Poster # B0151

Real-World Clinical and Anatomical Outcomes in Patients With Diabetic Macular Edema Treated With Faricimab: The FARETINA-DME Study

Durga Borkar, MD, MMCi[1]; David Tabano, PhD[2]; Stella Ko, MS, PharmD[2]; Theodore Leng, MD[3]; Jacqueline Shaia, MS[4]; Rachel Myers, MPH[5]; Andrew LaPrise, BS[5]; Ferhina Ali, MD, MPH[6]; and Rishi P. Singh, MD[4]

[1] Duke University Eye Center, Durham, NC; [2] Genentech, Inc., South San Francisco, CA; [3] Byers Eye Institute at Stanford, Stanford University School of Medicine, Palo Alto, CA; [4] Center for Ophthalmic Bioinformatics, Cole Eye Institute, Cleveland Clinic, Cleveland, OH; [5] Verana Health, San Francisco, CA; [6] Department of Ophthalmology, New York Medical College, Valhalla, NY

Contact Email: durgaborkarmd@gmail.com

Purpose

- Anti–vascular endothelial growth factor (VEGF) intravitreal agents for diabetic macular edema (DME) require frequent injections to mitigate vision loss
- Faricimab is the only bispecific antibody for intraocular use that independently binds and neutralizes both angiopoietin-2 (Ang-2) and VEGF-A
- The aim of this study is to describe the 1-year real-world clinical and anatomic outcomes with faricimab in patients with DME from the American Academy of Ophthalmology IRIS® Registry (**I**ntelligent **R**esearch **I**n **S**ight)

Conclusions and Limitations

FARETINA-DME uses real-world data from the IRIS® Registry for large sample, generalizable results, with over 9000 patients and 13,000 eyes treated with faricimab for DME through September 2023

This is an observational, noncontrolled study limited to information captured as part of routine clinical practice with no standardized measurements of visual acuity, anatomic outcomes available only for a subset of patients, and a lack of physician dosing frequency rationale

At faricimab initiation, approximately half of patient-eyes had 20/40 or better vision, with **most (74%) previously treated eyes having switched from aflibercept**. Mean prior treatment intervals was 7 weeks

Real-world improvements in **vision** and **anatomy** in **treatment-naïve eyes after 1 year of faricimab treatment**

Stable vision and **retinal fluid reduction** in **previously treated eyes**

Fewer injections were observed from 6 months onwards on faricimab, indicating treatment interval extension

Overall **rates of intraocular inflammation and endophthalmitis are lower than previously reported** in faricimab phase 3 clinical trials[1]

These findings **support the real-world effectiveness and durability of faricimab** for treatment of DME and its potential to reduce treatment burden for the patients, their caregivers, and the health care systems

Financial Disclosures

- DB: C): Allergan/AbbVie, Apellis, Genentech, Inc., Glaukos, Iveric Bio, Verana Health; R): Iveric Bio
- DT, SK: E): Genentech, Inc.
- TL: F): Astellas; C): Alcon, Apellis, Astellas, Graybug, Nanoscope, Protagonist, Regeneron, Roche/Genentech, Inc., Verana Health
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- RM, AL: N)
- FA: C): AbbVie/Allergan, Apellis, EyePoint, Genentech, Inc., Iveric Bio, OcuTerra, Optomed, Regeneron; R): Apellis, Iveric Bio
- RPS: C): 4DMT, Alcon, Alimera, Allergan/AbbVie, Apellis, Aviceda, Bausch + Lomb, Genentech, Inc., Iveric Bio, Regeneron

Study and Product Disclosures

- Faricimab is approved for the treatment of neovascular age-related macular degeneration, diabetic macular edema, and retinal vein occlusion in multiple countries worldwide. Faricimab is not currently approved for use outside these indications
- This study is a noninterventional, retrospective, secondary data use study, leveraging data from the IRIS® Registry. The study was considered exempt from institutional review board review as the research involved only the collection of existing data, which had been de-identified and are unable to be traced
- Funding was provided by Genentech, Inc. for the study and third-party writing assistance, which was provided by Sofia Pedro, PhD, of Envision Pharma Group

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Background

- Faricimab (Vabysmo™) was approved in the United States in January 2022 and Great Britain in May 2022 for DME treatment[2,3]
- Faricimab is the first bispecific antibody for intraocular use that independently binds and neutralizes both Ang-2 and VEGF-A with high specificity and potency[4]
- Other ongoing studies are collecting evidence of real-world faricimab treatment patterns and outcomes[5-7]:

