Early Real-World Use of Aflibercept 8 mg in Treatment-Naive Patients With Neovascular Age-Related Macular Degeneration

3095-B0108

Ferhina S. Ali, MD, MPH,[1] Steven Sherman, MPH,[2] Dana Murdock, PhD,[2] Keran Moll, PhD,[2] Nick Boucher, BS,[3] Nitish Mehta, MD,[4] Michael Javaheri, MD,[5] Durga Borkar, MD,[6] Theodore Leng, MD,[7] Rishi P. Singh, MD[8]

[1]New York Medical College, Valhalla, New York; [2]Regeneron Pharmaceuticals, Inc., Tarrytown, New York; [3]Vestrum Health, Naperville, Illinois; [4]Department of Ophthalmology, NYU Langone Health, New York, New York; [5]Retina Specialists of Beverly Hills, Beverly Hills, California; [6]Duke University Eye Center, Durham, North Carolina; [7]Byers Eye Institute, Stanford University School of Medicine, Palo Alto, California; [8]Cleveland Clinic Martin Hospitals, Cleveland Clinic Florida, Stuart, Florida

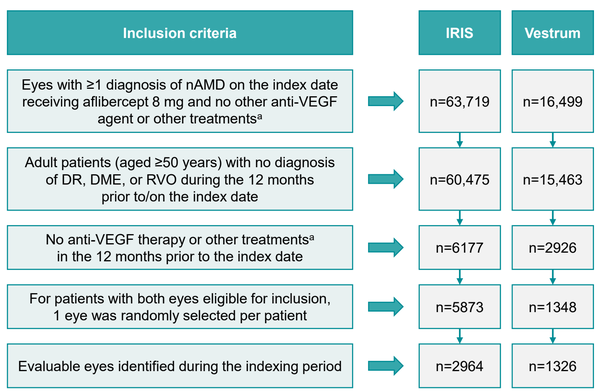
BACKGROUND & PURPOSE

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

METHODS

- Two cohorts of treatment-naive eyes with nAMD that 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 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.
DME, diabetic macular edema; DR, diabetic retinopathy; RVO, retinal vein occlusion; VEGF, vascular endothelial growth factor.

RESULTS

Table 1. Patient Characteristics on the Index Date

	IRIS (n=2964)	Vestrum (n=1326)
Mean age (SD), years	80 (7.7)	81 (7.7)
Male, n (%)	1107 (37)	475 (36)
Race/ethnicity, n (%)		
Hispanic or Latino	56 (2)	NA
White	2177 (86)	NA
Black or African American	27 (1)	NA
Asian or Pacific Islander	43 (2)	NA
Other	229 (9)	NA
Bilateral disease, n (%)	1018 (34)	434 (33)
Fellow eye treated with aflibercept 8 mg on the index date, n (%)	405 (14)	103 (8)
Mean VA (SD), ETDRS letters	54.9 (24.5)	53.7 (24.7)

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

Treatment Patterns

- Mean (SD) follow-up was 168.2 (110.4) and 200.8 (111.0) 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 3.5 (2.1) and 4.2 (2.2) for the IRIS and Vestrum cohorts, respectively (**Table 2**)

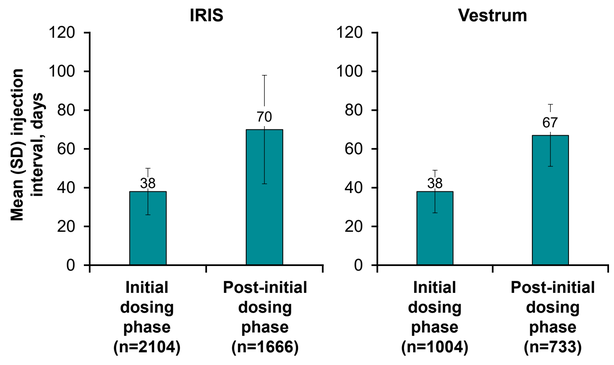
Table 2. Treatment Patterns During Follow-Up

	IRIS (n=2964)	Vestrum (n=1326)
Duration of follow-up, days		
Mean (SD)	168.2 (110.4)	200.8 (111.0)
Median (Q1, Q3)	173 (64, 245)	203 (101, 287)
Number of injections during follow-up		
Mean (SD)	3.5 (2.1)	4.2 (2.2)
Median (Q1, Q3)	3 (1, 5)	4 (2, 6)

Q, quartile.

