Week 96 Outcomes in Aflibercept 8 mg- and 2 mg-Treated Participants by Prior DME Treatment Status: a Subgroup Analysis of the Phase 2/3 PHOTON Trial

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Disclosures

- Michael Ip reports consulting fees: Alimera, Allergan, Amgen, Apellis, Astellas, Boehringer Ingelheim, Clearside Biomedical, Genentech, Inc., Novartis, **Regeneron Pharmaceuticals, Inc.,** Zeiss and Research Support: Boehringer Ingelheim, 4DMT, Apellis, Astellas, Biogen, Genentech, Lineage Cell Therapeutics, ONL Therapeutics, **Regeneron Pharmaceuticals, Inc.**, Regenexbio
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Background

- 44% of participants in PHOTON received prior treatment for DME
- Previous treatments for DME were laser, intravitreal anti-VEGF therapy, and corticosteroids
- We took this opportunity to evaluate visual acuity and anatomic outcomes (CRT and DRSS) in PHOTON participants by prior DME treatment status

CRT, central retinal thickness; DME, diabetic macular edema; DRSS, Diabetic Retinopathy Severity Scale; VEGF, vascular endothelial growth factor.

Baseline Demographics

	With Prior DME Treatment			Without Prior DME Treatment		
	2q8 (n=74)	8q12 (n=146)	8q16 (n=71)	2q8 (n=93)	8q12 (n=182)	8q16 (n=92)
Age, years	64.4 (8.9)	62.7 (10.9)	63.0 (8.4)	62.0 (10.4)	61.6 (11.3)	60.9 (10.3)
Female, %	45.9	39.7	40.8	44.1	33.0	38.0
Race, %						
White	64.9	69.2	77.5	68.8	71.4	79.3
Asian	21.6	19.9	18.3	15.1	10.4	10.9
Black or African American	9.5	7.5	4.2	11.8	13.2	6.5
American Indian or Alaskan Native	0.0	0.7	0.0	0.0	0.5	0.0
Other	2.7	1.4	0.0	2.2	2.2	1.1
Not reported	1.4	1.4	0.0	2.2	1.1	2.2
Hispanic or Latino, %	18.9	17.1	22.5	18.3	15.9	19.6
Duration of diabetes, years	16.7 (10.6)	16.2 (9.4)	16.6 (9.7)	15.5 (9.6)	14.5 (10.3)	15.0 (11.4)

Data are mean (SD) unless otherwise indicated.
SD, standard deviation.

