



Clinical improvements at Week 36 sustained to Week 64 with aflibercept 8 mg in macular edema following retinal vein occlusion, with significantly fewer injections compared to aflibercept 2 mg: Results from the QUASAR trial

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Disclosures

- **Richard P. Gale** is a consultant for AbbVie, Advanz, Apellis, Astellas, Bayer, Biogen, Boehringer Ingelheim, Novartis, Ocular Therapeutix, Outlook Therapeutics, and Roche; received grant funding from Bayer, Heidelberg Engineering, and Roche.
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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

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

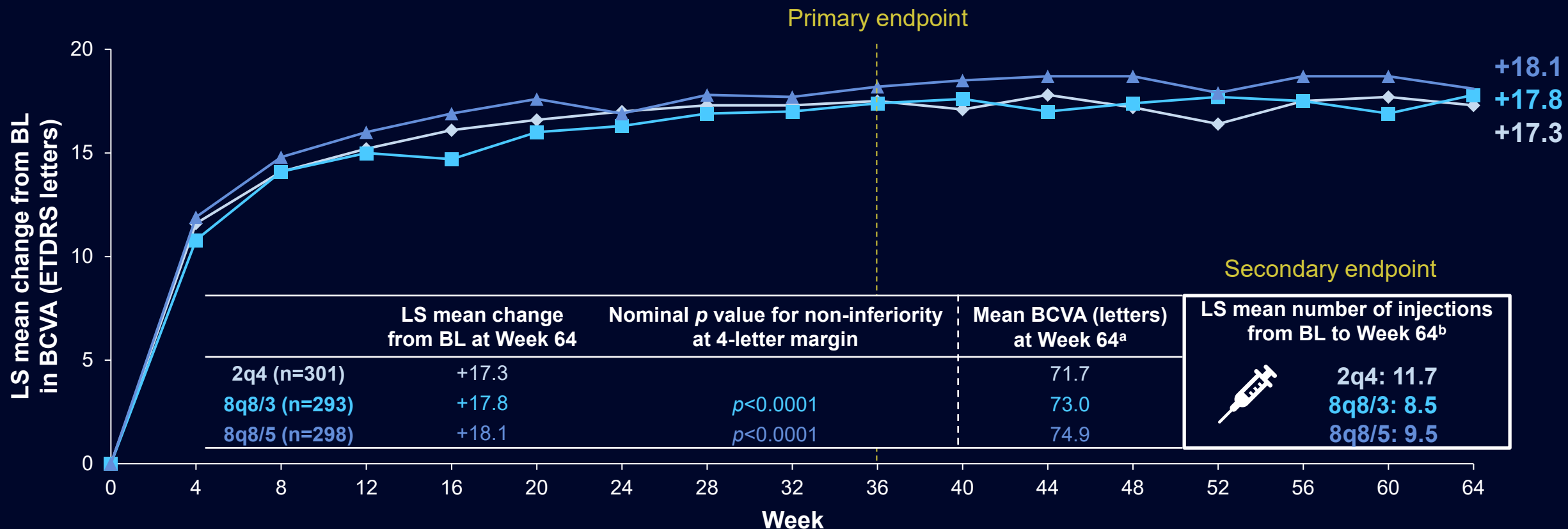
DRM for interval extension

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

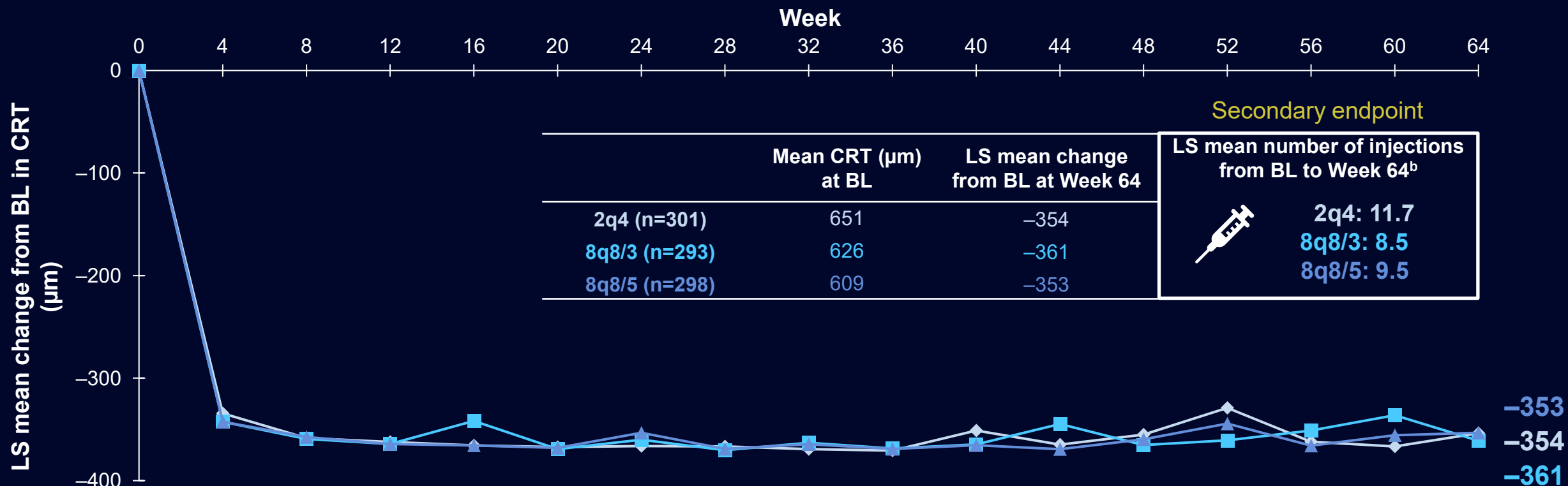
