Impact of baseline diabetes or hypertension on visual and anatomic outcomes among patients with treatment-naïve macular edema following retinal vein occlusion treated with aflibercept 8 mg versus 2 mg: A Week 64 QUASAR post hoc analysis

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on behalf of the QUASAR study investigators

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Disclosures

- **Christiana Dinah** serves as a speaker and/or consultant for AbbVie, Alimera Sciences, Apellis, Bayer, Boehringer Ingelheim, Eyepoint, Johnson & Johnson, Ocular Therapeutix, 4DMT and Roche; and has received grant funding from Apellis, Roche and Boehringer Ingelheim
  - **RPG** is a consultant for AbbVie, Advanz, Apellis, Astellas, Bayer, Biogen, Boehringer Ingelheim, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche; and has received grant funding from Bayer, Heidelberg Engineering, and Roche. **SMH** is a consultant or a member of the Speakers Bureau for AbbVie, Alimera Sciences/ANI, Astellas, Bayer, Biogen, Harrow, Iveric Bio, Regeneron Pharmaceuticals, Inc., and Sun Pharma. **VC** is a consultant for EyePoint Pharmaceuticals; has received grants from Bayer, Novartis, and Roche; and serves on advisory boards for Apellis, Bayer, Boehringer Ingelheim, EyePoint Pharmaceuticals, Novartis, and Roche. **YC** serves as a speaker for AbbVie, Bayer, Chengdu Kanghong, Novartis, and Roche. **AC** is a consultant for Alcon, Apellis, Astellas, Bayer, Boehringer Ingelheim, Novartis, Opthea, Roche, and Zeiss; and has received grant funding from Bayer, Novartis, and Roche. **MK** receives financial support from Alcon Japan, Hoya Surgical Optics, Otsuka Pharmaceutical, Santen, and Senju; and receives compensation or travel expenses from Alcon Japan, Bayer, Chugai, Hoya Surgical Optics, Kowa, Santen, Senju, and Wakamoto Pharma; and consulting fees from Chugai, Daicel, Hoya Surgical Optics, Senju, and Sony. **RoG** is an employee of Bayer Consumer Care AG. **TC** is an employee of Bayer plc. **SS, TM,** and **TN** are employees of Bayer AG. **FQS** is an employee of Regeneron Pharmaceuticals, Inc. **SL** is an employee, investor, and patent holder at Bayer Consumer Care AG
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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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- The QUASAR group wishes to thank all patients and investigators of the QUASAR trial

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

Primary endpoint

EOS Key secondary endpoint

	Day 1	W4	W8	W12	W16	W20	W24	W28	W32	W36	W40	W44	W48	W52	W56	W60	W64
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[c]	X	T&E	T&E	T&E	T&E	T&E	

DRM for interval shortening

Dosing interval shortened by 4 weeks beginning at Week 16 for 8q8/3, Week 24 for 8q8/5, or Week 40 for 2q4 if 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[d]

DRM for interval extension

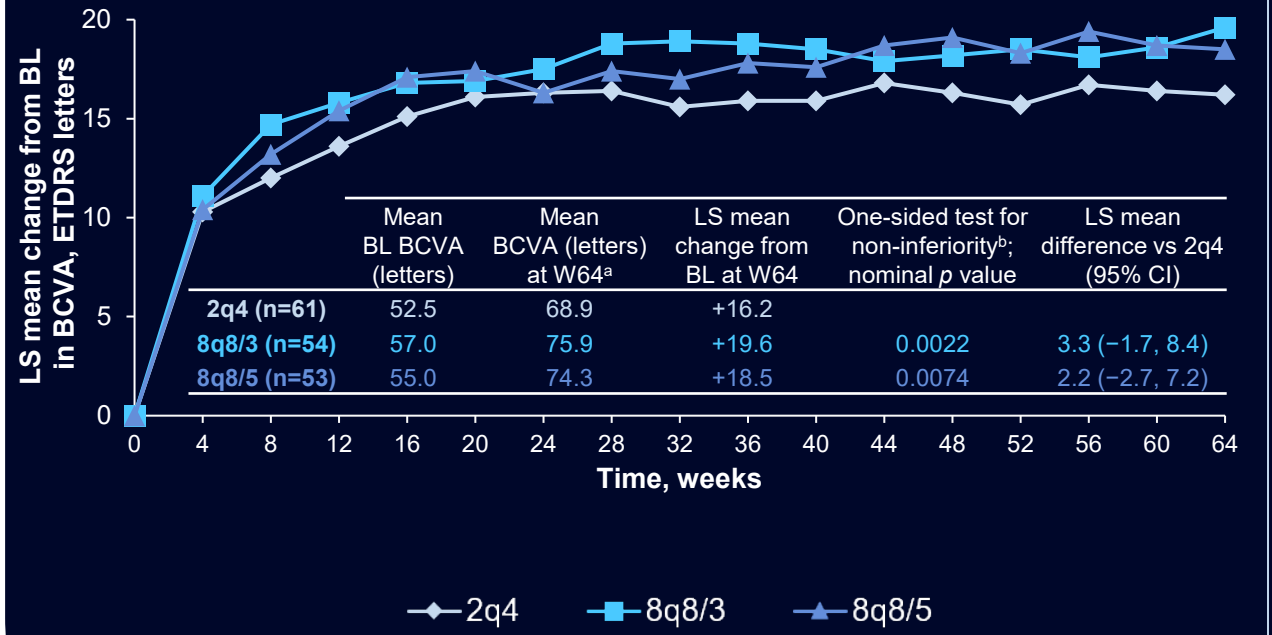
Dosing interval extended by 4 weeks starting at Week 32 for 8q8/3 and 2q4 and at Week 40 for 8q8/5 if both the following criteria were met at a dosing visit:

- BCVA loss of <5 letters from the reference visit,[d] 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. In this exploratory post hoc analysis, the least squares mean change from baseline in BCVA and CRT, and the number of injections were evaluated for each RVO subtype by baseline diabetes or hypertension. 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 from Week 16 for 8q8/3 or Week 24 for 8q8/5. [d]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.

