Impact of Baseline Central Retinal Thickness on Visual and Anatomic Outcomes in Macular Edema Following RVO: A QUASAR Post Hoc Analysis Through Week 36

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Disclosures

- Ehsan Rahimy reports serving as a speaker and consultant for AbbVie, Apellis, Harrow, and Regeneron Pharmaceuticals, Inc.; and consulting for EyePoint, Genentech, and Zeiss
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QUASAR: Study Design

A multicenter, randomized, double-masked, phase 3 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 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
Mean change in BCVA (noninferiority)

	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[c]

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,[d] 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 on Heidelberg (or <300 µm on 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. 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 visit for 8q8/3 and Week 20 visit for 8q8/5 and 2q4 (denoted by green boxes on table).
2q4, aflibercept 2 mg every 4 weeks; 8q8/3, aflibercept 8 mg every 8 weeks after 3 initial injections at 4-week intervals; 8q8/5, aflibercept 8 mg every 8 weeks after 5 initial injections at 4-week intervals; BCVA, best-corrected visual acuity; CRT, central retinal thickness; DRM, dose regimen modification; Q8, every 8 weeks; RVO, retinal vein occlusion; SD-OCT, spectral domain-optical coherence tomography; T&E, treat and extend; W, week.

Objective and Methods

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

- Data through Week 36 for the full analysis set were evaluated by RVO subtype (BRVO or CRVO/HRVO). Patients outcomes were evaluated by baseline CRT tertiles 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 Tertiles

BRVO

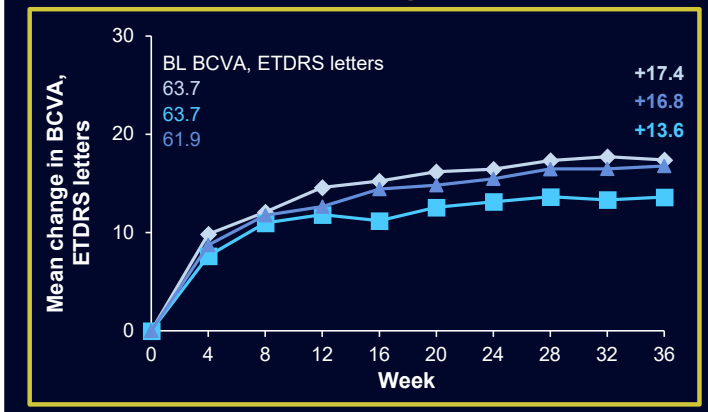
	T1: ≤452 µm			T2: >452 to ≤586 µm			T3: >586 µm		
	2q4 (n=48)	8q8/3 (n=53)	8q8/5 (n=54)	2q4 (n=55)	8q8/3 (n=52)	8q8/5 (n=49)	2q4 (n=46)	8q8/3 (n=54)	8q8/5 (n=56)
Age, mean (SD), years	63.0 (11.4)	64.9 (10.6)	66.0 (12.6)	66.6 (9.0)	65.9 (10.1)	64.5 (12.4)	64.9 (11.8)	64.7 (11.6)	64.5 (9.5)
Female, n (%)	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

