Early Insights on the Real-World Use of Aflibercept 8 mg Among Treatment-Naive Eyes With Diabetic Macular Edema

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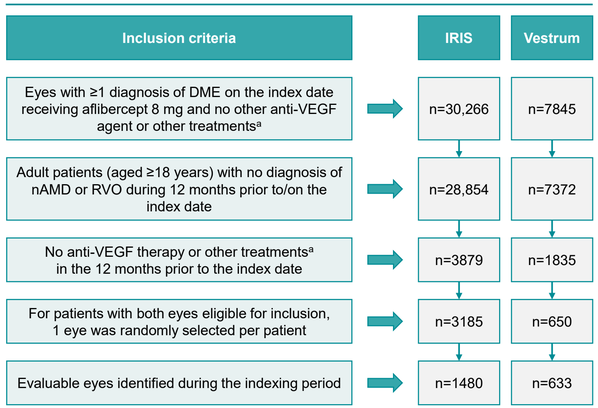
BACKGROUND & PURPOSE

- In the PHOTON trial, aflibercept 8 mg achieved non-inferior visual acuity (VA) outcomes with fewer injections compared to aflibercept 2 mg in patients with diabetic macular edema (DME) through 96 weeks[1,2]
- Real-world evidence for the use of aflibercept 8 mg in treatment-naive patients with DME could be informative for clinical practice
- This cohort study aimed to describe real-world outcomes in treatment-naive patients with DME that initiated aflibercept 8-mg treatment

METHODS

- Two cohorts of treatment-naive eyes with DME who initiated aflibercept 8 mg were identified from electronic health records in the Intelligent Research in Sight (IRIS®) Registry and Vestrum Health Retina database, respectively (**Figure 1**)
  - Eyes initiating aflibercept 8 mg between August 18, 2023, and June 30, 2024, for the IRIS cohort, or between August 18, 2023, and July 31, 2024, for the Vestrum cohort (indexing period), were followed from initiation (index date) until last visit, treatment switch, or missing information on treatment laterality, whichever occurred first
  - Data were available through December 31, 2024, for the IRIS cohort, and January 31, 2025, for the Vestrum cohort
- Injection intervals were estimated during the initial dosing phase (ie, first 3 injections or 90 days, whichever occurred first) and post-initial dosing phase
  - Injection intervals were assessed in eyes with ≥2 injections during the initial dosing phase, and in eyes with ≥1 injection during the post-initial dosing phase
- For a subset of eyes with VA available at the index date and at 90±30 days, change in VA from treatment initiation to 90 days (VA closest to 90 days within a ±30-day window) was obtained and stratified by VA on the index date (≤20/50 [≤65 Early Treatment of Diabetic Retinopathy Study {ETDRS} letters] or >20/50 [>65 ETDRS letters])

Figure 1. Inclusion Criteria and Attrition



Where n is the number of eyes. [a]Other treatments included intravitreal steroids and laser therapy.
nAMD, neovascular age-related macular degeneration; RVO, retinal vein occlusion; VEGF, vascular endothelial growth factor.

RESULTS

Table 1. Patient Characteristics on the Index Date

	IRIS (n=1480)	Vestrum (n=633)
Mean age (SD), years	65 (11.7)	65 (11.6)
Male, n (%)	834 (56)	368 (58)
Race/ethnicity, n (%)		
Hispanic or Latino	177 (14)	NA
White	680 (55)	NA
Black or African American	177 (14)	NA
Asian or Pacific Islander	46 (4)	NA
Other	158 (13)	NA
Bilateral disease, n (%)	1328 (90)	513 (81)
Fellow eye treated with aflibercept 8 mg on the index date, %	454 (31)	137 (22)
Mean VA (SD), ETDRS letters	59.0 (23.3)	59.9 (22.2)

NA, not available (due to limitation of the Vestrum database); SD, standard deviation.

Treatment Patterns

- Mean (SD) follow-up was 138.6 (109.5) and 206.3 (111.3) days for the IRIS and Vestrum cohorts, respectively (**Table 2**)
- Mean (SD) number of injections of aflibercept 8 mg during follow-up (including the index date) was 2.5 (1.8) and 3.1 (2.1) for the IRIS and Vestrum cohorts, respectively (**Table 2**)

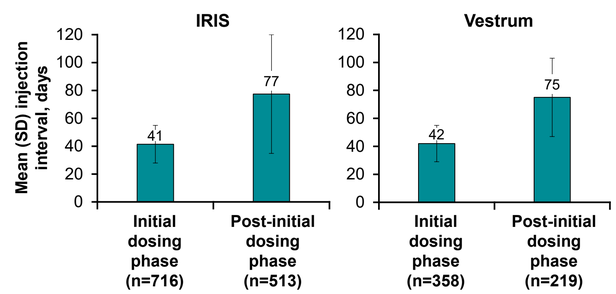
Table 2. Treatment Patterns During Follow-Up

	IRIS (n=1480)	Vestrum (n=633)
Duration of follow-up, days		
Mean (SD)	138.6 (109.5)	206.3 (111.3)
Median (Q1, Q3)	125 (38, 211)	207.5 (112, 291)
Number of injections during follow-up		
Mean (SD)	2.5 (1.8)	3.1 (2.1)
Median (Q1, Q3)	2 (1, 3)	3 (1, 5)

Q, quartile.