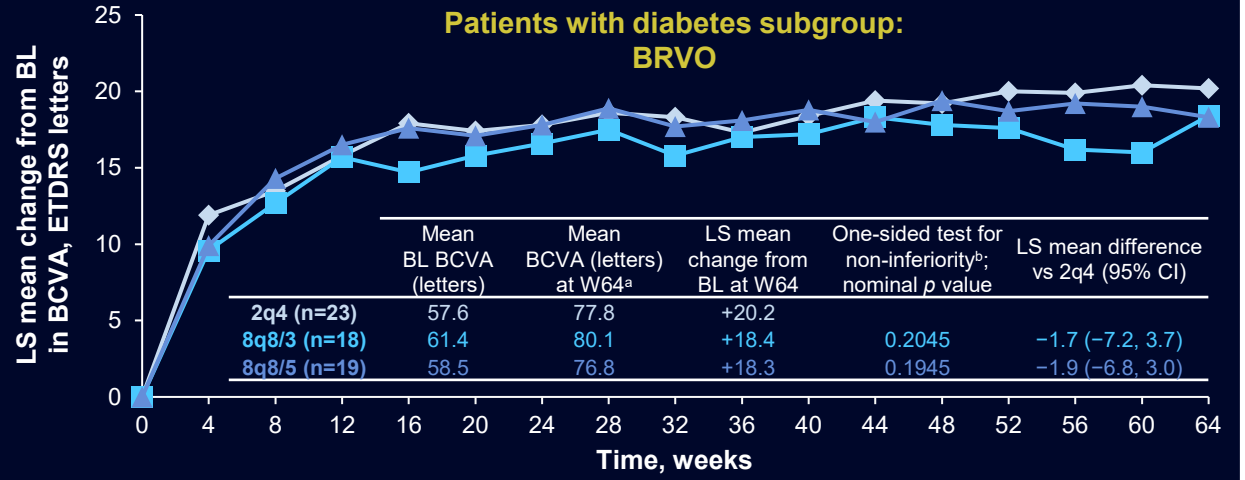
Aflibercept 8 mg Groups Showed Robust Visual Improvements Through W64 in Patients with Diabetes, with Similar Findings Across RVO Subtypes

Patients with diabetes subgroup: Overall RVO population



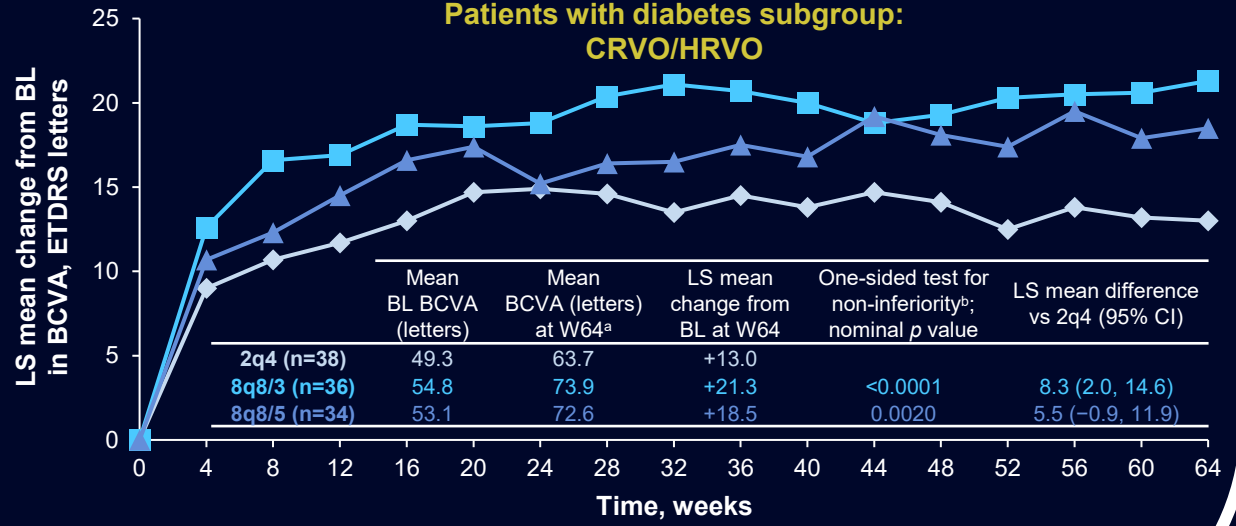
	Mean BL BCVA (letters)	Mean BCVA (letters) at W64[a]	LS mean change from BL at W64	One-sided test for non-inferiority[b]; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=61)	52.5	68.9	+16.2		
8q8/3 (n=54)	57.0	75.9	+19.6	0.0022	3.3 (−1.7, 8.4)
8q8/5 (n=53)	55.0	74.3	+18.5	0.0074	2.2 (−2.7, 7.2)

