Baseline Characteristics and Outcomes of Patients Treated With Aflibercept 8 mg at Shortened, Maintained, or Extended Dosing Intervals Through 96 Weeks in PHOTON

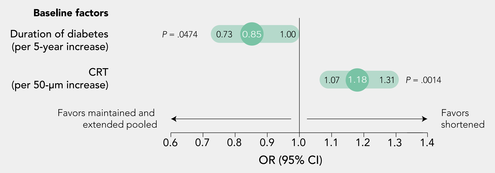
Hariprasad SM, Lee SC, on behalf of the PHOTON study investigators.
Presented at: the Macula Society Annual Meeting, February 12-15, 2025; Charlotte Harbor, Florida.
https://congresspublications.bayer.com/download/RGN_ENCORE_Mac%20Soc%202025_PHOTON%2096-WK%20dosing%20subcohort_HARIPRASAD_ORAL_10FEB25.pdf

The PHOTON trial was a phase 3, randomized, double-masked, active-controlled, non-inferiority trial evaluating aflibercept 8 mg in patients with diabetic macular edema (DME) over 96 weeks. This analysis evaluated baseline characteristics and visual and anatomic outcomes of patients with DME who had their dosing interval shortened, maintained, or extended through Week 96 in the PHOTON trial.

Patients were randomized (1:2:1) to receive intravitreal aflibercept 2 mg every 8 weeks (2q8) after 5 monthly doses, aflibercept 8 mg every 12 weeks (8q12) after 3 monthly doses, or aflibercept 8 mg every 16 weeks (8q16) after 3 monthly doses. From week 16, 8 mg group intervals could be shortened if disease activity criteria were met; extensions were allowed in year 2. The primary endpoint was the change in BCVA from baseline to week 48, with a non-inferiority margin of 4 letters.

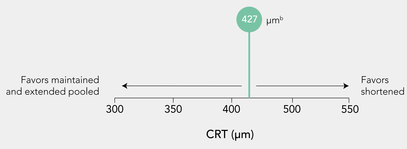
Baseline factors associated with interval shortening (vs maintenance/extension) through week 96 were analyzed

Multivariate analysis



ROC analysis: BCVA

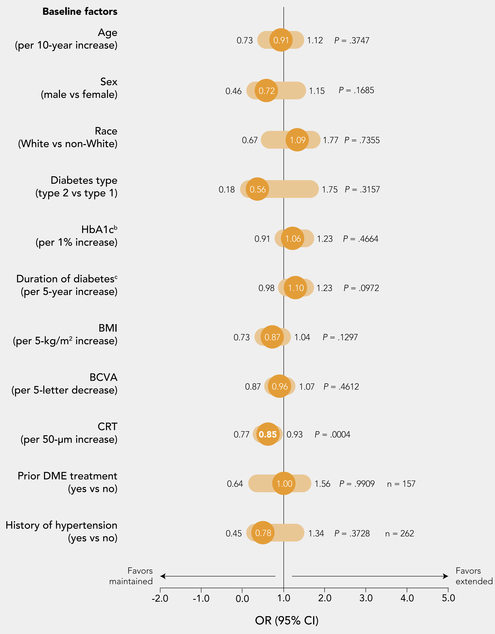
ROC analysis: CRT



Patients maintained or extended through Week 96 were used as the reference. Inferential statistics were calculated from a logistic regression model. Age (per 10-year increase), duration of diabetes (per 5-year increase), BCVA (per 5-letter decrease), and CRT (per 50-µm increase) were included in the stepwise logistic regression process.
[a]Area under the curve = 0.6301. [b]Area under the curve = 0.6703
CI = confidence interval; OR = odd ratio; ROC = receiver operating characteristic.

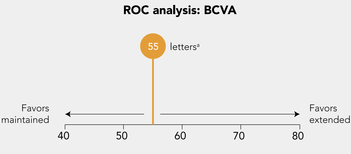
Baseline factors predicting interval extension (vs maintenance) through week 96 were analyzed

Univariate analysis (N = 340[a])

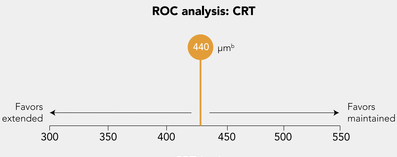


[a]N = 340 unless otherwise those noted. [b]N = 337. [c]N = 339.
BMI = body mass index; BCVA = best corrected visual acuity, CRT = central retinal thickness; DME = diabetic macular edema; HbA1c = hemoglobin A1c

ROC analysis: BCVA



ROC analysis: CRT



Patients maintained through Week 96 were used as the reference. Inferential statistics were calculated from a logistic regression model.
[a]Area under the curve = 0.5106. [b]Area under the curve = 0.6394.

Conclusions

Dosing intervals were shortened at any time in ≤17% of patients receiving aflibercept 8 mg through Week 96. Shorter duration of diabetes and higher CRT at baseline were predictors of dosing interval shortening whereas lower CRT at baseline was predictive of interval extension. Patients treated with aflibercept 8 mg achieved meaningful improvements in BCVA and CRT at Week 96 with a comparable safety profile to 2q8, regardless of dosing interval status.