Results from the QUASAR Study: Comparable Vision Gains with Aflibercept 8 mg and 2 mg in Treatment-naïve Macular Edema Secondary to Retinal Vein Occlusion

Varun Chaudhary,[1] Richard Gale,[2,3] Seenu M. Hariprasad,[4] Motohiro Kamei,[5] Youxin Chen,[6] Ramin Khoramnia,[7,8] Andrew Chang,[9] Lynne Brunck,[10] Rose Gilbert,[10] Sarah Schlief,[11] Franco Mendolia,[12] Alyson J. Berliner,[13] Fabiana Silva,[13] Sergio Leal,[10] Tobias Niesen,[14] on behalf of the QUASAR study investigators

[1]Department of Surgery, McMaster University, Hamilton, ON, Canada; [2]Hull York Medical School, University of York, York, UK; [3]York and Scarborough Teaching Hospital NHS Foundation Trust, York, UK; [4]Department of Ophthalmology and Visual Science, The University of Chicago, Chicago, IL, USA; [5]Department of Ophthalmology, Aichi Medical University, Aichi, Japan; [6]Peking Union Medical College Hospital, Peking Union Medical College and Chinese Academy of Medical Sciences, Beijing, China; [7]University Eye Clinic Heidelberg, Heidelberg, Germany; [8]Department of Ophthalmology, University Hospital Carl Gustav Carus, TU Dresden, Dresden, Germany; [9]Sydney Retina Clinic, Sydney, NSW, Australia; [10]Bayer Consumer Care AG, Basel, Switzerland; [11]Bayer AG, Berlin, Germany; [12]Bayer AG, Wuppertal, Germany; [13]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; [14]Bayer AG, Leverkusen, Germany

Presented at the 25th European Society of Retina Specialists (EURETINA), Paris, France, September 4–7, 2025

Disclosures

- **Varun Chaudhary** receives grants from Bayer, Novartis, and Roche; and serves on advisory boards for Alcon, Apellis, Bayer, Boehringer Ingelheim, Novartis, and Roche
  - **RG** is a consultant for AbbVie, Allergan, Apellis, Astellas, Bayer, Biogen, Boehringer Ingelheim, Novartis, Ocular Therapeutix, Roche, and Santen; and conducts research for Bayer, Novartis, and Roche. **SMH** reports being 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. **MK** receives financial support from Alcon Japan, Hoya Surgical Optics, Otsuka Pharmaceutical, Santen, and Senju; compensation or travel expenses from Alcon Japan, Bayer, Chugai, Hoya Surgical Optics, Kowa, Santen, Senju, and Wakamoto Pharma; and consultant fees from Chugai, Daisel, Hoya Surgical Optics, Senju, and SONY. **YC** serves as a speaker for AbbVie, Bayer, Chengdu Kanghong, Novartis, and Roche. **RK** receives research funding from Alimera, Bayer, Chengdu Kanghong, Novartis, Opthea, and Roche; and serves as a speaker for AbbVie, Alimera, Apellis, Bayer, Heidelberg Engineering, Novartis, and Roche. **AC** receives consultant fees from Alcon, Apellis, Astellis, Bayer, Novartis, Opthea, Roche, and Zeiss; and grant funding from Bayer, Novartis, and Roche. **LB** was an employee of Bayer Consumer Care AG at the time of the analysis. **RG** is an employee of Bayer Consumer Care AG. **TN, SS,** and **FM** are employees of Bayer AG. **AJB** and **FS** are employees of Regeneron Pharmaceuticals, Inc. **SL** is an employee, investor, and patent holder of Bayer Consumer Care AG
- The QUASAR trial (NCT05850520) was sponsored by Bayer AG (Leverkusen, Germany). The sponsor participated in the design and conduct of the study, analysis of the data, and preparation of this abstract
- This study included research conducted on human patients. Institutional Review Board/Institutional Ethics Committee approval was obtained prior to study initiation
- Medical writing support, under the direction of the author, was provided by ApotheCom and funded by Bayer Consumer Care AG, Basel, Switzerland, in accordance with Good Publication Practice (GPP) guidelines (*Ann Intern Med.* 2022;175:1298–1304)
- Aflibercept 8 mg is currently not on label for treating macular edema due to retinal vein occlusion; however, applications seeking approval of aflibercept 8 mg for macular edema due to retinal vein occlusion, including central, branch, and hemiretinal vein occlusion, have been submitted to the FDA and the EMA

QUASAR: Study Design

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

2q4
Aflibercept 2 mg every 4 weeks[a]
n=301

8q8/3
Aflibercept 8 mg every 8 weeks, after 3 initial monthly injections[a]
n=293

8q8/5
Aflibercept 8 mg every 8 weeks, after 5 initial monthly injections[a]
n=298

Primary endpoint
Mean change in BCVA (non-inferiority)

	Day 1	W4	W8	W12	W16	W20	W24	W28	W32	W36
2q4	X	X	X	X	X	X	X	X	X	T&E
8q8/3	X	X	X	o	X	o[b]	X	o[c]	X	T&E
8q8/5	X	X	X	X	X	o	X	o[c]	X	o[d]

