Real-World Use of Aflibercept 8 mg in Eyes With Diabetic Macular Edema (DME): Analysis of the Academy IRIS® Registry (ILLUMIN-8)

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Disclosures

- Dr Klufas reports consulting for Genentech, Regeneron Pharmaceuticals, Inc., Alimera, Bayer, Allergan/AbbVie, DORC/Zeiss, RegenXBio, Apellis, and 4DMT; speaker for Genentech, Regeneron Pharmaceuticals, Inc.; educational grant: Bausch and Lomb; equity holder: Horizon Surgical Systems
- Dr Ferrone was a former part-time employee of Apellis; has acted as Principal Investigator or Sub-investigator with research grant support for 4DMT, Alexion, Alkeus, Apellis, Aviceda, Belite, Boehringer Ingelheim, Cognition, EyeBio, EyePoint, Genentech, Janssen, Ophthea, Outlook, Regeneron Pharmaceuticals, Inc., RegenXBio, and Resolute; and received honorarium for acting as consultant for 4DMT, AbbVie/Allergan, Alcon, Alkeus, Annexon, Apellis, Aviceda, Genentech, Neurotech, Ophthea, Regeneron Pharmaceuticals, Inc., and Zeiss; honorarium for speaker fees from Regeneron Pharmaceuticals, Inc.; and travel grants from Alkeus and Regeneron Pharmaceuticals, Inc.
- Dr Do is a consultant to Boehringer Ingelheim, Genentech, Kodiak Sciences, Kriya, and Regeneron Pharmaceuticals, Inc.; has received research funding from Boehringer Ingelheim, Genentech, Kriya, and Regeneron Pharmaceuticals, Inc.; and has stock options from Kodiak Sciences
- Dr Javaheri reports consulting for Genentech, Regeneron Pharmaceuticals, Inc., and Apellis; research grants from Regeneron Pharmaceuticals, Inc.; speaker for Regeneron Pharmaceuticals, Inc., and Apellis
- Keran Moll, Dana J. Murdock, Eilish McCann, and Steven Sherman are employees of and hold stock/stock options in Regeneron Pharmaceuticals, Inc.
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Objective

ILLUMIN-8 aims to describe real-world treatment outcomes in patients with DME from the Academy IRIS® Registry[1] who were:

- **Treatment-naive and initiated aflibercept 8 mg**
- **Previously treated with aflibercept 2 mg and switched to aflibercept 8 mg**

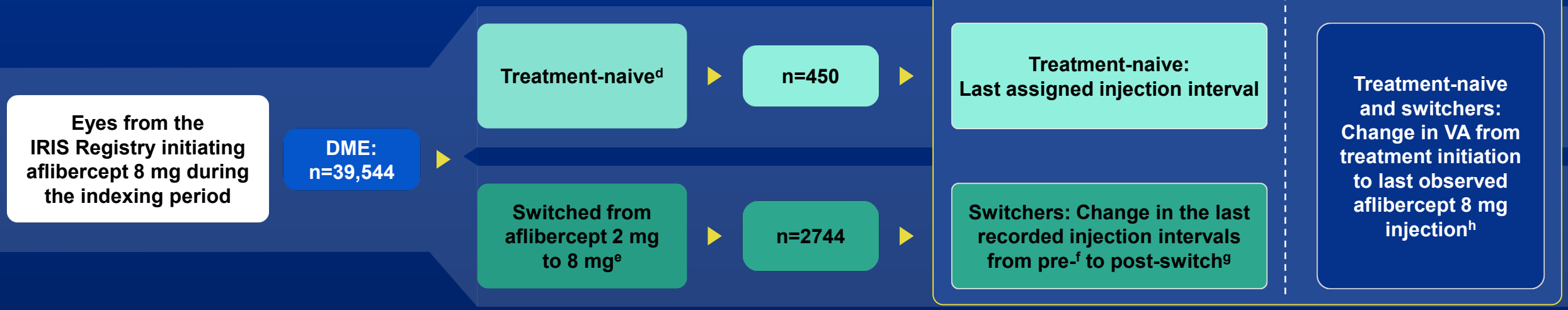
DME, diabetic macular edema; IRIS, Intelligent Research in Sight.