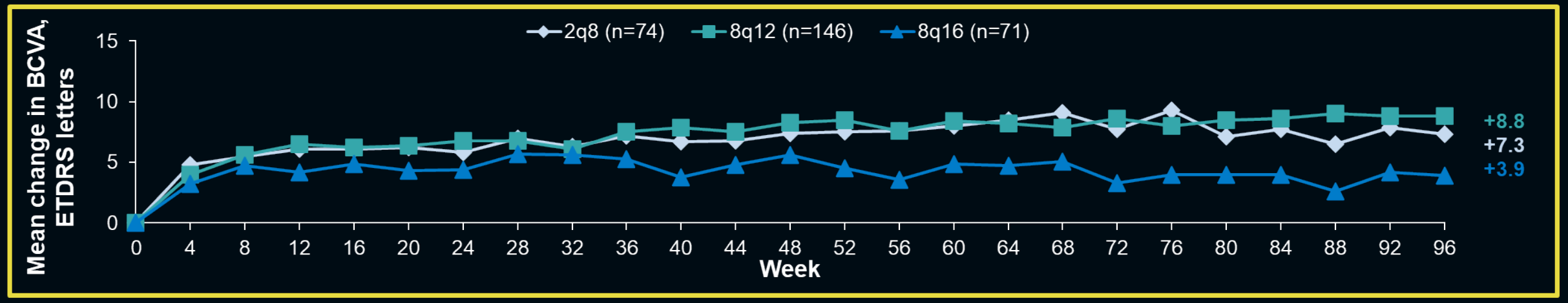
Baseline Ocular Characteristics

	With Prior DME Treatment			Without Prior DME Treatment		
	2q8 (n=74)	8q12 (n=146)	8q16 (n=71)	2q8 (n=93)	8q12 (n=182)	8q16 (n=92)
BCVA, ETDRS letters	62.1 (10.9)	62.2 (10.7)	58.6 (11.9)	61.0 (11.5)	64.8 (9.5)	63.7 (11.2)
Snellen equivalent, %						
20/32 (>73 to 78 letters)	14.9	16.4	5.6	9.7	19.2	20.7
20/40 or worse (≤73 letters)	85.1	83.4	94.4	90.3	80.8	79.3
CRT, µm	472.7 (162.3)	456.9 (123.9)	460.6 (109.3)	444.9 (127.1)	442.9 (130.2)	460.1 (124.7)
DRSS categories, %						
Better or equal to level 43	70.3	66.4	67.6	57.0	54.9	64.1
Level 47 or worse	25.7	28.1	23.9	36.6	39.6	31.5
Missing/ungradable	4.1	5.5	8.5	6.5	5.5	4.3

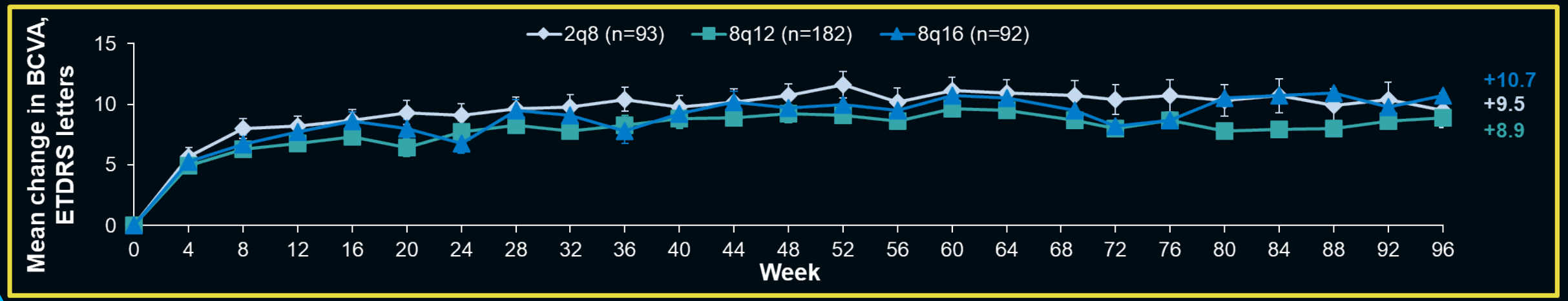
Data are mean (SD) unless otherwise indicated.
BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study.