DRM for interval shortening

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

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

DRM for interval extension

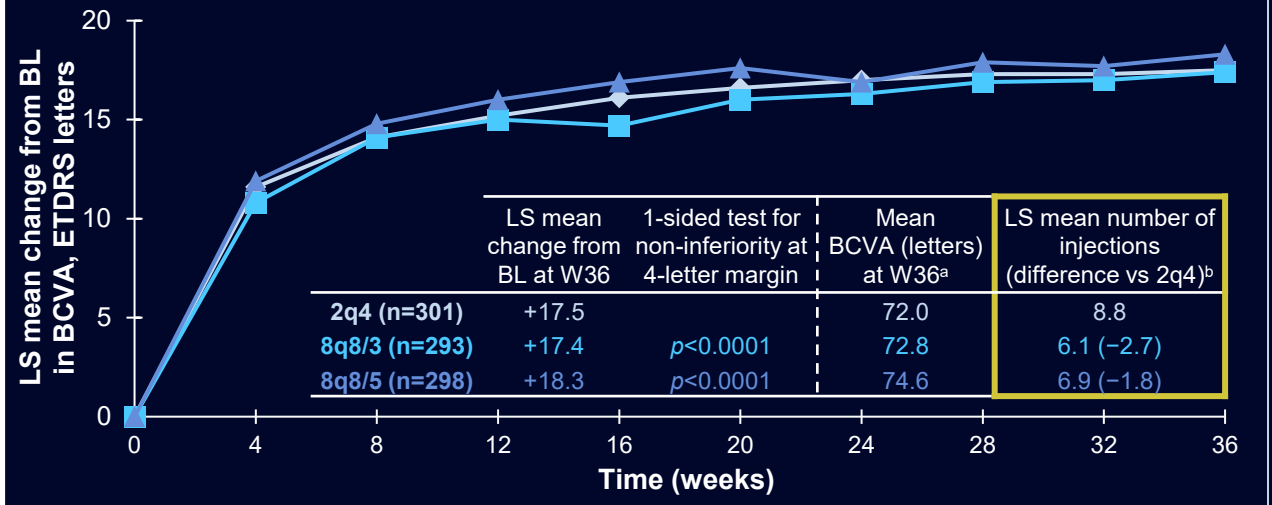
Dosing interval extended by 4 weeks starting at Week 32 for 8q8/3 and 2q4 and at Week 40 for 8q8/5 if both the following criteria are met at a dosing visit:

- BCVA loss of <5 letters from 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 participants meeting DRM criteria at Week 16. [c]Active injection for participants meeting DRM criteria at Week 16 or 24. [d]Active injection for participants 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; **RVO**, retinal vein occlusion; **SD-OCT**, spectral domain-optical coherence tomography; **T&E**, treat and extend; **W**, week.

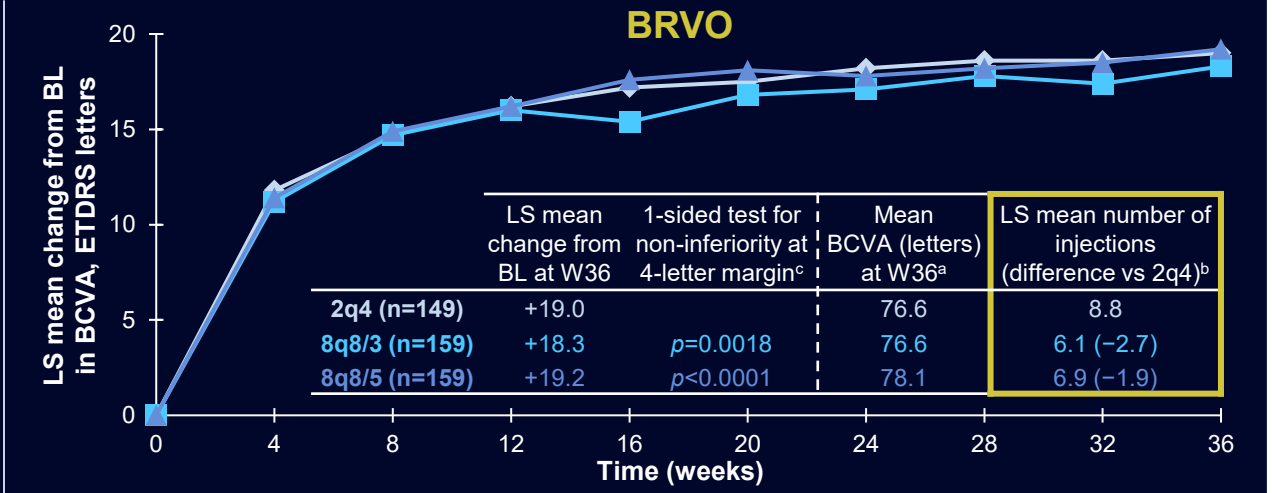
Both Aflibercept 8 mg Groups Achieved Non-inferior BCVA Gains Compared to Aflibercept 2 mg at Week 36, with Fewer Injections Overall and Across RVO Subtypes

Overall RVO Population



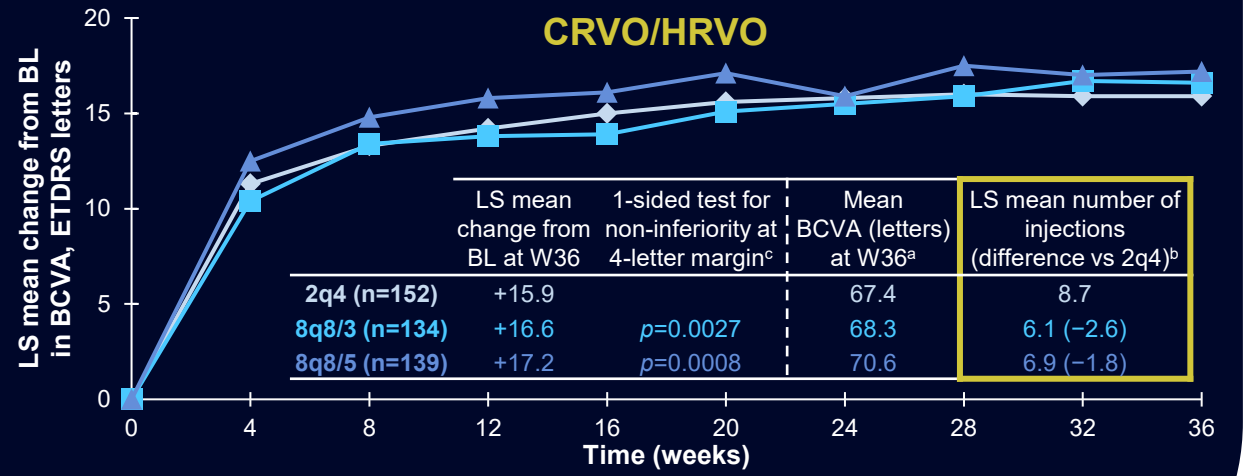
	LS mean change from BL at W36	1-sided test for non-inferiority at 4-letter margin	Mean BCVA (letters) at W36[a]	LS mean number of injections (difference vs 2q4)[b]
2q4 (n=301)	+17.5		72.0	8.8
8q8/3 (n=293)	+17.4	*p*<0.0001	72.8	6.1 (−2.7)
8q8/5 (n=298)	+18.3	*p*<0.0001	74.6	6.9 (−1.8)