1. Lee CS et al. *Ophthalmol* Sci. 2022:2:100112.

Study Design

Eligibility criteria

- Aged ≥18 years with DME on the index date[a,b]
- Initiated aflibercept 8 mg during the indexing period (August 18, 2023, to December 31, 2024), and no other treatments for DME (including laser therapy or intravitreal steroids) on the index date
- Received ≥1 aflibercept 8 mg injection(s) after the initial dosing phase,[c] with the last injection >12 months post-index date
- No diagnosis of nAMD or RVO during the baseline period (12 months prior to the index date) or on the index date



[a]For patients with both eyes treated on the index date and eligible for inclusion, 1 eye was randomly selected. [b]Index date: date of the first aflibercept 8 mg injection. [c]First 3 injections or 90 days, whichever occurred first. [d]Eyes that did not receive treatment with anti-VEGF, intravitreal steroid, or laser therapy during baseline period or on index date. [e]Eyes switched within 16 weeks prior to the index date with a last pre-switch injection interval ≥6 weeks. [f]≥12 months prior to the index date. [g]Eyes were stratified by mean injection interval before switching (6 to ≤8, >8 to ≤10, >10 to ≤12, >12 to ≤16, and >16 weeks). [h]Assessed in eyes with VA available at the index date and at the last injection, stratified by VA ≤65 ETDRS letters or >65 ETDRS letters at the index date.

ETDRS, Early Treatment Diabetic Retinopathy Study; nAMD, neovascular age-related macular degeneration; RVO, retinal vein occlusion; VA, visual acuity; VEGF, vascular endothelial growth factor.

Patient Demographics, Clinical Characteristics, and Follow-Up

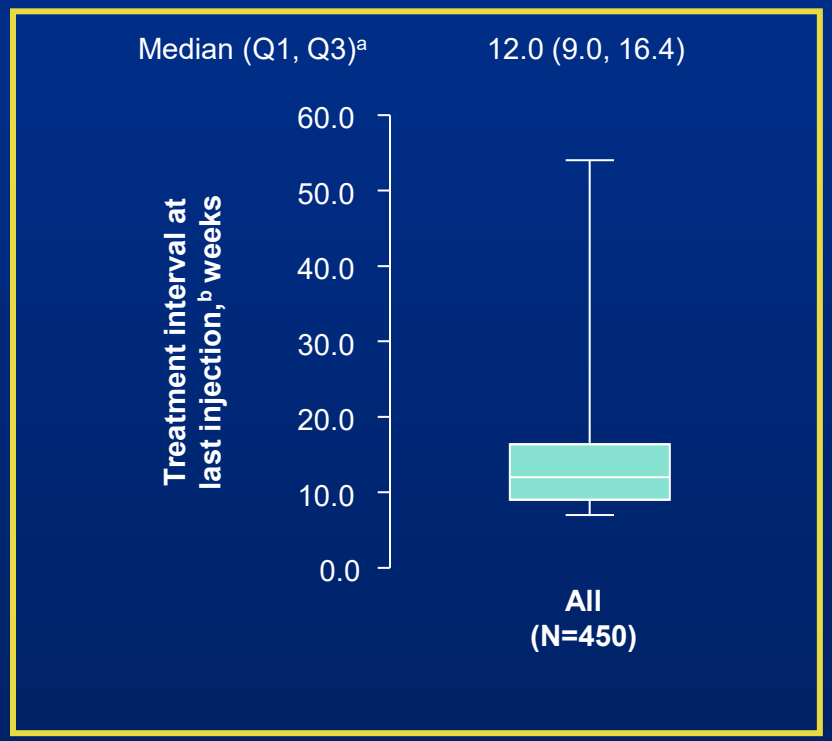
	Treatment-naive (n=450)	Switchers (n=2744)
Age, years, mean (SD)	68.3 (9.9)	66.8 (10.7)
Male, n (%)	257 (57.1)	1482 (54.0)
Race/Ethnicity, n (%)[a]		
Non-Hispanic White	250 (66.1)	1662 (68.6)
Non-Hispanic African American/Black	45 (11.9)	253 (10.5)
Other[b]	54 (14.3)	348 (14.4)
Hispanic or Latino	29 (7.7)	158 (6.5)
Bilateral DME, n (%)	415 (92.2)	2500 (91.1)
Follow-up		
Post-index follow-up, median (Q1, Q3), weeks	72.1 (63.0, 85.2)	75.3 (64.3, 88.1)
Post-index follow-up, mean (SD), weeks	75.3 (15.2)	77.1 (15.0)
Number of injections during follow-up,[c] mean (SD)	7.6 (2.7)	7.8 (2.3)

[a]Patients with missing values were excluded when calculating percentages. [b]Other includes Asian, Pacific Islander, or Other. [c]Number of aflibercept 8 mg injections inclusive of index date.
Q, quartile; SD, standard deviation.