Patients with diabetes subgroup: BRVO



	Mean BL BCVA (letters)	Mean BCVA (letters) at W64[a]	LS mean change from BL at W64	One-sided test for non-inferiority[b]; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=23)	57.6	77.8	+20.2		
8q8/3 (n=18)	61.4	80.1	+18.4	0.2045	−1.7 (−7.2, 3.7)
8q8/5 (n=19)	58.5	76.8	+18.3	0.1945	−1.9 (−6.8, 3.0)

Patients with diabetes subgroup: CRVO/HRVO

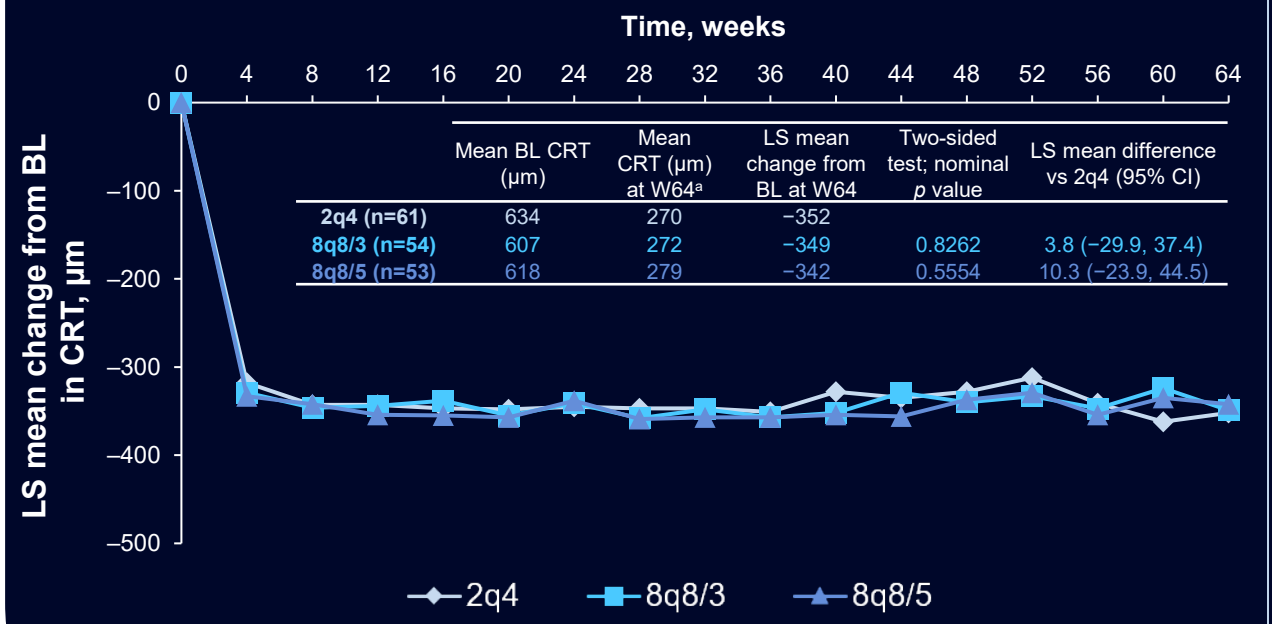


	Mean BL BCVA (letters)	Mean BCVA (letters) at W64[a]	LS mean change from BL at W64	One-sided test for non-inferiority[b]; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=38)	49.3	63.7	+13.0		
8q8/3 (n=36)	54.8	73.9	+21.3	<0.0001	8.3 (2.0, 14.6)
8q8/5 (n=34)	53.1	72.6	+18.5	0.0020	5.5 (−0.9, 11.9)

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 group (aflibercept 8q8/3, 8q8/5, 2q4); visit; and stratification variables: geographic region (Japan, Asia-Pacific, Europe, America), BL BCVA (<60 vs ≥60 letters), and, for the overall RVO population analysis only, RVO type (CRVO/HRVO vs BRVO). The model also included terms for the interactions between baseline BCVA and visit, and between treatment and visit. [a]Observed values (censoring data post intercurrent event); [b](4 letters).
BL, baseline; BRVO, branch retinal vein occlusion; **CI**, confidence interval; CRVO/HRVO, central/hemi retinal vein occlusion; **ETDRS**, Early Treatment Diabetic Retinopathy Study; **LS**, least squares.

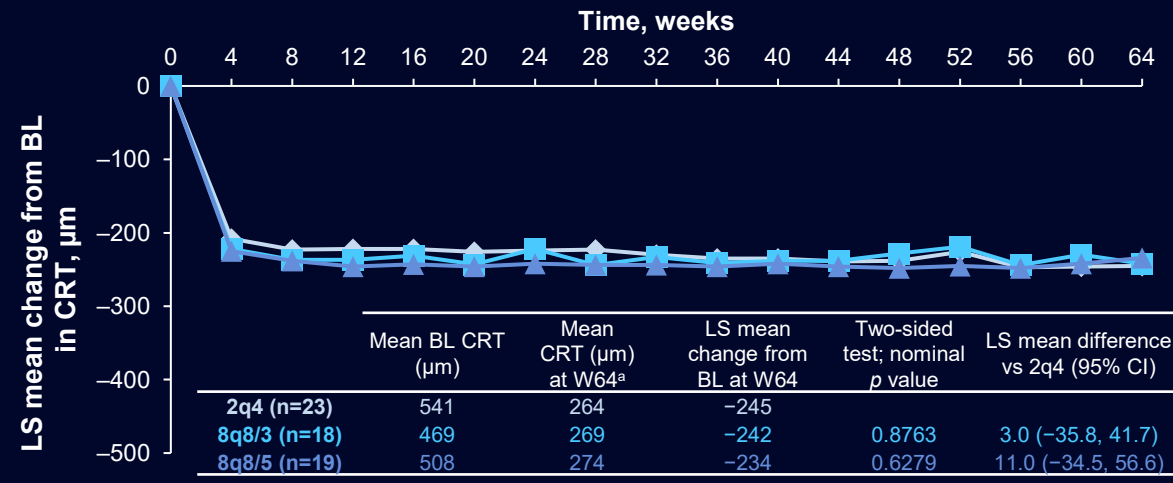
Aflibercept 8 mg Groups Showed Robust Anatomic Improvements Through W64 in Patients with Diabetes, with Similar Findings Across RVO Subtypes