BRVO



	LS mean change from BL at W36	1-sided test for non-inferiority at 4-letter margin[c]	Mean BCVA (letters) at W36[a]	LS mean number of injections (difference vs 2q4)[b]
2q4 (n=149)	+19.0		76.6	8.8
8q8/3 (n=159)	+18.3	*p*=0.0018	76.6	6.1 (−2.7)
8q8/5 (n=159)	+19.2	*p*<0.0001	78.1	6.9 (−1.9)

CRVO/HRVO

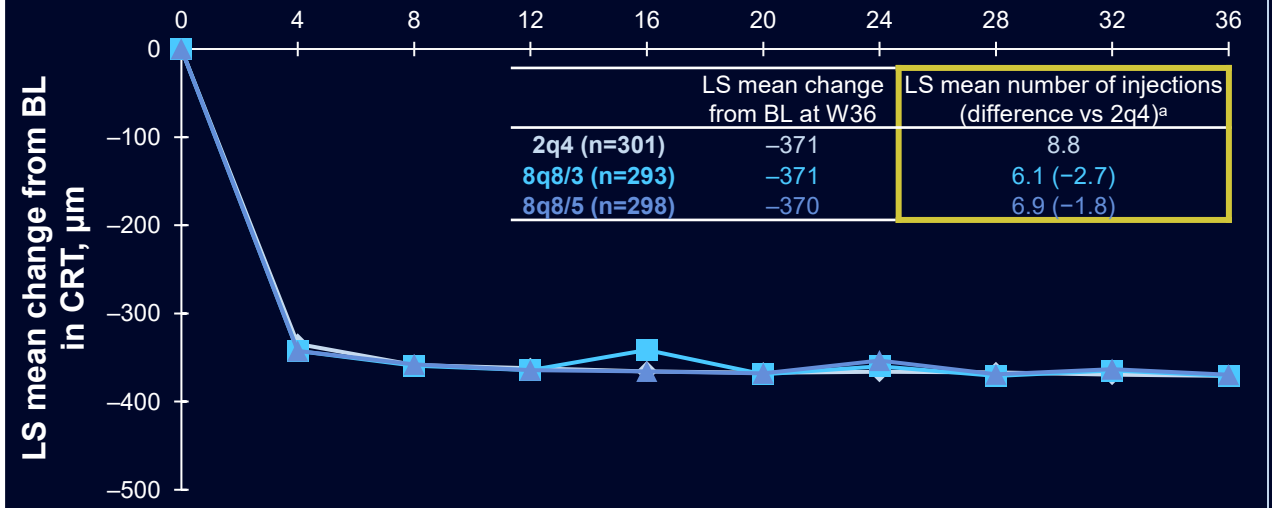


	LS mean change from BL at W36	1-sided test for non-inferiority at 4-letter margin[c]	Mean BCVA (letters) at W36[a]	LS mean number of injections (difference vs 2q4)[b]
2q4 (n=152)	+15.9		67.4	8.7
8q8/3 (n=134)	+16.6	*p*=0.0027	68.3	6.1 (−2.6)
8q8/5 (n=139)	+17.2	*p*=0.0008	70.6	6.9 (−1.8)

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]Missing endpoint values imputed using a multiple imputation procedure. Estimates based on a linear regression model, within the multiple imputation procedure, adjusted for BL BCVA, BL CRT, and stratification variables (geographic region [Japan vs Asia-Pacific vs Europe vs America], BCVA score [>60 vs ≥60], RVO type [CRVO/HRVO vs BRVO]). [c]Nominal *p*-values. **BL**, baseline; **BRVO**, branch retinal vein occlusion; **CI**, confidence interval; **CRVO**, central retinal vein occlusion; **ETDRS**, Early Treatment Diabetic Retinopathy Study; **HRVO**, hemiretinal vein occlusion; **LS**, least squares.

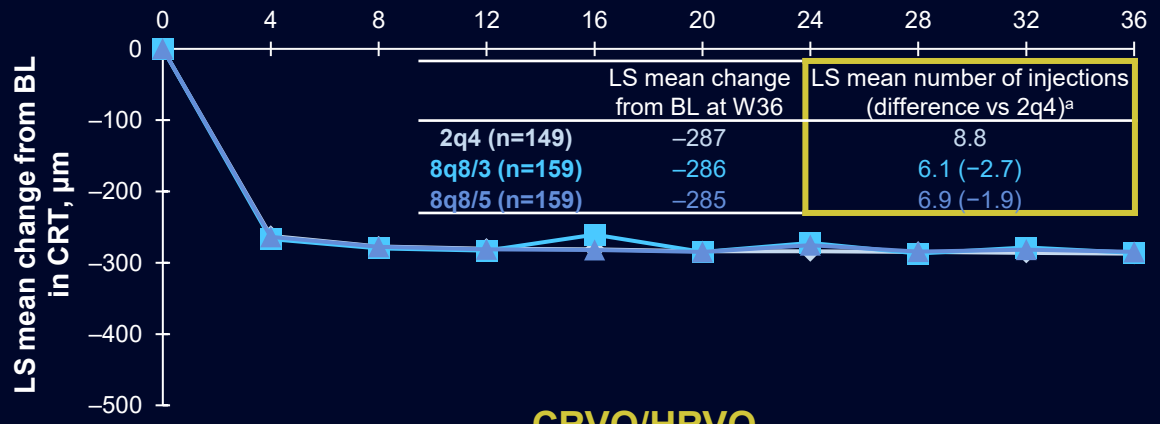
Both Aflibercept 8 mg Groups Achieved Robust CRT Reductions Compared to Aflibercept 2 mg at Week 36, with Fewer Injections Overall and Across RVO Subtypes

