Impact of Baseline Central Retinal Thickness on Visual and Anatomic Outcomes in Patients With Macular Edema Following Retinal Vein Occlusion: Post Hoc Analysis of the Phase 3 QUASAR Trial Through Week 36

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Background and Objective

- The phase 3 QUASAR trial met its primary endpoint, with aflibercept 8 mg achieving noninferior gains in BCVA and a robust reduction in CRT comparable to aflibercept 2 mg through Week 36[1]
- Understanding baseline factors associated with visual and anatomic outcomes can help treatment decisions and facilitate appropriate physician and patient expectations

This post hoc analysis evaluated the impact of baseline CRT on visual and anatomic outcomes in patients with macular edema following RVO treated with aflibercept 8 mg versus aflibercept 2 mg in QUASAR

BCVA, best-corrected visual acuity; CRT, central retinal thickness; RVO, retinal vein occlusion.

1. Gale R. Presented at: Angiogenesis; February 8, 2025; Virtual Edition.

QUASAR Study Design

Multicenter, randomized, double-masked study in patients with treatment-naive macular edema following RVO
Randomized at baseline 1 (2q4) : 1 (8q8/3) : 1 (8q8/5)

2q4
Aflibercept 2 mg every 4 weeks
n=301

8q8/3
Aflibercept 8 mg every 8 weeks after 3 initial monthly injections
n=293

8q8/5
Aflibercept 8 mg every 8 weeks after 5 initial monthly injections
n=298

Primary endpoint at Week 36
Change from baseline in BCVA (noninferiority)

Secondary endpoints at Week 36
Number of active injections from baseline
Change from baseline in CRT

End of study at Week 64

2q4, aflibercept 2 mg every 4 weeks; 8q8/3, aflibercept 8 mg every 8 weeks after 3 initial monthly injections; 8q8/5, aflibercept 8 mg every 8 weeks after 5 initial monthly injections.

QUASAR Dosing Regimen

	Day 1	Wk 4	Wk 8	Wk 12	Wk 16	Wk 20	Wk 24	Wk 28	Wk 32	Wk 36
2q4	X	X	X	X	X	X	X	X	X[b]	T&E
8q8/3	X	X	X	o	X[a]	o	X[a]	o	X[a,b]	T&E
8q8/5	X	X	X	X	X	o	X[a]	o	X[a]	o

☐ Indicates reference visit for DRM assessment (Week 12 for 8q8/3 and Week 20 for 2q4 and 8q8/5)

Primary endpoint
Mean change in BCVA (noninferiority)

[a]DRM: Interval Shortening

- Patients in the 8q8/3, 8q8/5, and 2q4 groups could qualify for interval shortening at a dosing visit beginning at Weeks 16, 24, and 40, respectively
- ***Criteria for interval shortening:***
  - >5-letter loss in BCVA from reference visit[c]
    AND
  - >50-µm increase in CRT from reference visit[c]
- Dosing intervals were shortened by 4-week increments if patients met the DRM criteria and their last dosing interval was ≥Q8

[b]DRM: Interval Extension

- Patients in the 2q4 and 8q8/3 groups could qualify for interval extension at a dosing visit beginning at Week 32 and those in 8q8/5 qualified at Week 40
- ***Criteria for interval extension:***
  - <5-letter loss in BCVA from reference visit[c]
    AND
  - CRT <320 µm on Heidelberg Spectralis (<300 µm on Cirrus or Topcon SD-OCT)
- Dosing intervals were extended by 4-week increments if DRM criteria were met

Stippled boxes = initial treatment phase; X = active injection; o = sham injection. Figure does not reflect all dosing options if the intervals are shortened.
[c]Reference visit defined as Week 12 for 8q8/3 and Week 20 for 8q8/5 and 2q4.
DRM, dose regimen modification; Q8, every 8 weeks; SD-OCT, spectral domain-optical coherence tomography; T&E, treat and extend; Wk, week.

Methods

- A tertile analysis by baseline CRT was conducted post hoc to evaluate visual and anatomic outcomes through Week 36 following treatment with aflibercept 8 mg and 2 mg in patients from QUASAR
- Data through Week 36 for the full analysis were evaluated by RVO subtype (BRVO or CRVO/HRVO). Patients were grouped by baseline CRT as follows:

BRVO

T1: ≤452 µm	**T2: >452 to ≤586 µm**	**T3: >586 µm**

CRVO/HRVO

T1: ≤576 µm	**T2: >576 to ≤798 µm**	**T3: >798 µm**

- Outcomes were summarized descriptively

BRVO, branch retinal vein occlusion; CRVO, central retinal vein occlusion; HRVO, hemiretinal vein occlusion; T, tertile.