Patients with diabetes subgroup: Overall RVO population



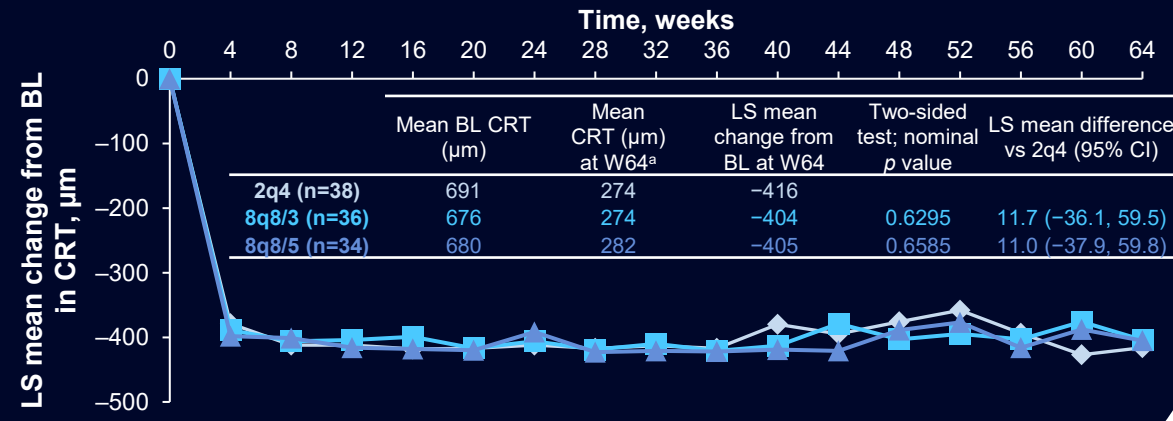
	Mean BL CRT (µm)	Mean CRT (µm) at W64[a]	LS mean change from BL at W64	Two-sided test; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=61)	634	270	−352		
8q8/3 (n=54)	607	272	−349	0.8262	3.8 (−29.9, 37.4)
8q8/5 (n=53)	618	279	−342	0.5554	10.3 (−23.9, 44.5)

Patients with diabetes subgroup: BRVO



	Mean BL CRT (µm)	Mean CRT (µm) at W64[a]	LS mean change from BL at W64	Two-sided test; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=23)	541	264	−245		
8q8/3 (n=18)	469	269	−242	0.8763	3.0 (−35.8, 41.7)
8q8/5 (n=19)	508	274	−234	0.6279	11.0 (−34.5, 56.6)

Patients with diabetes subgroup: CRVO/HRVO

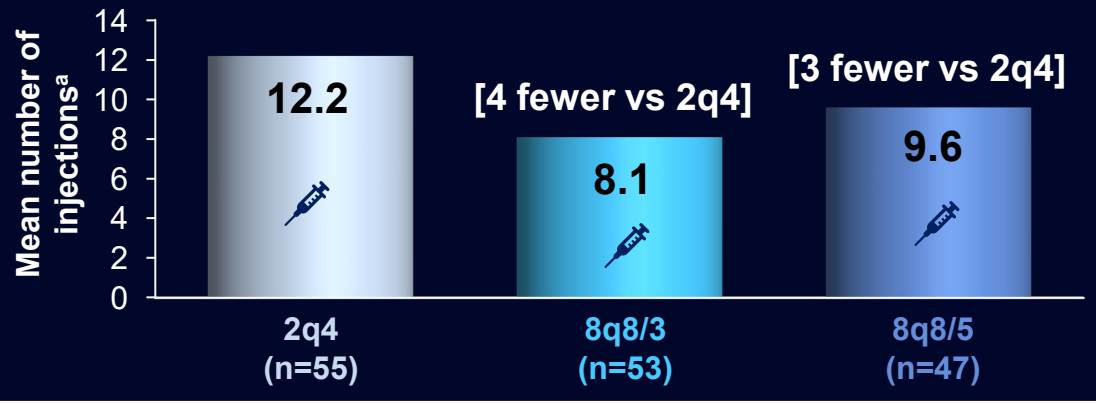


	Mean BL CRT (µm)	Mean CRT (µm) at W64[a]	LS mean change from BL at W64	Two-sided test; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=38)	691	274	−416		
8q8/3 (n=36)	676	274	−404	0.6295	11.7 (−36.1, 59.5)
8q8/5 (n=34)	680	282	−405	0.6585	11.0 (−37.9, 59.8)

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

Fewer Active Injections with Aflibercept 8 mg Versus Aflibercept 2 mg in Patients with Diabetes, with Similar Findings Across the CRVO/HRVO Subtype

Patients with diabetes subgroup: Overall RVO population



	LS mean difference vs 2q4 (95% CI)	Nominal *p* value[b]
2q4 (n=61)		
8q8/3 (n=54)	−4.0 (−4.5, −3.5)	<0.0001
8q8/5 (n=53)	−2.5 (−3.0, −1.9)	<0.0001