Overall RVO Population



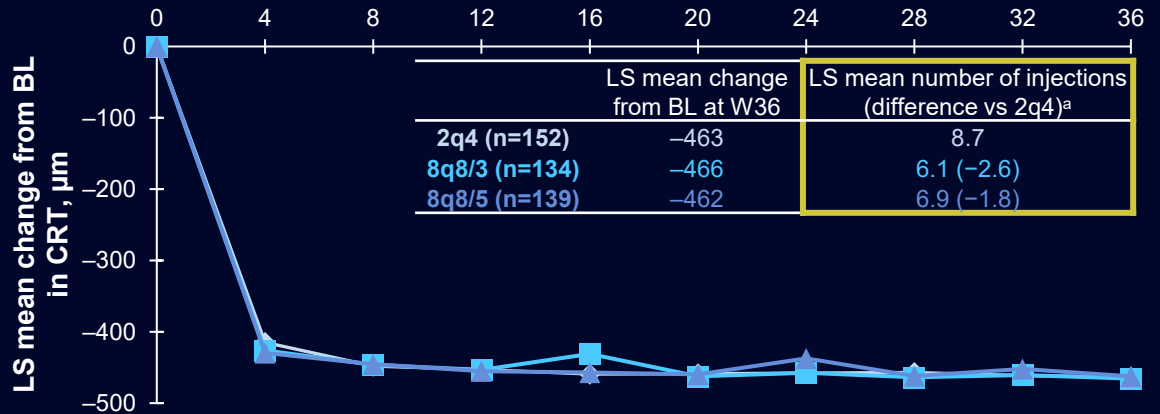
	LS mean change from BL at W36	LS mean number of injections (difference vs 2q4)[a]
2q4 (n=301)	–371	8.8
8q8/3 (n=293)	–371	6.1 (−2.7)
8q8/5 (n=298)	–370	6.9 (−1.8)

BRVO



	LS mean change from BL at W36	LS mean number of injections (difference vs 2q4)[a]
2q4 (n=149)	–287	8.8
8q8/3 (n=159)	–286	6.1 (−2.7)
8q8/5 (n=159)	–285	6.9 (−1.9)

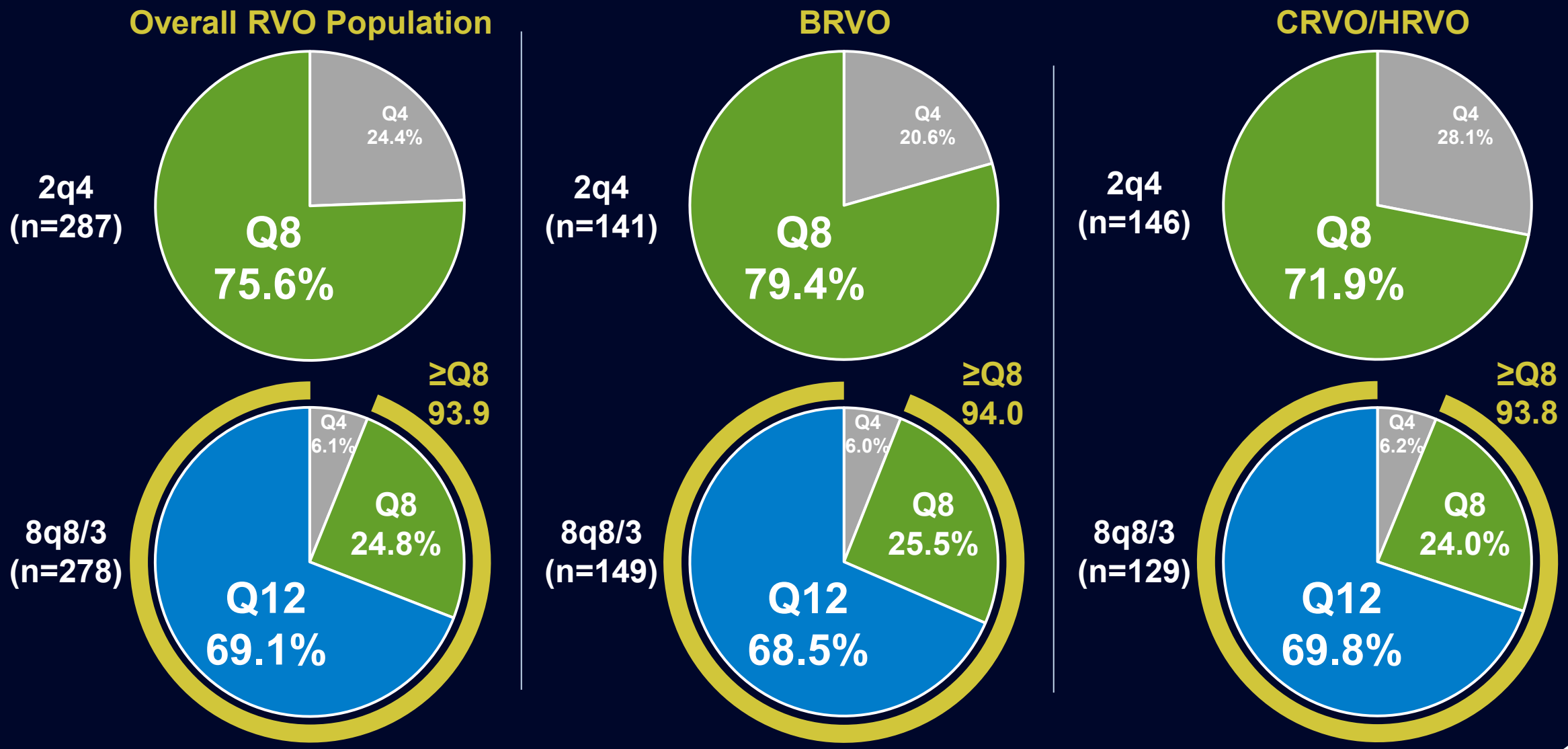
CRVO/HRVO



	LS mean change from BL at W36	LS mean number of injections (difference vs 2q4)[a]
2q4 (n=152)	–463	8.7
8q8/3 (n=134)	–466	6.1 (−2.6)
8q8/5 (n=139)	–462	6.9 (−1.8)

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, 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 interaction between baseline CRT and visit, and treatment and visit. [a]Missing endpoint values imputed using a multiple imputation procedure. Estimates based on a linear regression model, within the multiple imputation procedure, adjusted for BL BCVA, BL CRT, and stratification variables (geographic region [Japan vs Asia-Pacific vs Europe vs America], BCVA score [>60 vs ≥60], RVO type [CRVO/HRVO vs BRVO]).

