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Early Treatment Patterns and Outcomes in Patients With Diabetic Macular Edema Treated With Faricimab: an IRIS® Registry Analysis (FARETINA-DME)

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Objective

- To describe the baseline characteristics, initial injection frequency, and early clinical response of patients with DME initiating faricimab in the real world from the American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight)

Summary

- From the IRIS registry > 3100 patient eyes have been treated with faricimab for DME through September 2022
- Around 50% of eyes—both naïve and previously treated—started faricimab with 20/40 or better vision, with previous anti-VEGF treatment intervals of 7 weeks
  - More than three-quarters of the previously treated eyes had switched from aflibercept
- Most eyes had "extended" intervals (> 6 weeks)[a] prior to the initial 4 monthly doses per FDA label
  - 76% of previously treated *and* treatment-naive eyes, extended within 2 initial injections
- Visual acuity was stable after injections in previously treated patient eyes; visual acuity improvement was observed after 4 injections in treatment-naïve eyes
- The IRIS registry is a robust tool to understand treatment patterns and outcomes to faricimab post approval

[a] Among patient eyes who received 4 or more injections. "Extended" interval defined as faricimab injection > 6 weeks after previous faricimab injection.

Limitations

- The limitations of this study are that it is an observational, noncontrolled study with no standardized measurements of visual acuity, no anatomical outcomes to fully understand the treatment response, and a lack of physician dosing frequency rationale

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FARETINA DME

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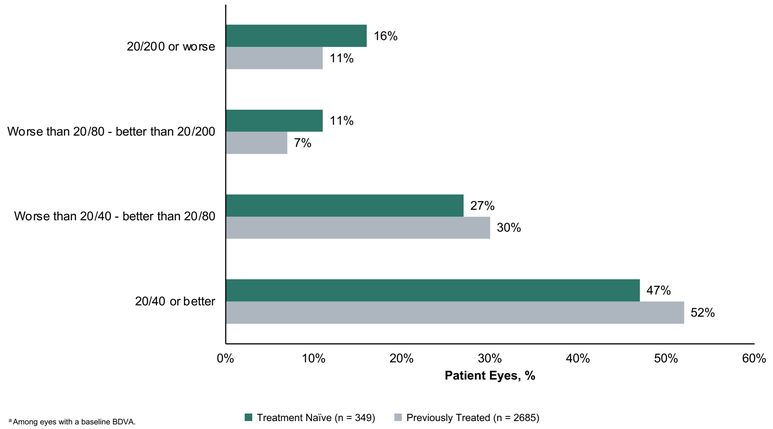
Results

1. Baseline Demographics

Baseline Demographic Characteristics (Patient Level)[a]	Previously Treated		Treatment Naïve	
	N	%	n	%
Number of patients	2129		311	
Number of eyes	2733		397	
Age				
Mean (SD)	67.9	(10.2)	67.7	(10.2)
18–64 years	634	(29.8)	90	(28.9)
65–74 years	941	(44.2)	135	(43.4)
75–84 years	473	(22.2)	70	(22.5)
85+ years	81	(3.8)	16	(5.1)
Sex				
Male	1190	(55.9)	172	(55.3)
Race				
White or Caucasian	1338	(62.8)	184	(59.2)
Black or African American	153	(7.2)	17	(5.5)
Asian	31	(1.5)	10	(3.2)
Other Race	180	(8.5)	22	(7.1)
Unknown	427	(20.1)	78	(25.1)
Ethnicity				
Hispanic	145	(6.8)	32	(10.3)
Non-Hispanic	1440	(67.6)	184	(59.2)
Unknown	544	(25.6)	95	(30.5)
Insurance/payer type at index date				
Medicare	1339	(62.9)	204	(65.6)
Medicaid	76	(3.6)	12	(3.9)
Commercial	530	(24.9)	64	(20.6)
Other	184	(8.6)	31	(10.0)

[a] Demographics captured at eye level for unilateral and bilateral patients across treatment-experienced and treatment naïve-patients. SD, standard deviation.

