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

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Disclosures

- Nitish Mehta has no disclosures to report. Steven Sherman, Dana Murdock, and Keran Moll are employees and stockholders of Regeneron Pharmaceuticals, Inc. Nick Boucher is an employee of Vestrum Health. Rishi P Singh reports personal fees from Apellis, Iveric Bio, EyePoint, REGENXBIO, Genentech, Bausch + Lomb, Zeiss, Alcon, and Regeneron Pharmaceuticals, Inc., and research grants from Janssen. 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. 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 has served as a speaker for Astellas and Genentech. Theodore Leng reports funding from Astellas and acted as a consultant for Astellas, Boehringer Ingelheim, Regeneron Pharmaceuticals, Inc., Roche/Genentech, Topcon, and Virtual Field. Michael Javaheri has acted as a speaker and consultant and partaken in advisory boards with Genentech and Regeneron Pharmaceuticals, Inc.
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Background and Objectives

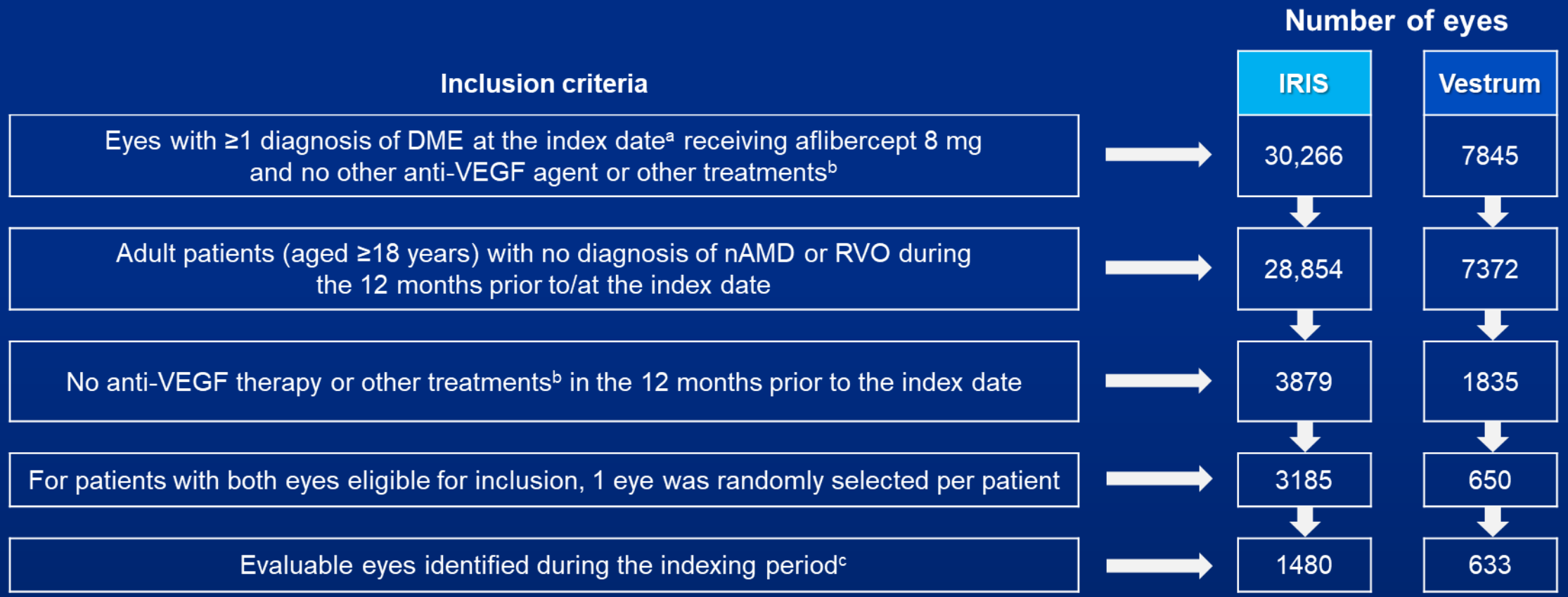
- In the PHOTON trial, aflibercept 8 mg with extended dosing demonstrated similar VA outcomes with fewer injections compared to aflibercept 2 mg through 96 weeks in patients with DME[1,2]
- Real-world evidence for the use of aflibercept 8 mg in treatment-naive patients with DME could be informative for clinical practice

This cohort study aimed to describe real-world outcomes in treatment-naive patients with DME who initiated treatment with aflibercept 8 mg

DME, diabetic macular edema; VA, visual acuity.