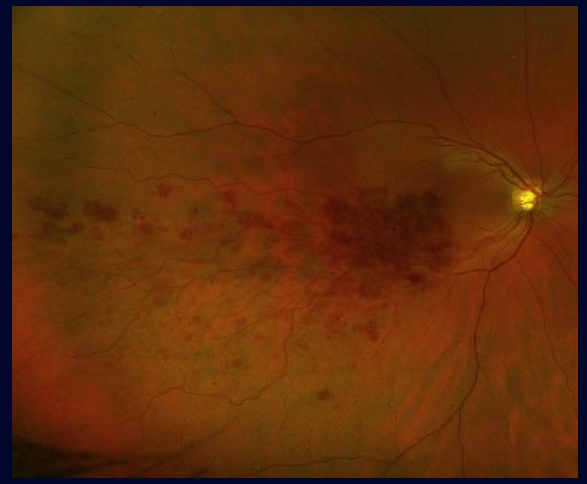
Last Assigned Dosing Interval at Week 36 for Patients Eligible for Interval Extension: Overall Population, BRVO, and CRVO/HRVO Subtypes

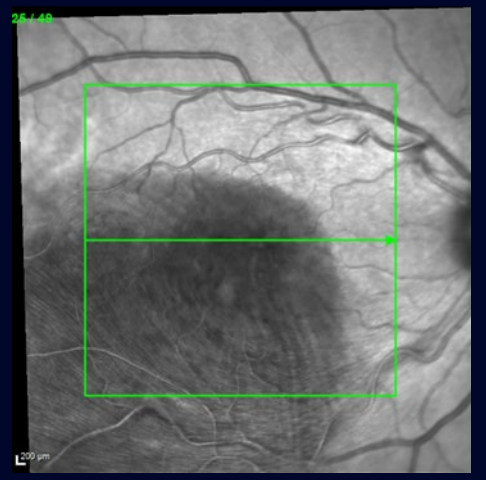


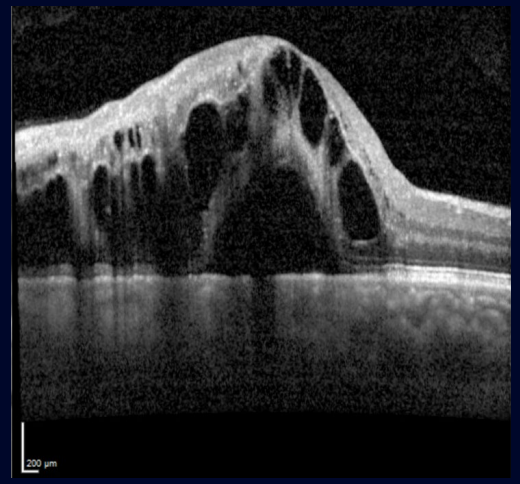
Safety analysis set. Patients completing Week 36. Per study design, dosing interval extension was not possible in the 8q8/5 group until Week 40. **Q4**, every 4 weeks; **Q8**, every 8 weeks; **Q12**, every 12 weeks.

BRVO Case Study: Baseline Visit

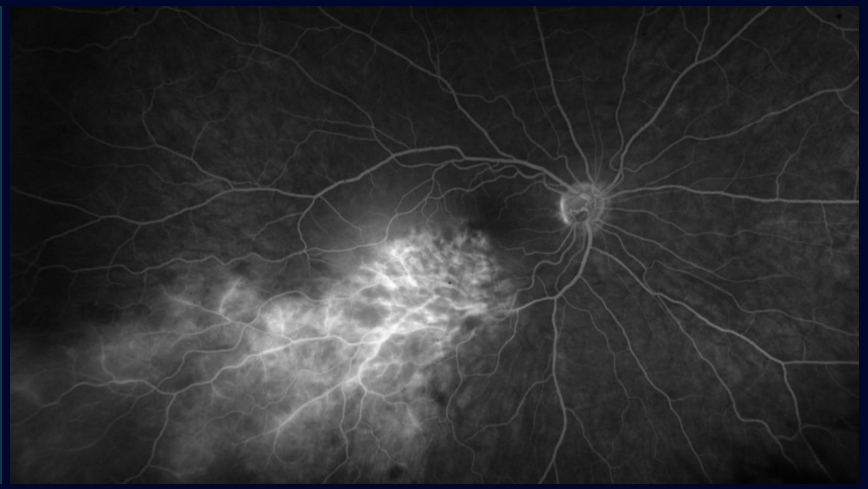
Baseline patient characteristics	
Age, years	52
Gender	Female
Ethnicity	White
Type of RVO	BRVO, right eye
Treatment arm	8q8/3
Baseline BCVA, ETDRS letters	35
Baseline CRT, µm	925
Past medical history	None
Past ocular history	None







Late frame angiogram at baseline visit shows extensive leakage of fluorescein



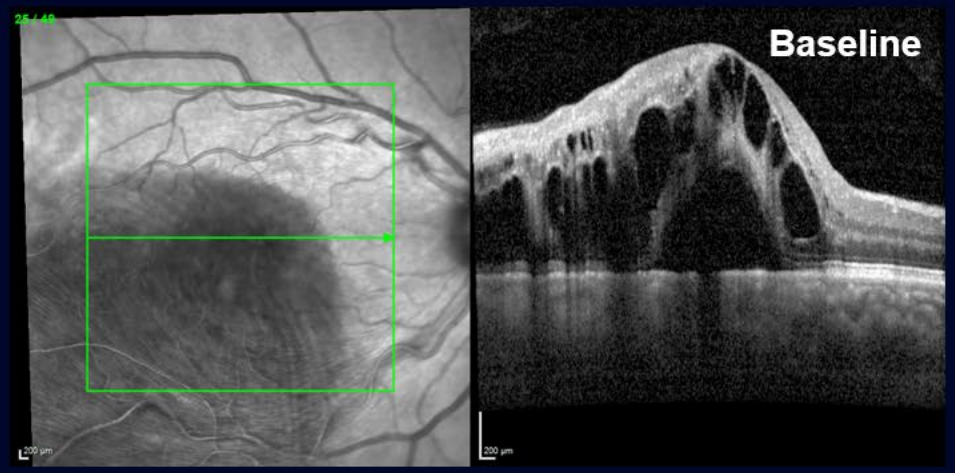
Patient received aflibercept 8 mg injection #1 (first initial monthly dose)