Patients with diabetes subgroup: BRVO



	LS mean difference vs 2q4 (95% CI)	Nominal *p* value
No convergence met[c]		

Patients with diabetes subgroup: CRVO/HRVO

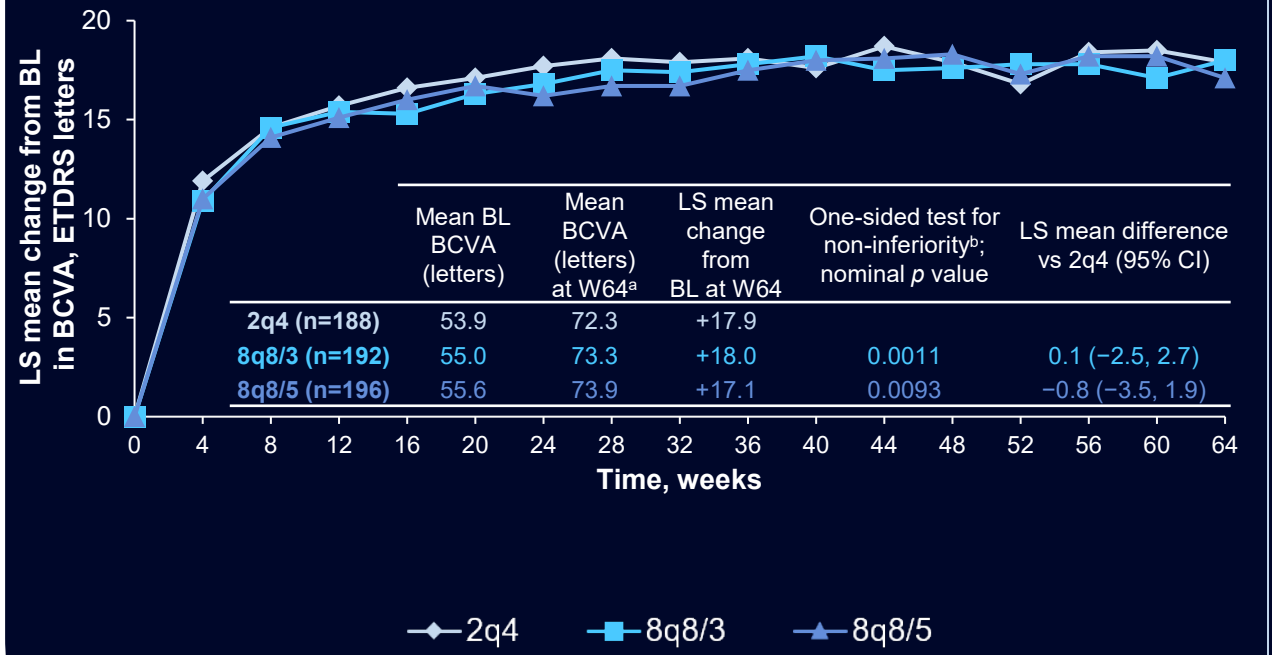


	LS mean difference vs 2q4 (95% CI)	Nominal *p* value[b]
2q4 (n=38)		
8q8/3 (n=36)	−4.1 (−4.8, −3.4)	<0.0001
8q8/5 (n=34)	−2.5 (−3.3, −1.6)	<0.0001

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], and, for the overall RVO population analysis only, RVO type (CRVO/HRVO vs BRVO), within the multiple imputation procedure. [a]Full analysis set. Observed cases, patients completing Week 64. [b]*p* values were calculated for LS means. [c]Sample size was too small (less than 20) to generate results.

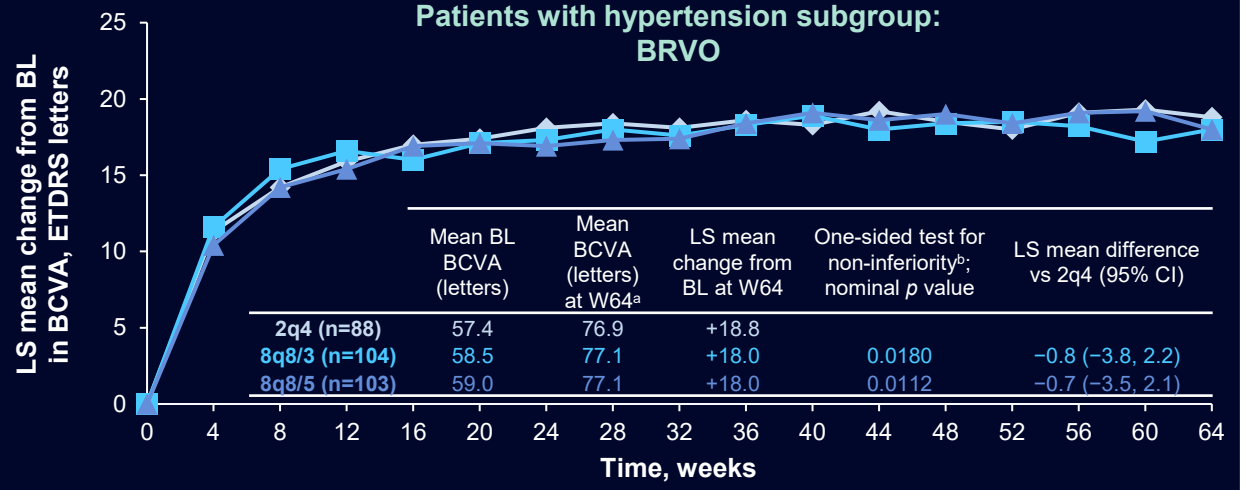
Aflibercept 8 mg Groups Showed Robust Visual Improvements Through W64 in Patients with Hypertension, with Similar Findings Across RVO Subtypes