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

Inclusion Criteria and Attrition



[a]Index date was the date of the first aflibercept 8-mg injection. [b]Other treatments included intravitreal steroids, or laser therapy. [c]Indexing period was 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.
IRIS, Intelligent Research in Sight; nAMD, neovascular age-related macular degeneration; RVO, retinal vein occlusion; VEGF, vascular endothelial growth factor.

Outcomes

- 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 post-index date, 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 at the index date (≤20/50 [≤65 ETDRS letters] or >20/50 [>65 ETDRS letters])

ETDRS, Early Treatment Diabetic Retinopathy Study.

Patient Characteristics at the Index Date

	IRIS (n=1480)	Vestrum (n=633)
Age, mean (SD), years	65 (11.7)	65 (11.6)
Males, 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 at the index date, n (%)	454 (31)	137 (22)
VA, mean (SD), ETDRS letters	59.0 (23.3)	59.9 (22.2)

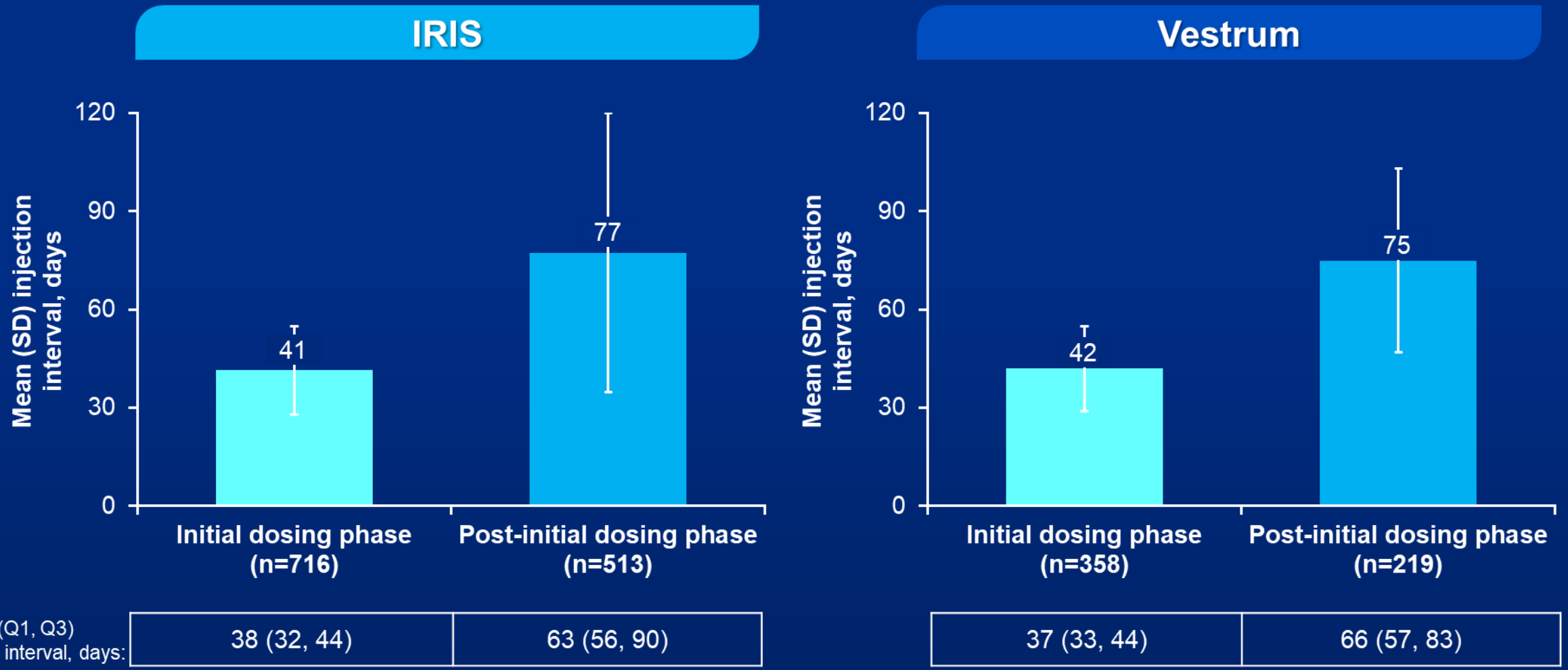
NA, not available (due to limitation of the Vestrum database); SD, standard deviation.