Mean Change in BCVA Through Week 96

With Prior DME Treatment



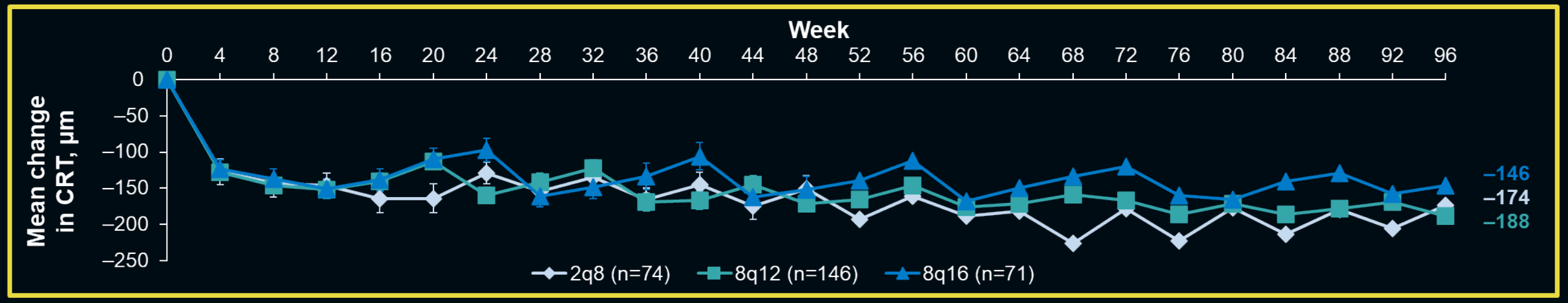
Without Prior DME Treatment



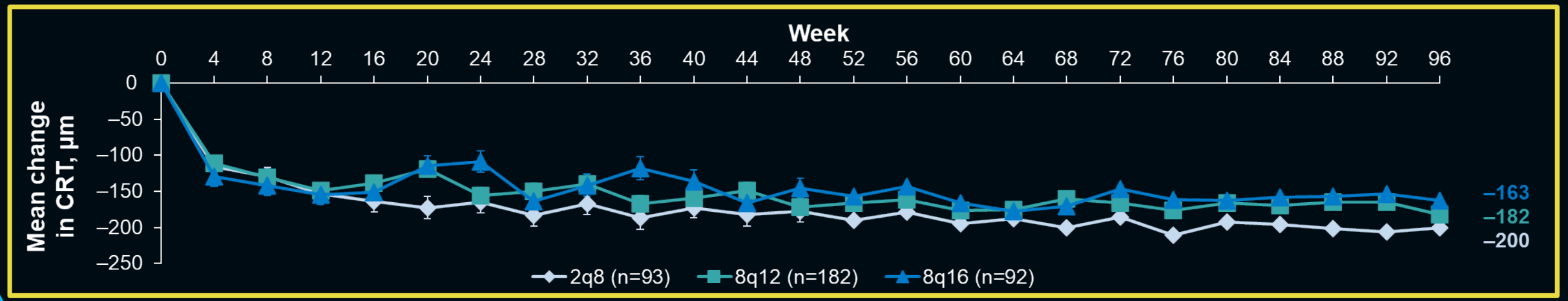
FAS, observed cases.
FAS, full analysis set.