TAHOE: An independent, physician-led, real-world study of faricimab in patients with DME

FARWIDE: A Roche-sponsored retrospective, observational, multicenter, real-world study evaluating faricimab treatment patterns in patients with neovascular age-related macular degeneration (nAMD) and DME in the United Kingdom

VOYAGER: A Roche-sponsored, noninterventional, prospective, multinational, multicenter study of faricimab (and the port delivery system with ranibizumab) in patients with nAMD and DME

Methods

- FARETINA-DME is an ongoing, retrospective study using electronic health records (EHR) data derived from US ophthalmology clinics contributing to the American Academy of Ophthalmology IRIS® Registry (**I**ntelligent **R**esearch **I**n **S**ight)
- The IRIS® Registry contains data from:
  - 540 million de-identified patient encounters
  - > 75 million de-identified unique patients
  - Contributed by about 16,000 clinicians from > 60 EHR systems across the United States
- Data analyzed identified patients diagnosed with DME who initiated faricimab treatment February 2022–September 2023
- Patients with ≥ 12 months of EHR data before faricimab initiation, known laterality, ≥ 6 months of follow-up data, and ≥ 2 best-documented visual acuity (BDVA) measures were included
- The central subfield thickness (CST) subgroup included patients with baseline CST measurement (0–30 days before index), ≥ 2 CST measurements in ≤ 180 days before index, and ≥ 2 CST measurements in 180 days post index
- The current analysis includes only patient-eyes with at least 12 months of follow-up

References

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Results

Faricimab DME Cohort

Record of first faricimab injection February 7, 2022–September 30, 2023
Patients, n = 101,497 (100%); Eyes, n = 132,375 (100%)

Eyes without documentation of nAMD on index date
Patients, n = 24,436 (24.1%); Eyes, n = 35,950 (27.2%)

Eyes with DME diagnosis, laterality, and known patient demographics, and ≥ 12 months data available before index date
Patients, n = 19,824 (19.5%); Eyes, n = 28,990 (21.9%)

≥ 6 months follow-up data after index date
Patients, n = 9753 (9.6%); Eyes, n = 13,972 (10.6%)

≥ 2 BDVA measures after index date
Patients, n = 9665 (9.5%); Eyes, n = 13,844 (10.5%)

≥ 12 months of follow-up
Patients, n = 3098 (3.1%); Eyes, n = 4224 (3.2%)

	Treatment Naïve	Previously Treated
12-Month Cohort	Patients: n = 447 (14.4%) Eyes: n = 538 (12.7%)	Patients: n = 2733 (88.2%) Eyes: n = 3686 (87.3%)

Index date is first injection of faricimab during study period. Treatment groups determined at the eye level. Treatment-naïve eyes are those with no evidence of anti-VEGF injections up to 12 months before initiating faricimab. BDVA, best-documented visual acuity; DME, diabetic macular edema; nAMD, neovascular age-related macular degeneration; VEGF, vascular endothelial growth factor.

Baseline Demographics of 12-Month DME Cohort

Baseline Characteristics (Patient-Level)	Treatment Naïve n = 447	Previously Treated n = 2733
Age at first faricimab injection, mean (SD)	68.2 (10.1)	67.6 (10.1)
Sex, n (%)		
Female	216 (48.3)	1255 (45.9)
Race, n (%)		
White or Caucasian	285 (63.8)	1846 (67.5)
Black or African American	30 (6.7)	174 (6.4)
Asian	11 (2.5)	52 (1.9)
Other	30 (6.7)	183 (6.7)
Unknown	91 (20.4)	478 (17.5)
Ethnicity, n (%)		
Hispanic	37 (8.3)	175 (6.4)
Non-Hispanic	275 (61.5)	1798 (65.8)
Unknown	135 (30.2)	760 (27.8)
Insurance Status, n (%)		
Medicare	314 (70.2)	1800 (65.9)
Medicaid	14 (3.1)	77 (2.8)
Commercial	88 (19.7)	631 (23.1)
Other	31 (6.9)	225 (8.2)
Baseline Visual Acuity (Patient Eyes): (12-Month Cohort), n (%)	**Treatment Naïve n = 522**	**Previously Treated n = 3586**
20/40 or better	257 (49.2)	1974 (55.0)
Worse than 20/40–20/80	141 (27.0)	1015 (28.3)
Worse than 20/80–better than 20/200	56 (10.7)	251 (6.9)
20/200 or worse	68 (13.0)	346 (9.6)

Treatment groups determined at the eye level. Treatment-naïve eyes are those with no evidence of anti-VEGF injections up to 12 months before initiating faricimab.
DME, diabetic macular edema; SD, standard deviation; VEGF, vascular endothelial growth factor.

