Aflibercept 8 mg for Retinal Vein Occlusion: Outcomes of the QUASAR Phase 3 Randomized Trial by RVO Type, BRVO or CRVO/HRVO

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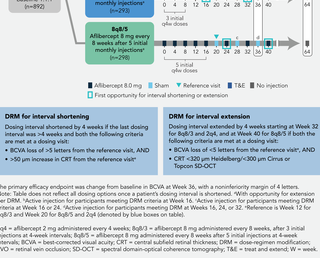
The QUASAR trial is the first randomized, double-masked, Phase 3 study to assess intravitreal aflibercept 8 mg in patients with treatment-naive macular edema secondary to retinal vein occlusion (RVO). The trial is evaluating three dosing strategies for aflibercept 8 mg, with interval adjustments allowed based on protocol-defined response criteria.

The primary endpoint and other key parameters were assessed at Week 36 as the study continued through Week 64. In this analysis of the Week 36 data, the impact of the BRVO and CRVO/HRVO subtypes on visual, anatomic, and durability outcomes were evaluated.

QUASAR is a 64-week multicenter, randomized, double-masked, Phase 3 study in patients with treatment-naive macular edema secondary to RVO



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 the reference visit, AND
- >50 µm increase in CRT from the reference visit[a]

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:

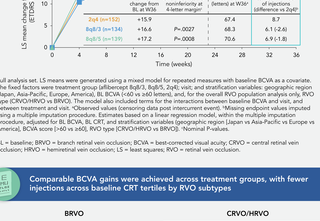
- BCVA loss of <5 letters from the reference visit[a], AND
- CRT <320 µm Heidelberg/<300 µm Cirrus or Topcon SD-OCT

The primary efficacy endpoint was change from baseline in BCVA at Week 36, with a noninferiority margin of 4 letters. Note: Table does not reflect all dosing options once a patient's dosing interval is shortened. *With opportunity for extension per DRM. [a]Active injection for participants meeting DRM criteria at Week 16. [b]Active injection for participants meeting DRM criteria at Week 16 or 24. [c]Active injection for participants meeting DRM at Weeks 16, 24, or 32. †Reference is Week 12 for 8q8/3 and Week 20 for 8q8/5 and 2q4 (denoted by blue 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.

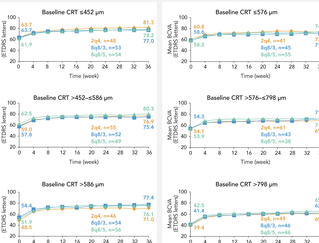
Both aflibercept 8 mg groups achieved noninferior BCVA gains compared to aflibercept 2 mg at Week 36 with fewer injections overall and across RVO subtypes

Overall RVO population



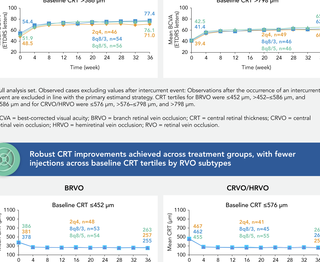
	LS mean change from BL at W36	One-sided test for 4-letter margin	Mean BCVA (letters) at W36[a]	LS mean number of injections (difference vs 2q4)[a]
2q4 (n=301)	+17.5		72.0	8.8
8q8/3 (n=293)	+17.4	P<.0001	72.8	6.1 (-2.7)
8q8/5 (n=298)	+18.3	P<.0001	74.6	6.9 (-1.8)

BRVO



	LS mean change from BL at W36	One-sided test for noninferiority at 4-letter margin[a]	Mean BCVA (letters) at W36[a]	LS mean number of injections (difference vs 2q4)[a]
2q4 (n=149)	+19.0		76.6	8.8
8q8/3 (n=159)	+18.3	P=.0018	76.6	6.1 (-2.7)
8q8/5 (n=159)	+19.2	P<.0001	78.1	6.9 (-1.9)

CRVO/HRVO



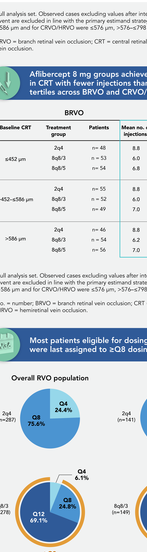
	LS mean change from BL at W36	One-sided test for noninferiority at 4-letter margin[a]	Mean BCVA (letters) at W36[a]	LS mean number of injections (difference vs 2q4)[a]
2q4 (n=152)	+15.9		67.4	8.7
8q8/3 (n=134)	+16.6	P=.0027	68.3	6.1 (-2.6)
8q8/5 (n=139)	+17.2	P=.0008	70.6	6.9 (-1.8)

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)). †Nominal P-values.