Baseline Characteristics of Patients With BRVO by Baseline CRT

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BRVO

	T1: ≤452 µm			T2: >452 to ≤586 µm			T3: >586 µm		
	2q4 (n=48)	8q8/3 (n=53)	8q8/5 (n=54)	2q4 (n=55)	8q8/3 (n=52)	8q8/5 (n=49)	2q4 (n=46)	8q8/3 (n=54)	8q8/5 (n=56)
Age, mean (SD), years	63.0 (11.4)	64.9 (10.6)	66.0 (12.6)	66.6 (9.0)	65.9 (10.1)	64.5 (12.4)	64.9 (11.8)	64.7 (11.6)	64.5 (9.5)
Female, n (%)	31 (64.6)	31 (58.5)	30 (55.6)	28 (50.9)	21 (40.4)	26 (53.1)	19 (41.3)	31 (57.4)	31 (55.4)
Race, n (%)									
White	26 (54.2)	31 (58.5)	27 (50.0)	28 (50.9)	31 (59.6)	28 (57.1)	27 (58.7)	25 (46.3)	30 (53.6)
Asian	20 (41.7)	17 (32.1)	23 (42.6)	24 (43.6)	16 (30.8)	16 (32.7)	17 (37.0)	24 (44.4)	24 (42.9)
Other[a]	2 (4.2)	5 (9.4)	4 (7.4)	3 (5.5)	5 (9.6)	5 (10.2)	2 (4.3)	5 (9.3)	2 (3.6)
Hispanic or Latino, n (%)	5 (10.4)	4 (7.5)	3 (5.6)	1 (1.8)	3 (5.8)	2 (4.1)	5 (10.9)	4 (7.4)	3 (5.4)
BCVA, mean (SD), ETDRS letters	63.7 (9.3)	63.7 (9.7)	61.9 (9.6)	59.0 (11.0)	57.8 (10.8)	62.5 (8.7)	48.5 (14.5)	54.4 (11.9)	51.9 (12.4)
CRT, mean (SD), µm	381.2 (43.6)	377.6 (48.8)	386.2 (47.6)	532.3 (41.4)	520.6 (39.9)	511.8 (42.7)	755.9 (129.0)	744.0 (116.4)	714.8 (126.4)
Total area of macular ischemia,[b] mean (SD), mm^2	4.5 (3.6)	3.8 (3.3)	4.6 (3.5)	6.1 (3.7)	6.7 (3.2)	5.9 (4.0)	7.5 (3.5)	6.6 (4.0)	7.8 (3.9)

Patients with BRVO in the FAS.
[a]Other includes Black or African American, Native Hawaiian or other Pacific Islander, Not reported, and Multiple categories.
[b]Macular ischemia was evaluated by FA; foveal avascular zone was not considered.
ETDRS, Early Treatment Diabetic Retinopathy Study; FA, fluorescein angiography; FAS, full analysis set.

Mean Change in BCVA Through Week 36 by Baseline CRT in Patients With BRVO

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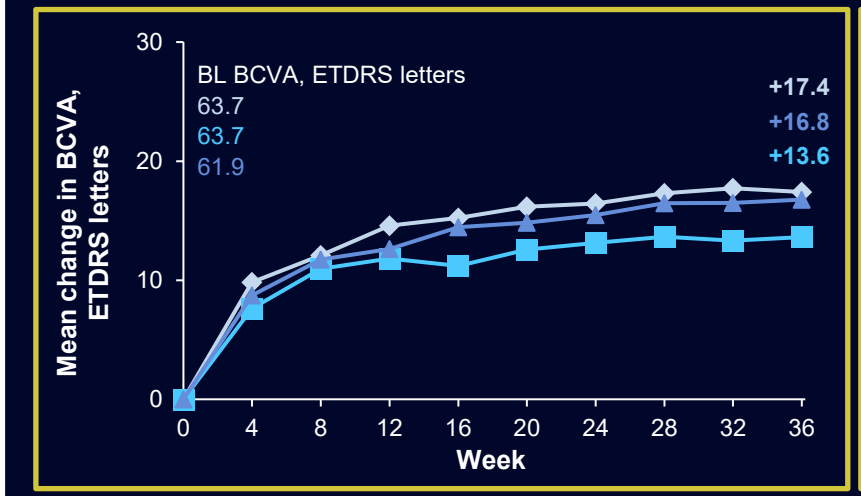
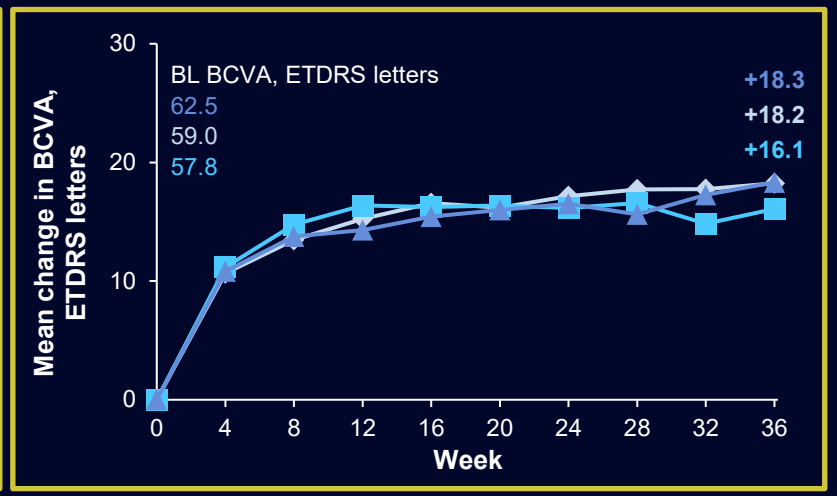
BRVO