Approximately 74% of Previously Treated Eyes Were Switched From Aflibercept

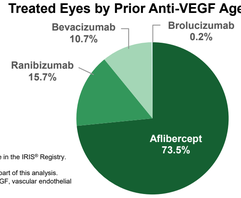
- Mean prior anti-VEGF injection frequency was approximately **6 injections** in prior 12 months
- Last prior treatment interval was on average **52 days (7 weeks)** apart
- Mean length of follow-up was **462 days for previously treated** eyes and **453 days for treatment-naïve** eyes

Prior Anti-VEGF Treatment Experience[a] (n = 3686)

Number of injections in 12-month pre-index period	
Mean (SD)	5.6 (2.8)
Treatment interval (days)[b]	
Mean (SD)	52.3 (39.4)

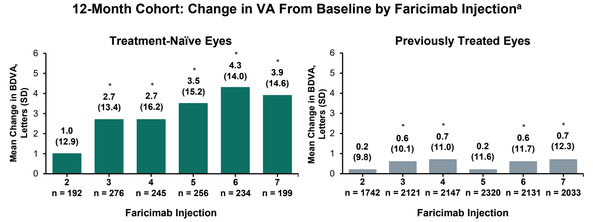
[a] Includes lookback of available medical record data ≥ 12 months before faricimab initiation date in the IRIS® Registry. Medical data lookback includes records for anti-VEGF samples.
[b] Among most recent prior 2 injections. Intravitreal corticosteroid use was not accounted for as part of this analysis.
DME, diabetic macular edema; IRIS®, Intelligent Research In Sight; SD, standard deviation; VEGF, vascular endothelial growth factor.

12-Month Cohort: Percentage of DME Previously Treated Eyes by Prior Anti-VEGF Agent



Vision Improved in Treatment-Naïve Eyes and Was Stable in Previously Treated Eyes

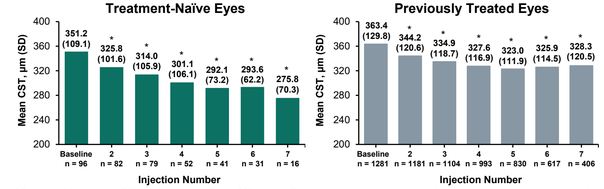
12-Month Cohort: Change in VA From Baseline by Faricimab Injection[a]



[a] Nominal *P* value < 0.05 vs baseline. *P* values are nominal and not adjusted for multiplicity; no formal statistical conclusion should be made based on the *P* values. [a] Among eyes with a baseline VA and ≥ 6 months of follow-up. Assessments were captured around the –6 to +7-day window around each injection visit.
BDVA, best-documented visual acuity; SD, standard deviation; VA, visual acuity.

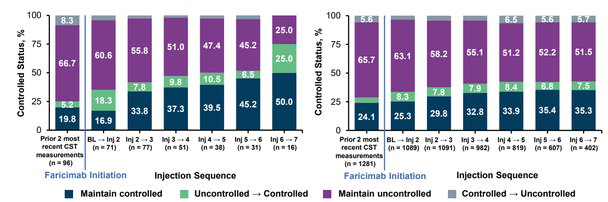
Mean CST Improved by –25 µm in Treatment-Naïve Eyes and –19 µm in Previously Treated Eyes After 2 Injections of Faricimab

Mean CST by Faricimab Injection (Among Patients With CST Available n = 1377 Eyes)[a]



* *P*-values calculated for change in CST from baseline. Nominal *P* value < 0.05 vs baseline. *P* values are nominal and not adjusted for multiplicity; no formal statistical conclusion should be made based on the *P* values. [a] Among eyes with a baseline CST measurement (0–30 days before index) (n = 1377) between February 7, 2022 and June 30, 2023, and 2+ CST measures in ≤ 180 days before index and 2+ CST in 180 days post index, excluding CST measurements ≤ 14 days after an injection. Approximately 16% of faricimab patient-eyes had CST measurements available in the IRIS® Registry. CST, central subfield thickness; IRIS®, Intelligent Research In Sight; SD, standard deviation.

