Real-World Treatment Patterns and Outcomes Among Eyes With Diabetic Macular Oedema (DMO) That Received > 6 Months of Faricimab Treatment in the UK: FARWIDE-DMO

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Conclusions

Faricimab Real-World Evidence (FARWIDE)-DMO is a real-world data study evaluating outcomes of faricimab treatment in the United Kingdom

At faricimab initiation, 27.1% of eyes in the 12-month study cohort were treatment naïve. The majority of eyes previously treated with anti–vascular endothelial growth factor (VEGF) (85.5%) had received aflibercept as their most recent anti-VEGF agent

Over 12 months, visual acuity (VA) improved by approximately 5 Early Treatment Diabetic Retinopathy Study (ETDRS) letters in treatment-naïve eyes and was maintained in previously treated eyes

- Percentage of eyes with VA ≥ 70 ETDRS letters increased from baseline (45.0%) to 12 months (66.0%) in treatment-naïve eyes and remained stable in previously treated eyes

Fewer injections were received on average during the second 6 months of faricimab compared with the first 6 months of treatment

- The high percentage of eyes receiving 4 loading doses contributed to the higher injection number in the first 6 months of treatment

Rates of intraocular inflammation and potentially infectious endophthalmitis were low and in line with rates observed in phase 3 faricimab trials and the US FARETINA study[1,2]

Real-world studies are robust tools to understand treatment responses to faricimab

Financial Disclosures

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- TP: Speaker Fees: Alimera, Allergan, Apellis, Bayer, Boehringer Ingelheim, Heidelberg Engineering, Novartis, Optos, Roche, ZEISS; Consulting: Boehringer Ingelheim, Roche
- CB: Advisory Board, Honoraria, Travel Support: Alimera, Apellis, Bayer, Boehringer Ingelheim, Janssen, Novartis, Roche
- LD: Advisory Board, Honoraria: Alimera, Allergan, Bayer, Biogen, Novartis, Roche
- CK: Advisory Board, Consulting, Honoraria: Alimera, Bayer, Boehringer Ingelheim, Roche
- IP: Honoraria: Allergan, Apellis, Bayer, Boehringer Ingelheim, Novartis
- GC, PD: Employee: Genentech, Inc.
- AD: Employee: F. Hoffmann-La Roche Ltd.
- MD: Employee: Medisoft Limited

Study and Product Disclosures

- In the UK, faricimab is approved for the treatment of neovascular age-related macular degeneration and diabetic macular oedema. Faricimab is not currently approved for use outside these indications in the UK
- This study is a non-interventional, retrospective, secondary data use study
- Caldicott Guardian approval was obtained prior to study initiation
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Background

- Faricimab is the first bispecific antibody for intraocular use that independently binds and neutralises both angiopoietin-2 and VEGF-A with high specificity and potency[3]
- Faricimab was approved in Great Britain in May 2022 for the treatment of diabetic macular oedema (DMO)
- The early adoption of faricimab in the United Kingdom provides an opportunity to study faricimab treatment patterns and effectiveness in the real-world context
- FARWIDE-DMO is a retrospective, observational study starting in 2022 to evaluate:
  - Faricimab uptake
  - Patient characteristics
  - Treatment frequency
  - VA outcomes

Methods

- Ophthalmic assessment, treatment and diagnostic information was obtained from the Medisoft Electronic Medical Records System at 27 NHS sites in the United Kingdom
- Data were collected between June 2022 and February 2024
- Extraction criteria:
  - Received ≥ 1 intravitreal injection of faricimab – initiated on or after 1 June 2022
  - ≥ 1 diagnosis of DMO recorded
  - No known participation in ≥ 1 of the pivotal faricimab clinical trials
- Inclusion criteria:
  - Documented diagnosis for DMO and no concomitant neovascular age-related macular degeneration or retinal vein occlusion
  - No participation in any intravitreal injection trials
  - No inconclusive anti-VEGF history
  - ≥ 1 faricimab injection after June 2022

Limitations

- Measurements are non-standardised and data capture is limited to what is collected in routine clinical practice
- These data are specific to the United Kingdom and may not be readily generalisable to other jurisdictions

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3. Regula JT et al. *EMBO Mol Med*. 2016;8(11):1265-1288, with erratum in Regula JT et al. *EMBO Mol Med*. 2019;11(5):e10666.
4. UK Ministry of Housing, Communities & Local Government. The English Indices of Deprivation 2019. Accessed April 30, 2024. https://assets.publishing.service.gov.uk/media/5dfb3d7ce5274a3432700cf3/IoD2019_FAQ_v4.pdf

Results

1. Patient Attrition

Patient-eyes were extracted if they met the following criteria:
- They have received ≥ 1 intravitreal injection of faricimab – initiated on or after 1 June 2022
- They have ≥ 1 diagnosis of DMO recorded
- They are not known to have participated in ≥ 1 of the pivotal faricimab clinical trials

Total extracted eyes
Patients, n = 4125; Eyes, n = 5777

- Patient-eye has diagnosis of DMO on or before index (first) faricimab injection date
- Age of ≥ 18 years at index date
- Patient-eye has no concomitant diagnosis of nAMD or RVO
- No known participation in IVI trials
- Patient-eye does not have inconclusive anti-VEGF history at index date

Total Study Population	**Patients, n = 3709; Eyes, n = 5182**	
	Treatment-naïve eyes[a] n = 2040 (39.4%)	Previously treated eyes[b] n = 3142 (60.6%)
12-Month Cohort	**Patients, n = 580; Eyes, n = 794**	
	Treatment-naïve eyes n = 215 (27.1%)	Previously treated eyes n = 579 (72.9%)

[a] Treatment-naïve eyes are those with no evidence of anti-VEGF or steroid implant treatment at any time before initiating faricimab. [b] Previously treated eyes are defined as those that received ≥ 1 prior anti-VEGF or steroid implant treatment any time before faricimab initiation at the participating site. DMO, diabetic macular oedema; IVI, intravitreal injection; nAMD, neovascular age-related macular degeneration; RVO, retinal vein occlusion; VEGF, vascular endothelial growth factor.

