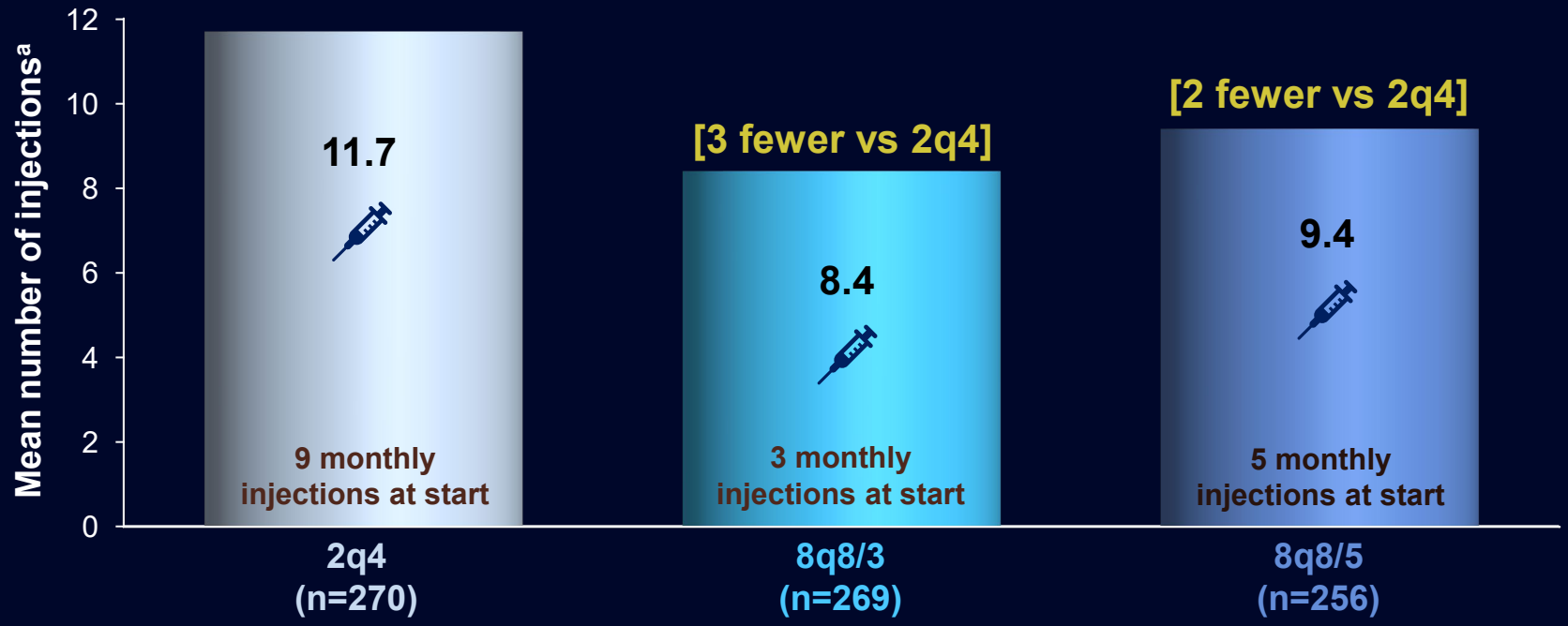
	LS mean change from BL at Week 64	Nominal *p* value for non-inferiority at 4-letter margin	Mean BCVA (letters) at Week 64[a]
2q4 (n=301)	+17.3		71.7
8q8/3 (n=293)	+17.8	*p*<0.0001	73.0
8q8/5 (n=298)	+18.1	*p*<0.0001	74.9

Mean number of injections from BL to Week 64[b]

2q4: 11.7
8q8/3: 8.4
8q8/5: 9.4

Full analysis set. LS means were generated using a mixed model for repeated measures with baseline BCVA as a covariate. The fixed factors were treatment arm (aflibercept 8q8/3, 8q8/5, or 2q4), visit, and stratification variables: geographic region (Japan, Asian-Pacific, Europe, or America), BL BCVA (<60 vs ≥60 letters), and RVO type (CRVO/HRVO vs BRVO). The model also included terms for the interactions between BL BCVA and visit, and between treatment and visit. [a]Observed values (censoring data post intercurrent event). [b]Observed values, patients completing Week 64.

