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Early Treatment Patterns and Outcomes in Patients With Neovascular Age-Related Macular Degeneration Initiating Faricimab: an IRIS® Registry Analysis (FARETINA-AMD)

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Objective

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

Summary

- The IRIS registry is a robust tool to understand treatment pattern and outcomes to faricimab
- FARETINA-AMD provides critical information on the early use, practice patterns, treatment responses in the largest real-world cohort to date in this indication
- Approximately half of all eyes (previously treated and treatment naive) reported vision of 20/40 or better upon initiation faricimab therapy. Previously treated patients were on prior intervals of at least 5 weeks
- Most eyes had “extended” intervals (> 6 weeks)[a] prior to the initial 4 monthly doses per FDA label
  - > 53% of eyes “extended” in 1–2 injections
- Visual acuity was stable after 4 injections in previously treated patient eyes, and steady improvement was seen in treatment-naïve eyes over the course of treatment
- The study is ongoing and provides the most generalizable information to date on real-world treatment patterns and outcomes of faricimab treatment post approval, with more data expected shortly

[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 treatment response, and a lack of physician dosing frequency rationale

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FARETINA AMD

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Results

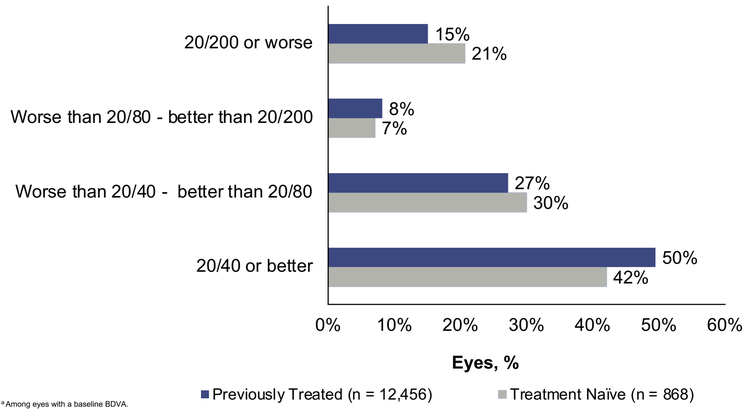
1. Baseline Demographics

Baseline Demographic Characteristics (Patient Level)[a]	Previously Treated		Treatment Naïve	
	N	%	n	%
Number of patients	10,950		880	
Number of eyes	12,803		1028	
Age				
Mean (SD)	80.4	(7.8)	80.6	(8.7)
18–64 years	277	(2.6%)	27	(3.0%)
65–74 years	2187	(20.0%)	160	(18.2%)
75–84 years	4844	(44.2%)	382	(43.4%)
85+ years	3642	(33.3%)	311	(35.3%)
Sex				
Female	6283	(57.4%)	535	(60.8%)
Race				
White or Caucasian	8232	(75.2%)	676	(76.8%)
Black or African American	71	(0.6%)	8	(0.9%)
Asian	154	(1.4%)	12	(1.4%)
Other race	655	(6.0%)	38	(4.3%)
Unknown	1838	(16.8%)	146	(16.6%)
Ethnicity				
Hispanic	202	(1.8%)	14	(1.6%)
Non-Hispanic	7990	(73.0%)	627	(71.3%)
Unknown	2758	(25.2%)	239	(27.2%)
Insurance/payer type at index date				
Medicare	9453	(86.3%)	771	(87.6%)
Medicaid	58	(0.5%)	9	(1.0%)
Commercial	1128	(10.3%)	68	(7.7%)
Other	311	(2.8%)	32	(3.6%)

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

2. Baseline Visual Acuity of Eyes Initiating Faricimab in the Real World Was Generally Better Than in Clinical Trial Populations

- On average, 19.8% of patients initiating anti-VEGF therapy in clinical trials have visual acuity better than 20/40[1]
  - In TENAYA/LUCERNE, around 14% had vision 20/32 or better[2]
- Nearly 50% of eyes initiated faricimab at 20/40 or better BDVA[a]



[a] Among eyes with a baseline BDVA.

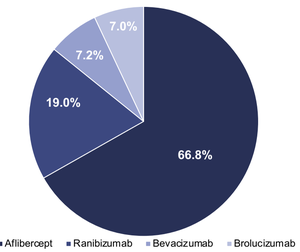
3. Most Patients Initiating Faricimab Were Previously Treated With Anti-VEGF

- Prior mean anti-VEGF injection frequency was around 7 injections, 6 weeks apart

Prior Anti-VEGF Treatment Experience[a] (n = 12,803)

Number of Injections in Prior 12 Months	
Mean (SD)	7.5 (2.9)
Previously Treated Interval (Days)	
Mean (SD)	42.8 (22.0)
Time From Prior Injection to Index (Days)	
Mean (SD)	50.5 (34.7)
Number of Distinct Agents in Prior 12 Months, n (%)	
1	10,512 (82.1)
2	2102 (16.4)
3	186 (1.5)
4	3 (0.0)

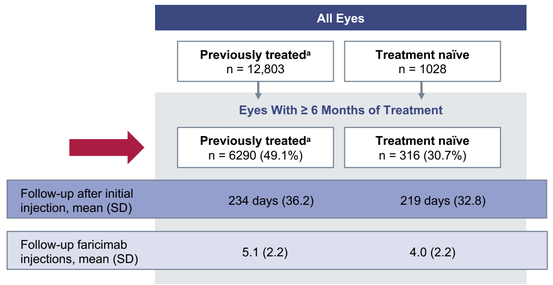
Percentage of Eyes Treated With Anti-VEGF Agent Immediately Prior to Faricimab (n = 12,803)



[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.

