Outcomes of Patients with Diabetic Macular Edema and Baseline Best-corrected Visual Acuity 20/50 or Worse or 20/40 or Better Treated With Aflibercept 8 mg and 2 mg in the Phase 2/3 PHOTON Trial

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METHODS

Objective: This analysis evaluated visual and anatomic outcomes with aflibercept 8 mg and 2 mg in patients with DME by baseline BCVA (20/50 or worse versus 20/40 or better)

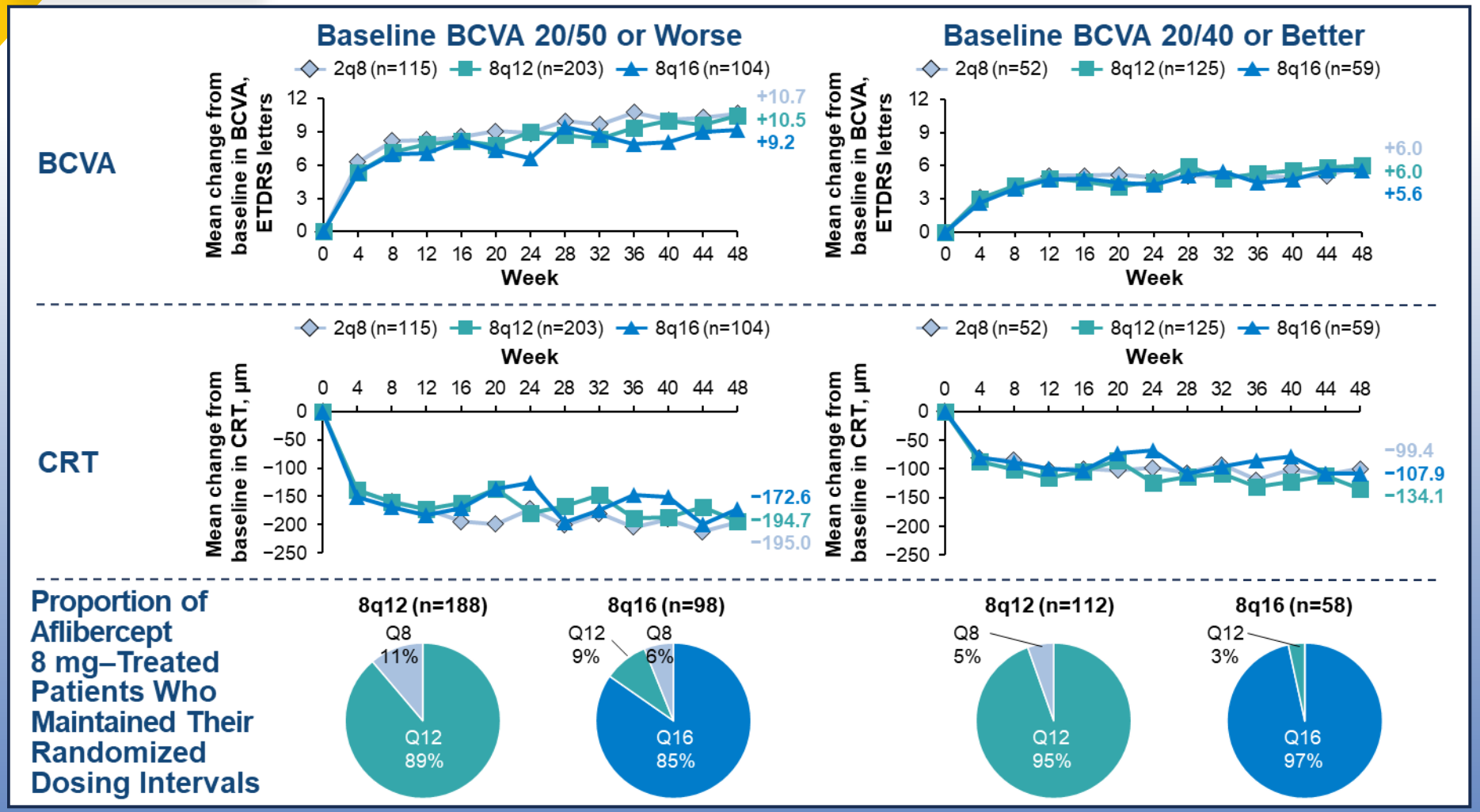
- This is a post hoc analysis of PHOTON trial data through Week 48 in patients with DME who were randomized 1:2:1 to receive intravitreal aflibercept 2q8, 8q12, or 8q16
- Patients in the FAS were analyzed in subgroups as follows:

Baseline BCVA 20/50 or worse:	<69 ETDRS letters
Baseline BCVA 20/40 or better:	≥69 ETDRS letters

- Key outcomes assessed include:
  - Mean change in BCVA through Week 48
  - Mean change in CRT through Week 48
  - Proportion of patients in the 8q12 and 8q16 arms who maintained their original randomized dosing intervals through Week 48
- All analyses were descriptive

2q8, aflibercept 2 mg every 8 weeks after 5 initial monthly injections; 8q12, aflibercept 8 mg every 12 weeks after 3 initial monthly injections; 8q16, aflibercept 8 mg every 16 weeks after 3 initial monthly injections; BCVA, best corrected visual acuity; CRT, central retinal thickness; DME, diabetic macular edema; ETDRS, Early Treatment Diabetic Retinopathy Study; FAS, full analysis set