Treatment Patterns 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)	208 (112, 291)
Number of injections during follow-up[a]		
Mean (SD)	2.5 (1.8)	3.1 (2.1)
Median (Q1, Q3)	2 (1, 3)	3 (1, 5)

[a]Including the index date (date of the first aflibercept 8-mg injection).
Q, quartile.

Mean Injection Interval During Follow-Up

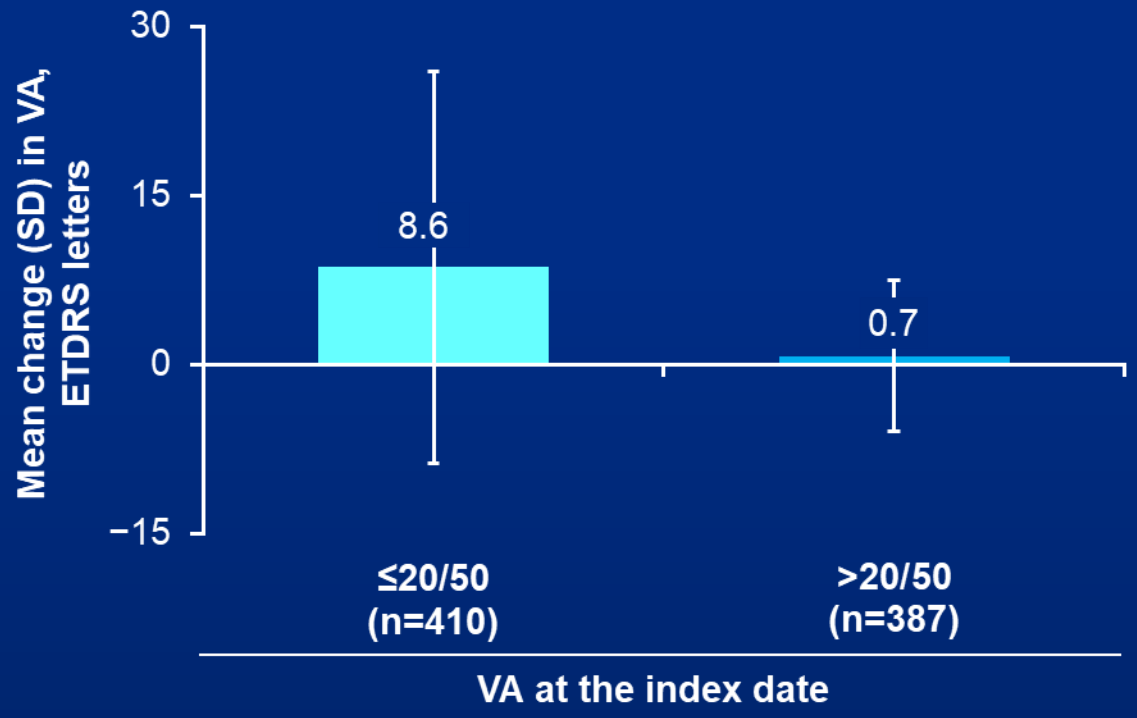


Median (Q1, Q3) injection interval, days:	IRIS	Vestrum
Initial dosing phase	38 (32, 44)	37 (33, 44)
Post-initial dosing phase	63 (56, 90)	66 (57, 83)

Values above the bars indicate the mean injection interval in days.
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.