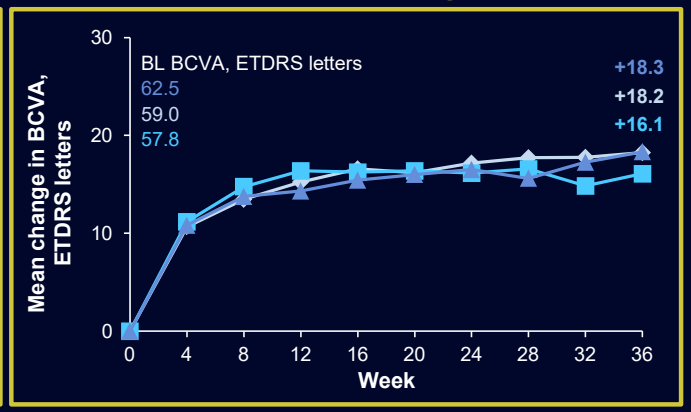
BRVO

T1: ≤452 µm



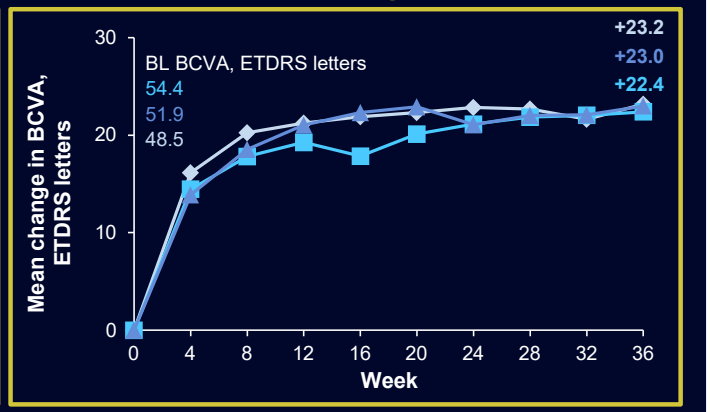
	Mean number of injections[a]
2q4 (n=48)	8.8
8q8/3 (n=53)	6.0
8q8/5 (n=54)	6.8

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

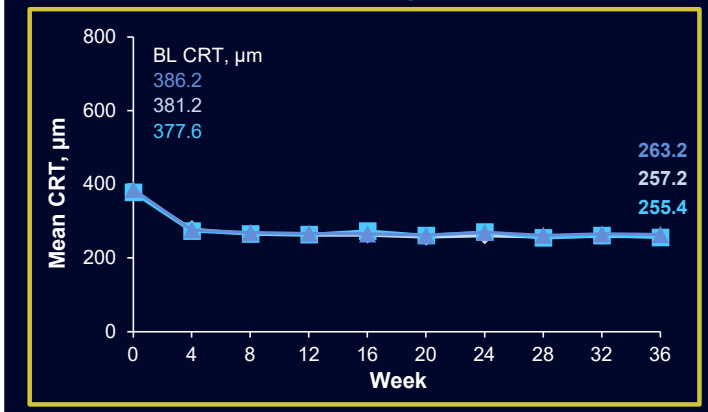
In BRVO, aflibercept 8 mg achieved robust improvements in BCVA through Week 36, with fewer injections than aflibercept 2 mg across all baseline CRT tertiles

Patients with BRVO in the FAS, observed cases excluding intercurrent events.
[a]Patients who completed the Week 36 visit.
BL, baseline; ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set.

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

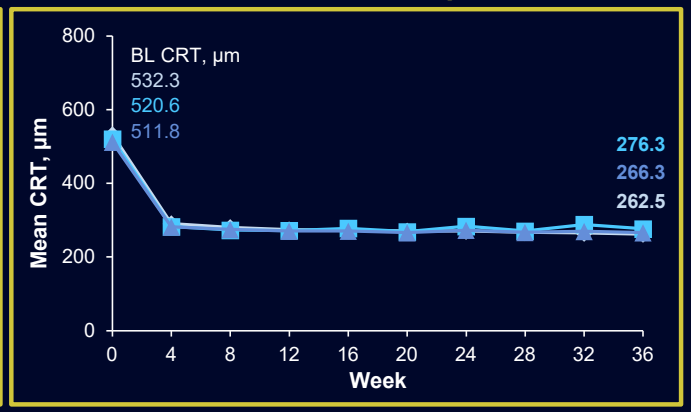
BRVO

T1: ≤452 µm



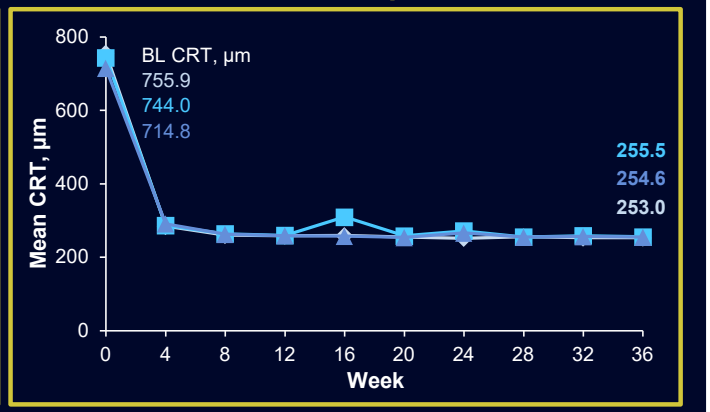
	Mean number of injections[a]
2q4 (n=48)	8.8
8q8/3 (n=53)	6.0
8q8/5 (n=54)	6.8