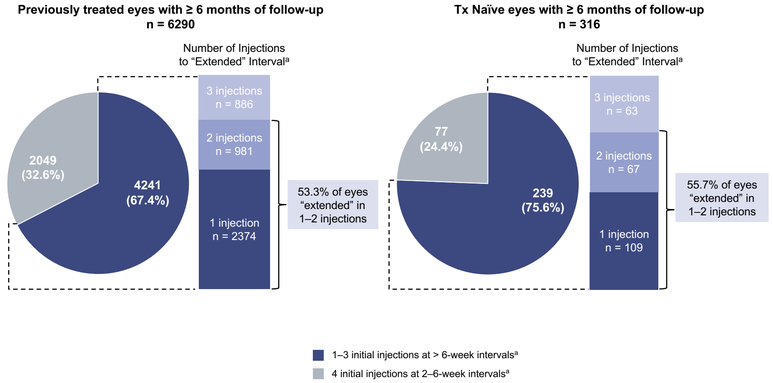
4. Over One-Third of Eyes Treated With Faricimab Have ≥ 6 Months of Follow-Up in the IRIS Registry

- Mean (SD) injection frequency for eyes with ≥ 6 months of follow-up was 5.1 (2.2) for previously treated eyes and 4.0 (2.2) for treatment-naïve eyes



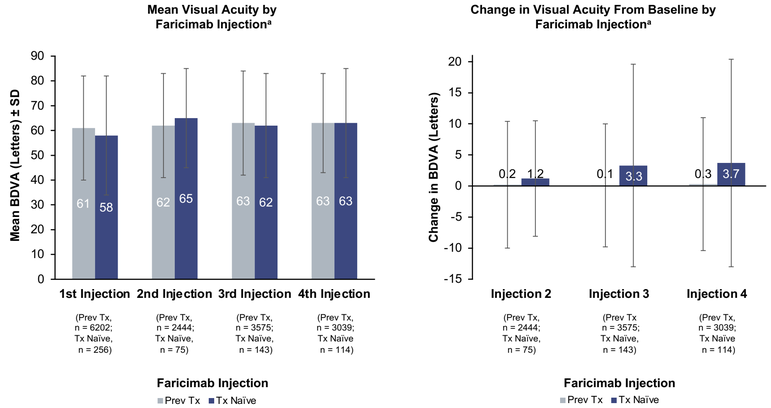
[a] Previously treated with anti-VEGF agents in prior 12 months. Anti-VEGF agents include aflibercept, bevacizumab, brolucizumab, and ranibizumab.

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



[a]“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 of Follow-Up and Visual Acuity Improvements Were Observed in Treatment-Naïve Eyes



[a]Among eyes with a baseline visual acuity. BDVA assessed at each injection of faricimab, ± 7 days.

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[3]
- Faricimab (Vabysmo™) was approved in January 2022 for the treatment of nAMD and DME[3]
- Real-world evidence is growing in patients treated with faricimab regarding their treatment patterns and outcomes.[4-6]
  So far this includes:
  - TRUCKEE: An independent, physician-led, real-world study of faricimab in patients with nAMD[4]
  - 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[5]
  - VOYAGER: A noninterventional, prospective, multinational, multicenter study of faricimab (and the port delivery system) in patients with nAMD and DME[6]

Methods

- FARETINA-nAMD 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 nAMD cohort

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

↓

Eyes with documentation of nAMD on index date
Patients, n = 13,507 (81.8%)
Eyes, n = 15,889 (80.2%)

↓

At least 12 months' data available prior to index date
Patients, n =11,902 (72.1%)
Eyes, n = 14,095 (71.1%)

↓

Eyes with laterality and known patient demographics
Patients, n = 11,692 (70.8%)
Eyes, n = 13,831 (69.8%)

↓

Previously treated
Patients: n = 10,950
Eyes: n = 12,803

Treatment naïve:
Patients: n = 880
Eyes: n = 1028

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.

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1. Adapted from Ho AC et al. *Ophthalmic Surg Lasers Imaging Retina*. 2020;51:633-639.
2. Heier JS et al. *Lancet*. 2022;399:729-740.
3. VABYSMO [package insert]. South San Francisco, CA: Genentech, Inc; 2022.
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Financial Disclosures

- DB: Consultant: Allergan/AbbVie, Glaukos, Iveric Bio
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- RPS: Research Grant: Aerie, Apellis, Graybug; Consultant: Alcon, Bausch + Lomb, Genentech, Inc., Gyroscope, Novartis, Regeneron

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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