T1: ≤452 µm



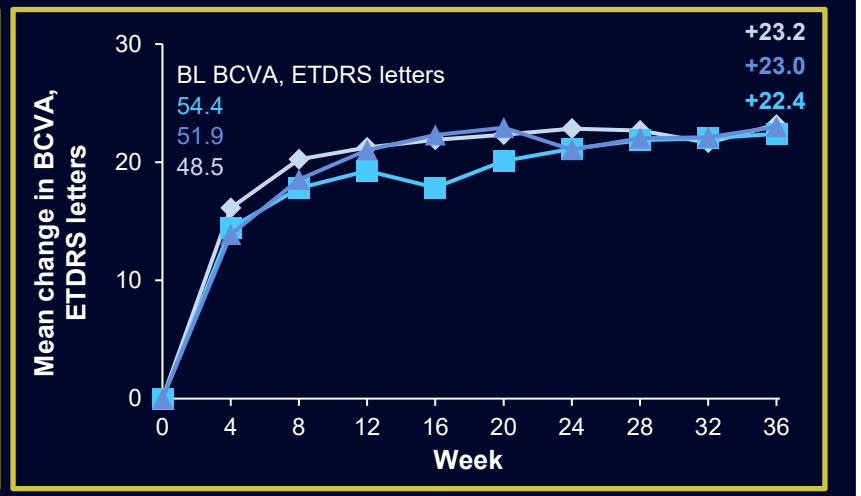
	Mean number of injections[a]
2q4 (n=48)	8.8
8q8/3 (n=53)	6.0
8q8/5 (n=54)	6.8

T2: >452 to ≤586 µm



	Mean number of injections[a]
2q4 (n=55)	8.8
8q8/3 (n=52)	6.0
8q8/5 (n=49)	7.0

T3: >586 µm



	Mean number of injections[a]
2q4 (n=46)	8.8
8q8/3 (n=54)	6.2
8q8/5 (n=56)	7.0

In BRVO, aflibercept 8 mg achieved robust improvements in BCVA through Week 36, with fewer injections than aflibercept 2 mg across all baseline CRT tertiles

Patients with BRVO in the FAS, observed cases excluding intercurrent events.
[a]Patients who completed the Week 36 visit.
BL, baseline.

Mean CRT Through Week 36 by Baseline CRT in Patients With BRVO

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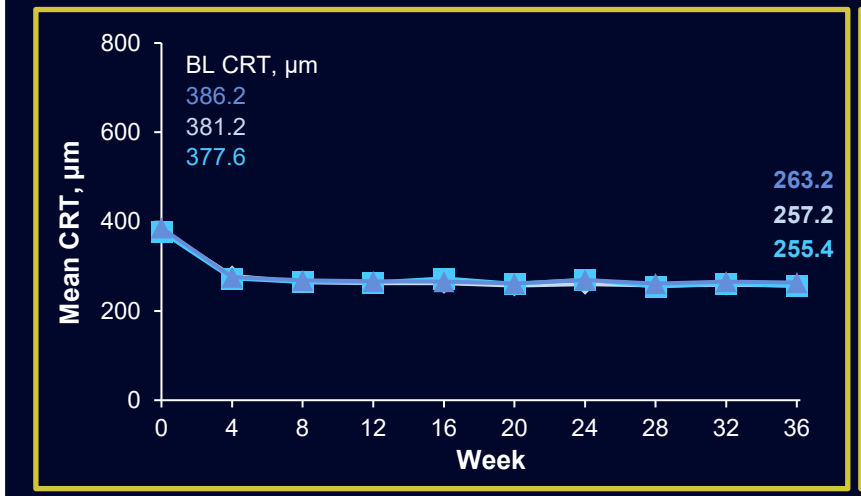
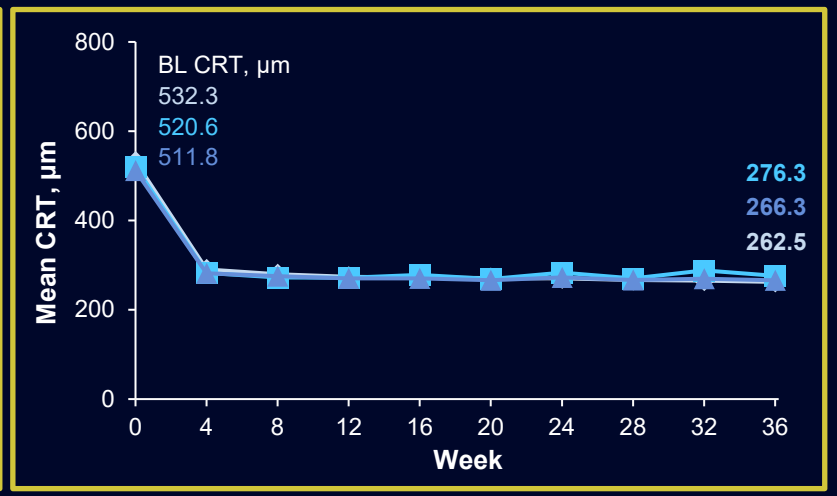
BRVO