2. Nearly 50% of Eyes That Initiated Faricimab Treatment Had a BDVA of 20/40 or Better[a]



[a] Among eyes with a baseline BDVA.

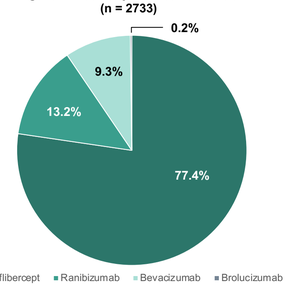
3. Most Patients Initiating Faricimab Were Previously Treated With Anti-VEGF

- Mean Anti-VEGF injection frequency in prior 12 months was almost 6 injections, 7 weeks apart

Prior Anti-VEGF Treatment Experience[a] (n = 2733)

Number of Injections in 12-month Pre-Index Period	
Mean (SD)	5.8 (2.9)
Treatment Interval (Days)	
Mean (SD)	50.4 (35.1)
Time From Last Injection to Index (Days)	
Mean (SD)	67.8 (60.3)
Number of Distinct Agents in 12-Month Pre-Index Period, n (%)	
1	2260 (82.7)
2	447 (16.4)
3	25 (0.9)
4	1 (0.0)

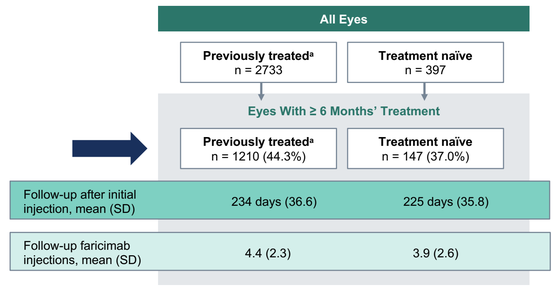
Percentage of Eyes Treated With Anti-VEGF Agent Immediately Prior to Faricimab (n = 2733)



[a] Includes lookback of available medical record data ≥ 12 months prior to faricimab initiation date in the IRIS registry. Medical data lookback includes records for anti-VEGF samples.

4. Over One-Third of Eyes Treated With Faricimab Have ≥ 6 Months of Follow-Up in the IRIS Registry

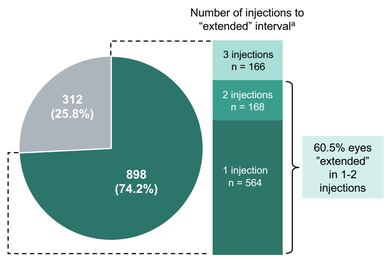
- Mean (SD) injection frequency for eyes with ≥ 6 months follow-up was 4.4 (2.3) for previously treated eyes and 3.9 (2.6) for treatment-naïve eyes



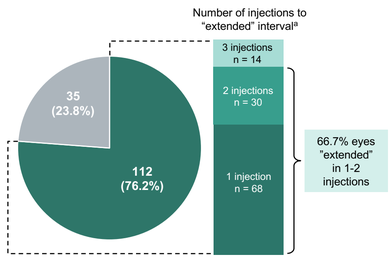
[a] Previously treated with anti-VEGF agents in prior 12 months. Anti-VEGF agents include aflibercept, bevacizumab, brolucizumab, and ranibizumab.

5. Most Eyes Had an "Extended" Interval (> 6 Weeks) After 2 Injections of Faricimab

Previously Treated Eyes With ≥ 6 Months Follow-Up (n = 1210)



Treatment-Naïve Eyes With ≥ 6 Months Follow-Up (n = 147)

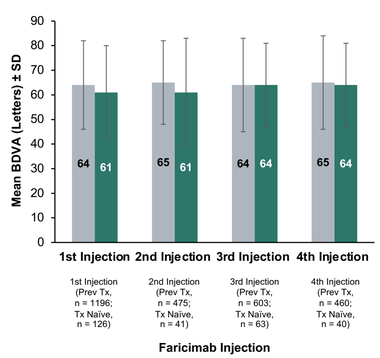


1–3 initial injections at > 6-week intervals[a]
4 initial injections at 2–6-week intervals[a]

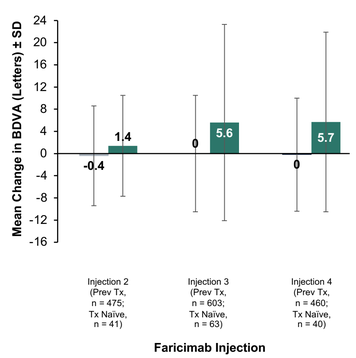
[a] Among patient eyes who received 4 or more injections. "Extended" interval defined as faricimab injection > 6 weeks after previous faricimab injection.