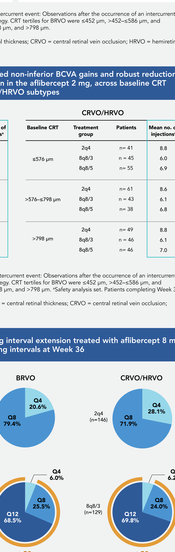
BL = baseline; BRVO = branch retinal vein occlusion; BCVA = best-corrected visual acuity; CRVO = central retinal vein occlusion; HRVO = hemiretinal vein occlusion; LS = least squares; RVO = retinal vein occlusion.

Comparable BCVA gains were achieved across treatment groups, with fewer injections across baseline CRT tertiles by RVO subtypes

BRVO



CRVO/HRVO



Full analysis set. Observed cases excluding values after intercurrent event. Observations after the occurrence of an intercurrent event are excluded in line with the primary estimand strategy. CRT tertiles for BRVO were ≤452 µm, >452–≤586 µm, and >586 µm and for CRVO/HRVO were ≤576 µm, >576–≤798 µm, and >798 µm.

BCVA = best-corrected visual acuity; BRVO = branch retinal vein occlusion; CRT = central retinal thickness; CRVO = central retinal vein occlusion; HRVO = hemiretinal vein occlusion; RVO = retinal vein occlusion.

Robust CRT improvements achieved across treatment groups, with fewer injections across baseline CRT tertiles by RVO subtypes

BRVO

CRVO/HRVO

Full analysis set. Observed cases excluding values after intercurrent event. Observations after the occurrence of an intercurrent event are excluded in line with the primary estimand strategy. CRT tertiles for BRVO were ≤452 µm, >452–≤586 µm, and >586 µm and for CRVO/HRVO were ≤576 µm, >576–≤798 µm, and >798 µm.

BRVO = branch retinal vein occlusion; CRT = central retinal thickness; CRVO = central retinal vein occlusion; HRVO = hemiretinal vein occlusion.

Aflibercept 8 mg groups achieved non-inferior BCVA gains and robust reductions in CRT with fewer injections than in the aflibercept 2 mg, across baseline CRT tertiles across BRVO and CRVO/HRVO subtypes

BRVO

Baseline CRT	Treatment group	Patients	Mean no. of injections[a]
≤452 µm	2q4	n= 48	8.8
	8q8/3	n = 53	6.0
	8q8/5	n= 54	6.8
>452–≤586 µm	2q4	n= 55	8.8
	8q8/3	n = 52	6.0
	8q8/5	n= 49	7.0
>586 µm	2q4	n= 46	8.8
	8q8/3	n = 54	6.2
	8q8/5	n= 56	7.0

CRVO/HRVO

Baseline CRT	Treatment group	Patients	Mean no. of injections[a]
≤576 µm	2q4	n= 41	8.8
	8q8/3	n = 45	6.0
	8q8/5	n= 55	6.9
>576–≤798 µm	2q4	n= 61	8.6
	8q8/3	n = 43	6.1
	8q8/5	n= 38	6.8
>798 µm	2q4	n= 49	8.8
	8q8/3	n = 46	6.1
	8q8/5	n= 46	7.0

Full analysis set. Observed cases excluding values after intercurrent event. Observations after the occurrence of an intercurrent event are excluded in line with the primary estimand strategy. CRT tertiles for BRVO were ≤452 µm, >452–≤586 µm, and >586 µm and for CRVO/HRVO were ≤576 µm, >576–≤798 µm, and >798 µm. [a]Safety analysis set. Patients completing Week 36.

no. = number; BRVO = branch retinal vein occlusion; CRT = central retinal thickness; CRVO = central retinal vein occlusion; HRVO = hemiretinal vein occlusion.

Most patients eligible for dosing interval extension treated with aflibercept 8 mg were last assigned to ≥Q8 dosing intervals at Week 36

Overall RVO population

BRVO

CRVO/HRVO

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

Conclusion

- **The aflibercept 8 mg q8w/3 and 8 mg q8/5 groups achieved noninferior BCVA gains and robust reductions in CRT at Week 36 with fewer injections than the aflibercept 2 mg q4w group, with consistent results across RVO and CRVO/HRVO subtypes**
- **Mean BCVA gains and CRT improvements were similar across baseline CRT tertiles, with fewer injections after treatment with aflibercept 8 mg compared with aflibercept 2 mg across BRVO and CRVO/HRVO subtypes**
- **Approximately 94% of patients across both RVO subtypes in the aflibercept 8 mg q8w/3 group were last assigned to ≥8-week dosing intervals at Week 36**
- **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**