T1: ≤452 µm



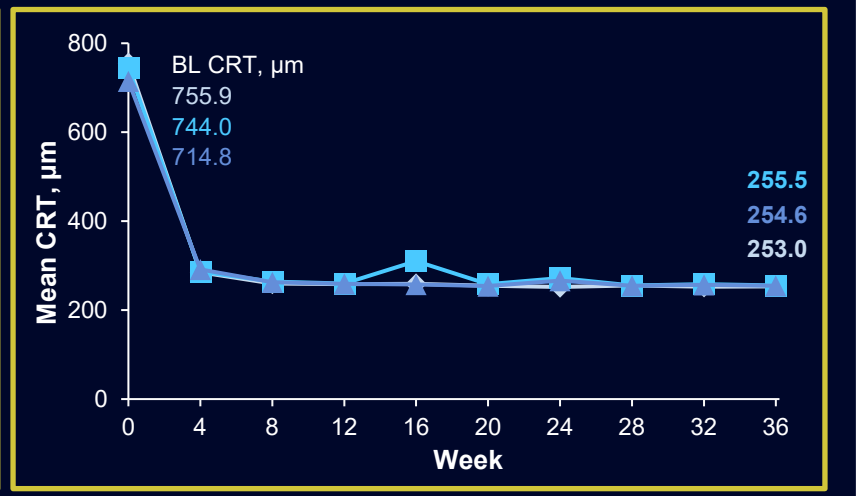
	Mean number of injections[a]
2q4 (n=48)	8.8
8q8/3 (n=53)	6.0
8q8/5 (n=54)	6.8

T2: >452 to ≤586 µm



	Mean number of injections[a]
2q4 (n=55)	8.8
8q8/3 (n=52)	6.0
8q8/5 (n=49)	7.0

T3: >586 µm



	Mean number of injections[a]
2q4 (n=46)	8.8
8q8/3 (n=54)	6.2
8q8/5 (n=56)	7.0

In BRVO, aflibercept 8 mg achieved robust CRT reduction through Week 36, with fewer injections than aflibercept 2 mg across all baseline CRT tertiles

Patients with BRVO in the FAS, observed cases excluding intercurrent events.
[a]Patients who completed the Week 36 visit.

Last Assigned Dosing Interval at Week 36 by Baseline CRT in Patients With BRVO

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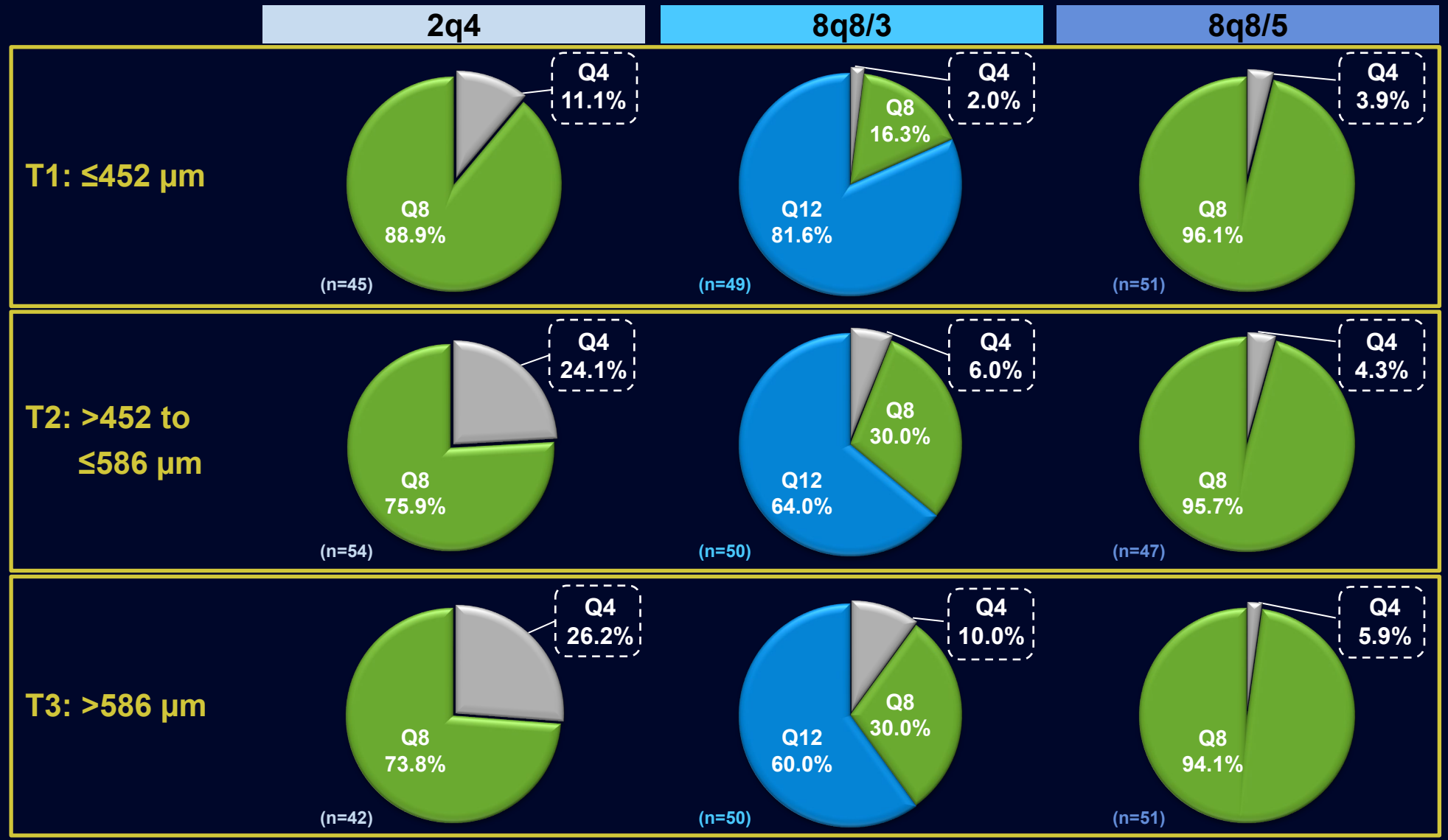
BRVO



8q8/5 group:
Per DRM criteria, patients could not qualify for dosing interval extension until Week 40

Patients with CRVO/HRVO in the FAS who completed the Week 36 visit. Values may not add up to 100% because of rounding.