The primary efficacy endpoint was change from baseline in BCVA at Week 36, with a non-inferiority margin of 4 letters. Stippled boxes = initial treatment phase; X = active injection; o = sham injection. Note: Table does not reflect all dosing options once a patient's dosing interval is shortened. ^aWith opportunity for extension per DRM. ^bActive injection for patients meeting DRM criteria at Week 16. ^cActive injection for patients meeting DRM criteria from Week 16 for 8q8/3 or Week 24 for 8q8/5. ^dReference 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 Arms Continued to Maintain Robust Improvements in BCVA Through Week 64



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. ^aObserved values (censoring data post intercurrent event). BL, baseline; LS, least squares.

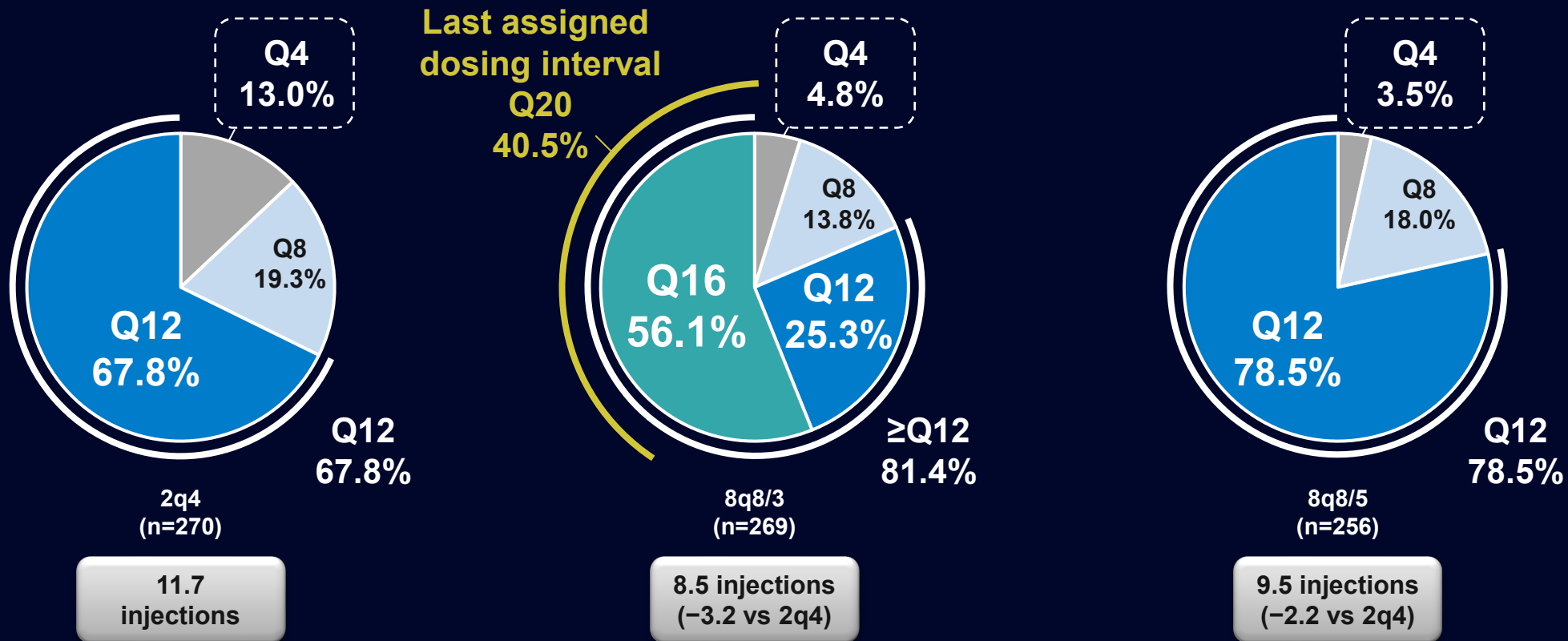
Aflibercept 8 mg Arms Maintained Robust Anatomic Improvements Through Week 64, with Higher Fluid-Free Rates and Significantly Fewer Injections Compared with Aflibercept 2 mg