Patients with hypertension subgroup: Overall RVO population



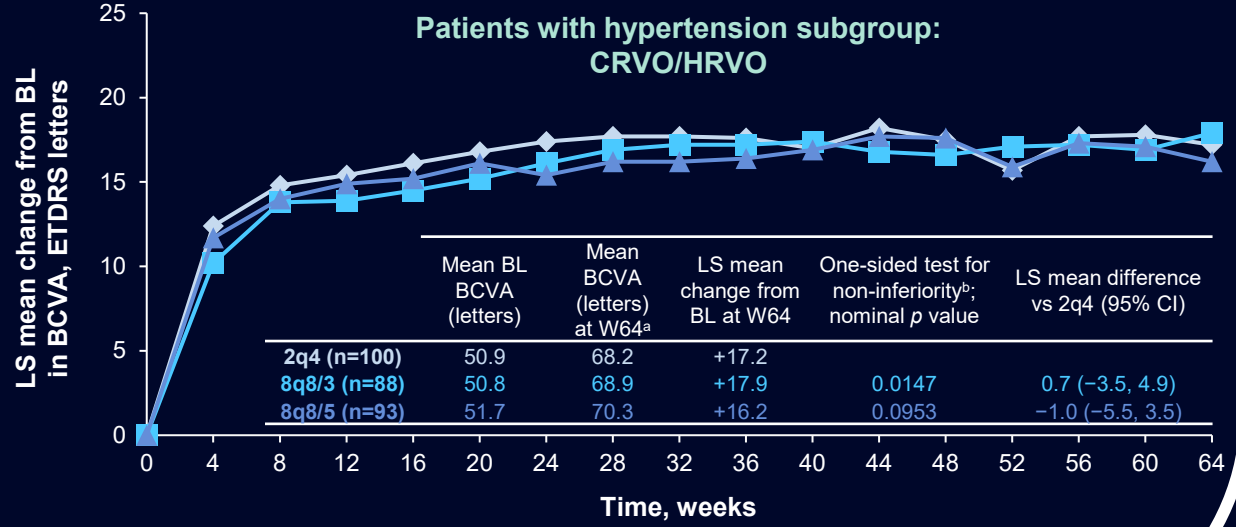
	Mean BL BCVA (letters)	Mean BCVA (letters) at W64[a]	LS mean change from BL at W64	One-sided test for non-inferiority[b]; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=188)	53.9	72.3	+17.9		
8q8/3 (n=192)	55.0	73.3	+18.0	0.0011	0.1 (−2.5, 2.7)
8q8/5 (n=196)	55.6	73.9	+17.1	0.0093	−0.8 (−3.5, 1.9)

Patients with hypertension subgroup: BRVO



	Mean BL BCVA (letters)	Mean BCVA (letters) at W64[a]	LS mean change from BL at W64	One-sided test for non-inferiority[b]; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=88)	57.4	76.9	+18.8		
8q8/3 (n=104)	58.5	77.1	+18.0	0.0180	−0.8 (−3.8, 2.2)
8q8/5 (n=103)	59.0	77.1	+18.0	0.0112	−0.7 (−3.5, 2.1)