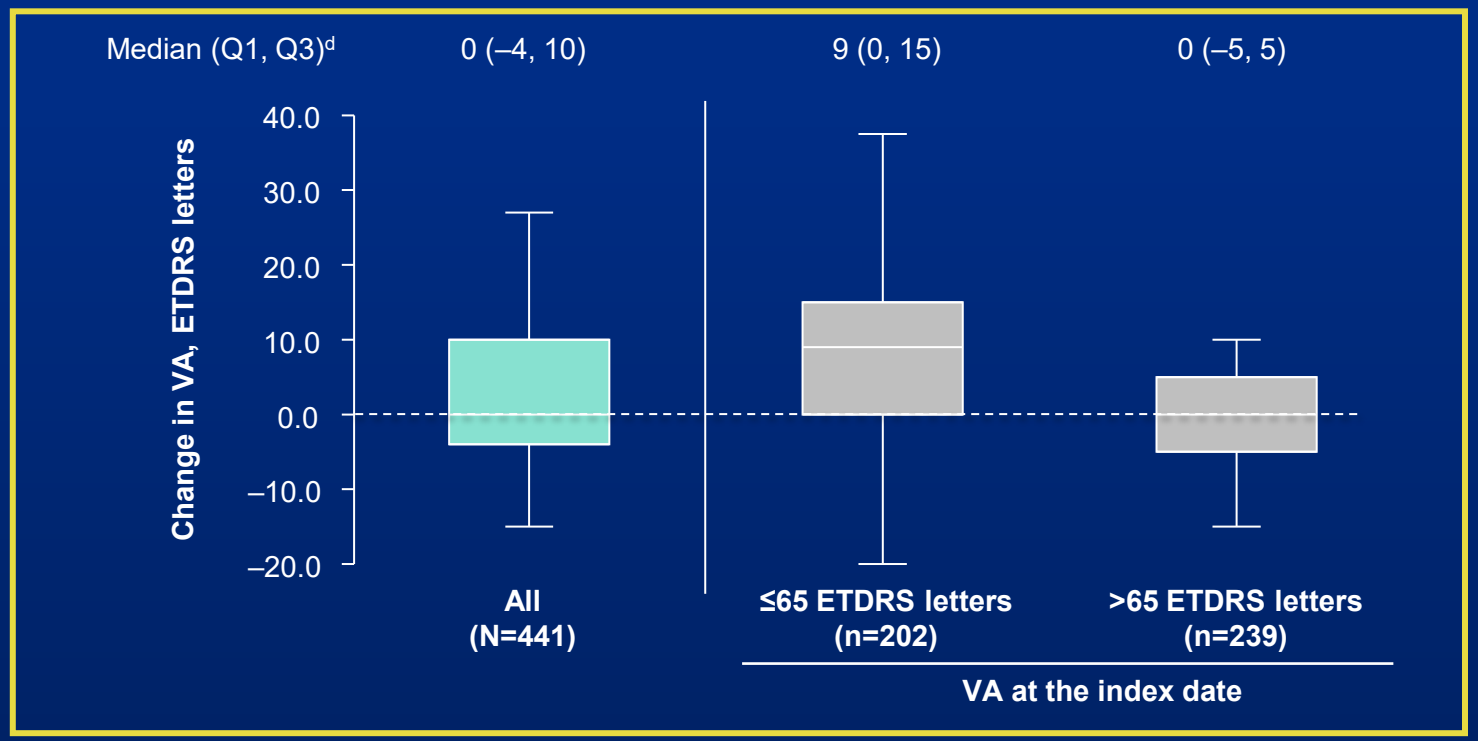
Treatment-Naive DME: Injection Interval and Change in VA at >12 Months with Aflibercept 8 mg

- The median last observed injection interval after initiating aflibercept 8 mg was 12.0 weeks
- VA at index date was maintained during follow-up, with visual improvements observed for eyes with lower VA at index date

Last Observed Injection Interval



Change in VA in the Overall Cohort and by Baseline VA Subgroups[c]