Baseline Characteristics of Patients With CRVO/HRVO by Baseline CRT

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CRVO/ HRVO

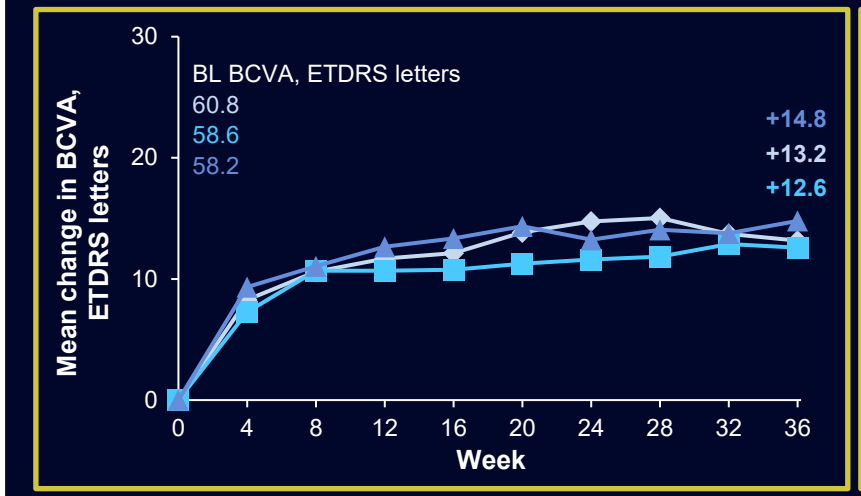
	T1: ≤576 µm			T2: >576 to ≤798 µm			T3: >798 µm		
	2q4 (n=41)	8q8/3 (n=45)	8q8/5 (n=55)	2q4 (n=61)	8q8/3 (n=43)	8q8/5 (n=38)	2q4 (n=49)	8q8/3 (n=46)	8q8/5 (n=46)
Age, mean (SD), years	67.8 (12.4)	66.1 (11.7)	65.2 (11.4)	69.3 (10.4)	66.5 (13.0)	68.8 (13.0)	63.5 (14.5)	67.3 (12.8)	66.9 (10.0)
Female, n (%)	17 (41.5)	17 (37.8)	23 (41.8)	27 (44.3)	18 (41.9)	15 (39.5)	21 (42.9)	18 (39.1)	21 (45.7)
Race, n (%)									
White	29 (70.7)	34 (75.6)	37 (67.3)	36 (59.0)	26 (60.5)	24 (63.2)	32 (65.3)	26 (56.5)	31 (67.4)
Asian	10 (24.4)	8 (17.8)	14 (25.5)	16 (26.2)	12 (27.9)	9 (23.7)	13 (26.5)	14 (30.4)	11 (23.9)
Other[a]	2 (4.9)	3 (6.7)	4 (7.3)	9 (14.8)	5 (11.6)	5 (13.2)	4 (8.2)	6 (13.0)	4 (8.7)
Hispanic or Latino, n (%)	2 (4.9)	4 (8.9)	2 (3.6)	5 (8.2)	4 (9.3)	3 (7.9)	4 (8.2)	6 (13.0)	1 (2.2)
BCVA, mean (SD), ETDRS letters	60.8 (10.1)	58.6 (12.3)	58.2 (13.0)	54.1 (10.9)	54.3 (14.3)	53.9 (11.8)	39.4 (14.3)	41.4 (12.1)	42.5 (13.8)
CRT, mean (SD), µm	467.1 (80.0)	461.6 (81.2)	455.0 (72.9)	694.2 (57.3)	678.5 (58.5)	689.1 (68.9)	1050.0 (191.9)	1005.5 (185.8)	964.8 (135.2)
Total area of macular ischemia,[b] mean (SD), mm^2	2.2 (3.6)	4.2 (6.3)	3.5 (5.2)	1.1 (2.4)	2.6 (4.1)	1.3 (3.2)	4.8 (7.8)	4.1 (6.4)	3.8 (6.8)

Patients with CRVO/HRVO in the FAS.
[a]Other includes Black or African American, American Indian or Alaska Native, Not reported, and Multiple categories.
[b]Macular ischemia was evaluated by FA; foveal avascular zone was not considered.