Mean Change in CRT Through Week 96

With Prior DME Treatment



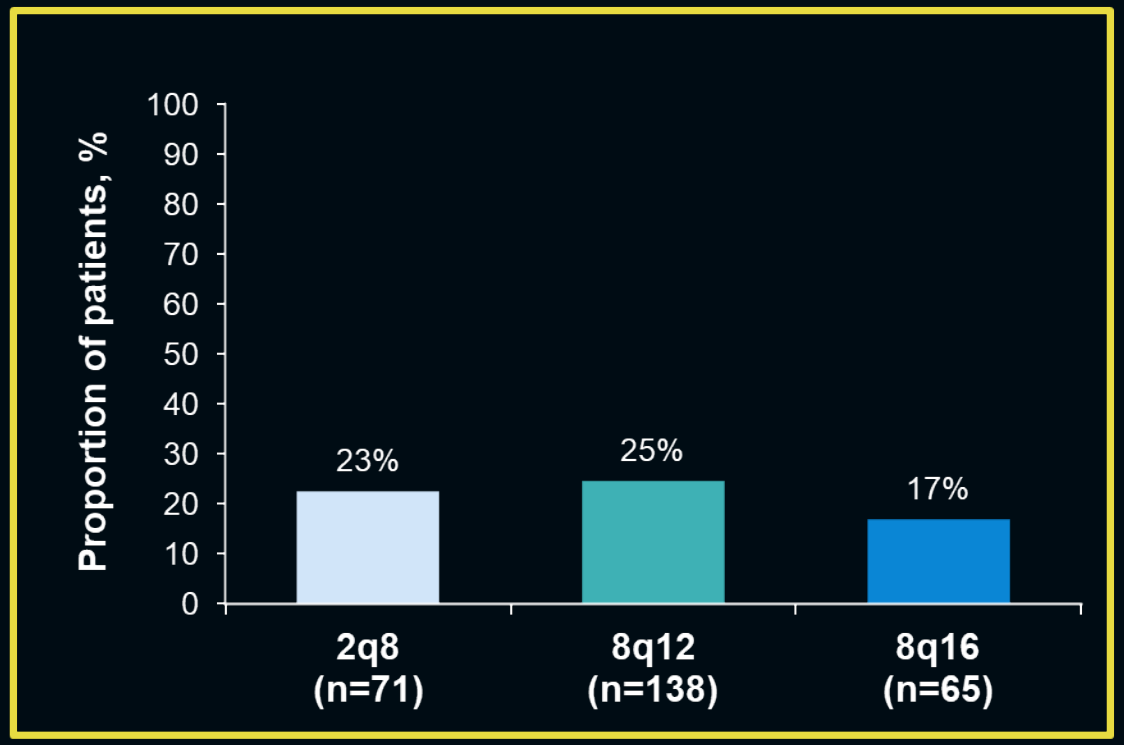
Without Prior DME Treatment



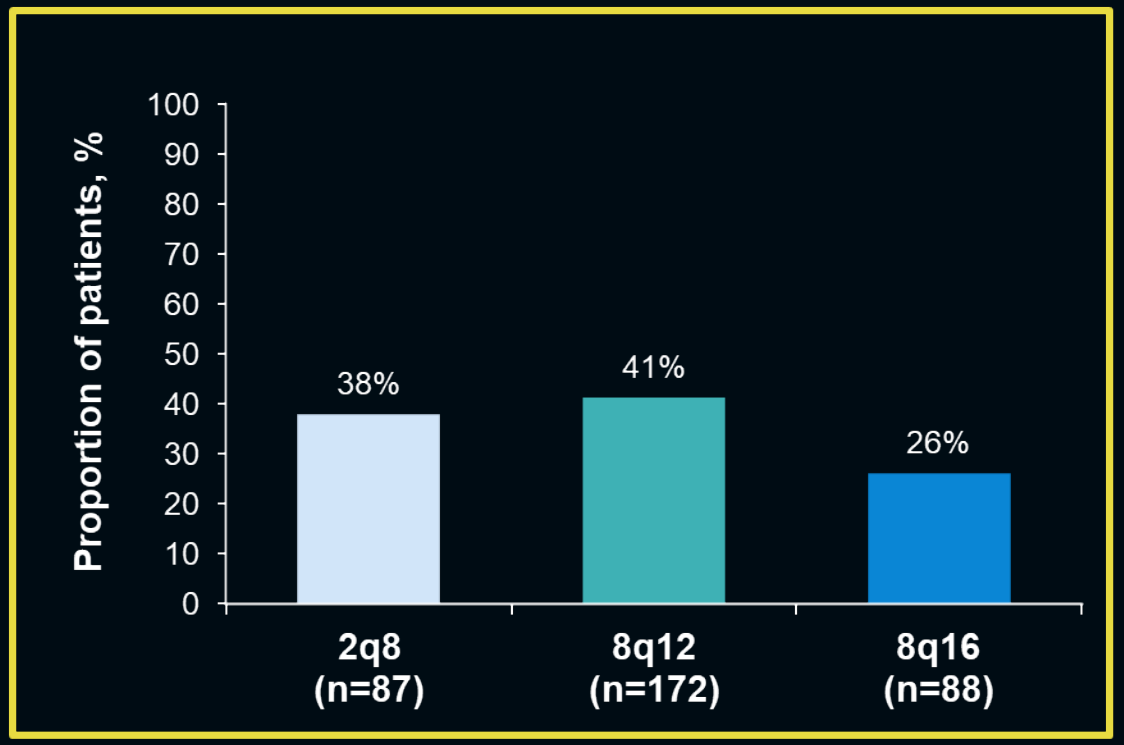
FAS, observed cases.