6. Visual Acuity Was Stable Over the Course of 4 Injections Among Patients With ≥ 6 months Follow-Up and Visual Acuity Improvement Was Observed in Treatment-Naïve Eyes

Mean Visual Acuity by Faricimab Injection[a]



Change in Visual Acuity From Baseline by Faricimab Injection[a]



[a] Among eyes with a baseline visual acuity.

Background

- Faricimab is the first bispecific antibody for intraocular use that independently binds and neutralizes both angiopoietin-2 and VEGF-A with high specificity and potency[1]
- Faricimab (Vabysmo™) was approved in January 2022 for the treatment of nAMD and DME[1]
- Real-world evidence is growing in patients treated with faricimab regarding their treatment patterns and outcomes[2-4]
  So far this includes:
  - TRUCKEE: An independent, physician-led, real-world study of faricimab in patients with nAMD
  - Rush RB et al (2022): Retrospective case-controlled study in patients with DME at a single private practice who were switched to faricimab from aflibercept[3]
  - VOYAGER: A noninterventional, prospective, multinational, multicenter study of faricimab (and the port delivery system) in patients with nAMD and DME[4]

Methods

- FARETINA-DME is a retrospective, real-world study using data from the IRIS Registry
- The IRIS Registry contains:
  - > 540 million de-identified patient encounters
  - > 75 million de-identified unique patients
  - Contributed by about 16,000 clinicians from > 60 electronic medical record systems across the US
- Patients receiving ≥ 4 faricimab injections were included in injection intervals and BDVA analyses
- Injection intervals were categorized as "extended" if any interval was > 6 weeks apart

Faricimab DME cohort

Record of first faricimab injection
Feb 7, 2022 – Sep 30, 22
Patients, n = 16,512 (100%)
Eyes, n = 19,821 (100%)

↓

Eyes with documentation of DME on index date
Patients, n = 2833 (17.2%)
Eyes, n = 3709 (18.7%)

↓

At least 12 months data available prior to index date
Patients, n = 2433 (14.7%)
Eyes, n = 3178 (16.0%)

↓

Eyes with laterality and known patient demographics
Patients, n = 2398 (14.5%)
Eyes, n = 3130 (15.8%)

↓

Previously treated	Treatment naïve:
Patients: n = 2129	**Patients: n = 311**
Eyes: n = 2733	**Eyes: n = 397**

Abbreviations

BDVA, best-documented visual acuity; DME, diabetic macular edema; FDA, Food and Drug Administration; nAMD, neovascular age-related macular degeneration; Prev, previous; SD, standard deviation; Tx, treatment; VEGF-A, vascular endothelial growth factor-A.

References

1. VABYSMO [package insert]. South San Francisco, CA: Genentech, Inc; 2022.
2. Bhandari R. Presented at: American Association of Ophthalmology Annual Meeting; July 13–14, 2022; New York, NY.
3. Rush RB et al. *Clin Ophthalmol*. 2022;16:2797-2801.
4. VOYAGER Clinical Trial [NCT05476926]. Accessed April 7, 2023. https://clinicaltrials.gov/ct2/show/NCT05476926

Financial Disclosures

- DT, VG: Employee: Genentech, Inc.
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Study and Product Disclosures

- Faricimab is approved for the treatment of neovascular age-related macular degeneration and diabetic macular edema in multiple countries worldwide and is not currently approved for use outside these indications
- This study includes research conducted on human subjects
- Institutional Review Board approval was obtained prior to study initiation
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