Mean Change in BCVA Through Week 36 by Baseline CRT in Patients With CRVO/HRVO

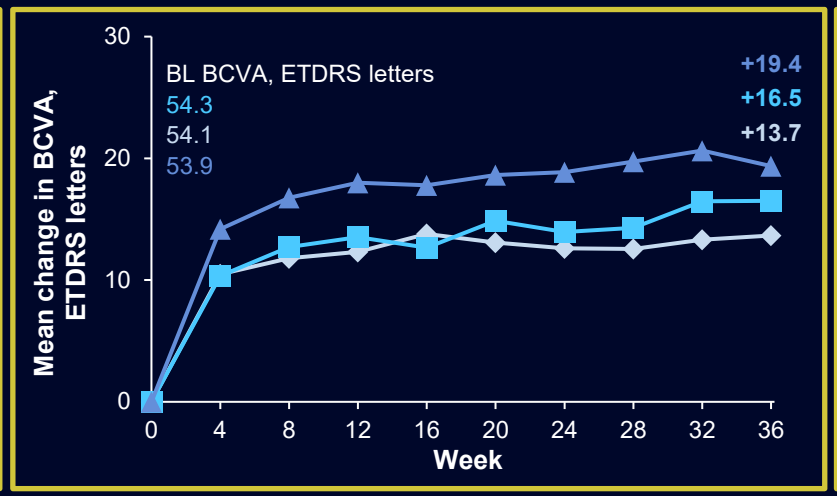
quasar
CRVO/ HRVO

T1: ≤576 µm



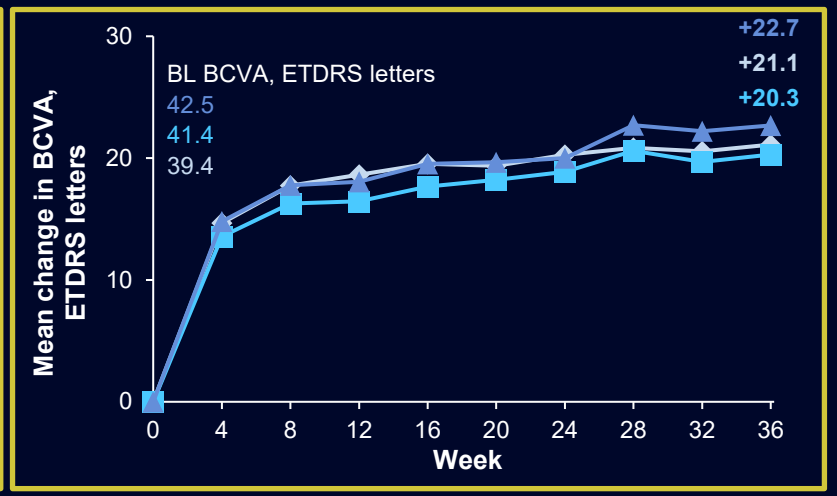
	Mean number of injections[a]
2q4 (n=41)	8.8
8q8/3 (n=45)	6.0
8q8/5 (n=55)	6.9

T2: >576 to ≤798 µm



	Mean number of injections[a]
2q4 (n=61)	8.6
8q8/3 (n=43)	6.1
8q8/5 (n=38)	6.8

T3: >798 µm



	Mean number of injections[a]
2q4 (n=49)	8.8
8q8/3 (n=46)	6.1
8q8/5 (n=46)	7.0

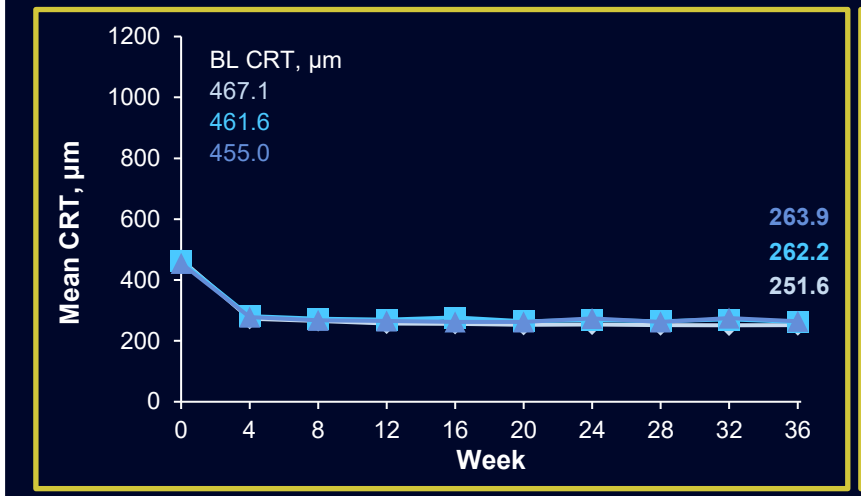
In CRVO/HRVO, aflibercept 8 mg achieved robust improvements in BCVA through Week 36, with fewer injections than aflibercept 2 mg across all baseline CRT tertiles

Patients with CRVO/HRVO in the FAS, observed cases excluding intercurrent events.
[a]Patients who completed the Week 36 visit.