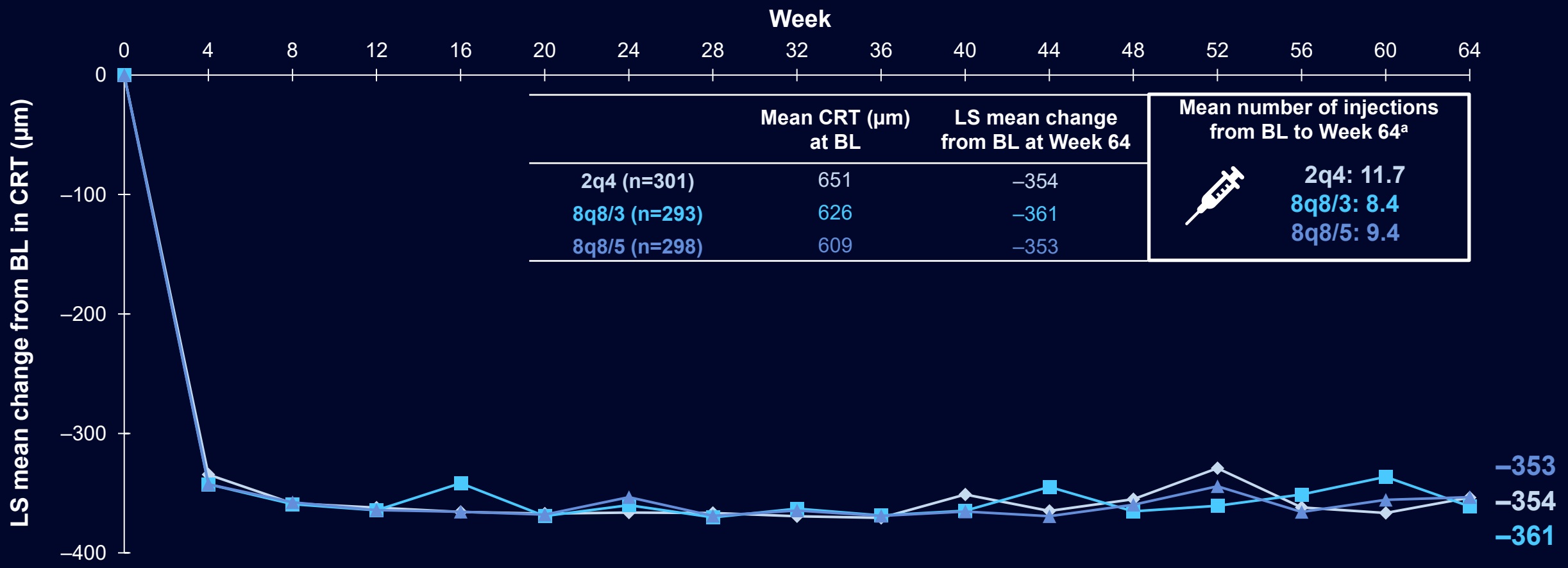
Key Secondary Efficacy Endpoint at Week 64: Significantly Fewer Number of Active Injections with Aflibercept 8 mg Compared with Aflibercept 2 mg



	LS mean (SE)	Difference vs 2q4 (95% CI)	*p* value
2q4 (n=301)	11.7 (0.1)		
8q8/3 (n=293)	8.5 (0.1)	−3.2 (−3.5, −3.0)	<0.0001
8q8/5 (n=298)	9.5 (0.1)	−2.2 (−2.4, −2.0)	<0.0001

Full analysis set. Missing endpoint values imputed using a multiple imputation procedure. Based on a linear regression model (LS means and CI) and a non-parametric rank analysis of covariance (*p* value), adjusted for BL BCVA, BL CRT, and stratification variables (geographic region [Japan, Asia-Pacific, Europe, or America], BCVA score [>60 vs ≥60 letters], RVO type [CRVO/HRVO vs BRVO]), within the multiple imputation procedure. [a]Full analysis set. Observed cases, patients completing Week 64.
CI, confidence interval; **SE**, standard error.