Patients with hypertension subgroup: CRVO/HRVO

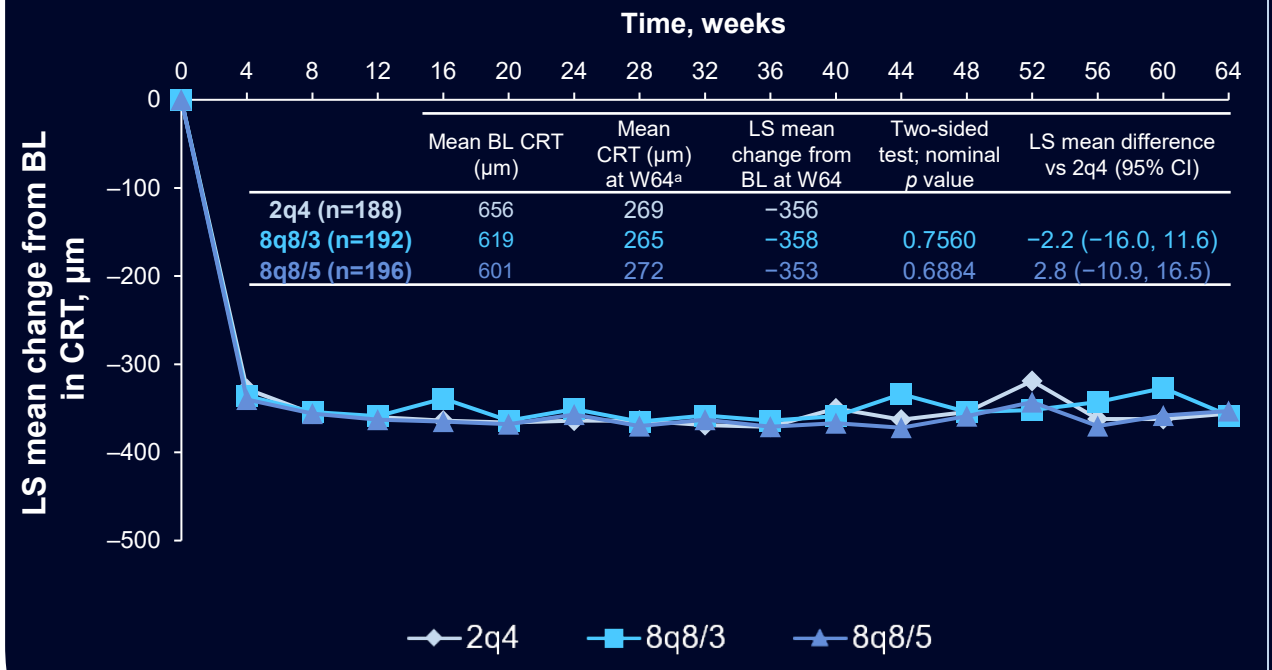


	Mean BL BCVA (letters)	Mean BCVA (letters) at W64[a]	LS mean change from BL at W64	One-sided test for non-inferiority[b]; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=100)	50.9	68.2	+17.2		
8q8/3 (n=88)	50.8	68.9	+17.9	0.0147	0.7 (−3.5, 4.9)
8q8/5 (n=93)	51.7	70.3	+16.2	0.0953	−1.0 (−5.5, 3.5)

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 group (aflibercept 8q8/3, 8q8/5, 2q4); visit, and stratification variables: geographic region (Japan, Asia-Pacific, Europe, America), BL BCVA (<60 vs ≥60 letters), and, for the overall RVO population analysis only, RVO type (CRVO/HRVO vs BRVO). The model also included terms for the interactions between baseline BCVA and visit, and between treatment and visit. [a]Observed values (censoring data post intercurrent event); [b](4 letters).

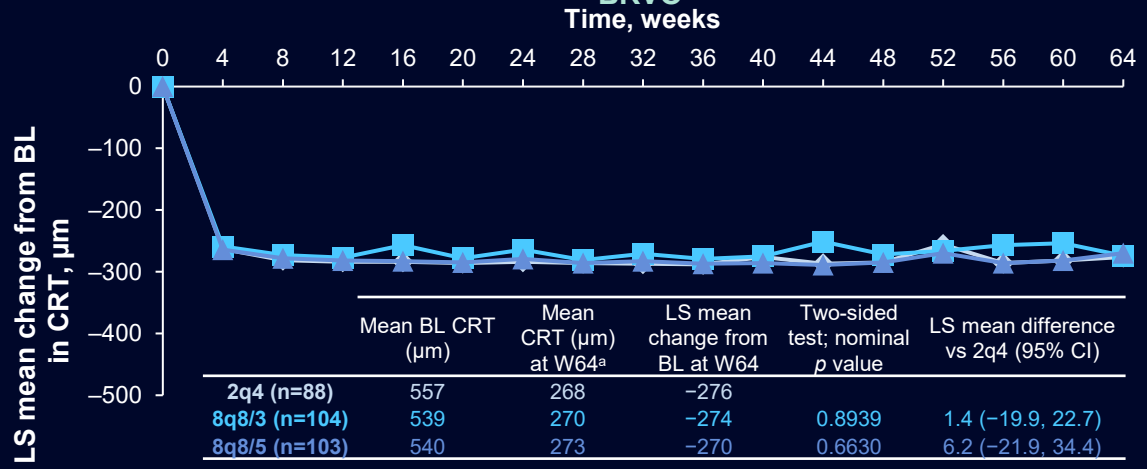
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Patients with hypertension subgroup: Overall RVO population



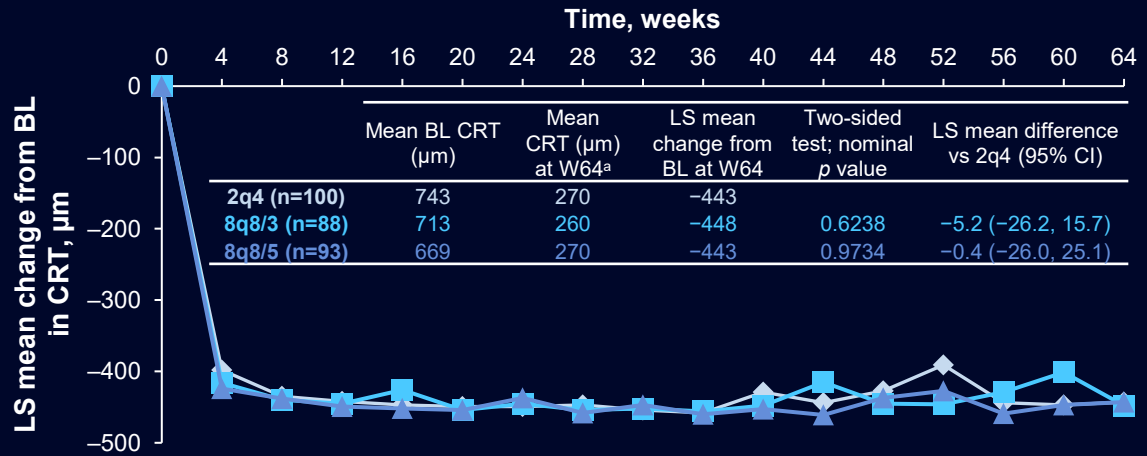
	Mean BL CRT (µm)	Mean CRT (µm) at W64[a]	LS mean change from BL at W64	Two-sided test; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=188)	656	269	−356		
8q8/3 (n=192)	619	265	−358	0.7560	−2.2 (−16.0, 11.6)
8q8/5 (n=196)	601	272	−353	0.6884	2.8 (−10.9, 16.5)