Mean CRT Through Week 36 by Baseline CRT in Patients With CRVO/HRVO

quasar
CRVO/ HRVO

T1: ≤576 µm



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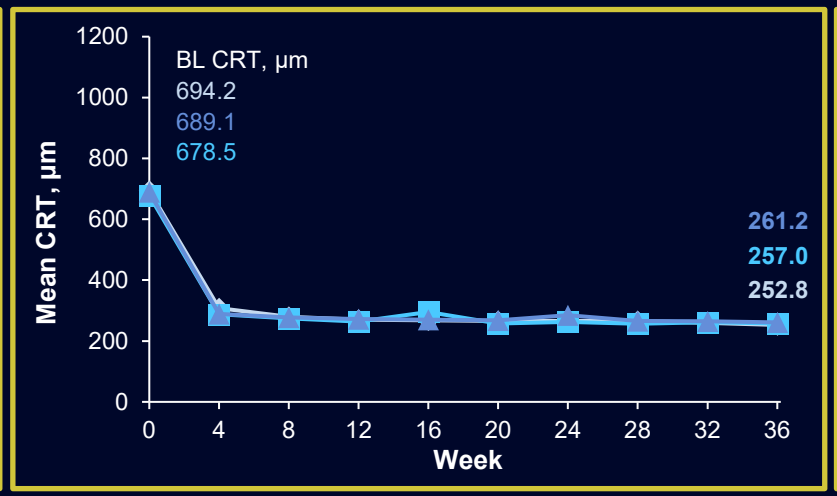
T2: >576 to ≤798 µm



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2q4 (n=61)	8.6
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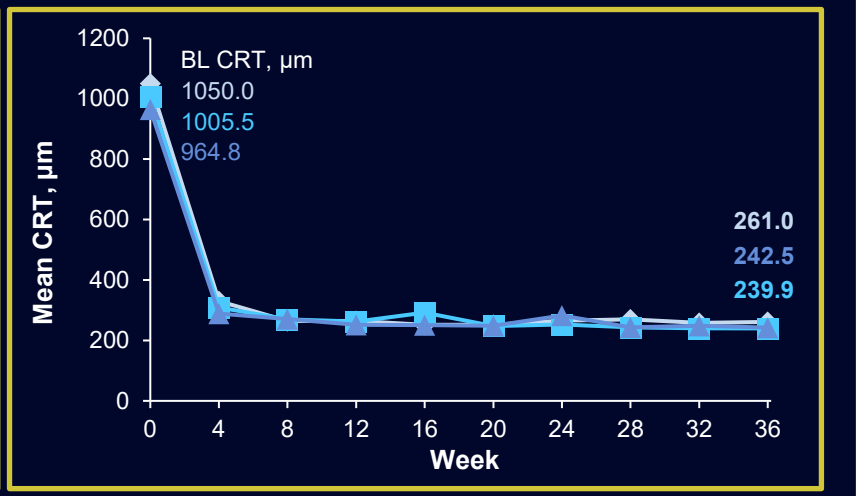
8q8/5 (n=38)	6.8

T3: >798 µm



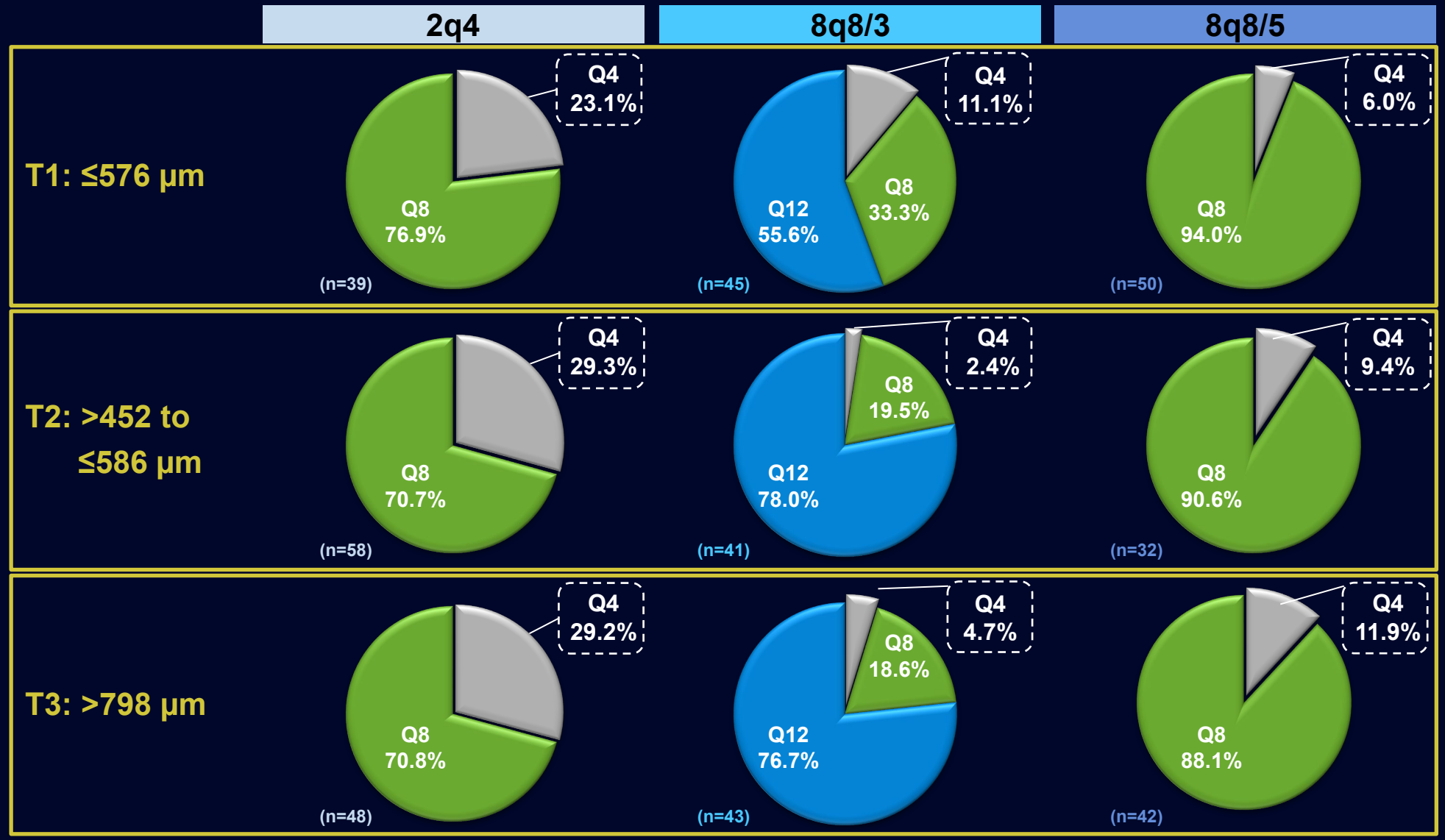
	Mean number of injections[a]
2q4 (n=49)	8.8
8q8/3 (n=46)	6.1
8q8/5 (n=46)	7.0