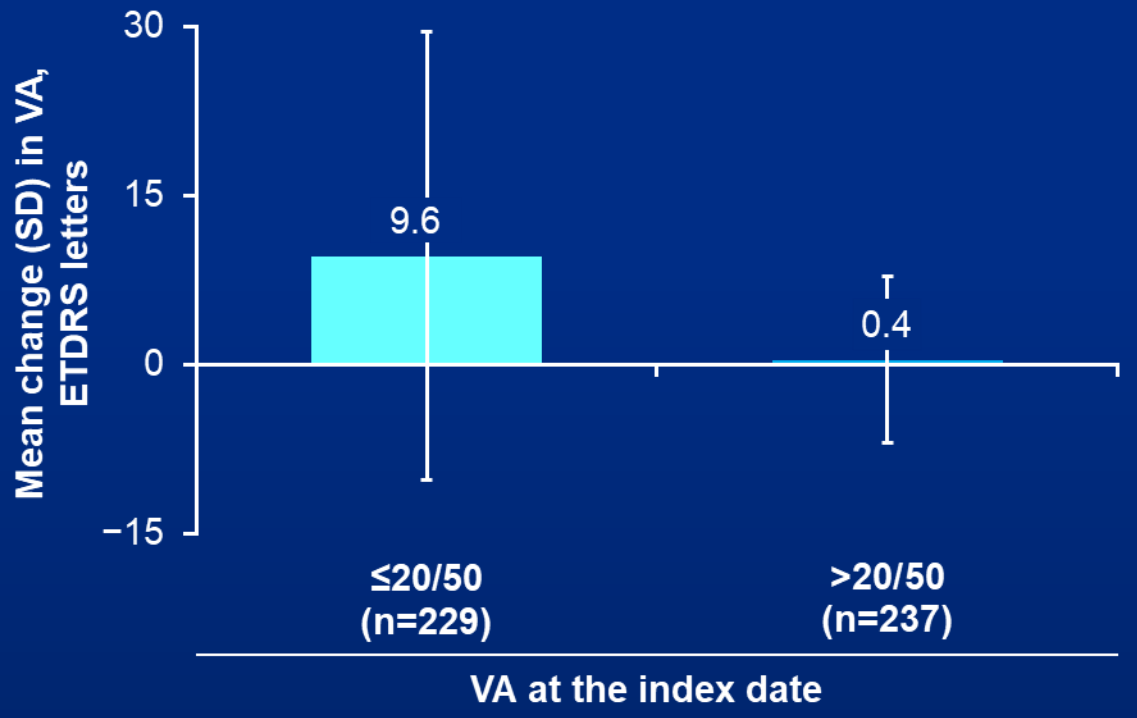
Mean Change in VA at 90 Days by VA at the Index Date

IRIS



Mean (SD) VA at the index date, ETDRS letters:	45.6 (22.0)	76.2 (5.1)