Proportion of Participants With ≥2-Step DRSS Improvement From Baseline at Week 96

With Prior DME Treatment



Without Prior DME Treatment

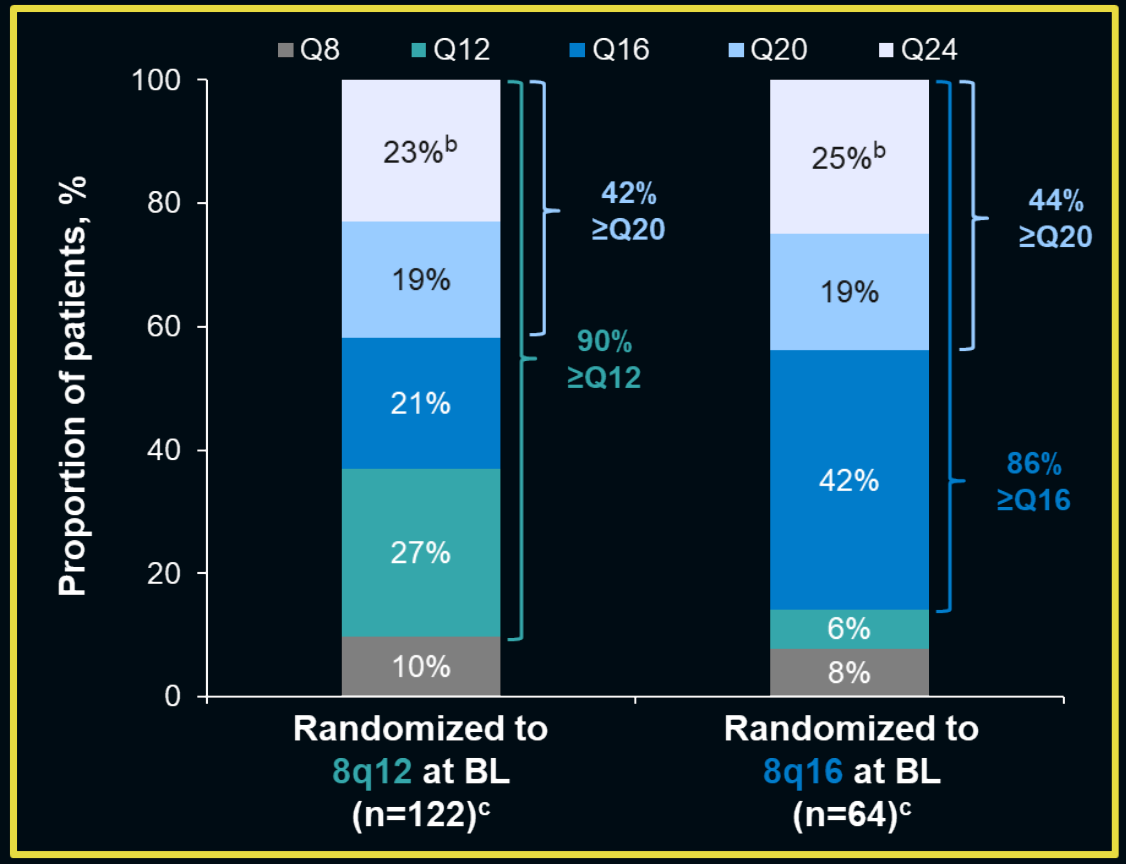


FAS, LOCF.
LOCF, last observation carried forward.