More patients treated with aflibercept 8 mg (73.8%) versus 2 mg (66.0%) were fluid-free in the central subfield at Week 64^b

Full analysis set. LS means were generated using a mixed model for repeated measures 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. ^aObserved values, patients completing Week 64. Fluid resolution defined as no IRF and no SRF in central subfield. **IRF**, intraretinal fluid; **SRF**, subretinal fluid.

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

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

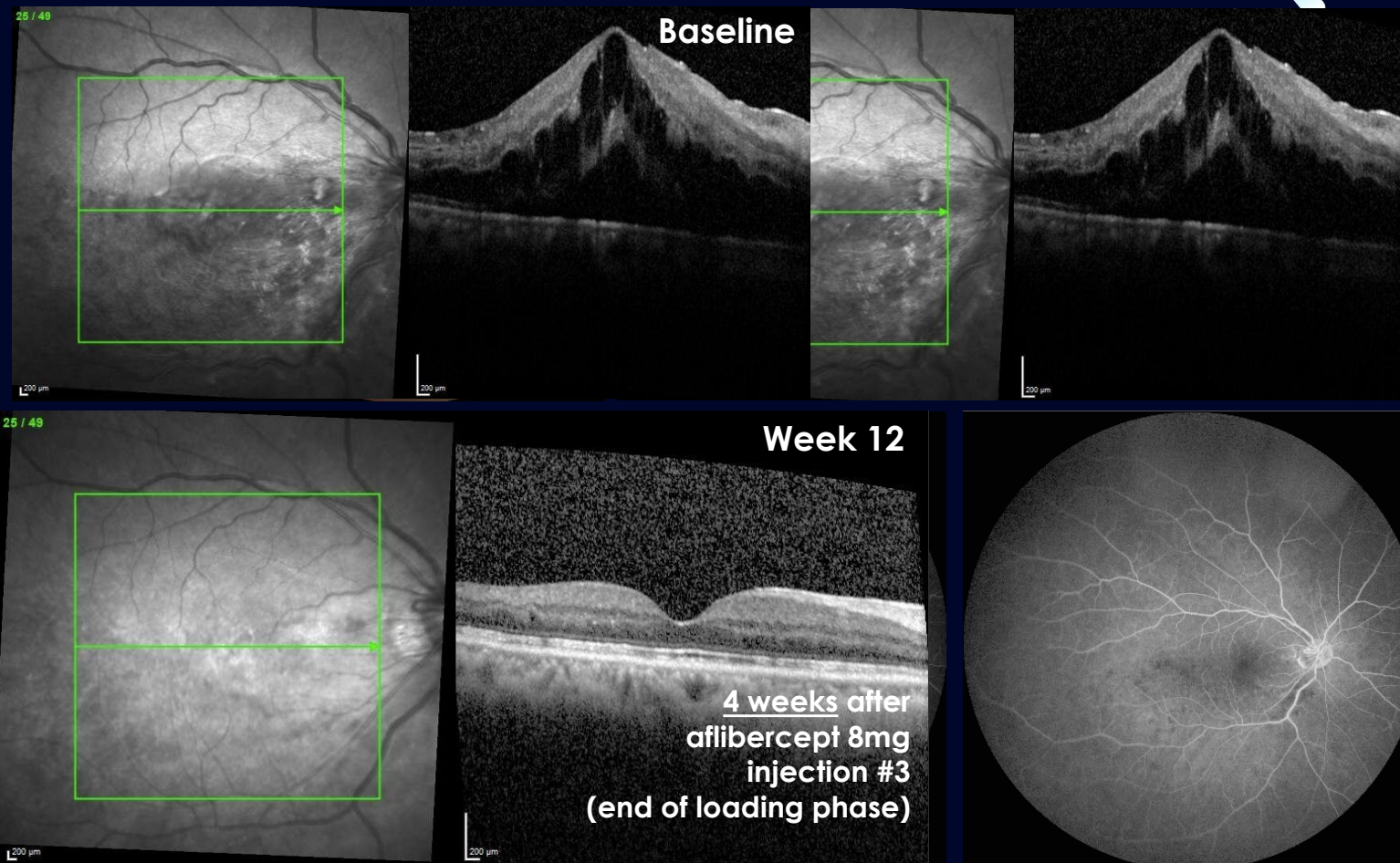
The most common ocular TEAEs overall were cataract, intraocular pressure increase, visual acuity reduced, and conjunctival haemorrhage

Safety analysis set.