Aflibercept 8 mg is not indicated in RVO. RVO indication is not approved in the EU (EMA ongoing procedure). For prescribing and safety profile information for aflibercept 8 mg or aflibercept 2 mg, please consult local guidance. This patient case is taken from the Phase 3 QUASAR study (NCT05850520). **EMA**, European Medicines Agency; **EU**, European Union.

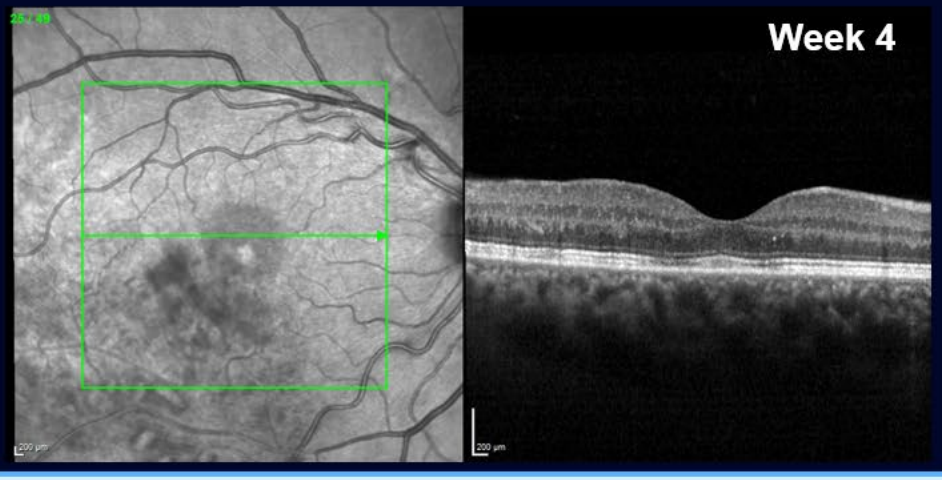
BRVO Case Study: Week 4

4 weeks after aflibercept 8 mg injection #1

Baseline	
BCVA, ETDRS letters	35
Baseline CRT, µm	925



Week 4	
BCVA, ETDRS letters (Change from baseline)	60 (+25)
CRT, µm (Change from baseline)	265 (−660)
Current treatment interval	Q4



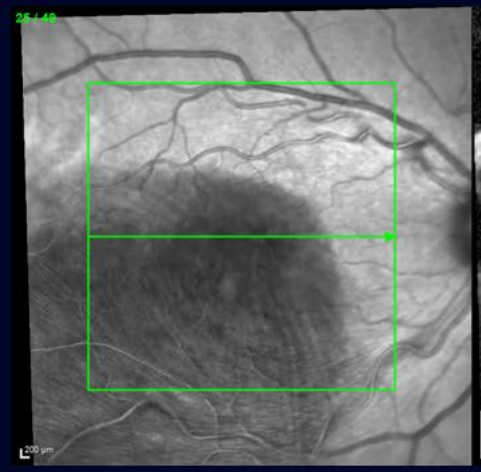
Patient received aflibercept 8 mg injection #2 (second initial monthly dose)

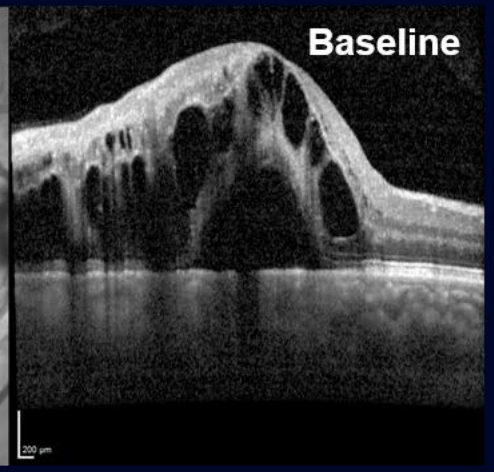
Aflibercept 8 mg is not indicated in RVO. RVO indication is not approved in the EU (EMA ongoing procedure). For prescribing and safety profile information for aflibercept 8 mg or aflibercept 2 mg, please consult local guidance. This patient case is taken from the Phase 3 QUASAR study (NCT05850520).

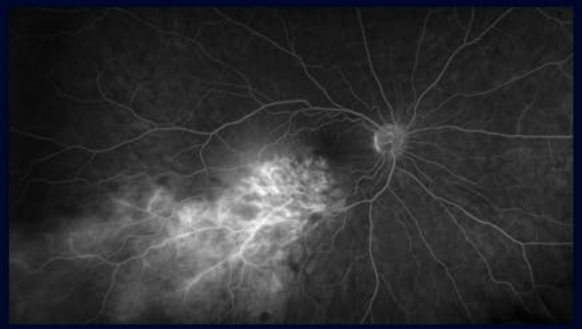
BRVO Case Study: Week 12 (reference visit)

4 weeks after aflibercept 8 mg injection #3 (third initial monthly dose)