Aflibercept 8 mg Arms Maintained Robust Anatomic Improvements Through Week 64, with Significantly Fewer Injections Compared with Aflibercept 2 mg



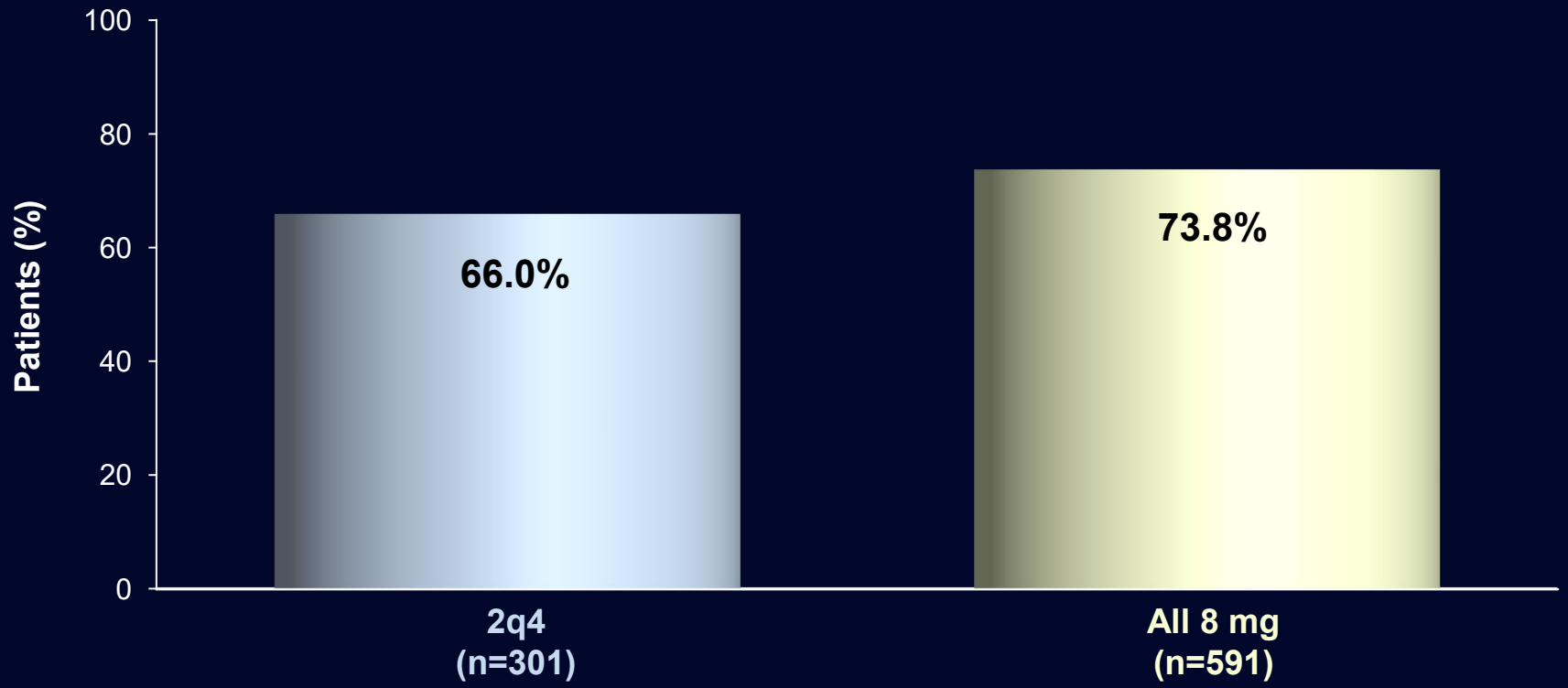
	Mean CRT (µm) at BL	LS mean change from BL at Week 64
2q4 (n=301)	651	–354
8q8/3 (n=293)	626	–361
8q8/5 (n=298)	609	–353