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



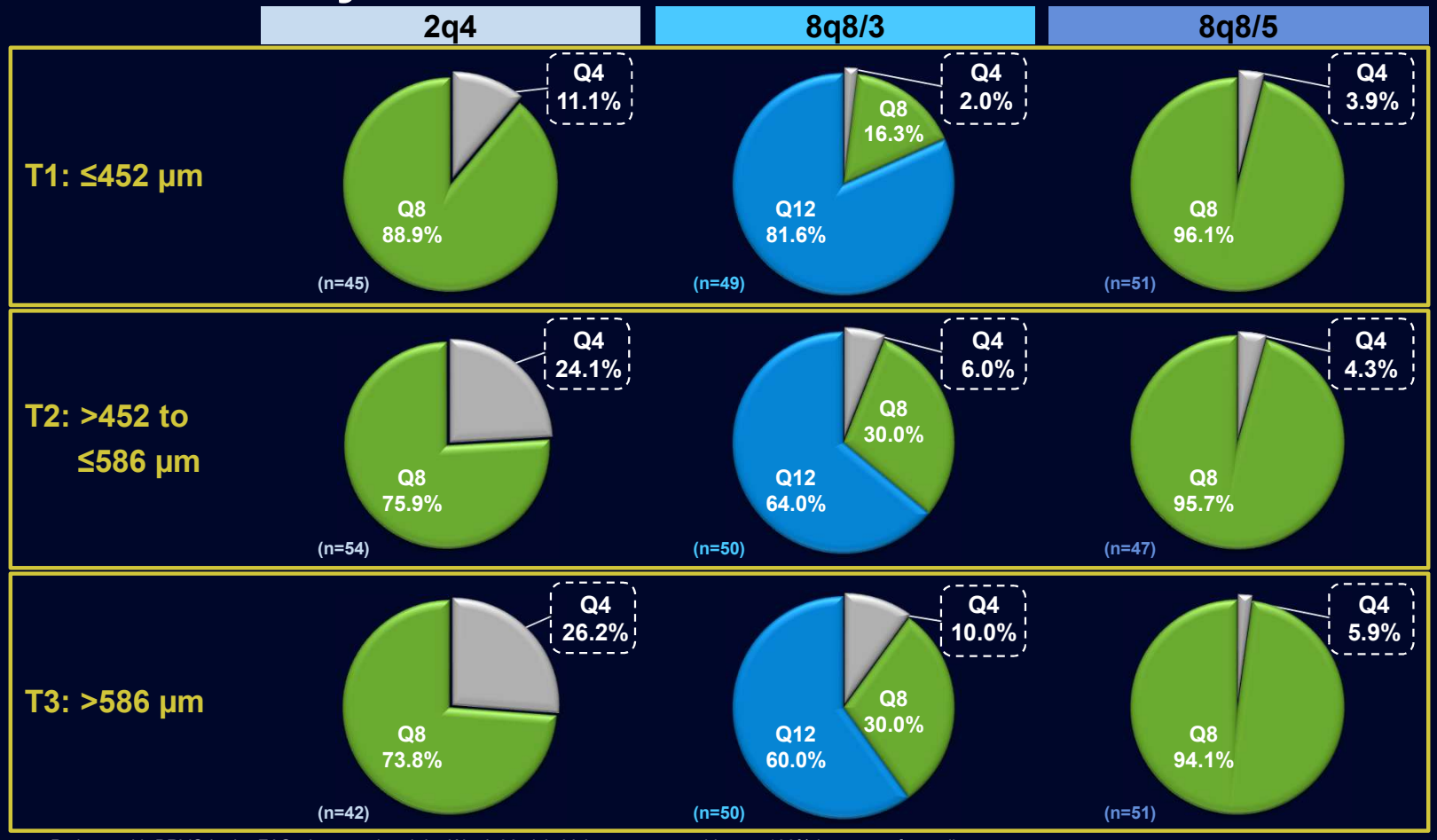
	Mean number of injections[a]
2q4 (n=46)	8.8
8q8/3 (n=54)	6.2
8q8/5 (n=56)	7.0

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

BRVO



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

Patients with BRVO in the FAS who completed the Week 36 visit. Values may not add up to 100% because of rounding.
Q4, every 4 weeks; Q12, every 12 weeks.