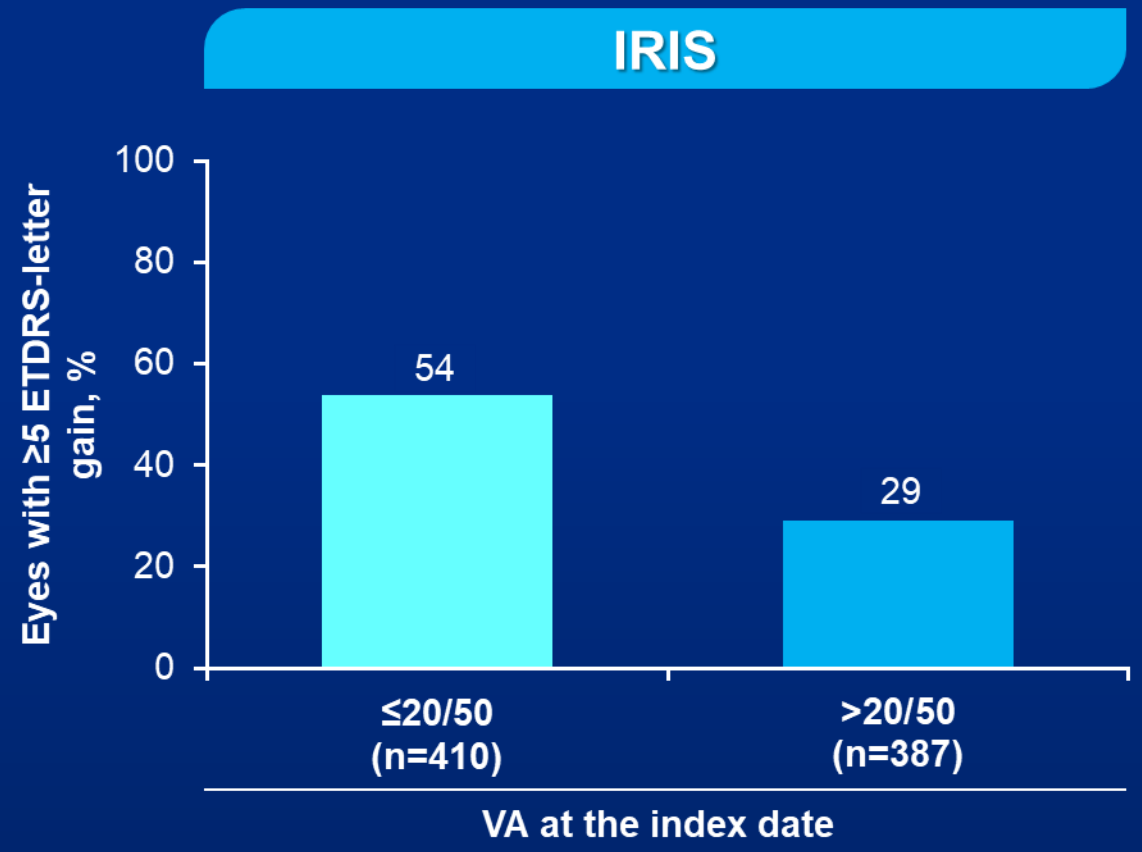
Vestrum

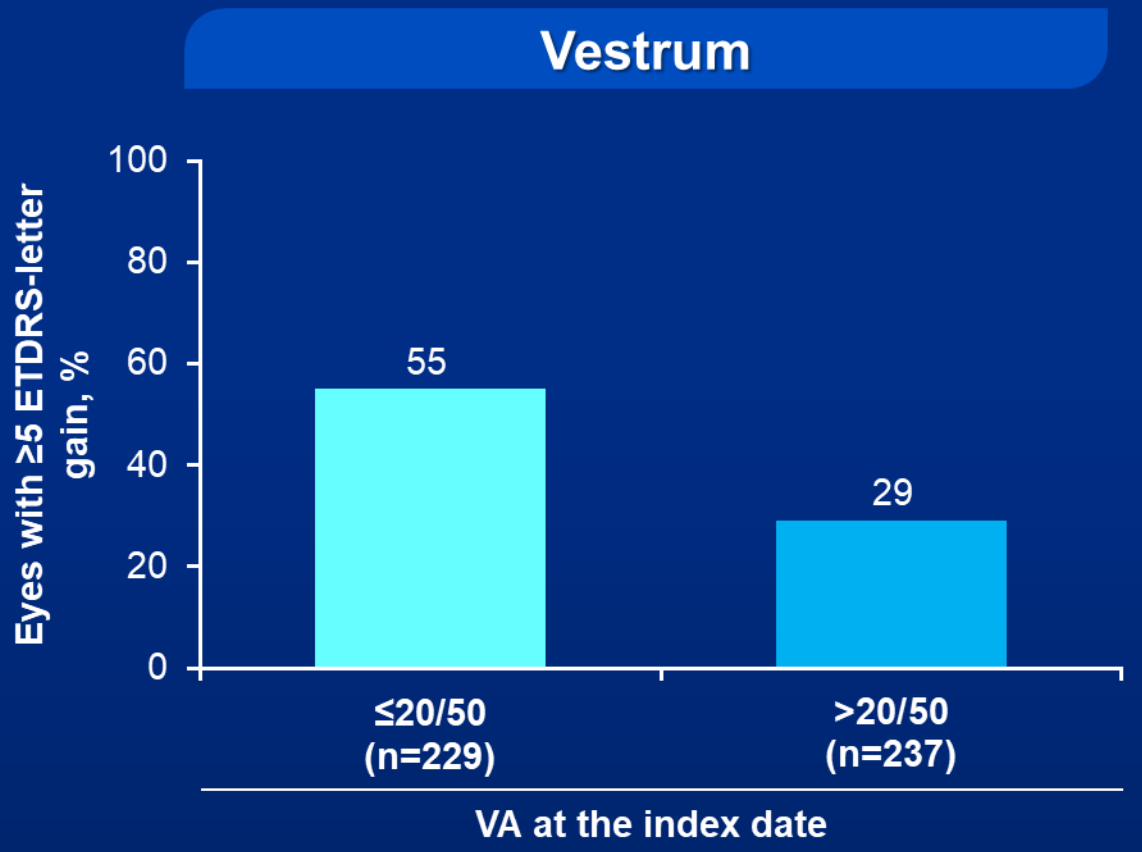


45.9 (21.6)	75.3 (5.4)

Values above the bars indicate the mean change in VA interval in ETDRS letters.
Includes a subset of eyes with VA available at the index date and at 90±30 days post-index date.