Mean number of injections from BL to Week 64[a]

2q4: 11.7
8q8/3: 8.4
8q8/5: 9.4

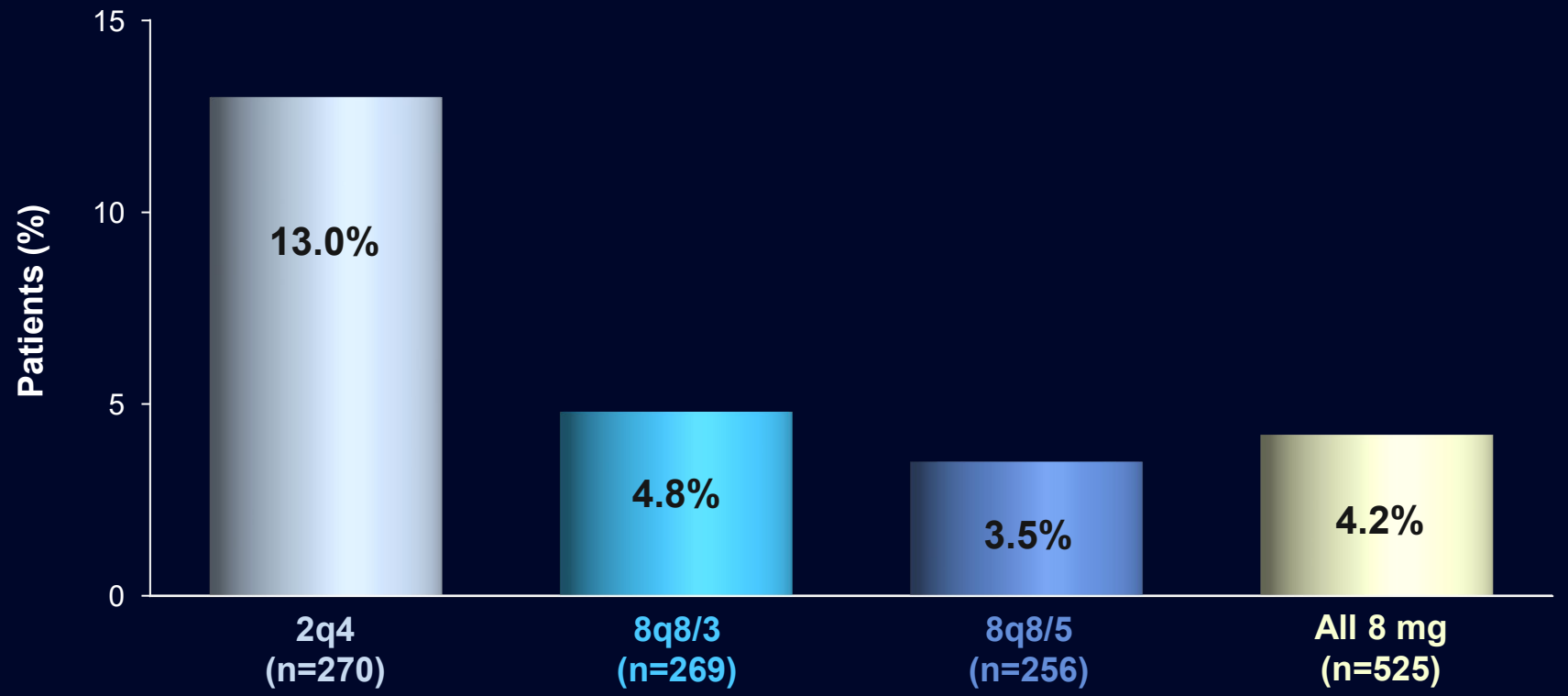
Full analysis set. LS means were generated using a mixed model for repeated measures was used with BL CRT measurement as a covariate, treatment arm, visit, and the stratification variables: geographic region (Japan, Asia–Pacific, Europe, or America), baseline BCVA (<60 vs ≥60 letters), and RVO type (CRVO/HRVO vs BRVO) as fixed factors. The model also included terms for the interactions between BL CRT and visit, and between treatment and visit. [a]Observed values, patients completing Week 64.