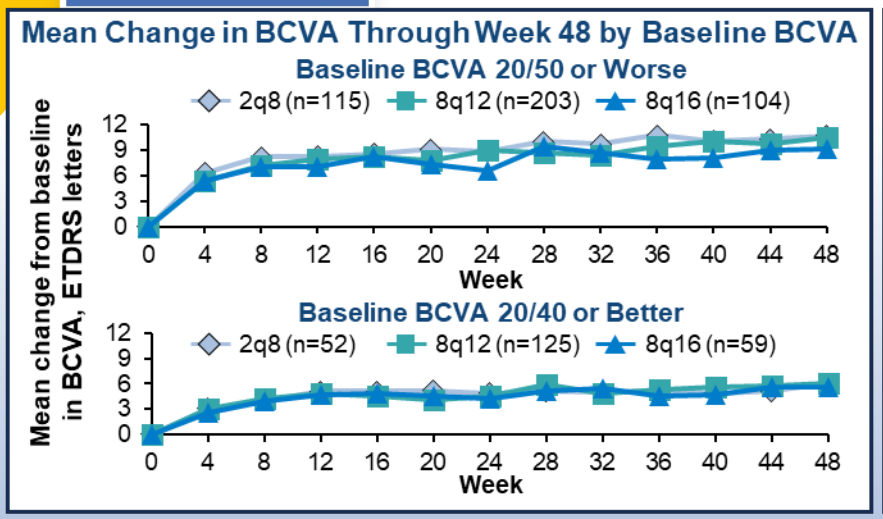
RESULTS

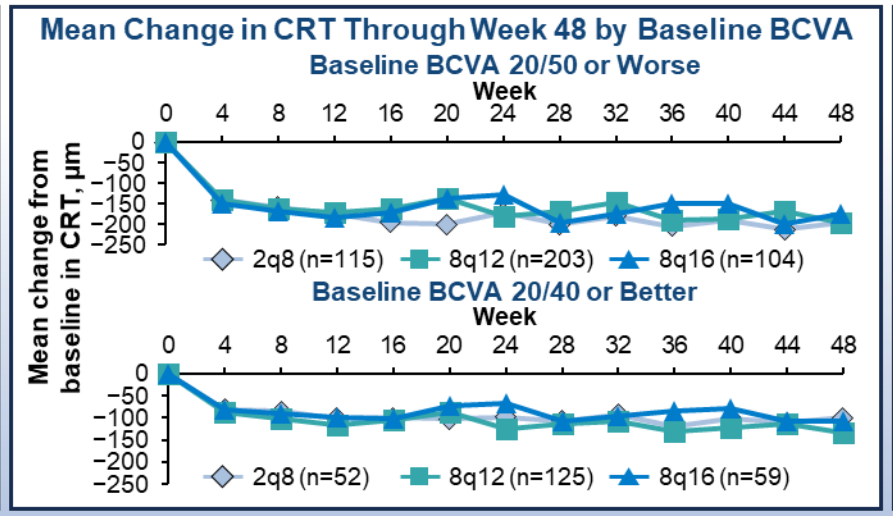


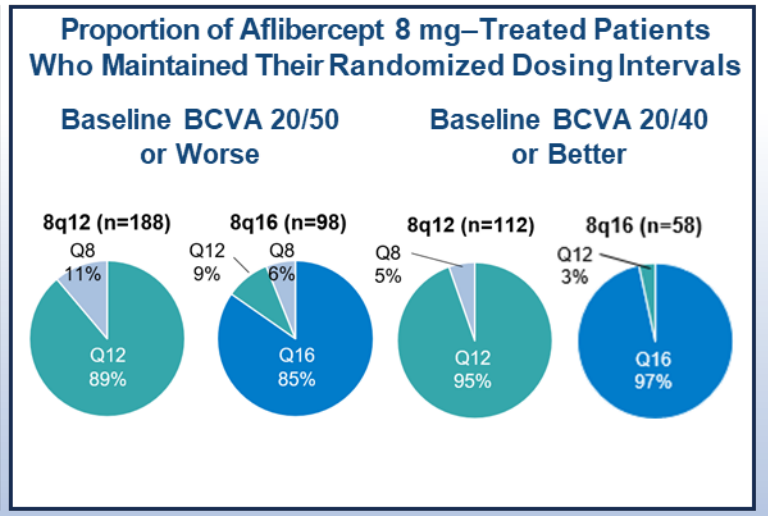
- Improvements in BCVA and CRT through Week 48 were comparable across all 3 treatment groups. However, the magnitude of improvement was numerically greater in patients with baseline BCVA 20/50 or worse versus those with baseline BCVA 20/40 or better
- A large majority of aflibercept 8 mg–treated patients maintained their randomized dosing intervals through Week 48

Q8, every 8 weeks; Q12, every 12 weeks; Q16, every 16 weeks

DISCUSSION







- Aflibercept 8 mg demonstrated meaningful visual and anatomic improvements from baseline to Week 48 in patients with DME, irrespective of baseline BCVA
- Patients with baseline BCVA 20/50 or worse achieved numerically greater visual gains and improvements in CRT than those with baseline BCVA 20/40 or better with both aflibercept 8 mg and 2 mg
- Although most patients maintained their randomized dosing intervals regardless of baseline BCVA, numerically fewer patients with baseline BCVA 20/50 or worse (vs 20/40 or better) maintained their randomized interval