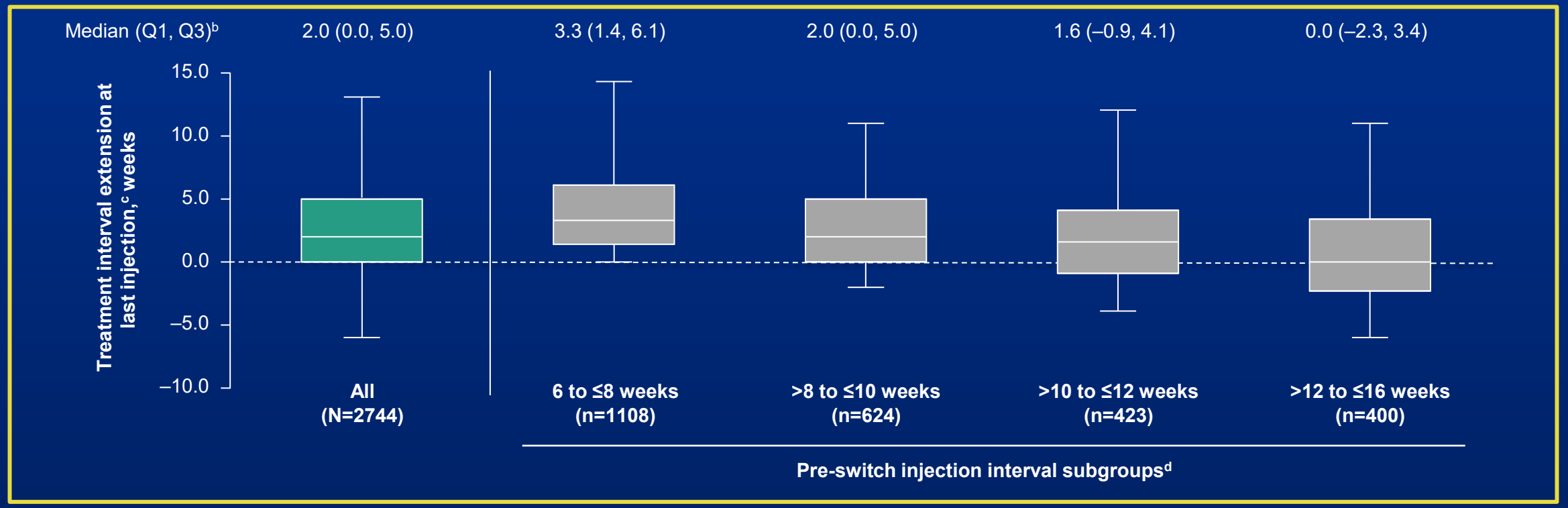


Boxes show median (middle line) and Q1 and Q3 (upper and lower bounds); whiskers show the 5% and 95% percentiles.
[a]The mean (SD) last observed injection interval was 16.9 (15.4). [b]>12 months post-index date. [c]From the index date to last injection. [d]Mean change (SD) in VA was 3.4 (16.7) in the overall cohort, 8.7 (20.1) in eyes with VA at index date of ≤65 ETDRS letters, and –1.1 (11.4) in eyes with VA of >65 ETDRS letters at index date.

Switching From Aflibercept 2 mg to 8 mg: Injection Interval and Change in VA at >12 Months

- **Median duration of the last treatment interval in eyes switched from aflibercept 2 mg to 8 mg was 12.0 weeks**
- **This represents an extension of 2.0 weeks versus the last pre-switch interval**
- **VA was maintained during follow-up[a]**

Change in Injection Interval in the Overall Cohort and by Pre-Switch Injection Interval Subgroups



Boxes show median (middle line) and Q1 and Q3 (upper and lower bounds); whiskers show the 5% and 95% percentiles.

[a]The median (Q1, Q3) change in VA from index date to last injection was 0 (–5, 5) letters in the overall cohort switched from aflibercept 2 mg to 8 mg , and 0 (–4, 9) and 0 (–5, 0) letters in VA subgroups with ≤65 and >65 ETDRS letters, respectively. [b]Mean change (SD) in the injection interval was 3.0 (7.9) in the overall cohort, and 4.9 (6.3), 3.2 (5.2), 2.7 (7.0), and 1.9 (9.6) in eyes with pre-switch interval injections of 6 to ≤8 weeks, >8 to ≤10 weeks, >10 to ≤12 weeks and >12 to ≤16 weeks, respectively. [c]>12 months post-index date. [d]The number of eyes in each subgroup do not add up to the number of all eyes, because 189 patients had a pre-switch interval of >16 weeks. This subgroup is not shown on the figure.

Limitations and Conclusions

ILLUMIN-8

- Limitations of this study include that data was obtained from electronic medical records, which may not have captured patients' complete medical history, and that BCVA data were not consistently available
- In treatment-naive and previously treated eyes, the median last observed injection interval beyond 1 year was 12.0 weeks, with VA maintained overall
- Treatment-naive eyes with low baseline VA (≤65 ETDRS letters) showed the greatest visual improvement