Proportion of Eyes With ≥5 ETDRS-Letter Gain at 90 Days by VA at the Index Date





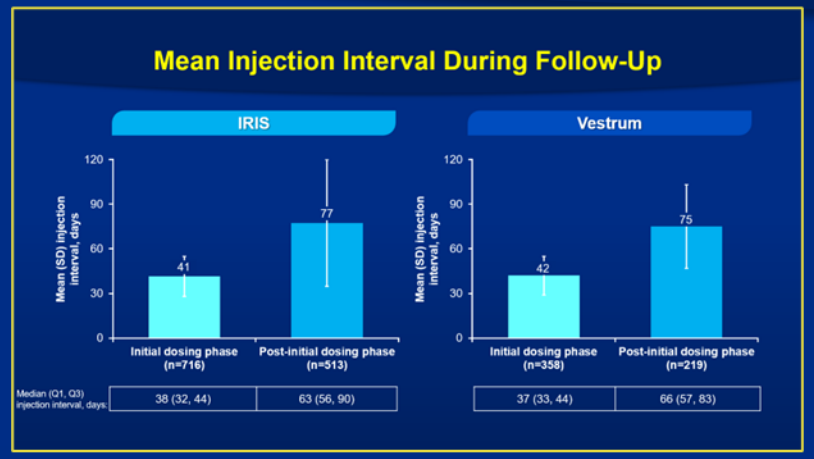
Mean (SD) VA at the index date, ETDRS letters:	≤20/50	>20/50
IRIS	45.6 (22.0)	76.2 (5.1)
Vestrum	45.9 (21.6)	75.3 (5.4)

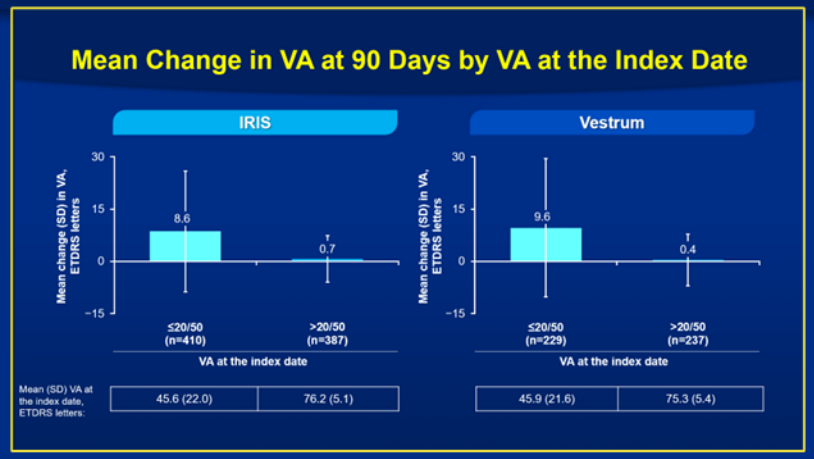
Values above the bars indicate the proportion of patients with ≥5 ETDRS-letter gain.
Includes a subset of eyes with VA available at the index date and at 90±30 days post-index date.

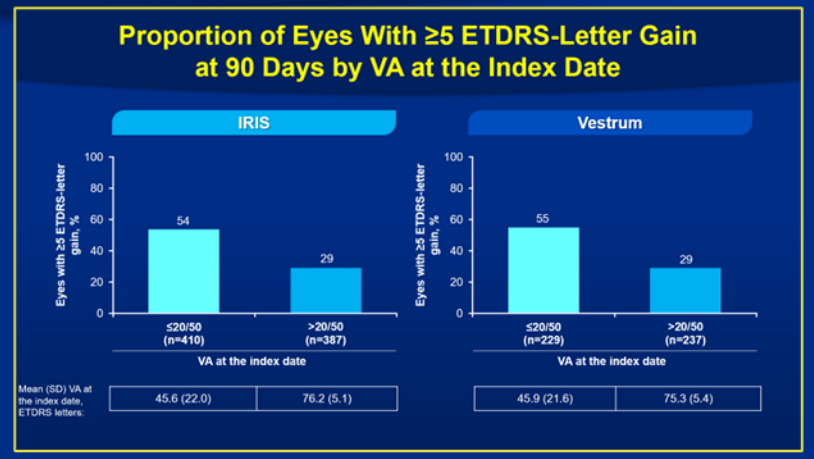
Limitations

- This study was based on data from electronic medical records, which may not reflect patients' full medical history, including treatment history
- This analysis 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 at 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 at 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, over a mean duration of ~20 weeks and ~29 weeks of follow up in the IRIS and Vestrum cohorts, respectively
- 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