More Patients Treated with Aflibercept 8 mg Versus 2 mg Were Fluid-Free in the Central Subfield, with Fewer Injections at Week 64



Full analysis set. Observed values (censoring data post intercurrent event).
Fluid resolution defined as no IRF and no SRF in central subfield.
IRF, intraretinal fluid; **SRF**, subretinal fluid.

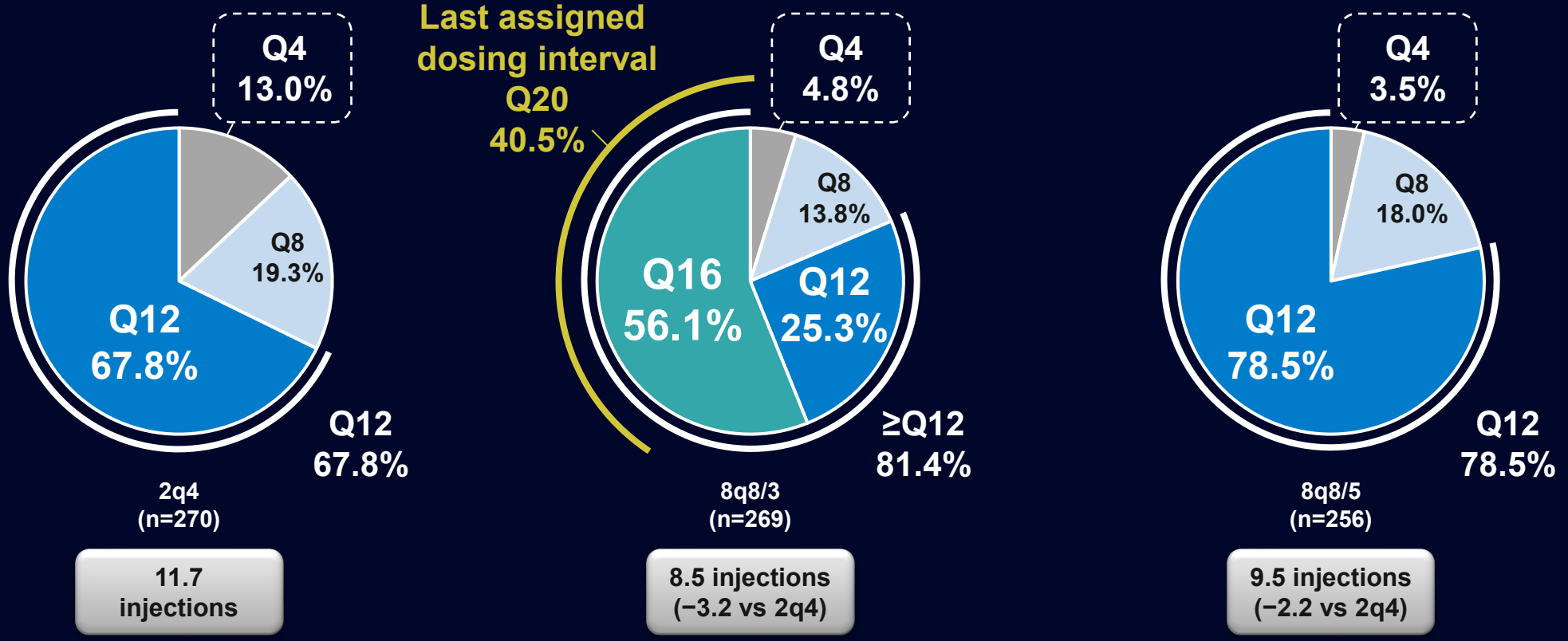
Last Completed Dosing Interval at Week 64: Proportion of Patients Requiring Q4 Dosing