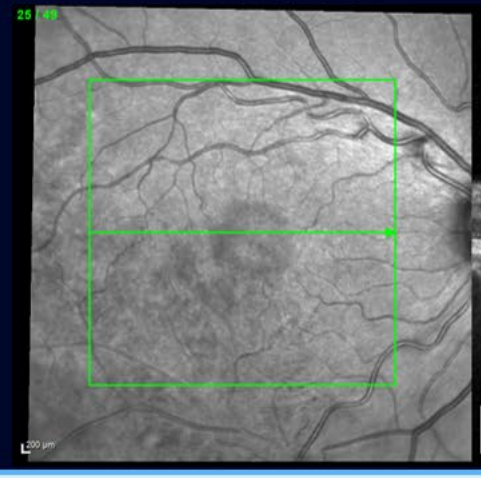
Baseline	
BCVA, ETDRS letters	35
Baseline CRT, µm	925

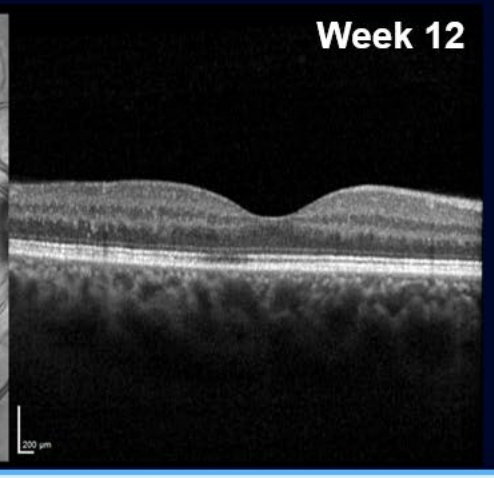


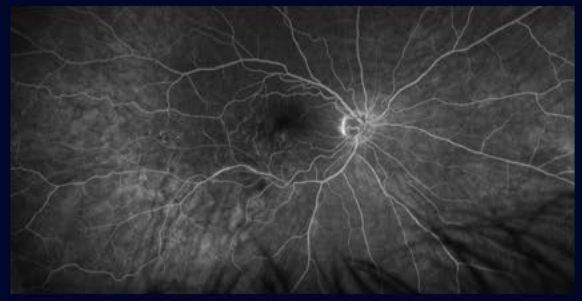




Week 12	
BCVA, ETDRS letters (Change from baseline)	65 (+30)
CRT, µm (Change from baseline)	258 (−667)
Current treatment interval	Q8







No detectable leakage of fluorescein at Week 12

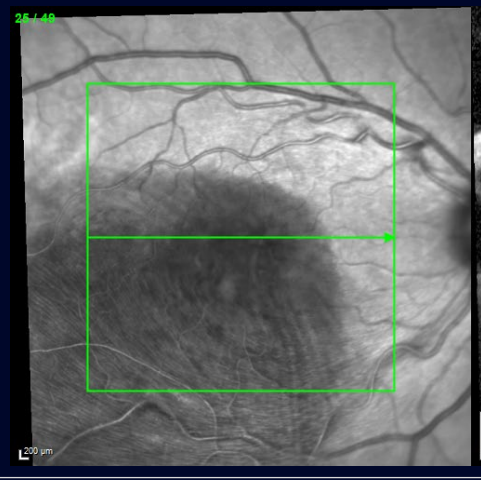
No aflibercept 8 mg injection was given at Week 12

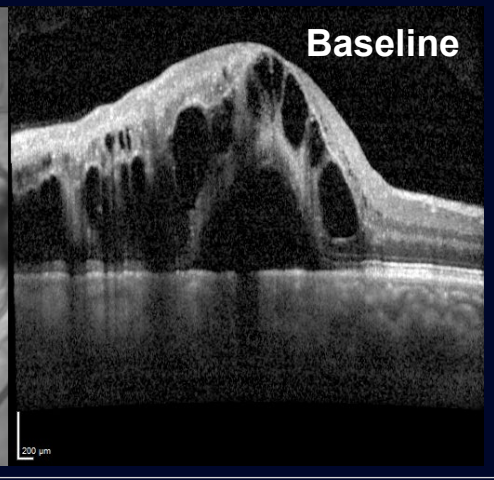
Aflibercept 8 mg is not indicated in RVO. RVO indication is not approved in the EU (EMA ongoing procedure). For prescribing and safety profile information for aflibercept 8 mg or aflibercept 2 mg, please consult local guidance. This patient case is taken from the Phase 3 QUASAR study (NCT05850520).

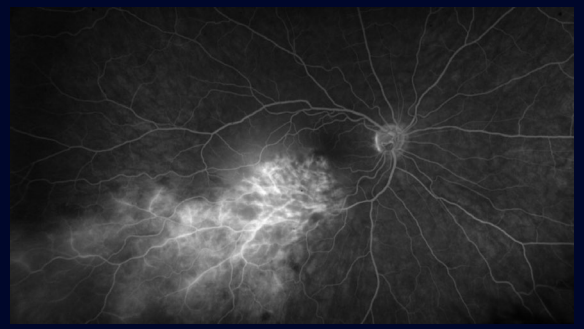
BRVO Case Study: Week 36

4 weeks after aflibercept 8 mg injection #6

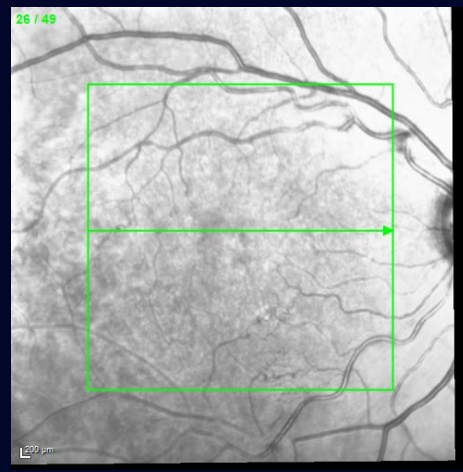
Baseline	
BCVA, ETDRS letters	35
Baseline CRT, µm	925