Baseline Characteristics of Patients With CRVO/HRVO by Baseline CRT Tertiles

CRVO/ HRVO

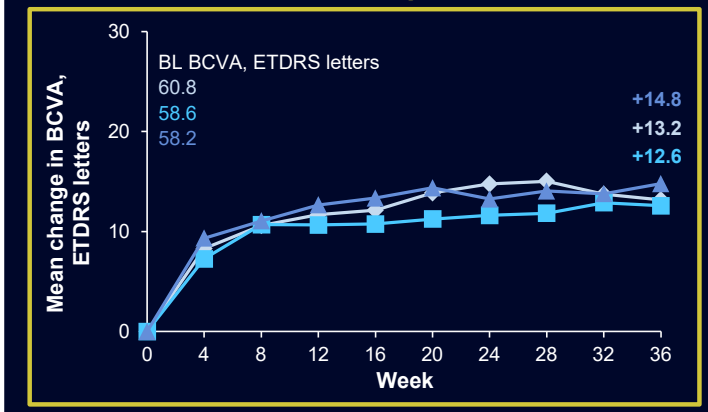
	T1: ≤576 µm			T2: >576 to ≤798 µm			T3: >798 µm		
	2q4 (n=41)	8q8/3 (n=45)	8q8/5 (n=55)	2q4 (n=61)	8q8/3 (n=43)	8q8/5 (n=38)	2q4 (n=49)	8q8/3 (n=46)	8q8/5 (n=46)
Age, mean (SD), years	67.8 (12.4)	66.1 (11.7)	65.2 (11.4)	69.3 (10.4)	66.5 (13.0)	68.8 (13.0)	63.5 (14.5)	67.3 (12.8)	66.9 (10.0)
Female, n (%)	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

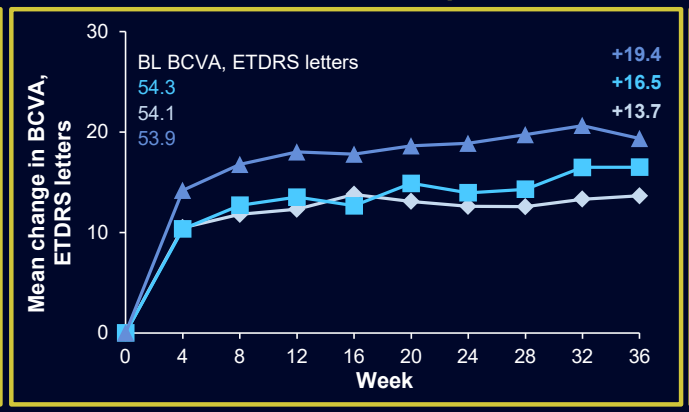
CRVO/ HRVO

T1: ≤576 µm



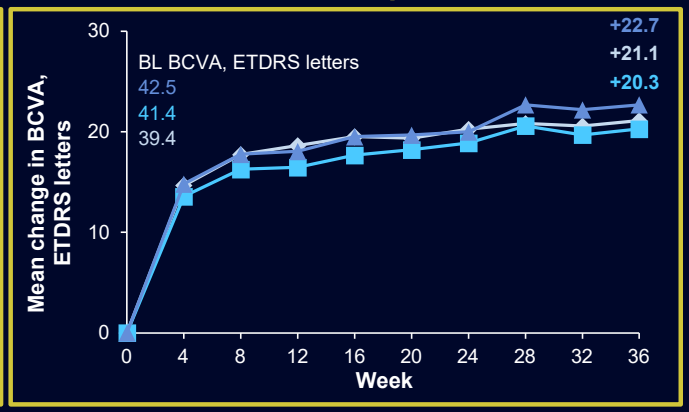
	Mean number of injections[a]
2q4 (n=41)	8.8
8q8/3 (n=45)	6.0
8q8/5 (n=55)	6.9

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

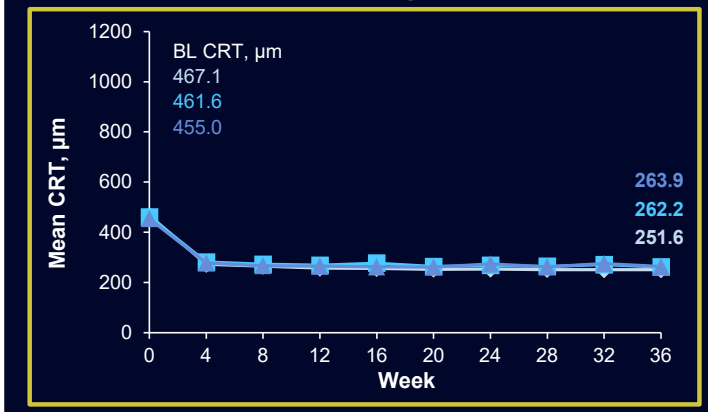
In CRVO/HRVO, aflibercept 8 mg achieved robust improvements in BCVA through Week 36, with fewer injections than aflibercept 2 mg across all baseline CRT tertiles