In CRVO/HRVO, aflibercept 8 mg achieved robust CRT reduction through Week 36, with fewer injections than aflibercept 2 mg across all baseline CRT tertiles

Patients with CRVO/HRVO in the FAS, observed cases excluding intercurrent events.
[a]Patients who completed the Week 36 visit.

Last Assigned Dosing Interval at Week 36 by Baseline CRT in Patients With CRVO/HRVO

quasar CRVO/HRVO



8q8/5 group:
Per DRM criteria, patients could not qualify for dosing interval extension until Week 40

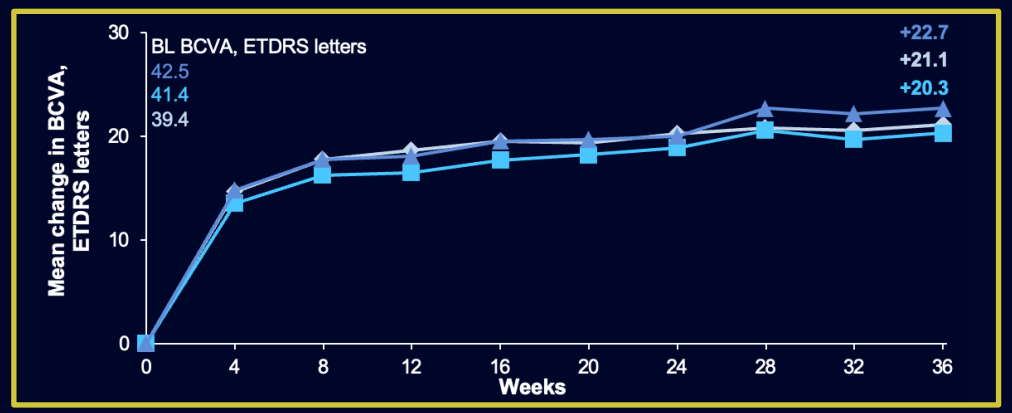
Patients with CRVO/HRVO in the FAS who completed the Week 36 visit. Values may not add up to 100% because of rounding.

Conclusions

- Aflibercept 8 mg achieved robust visual and anatomic improvements through Week 36 in patients with macular edema following RVO across all baseline CRT tertiles with fewer injections compared with aflibercept 2 mg
- Substantially fewer patients required Q4 dosing with aflibercept 8 mg compared with 2 mg at Week 36 regardless of baseline CRT tertile and RVO type

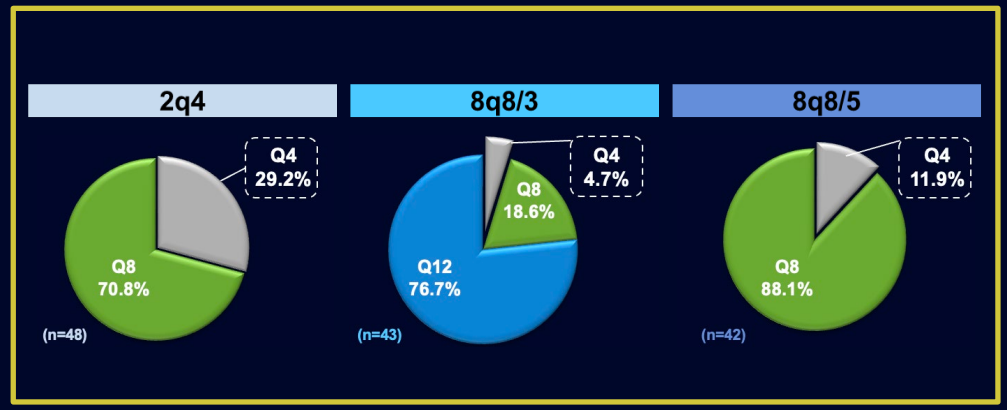
Mean Change in BCVA Through Week 36 by Baseline CRT[a]
T3: >798 µm

CRVO/HRVO



Last Assigned Dosing Interval at Week 36 by Baseline CRT[b]
T3: >798 µm

CRVO/HRVO



[a]Patients with CRVO/HRVO in the FAS, observed cases excluding intercurrent events.
[b]Patients with CRVO/HRVO in the FAS who completed the Week 36 visit. Values may not add up to 100% because of rounding.