- During the initial dosing phase, the mean (SD) injection interval was 38 (12) and 38 (11) days for the IRIS and Vestrum cohorts, respectively (**Figure 2**)
- The mean (SD) post-initial dosing phase injection interval was 70 (28) and 67 (16) days for the IRIS and Vestrum cohorts, respectively (**Figure 2**)

Figure 2. Mean Injection Interval During Follow-Up

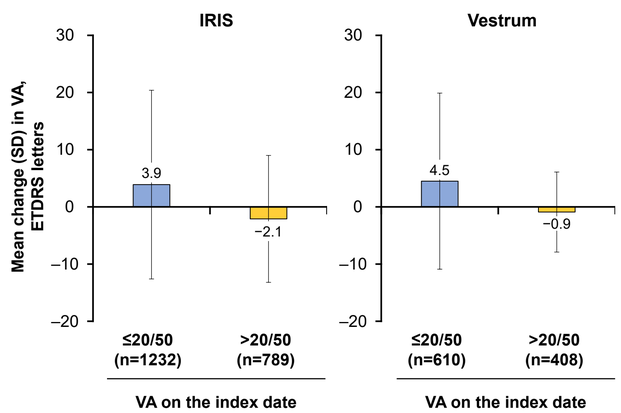


	IRIS		Vestrum	
Median (Q1, Q3) injection interval, days	35 (32, 42)	63 (56, 74)	35 (32, 42)	63 (57, 73)

Visual Outcomes

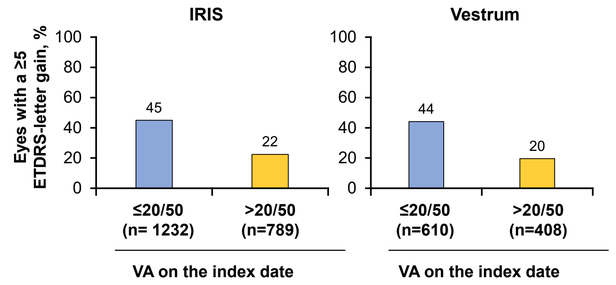
- Mean (SD) VA on the index date in the IRIS and Vestrum cohorts, respectively, was 42.4 (21.9) and 40.4 (22.0) letters for eyes with VA ≤20/50 on the index date, and 76.0 (5.2) and 74.9 (5.2) letters for eyes with VA >20/50 on the index date
- Mean (SD) change in VA at 90 days in the IRIS and Vestrum cohorts, respectively, was +3.9 (16.5) and +4.5 (15.4) letters for eyes with VA ≤20/50 on the index date, and –2.1 (11.1) and –0.9 (7.0) 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 the IRIS and Vestrum cohorts with a ≥5 ETDRS-letter gain at 90 days was 45% and 44% among eyes with VA ≤20/50 on the index date, and 22% and 20% 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 nAMD, 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 nAMD achieved injection intervals of ~70 days (~10 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 nAMD in the real world

REFERENCES

1. Lanzetta P et al. *Lancet*. 2024;403:1141–1152.
2. Korobelnik J. Presented at the American Academy of Ophthalmology Meeting; November 3-6, 2023; San Francisco, CA.

ACKNOWLEDGMENTS & DISCLOSURES

- Ferhina S. Ali has received honoraria and served on speaker bureaus for 4DMT, Allergan, Apellis, EyePoint, Genentech, Iveric Bio, OcuTerra, Optomed, Ocuphire, Outlook Therapeutics, and Regeneron Pharmaceuticals, Inc. Steven Sherman, Dana Murdock, and Keran Moll are employees of and stockholders in Regeneron Pharmaceuticals, Inc. Nick Boucher is an employee of Vestrum Health. Nitish Mehta has no disclosures to report. Michael Javaheri has acted as a speaker and consultant, and partaken in advisory boards, for Genentech and Regeneron Pharmaceuticals, Inc. Durga Borkar has acted as a consultant for 4DMT, Alimera Sciences, Astellas, Apellis, AbbVie/Allergan, EyePoint, Genentech, Glaukos, ONL Therapeutics, Regeneron Pharmaceuticals, Inc., and Verana Health, and as a speaker for Astellas and Genentech. Theodore Leng has received funding from Astellas, and acted as a consultant for Astellas, Boehringer Ingelheim, Regeneron Pharmaceuticals, Inc., Roche/Genentech, Topcon, and Virtual Field. Rishi P. Singh has received personal fees from Apellis, Iveric Bio, EyePoint, REGENXBIO, Genentech, Bausch + Lomb, Zeiss, Alcon, and Regeneron Pharmaceuticals, Inc., and research grants from Janssen
- This analysis was sponsored by Regeneron Pharmaceuticals, Inc. (Tarrytown, NY). The sponsor participated in the design and conduct of the study, analysis of the data, and preparation of this poster
- Medical writing support was provided by Matthew Young, DPhil, and editorial support by Jess Fawcett, BSc, of Core (a division of Prime, London, UK), funded by Regeneron Pharmaceuticals, Inc. according to Good Publication Practice guidelines