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

CRVO/ HRVO

T1: ≤576 µm



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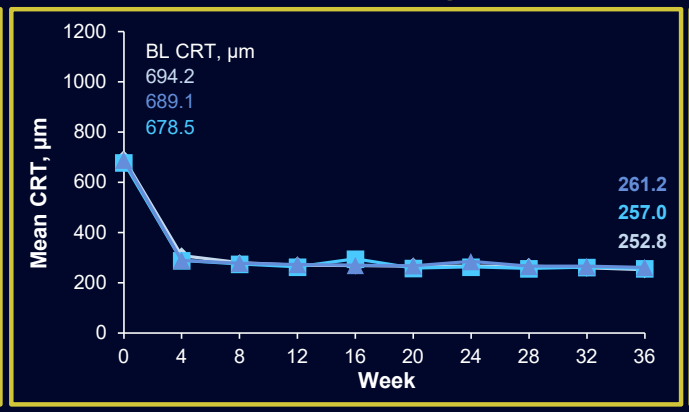
8q8/5 (n=55)	6.9

T2: >576 to ≤798 µm



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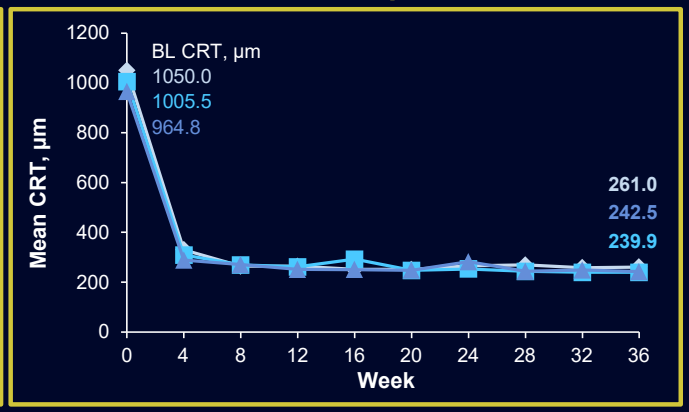
8q8/3 (n=43)	6.1
8q8/5 (n=38)	6.8

T3: >798 µm



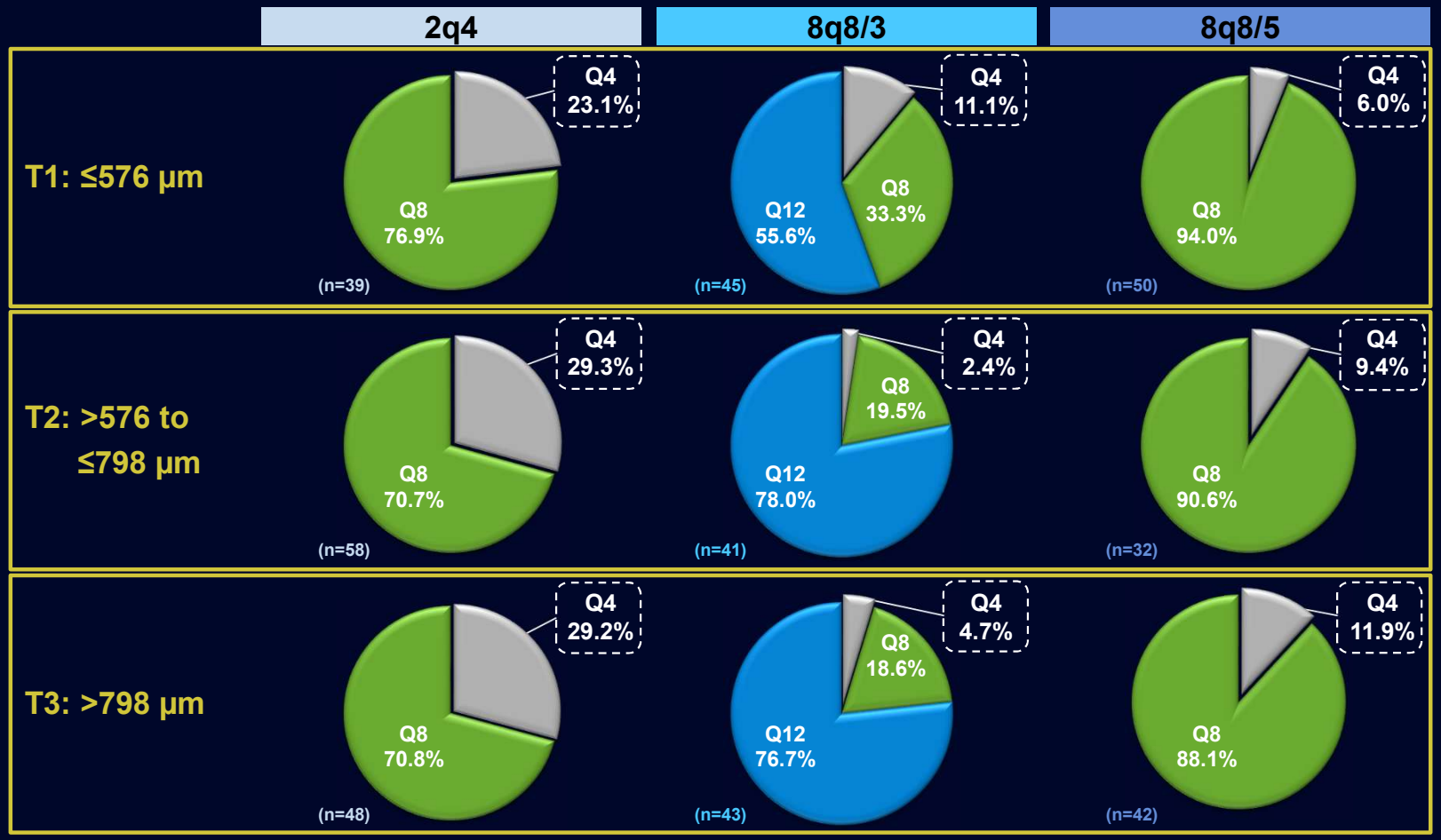
	Mean number of injections[a]
2q4 (n=49)	8.8
8q8/3 (n=46)	6.1
8q8/5 (n=46)	7.0