Patients with hypertension subgroup: BRVO



	Mean BL CRT (µm)	Mean CRT (µm) at W64[a]	LS mean change from BL at W64	Two-sided test; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=88)	557	268	−276		
8q8/3 (n=104)	539	270	−274	0.8939	1.4 (−19.9, 22.7)
8q8/5 (n=103)	540	273	−270	0.6630	6.2 (−21.9, 34.4)

Patients with hypertension subgroup: CRVO/HRVO

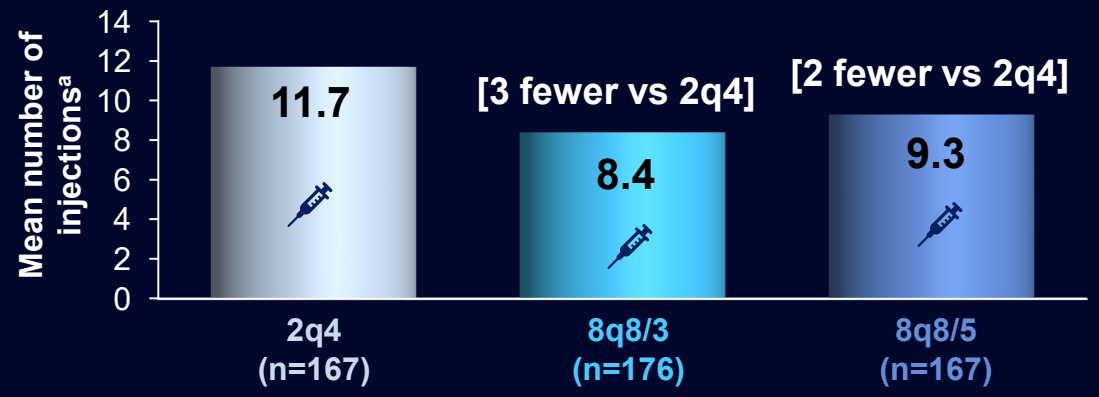


	Mean BL CRT (µm)	Mean CRT (µm) at W64[a]	LS mean change from BL at W64	Two-sided test; nominal *p* value	LS mean difference vs 2q4 (95% CI)
2q4 (n=100)	743	270	−443		
8q8/3 (n=88)	713	260	−448	0.6238	−5.2 (−26.2, 15.7)
8q8/5 (n=93)	669	270	−443	0.9734	−0.4 (−26.0, 25.1)

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

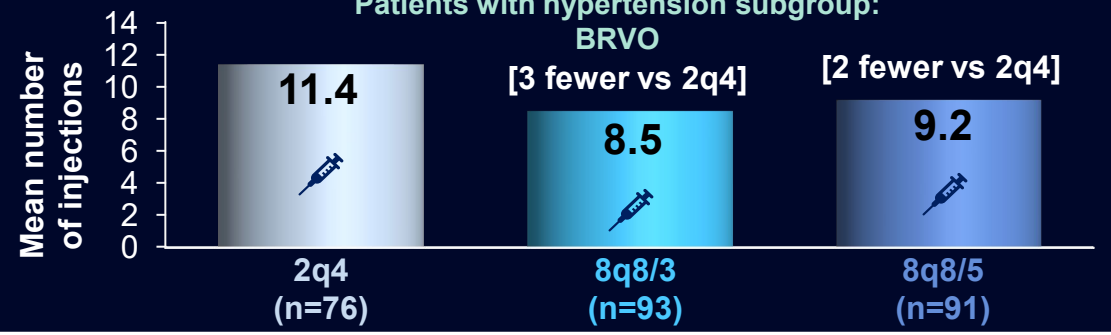
Fewer Active Injections with Aflibercept 8 mg Versus Aflibercept 2 mg in Patients with Hypertension, with Similar Findings Across RVO Subtypes

Patients with hypertension subgroup: Overall RVO population



	LS mean difference vs 2q4 (95% CI)	Nominal *p* value[b]
2q4 (n=188)		
8q8/3 (n=192)	−3.3 (−3.6, −3.0)	<0.0001
8q8/5 (n=196)	−2.3 (−2.6, −2.0)	<0.0001

Patients with hypertension subgroup: BRVO



	LS mean difference vs 2q4 (95% CI)	Nominal *p* value[b]
2q4 (n=88)		
8q8/3 (n=104)	−3.0 (−3.3, −2.6)	<0.0001
8q8/5 (n=103)	−2.1 (−2.5, −1.8)	<0.0001

Patients with hypertension subgroup: CRVO/HRVO



	LS mean difference vs 2q4 (95% CI)	Nominal *p* value[b]
2q4 (n=100)		
8q8/3 (n=88)	−3.6 (−4.1, −3.1)	<0.0001
8q8/5 (n=93)	−2.5 (−3.0, −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], and, for the overall RVO population analysis only, RVO type (CRVO/HRVO vs BRVO), within the multiple imputation procedure. [a]Full analysis set. Observed cases, patients completing Week 64. [b]*p* values were calculated for LS means.

Summary of 64-week Results by Comorbidities from the QUASAR Trial

- In patients with **diabetes or hypertension**, aflibercept 8 mg showed **robust gains in BCVA and reductions in CRT with fewer injections** versus aflibercept 2 mg at Week 64, with similar findings across BRVO or CRVO/HRVO subtypes
- Patients with **CRVO/HRVO and comorbid diabetes** treated with aflibercept 8 mg **achieved numerically greater visual gains** from baseline **with fewer injections** versus aflibercept 2 mg
- The analysis suggests that aflibercept 8 mg provides patients with diabetes or hypertension **robust and durable visual and anatomic improvements with fewer injections**, potentially **reducing treatment burden** while **maintaining clinical benefits** across RVO subtypes