APTC, Anti-Platelet Trialists' Collaboration; TEAE, treatment-emergent adverse event.

QUASAR Patient Case Week 12 (No Injection Given)

Baseline	
BCVA, ETDRS letters	56
Baseline CRT, μm	903
Gender	Female
Ethnicity	White
Type of RVO	BRVO, right eye
Treatment arm	808/3
Week 12	
BCVA, ETDRS letters (Change from baseline)	77 (+21)
CRT, μm (Change from baseline)	256 (-647)
IOP, mmHg	14
Current treatment interval	Q8
Next assigned treatment interval	—

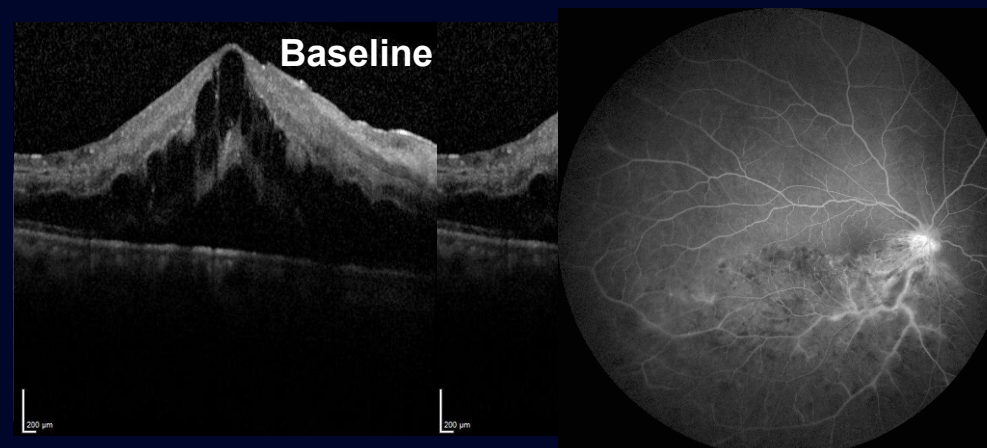


The next **aflibercept 8mg** injection was given at Week 16

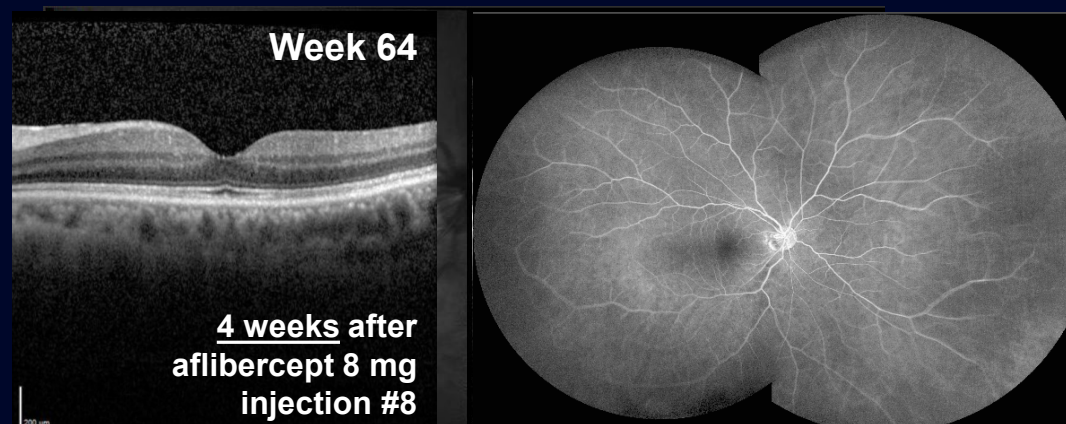
Aflibercept 8 mg is not approved for use in patients with macular oedema secondary to RVO in all countries. For prescribing and safety profile information for aflibercept 8 mg or aflibercept 2 mg, please consult local guidance. This patient case is taken from the Phase III QUASAR study (NCT05850520). This case study is representative only and individual patient responses may vary.
IOP, intraocular pressure.

QUASAR Patient Case: Week 64

Baseline	
BCVA, ETDRS letters	56
Baseline CRT, μm	903



Week 64	
BCVA, ETDRS letters (Change from baseline)	83 (+27)
CRT, μm (Change from baseline)	258 (-645)
IOP, mmHg	13
Current treatment interval	Q20
Next assigned treatment interval	N/A



No detectable leakage of fluorescein at Week 64



Patient assigned to Q20 treatment interval (not completed)

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T&E, treat-and-extend.

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 $\geq$ 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