In CRVO/HRVO, aflibercept 8 mg achieved robust 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

CRVO/ HRVO



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

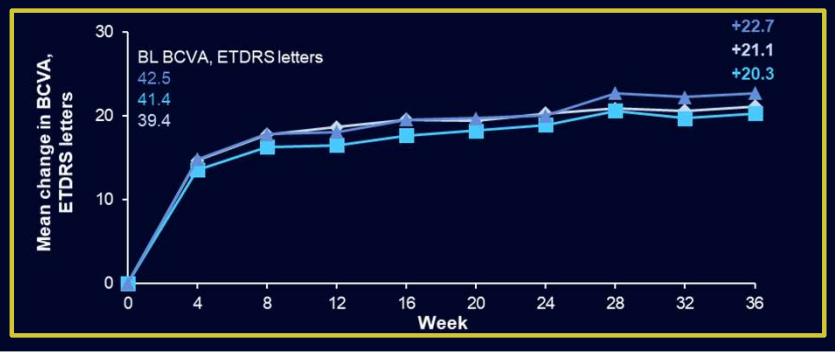
Patients with CRVO/HRVO in the FAS who completed the Week 36 visit. Values may not add up to 100% because of rounding.

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 to aflibercept 2 mg
- Substantially fewer patients required Q4 dosing with aflibercept 8 mg compared to 2 mg at Week 36 regardless of baseline CRT tertile and RVO type

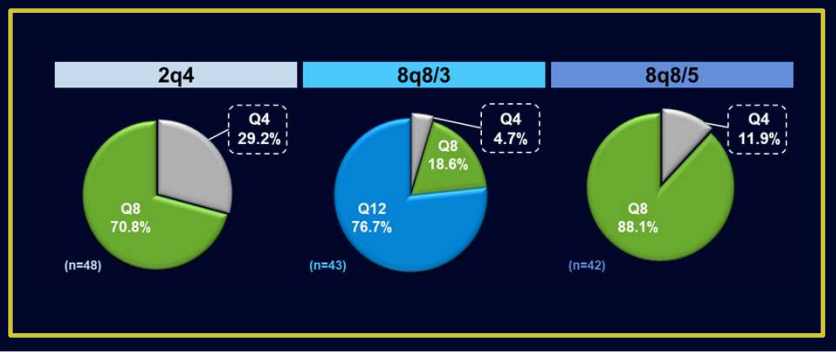
Mean Change in BCVA Through Week 36 by Baseline CRT[a]
T3: >798 µm

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.