- During the initial dosing phase, the mean (SD) injection interval was 41 (14) and 42 (13) days for the IRIS and Vestrum cohorts, respectively (**Figure 2**)
- The mean (SD) post-initial dosing phase injection interval was 77 (43) and 75 (28) days for the IRIS and Vestrum cohorts, respectively (**Figure 2**)

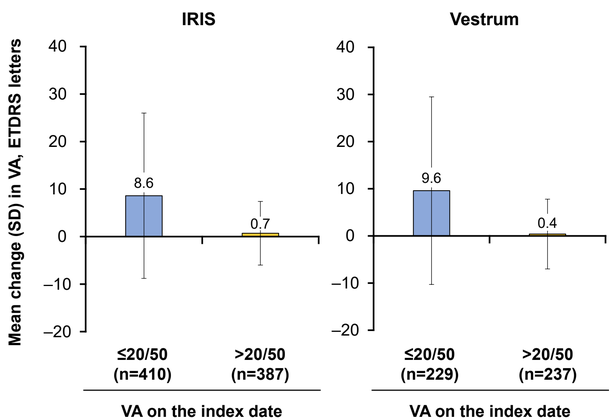
Figure 2. Mean Injection Interval During Follow-Up



Visual Outcomes

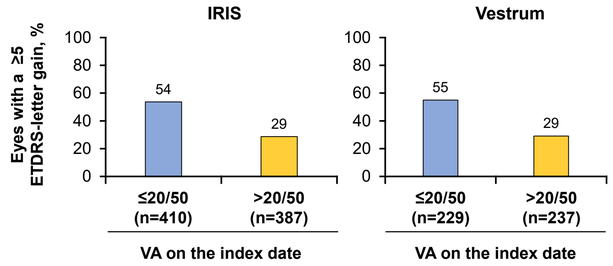
- Mean (SD) VA on the index date in the IRIS and Vestrum cohorts, respectively, was 45.6 (22.0) and 45.9 (21.6) letters for eyes with VA ≤20/50 on the index date, and 76.2 (5.1) and 75.3 (5.4) letters for eyes with VA >20/50 on the index date
- Mean change (SD) in VA at 90 days in the IRIS and Vestrum cohorts, respectively, was +8.6 (17.4) and +9.6 (19.9) letters for eyes with VA ≤20/50 on the index date, and +0.7 (6.7) and +0.4 (7.4) letters for eyes with VA >20/50 on the index date (**Figure 3**)

Figure 3. Mean Change in VA at 90 Days by VA on the Index Date



- The respective proportion of eyes in IRIS and Vestrum cohorts with a ≥5 ETDRS-letter gain at 90 days was 54% and 55% among eyes with VA ≤20/50 on the index date, and 29% and 29% among eyes with VA >20/50 on the index date (**Figure 4**)

Figure 4. Proportion of Eyes With a ≥5 ETDRS-Letter Gain at 90 Days by VA on the Index Date



Limitations

- This study was based on data from electronic medical records, which may not reflect patients' full medical history, including prior treatment history
- This study represents early real-world experience with aflibercept 8 mg and had a limited follow-up period

CONCLUSIONS

- In this early real-world analysis of the IRIS and Vestrum databases of treatment-naive patients with DME, eyes with VA ≤20/50 on the index date achieved clinically meaningful improvements in vision with aflibercept 8 mg at the end of the initial dosing phase
  - Mean VA remained stable in eyes with good baseline vision (VA >20/50 on the index date), likely due to the ceiling effect minimizing potential improvement
- On average, patients with treatment-naive DME achieved injection intervals of ~75 days (~11 weeks) with aflibercept 8 mg
- Additional analyses with longer follow-up periods are ongoing to assess the long-term effect of aflibercept 8 mg on durability and outcomes in patients with treatment-naive DME in the real world

REFERENCES

1. Brown DM et al. *Lancet*. 2024;403:1153–1163.
2. Do D. Presented at the American Academy of Ophthalmology Meeting; November 3-6, 2023; San Francisco, CA.

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