~3 times fewer patients completed the study on a Q4 dosing interval with aflibercept 8 mg versus 2 mg, despite the ability for all patients to be treated at extended intervals

Full analysis set. Patients completing Week 64. Dosing intervals could be extended by 4 weeks starting at Week 32 for 8q8/3 and 2q4, and at Week 40 for 8q8/5 if DRM were met.
Q4, every 4 weeks.

Last Completed Dosing Intervals at Week 64



80% of patients treated with aflibercept 8 mg had a last completed interval of Q12 or longer

~3 times fewer patients needed to stay at Q4 with aflibercept 8 mg versus 2 mg

40.5% of patients in the 8q8/3 arm had a last assigned dosing interval of Q20

Full analysis set. Patients completing Week 64. Per study design, extension was possible starting from Week 32 with 2q4 and 8q8/3 and from Week 40 with 8q8/5.
Q12, every 12 weeks; **Q16**, every 16 weeks; **Q20**, every 20 weeks.

Ocular and Non-ocular Safety Through Week 64

	2q4 (n=301)	8q8/3 (n=293)	8q8/5 (n=298)	All 8 mg (n=591)
Ocular TEAEs in the study eye, %	42.2	45.7	39.6	42.6
Serious ocular TEAEs in the study eye, %	2.7	1.7	1.7	1.7
Intraocular inflammation in the study eye, %	1.7	1.4	0.7	1.0
Anterior chamber cell	0.3	0	0	0
Eye inflammation	0.3	0	0	0
Iritis	0	0.3	0	0.2
Uveitis	0	0	0.7	0.3
Vitritis	0	0.7	0	0.3
Endophthalmitis	1.0	0.3	0	0.2
Serious non-ocular TEAEs, %	12.0	11.3	11.1	11.2
APTC events, %	2.0	0.7	2.3	1.5
Deaths, %	1.0	0.7	1.7	1.2

Aflibercept 8 mg was consistent with the established safety profile of aflibercept 2 mg and 8 mg

The most common ocular TEAEs overall were cataract, intraocular pressure increase, visual acuity reduced, and conjunctival haemorrhage

Safety analysis set.
APTC, Anti-Platelet Trialists' Collaboration; **TEAE**, treatment-emergent adverse event.

Summary of Key 64-week Results from QUASAR

Efficacy

- **Improvements in BCVA and CRT** achieved at Week 36 were **maintained through Week 64** across all treatment groups with **up to 3.2 fewer injections** with aflibercept 8 mg compared with aflibercept 2 mg
- At Week 64, **more patients treated with aflibercept 8 mg were fluid-free** in the central subfield compared with those on aflibercept 2 mg

Dosing intervals

- **Approximately 80%** of patients treated with aflibercept 8 mg achieved **dosing intervals of ≥Q12 weeks**, with 41% of those in the 8q8/3 arm being assigned to Q20 dosing intervals at Week 64
- Nearly 3-fold **fewer patients required Q4 dosing** with aflibercept 8 mg at Week 64, despite patients on aflibercept 2 mg having the opportunity to extend dosing intervals

Safety

- Safety data of aflibercept 8 mg in patients with RVO from QUASAR through Week 64 were **comparable to the known safety profile** of aflibercept 2 mg and 8 mg

The QUASAR group wishes to thank all patients and investigators of the QUASAR trial