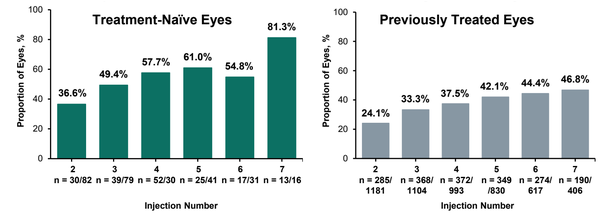
Eyes With Disease Control (CST ≤ 280 µm) Increased to 75% After 7 Faricimab Injections in Treatment-Naïve Patients With DME



For clarity, only percentages of 5% or higher are displayed. [a] Among eyes with a baseline CST measurement (0–30 days before index) (n = 1377) between February 7, 2022 and June 30, 2023, and 2+ CST measures in ≤ 180 days before index and 2+ CST in 180 days post index, excluding CST measurements ≤ 14 days after an injection. Approximately 16% of faricimab patient-eyes had CST measurements available in the IRIS® Registry. BL, baseline; CST, central subfield thickness; DME, diabetic macular edema; Inj, injection; IRIS®, Intelligent Research In Sight.

~81% of Treatment-Naïve Eyes That Received 7 Injections Achieved at Least 10% CST Reduction vs Baseline

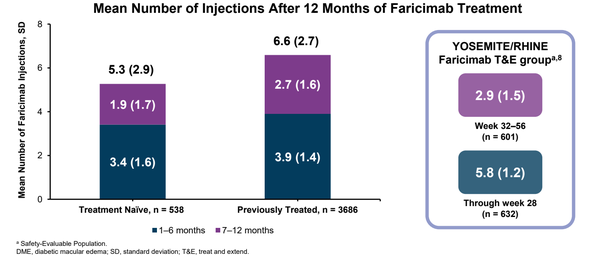
Proportion of Patients With ≥ 10% Reduction in CST by Faricimab Injection[a]



[a] Among eyes with a baseline CST measurement (0–30 days before index) (n = 1377) between February 7, 2022 and June 30, 2023, and 2+ CST measures in ≤ 180 days before index and 2+ CST in 180 days post index, excluding CST measurements ≤ 14 days after an injection. Approximately 16% of faricimab patient-eyes had CST measurements available in the IRIS® Registry. CST, central subfield thickness; IRIS®, Intelligent Research In Sight.

Faricimab Treatment Interval Extension Evident in Latter 6 Months of Year 1 in DME

Mean Number of Injections After 12 Months of Faricimab Treatment



[a] Safety-Evaluable Population.
DME, diabetic macular edema; SD, standard deviation; T&E, treat and extend.

Real-World Use of Faricimab and Observed Rates of IOI and Endophthalmitis

Number of Injections Across FARETINA-AMD/DME Cohorts	Treatment-Naïve Injections (n = 19,578)	Previously Treated Injections (n = 256,668)
Endophthalmitis, n (%)[a,b]	11 (0.06%)	138 (0.05%)
IOIs, n (%)[a,b]	23 (0.12%)	249 (0.1%)

[a] Among 26,278 nAMD and 6343 DME patients and approximately 276,246 injections meeting the inclusion/exclusion criteria of the FARETINA-AMD/DME studies. First diagnosis (identified by ICD-10 diagnosis codes of endophthalmitis [H44.0, H44.19, and H20.053), iridocyclitis and iritis [H20.00, H20.01, H20.02, H20.1, H20.9], uveitis [H30.0, H30.1, H30.2, H30.8, H30.9, H44.1], and vitritis [H43.89]) in the IRIS® Registry EHR following faricimab initiation with no diagnoses at least 12 months prior among patient eyes with the following criteria:

1) Diagnosis of nAMD or DME, initiating faricimab February 7, 2022 through June 30, 2023 in the IRIS® Registry, and known laterality
2) ≥ 12 months of medical data BEFORE initiating faricimab in the IRIS® Registry
3) At least 6 months of data available after faricimab initiation
4) At least 2 BDVA measures on or after faricimab initiation

AE, adverse event; AMD, age-related macular degeneration; BDVA, best-documented visual acuity; DME, diabetic macular edema; EHR, electronic health record; ICD-10, International Classification of Diseases, Tenth Revision; IOI, intraocular inflammation; IRIS®, Intelligent Research In Sight; nAMD, neovascular age-related macular degeneration.

[b] FARETINA AMD/DME is a noninterventional, retrospective, observational study of real-world treatment patterns and outcomes of patients in the United States. The study leverages the IRIS® Registry. All patients in the IRIS® Registry are de-identified and are unable to be traced. AEs derived from ICD-10 diagnosis codes may not accurately reflect incidence or prevalence of real-world AEs.