Large Proportion of Patients Qualified for Interval Extension in Year 2[a]

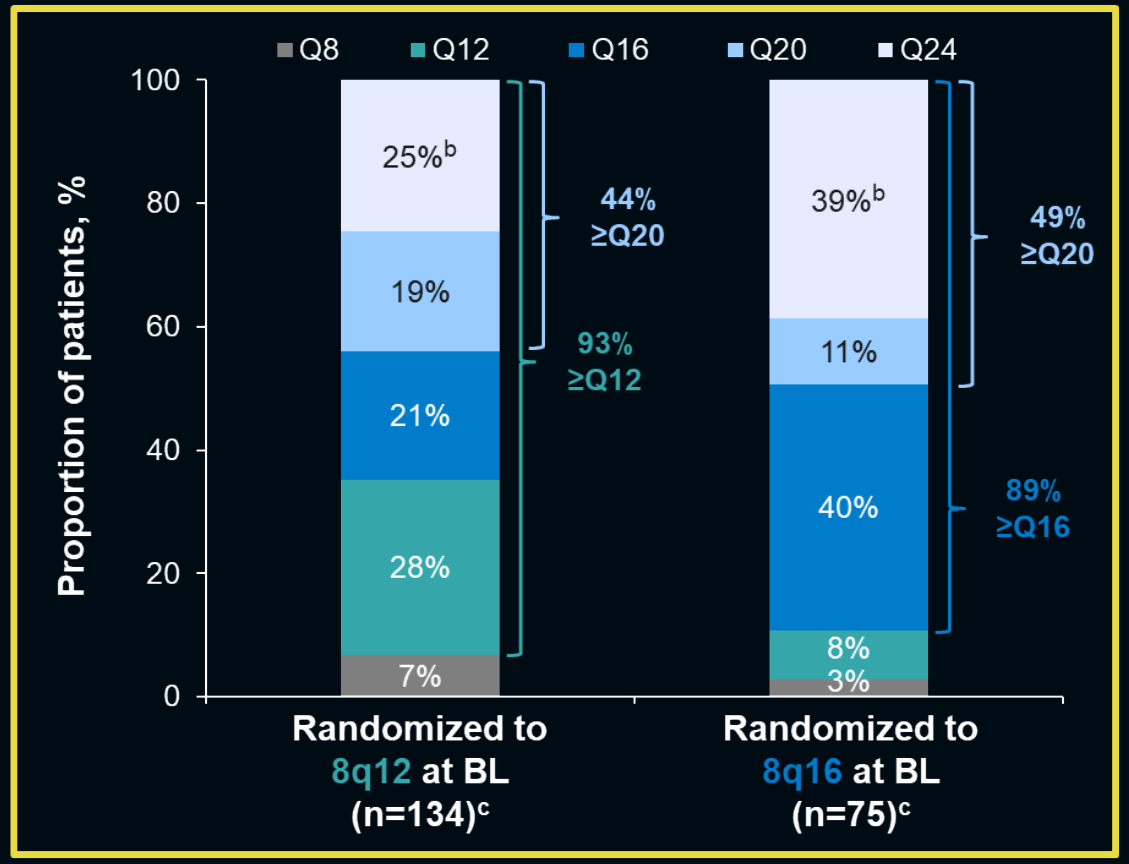
With Prior DME Treatment

Last Assigned



Without Prior DME Treatment

Last Assigned



[a]Dosing intervals were extended in Year 2 if patients had <5-letter loss in BCVA from Week 12 and CRT <300 µm (or <320 µm on Spectralis). [b]Patients were assigned to 24-week dosing intervals if they continued to meet extension criteria but there was not sufficient time to complete the interval within the 96-week study period. [c]Patients completing Week 96.
Values may not add up to 100% due to rounding.
BL, baseline.

Conclusions

- In the 8q16 subgroup with prior DME treatment, the mean BCVA gain from baseline to Week 96 was lower compared with the other subgroups suggesting that some participants in this subgroup may have benefited from more frequent treatment
  - This may have been a particularly recalcitrant subgroup as the baseline VA in this group was lower than the other subgroups
- CRT improvements were generally comparable at Week 96 irrespective of prior DME treatment status
- Proportions of participants with a ≥2-step improvement in DRSS at Week 96 trended numerically higher in the without versus with prior DME treatment subgroup
- Similar proportions of 8q12 and 8q16 patients had a last assigned dosing interval of at least 20 weeks at Week 96 irrespective of prior DME treatment status