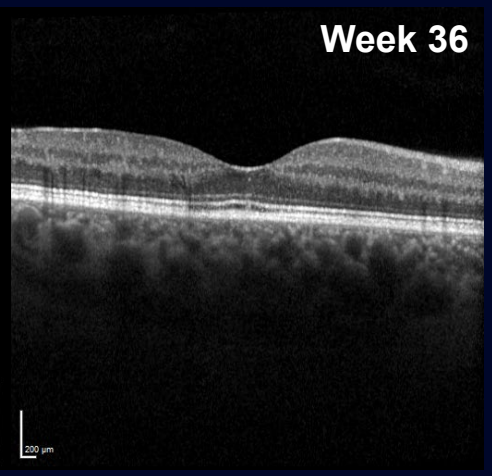


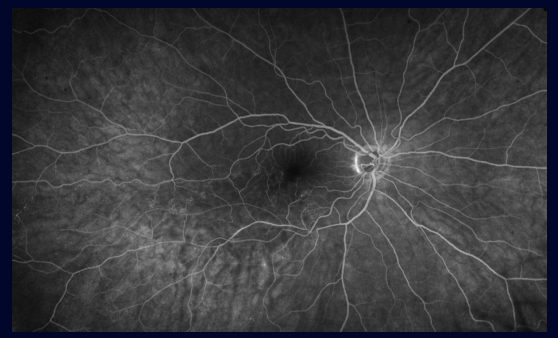




Week 36	
BCVA, ETDRS letters (Change from baseline)	85 (+50)
CRT, µm (Change from baseline)	250 (−675)
Current treatment interval	Q8







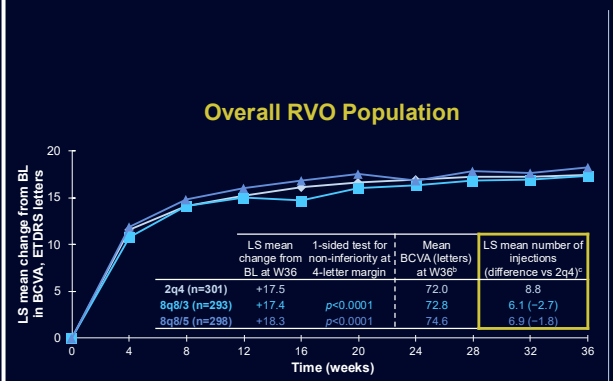
No detectable leakage of fluorescein at Week 36

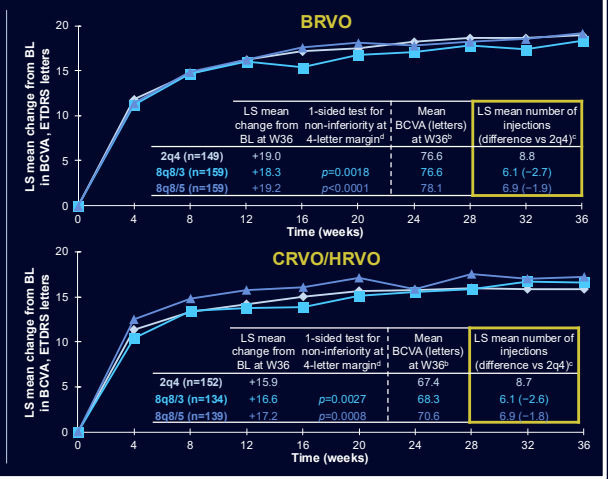
Aflibercept 8 mg is not indicated in RVO. RVO indication is not approved in the EU (EMA ongoing procedure). For prescribing and safety profile information for aflibercept 8 mg or aflibercept 2 mg, please consult local guidance. This patient case is taken from the Phase 3 QUASAR study (NCT05850520).

QUASAR: Paradigm Shift in the Treatment of RVO with Aflibercept 8 mg

- Aflibercept 8q8/3 and 8q8/5 groups achieved **non-inferior BCVA gains and robust reductions in CRT,** with fewer injections than in the aflibercept 2q4 group at Week 36, overall and across BRVO and CRVO/HRVO subtypes
- Approximately **94% of patients in the aflibercept 8q8/3 group achieved a last assigned dosing interval of ≥8 weeks,** overall and across BRVO and CRVO/HRVO subtypes
- The safety profile of aflibercept 8 mg in patients with macular edema secondary to RVO was **consistent with the established safety profile of aflibercept 2 mg and 8 mg**

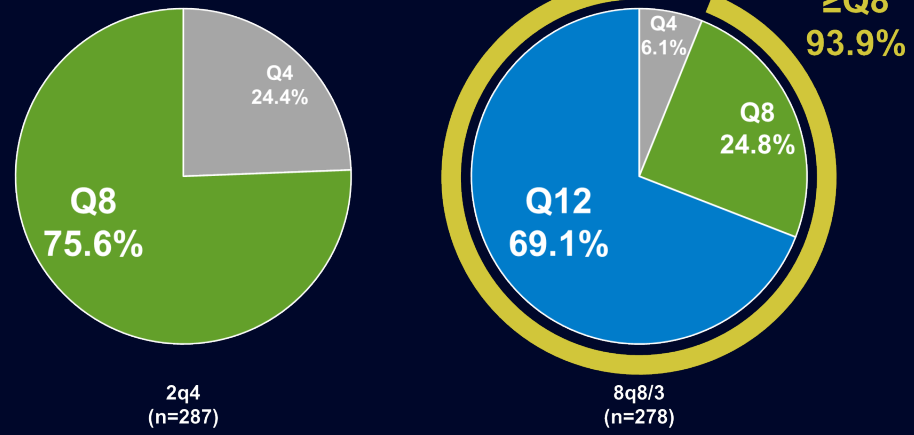
Both Aflibercept 8 mg Groups Achieved Non-inferior BCVA Gains Compared to Aflibercept 2 mg at Week 36,[a] with Fewer Injections Overall and Across RVO Subtypes





Last Assigned Dosing Interval at Week 36 for Patients Eligible for Interval Extension[e]

Overall RVO Population



[a]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. [b]Observed values (censoring data post intercurrent event). [c]Missing endpoint values imputed using a multiple imputation procedure. Estimates based on a linear regression model, within the multiple imputation procedure, adjusted for BL BCVA, BL CRT, and stratification variables (geographic region [Japan vs Asia-Pacific vs Europe vs America], BCVA score [>60 vs ≥60], RVO type [CRVO/HRVO vs BRVO]). [d]Nominal *p*-values. [e]Safety analysis set. Patients completing Week 36.