2. Patient Demographics at Index Faricimab Treatment (Baseline), 12-Month Cohort

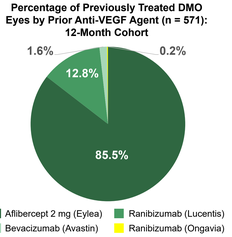
Characteristics at Index Faricimab Injection (Patient-Level)	n = 580
Age at first faricimab injection, mean (SD)	62.9 (10.9)
Sex, n (%)[a]	
Female	238 (41.0)
Race, n (%)	
White/White British/White Irish	347 (59.8)
Asian/Asian British	40 (6.9)
Black/Black British	17 (2.9)
Chinese	2 (0.3)
Other[b]	9 (1.6)
Unknown	165 (28.4)
Index of Multiple Deprivation Deciles, n (%)[4]	
1–2 (most deprived)	134 (23.1)
3–4	151 (26.0)
5–6	110 (19.0)
7–8	94 (16.2)
9–10 (least deprived)	84 (14.5)
Unknown	7 (1.2)

[a] Male, n = 340 (58.6%), not stated, n = 2 (0.3%). [b] Includes any other ethnic group and any other mixed background. The deciles are calculated by ranking the 32,844 LSOAs in England from most deprived to least deprived and dividing them into 10 equal groups. LSOAs in decile 1 fall within the most deprived 10% of LSOAs nationally and LSOAs in decile 10 fall within the least deprived 10% of LSOAs nationally. LSOA, Lower Layer Super Output Area; SD, standard deviation.

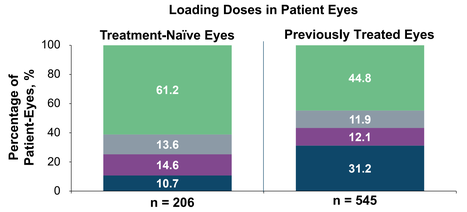
3. For 86% of Eyes Previously Treated With Anti-VEGF, Aflibercept 2 mg Was the Last Anti-VEGF Agent Received Before Initiating Faricimab

Duration of Anti-VEGF Treatment Pre-Index (Years)[a]	
Mean (SD)	3.0 (2.5)
Total Number of Injections Pre-Index Period	
Mean (SD)	18.2 (14.2)
Median (Q1, Q3)	14 (8, 25)
Number of Distinct Anti-VEGF Agents at Any Time Pre-Index Period, n (%)	
1	426 (74.6)
2	128 (22.4)
3	17 (3.0)

[a] Number of years between the first anti-VEGF injection and the first faricimab injection. DMO, diabetic macular oedema; Q, quartile; SD, standard deviation; VEGF, vascular endothelial growth factor.

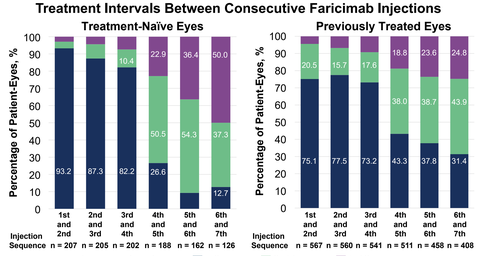


4. Loading Doses in Patient Eyes: 12-Month Follow-Up



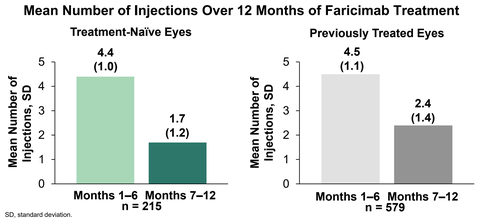
Count is among eyes with ≥ 4 faricimab injections.

5. Percentage of Patient-Eyes on Treatment Intervals ≥ 8 Weeks is Higher After the Fourth Injection



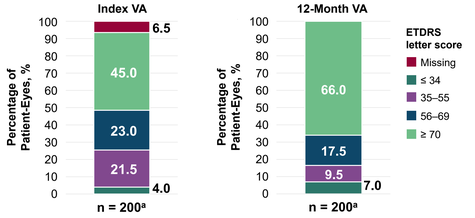
Percentages <10% are not displayed for clarity.

6. Mean Injections in Months 7–12 of Faricimab Treatment Were Lower Than Months 1–6 in Treatment-Naïve and Previously Treated Eyes



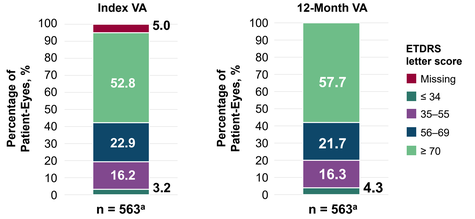
SD, standard deviation.

7. Percentage of Treatment-Naïve Eyes With VA ≥ 70 ETDRS Letters Increased From Index to 12 Months



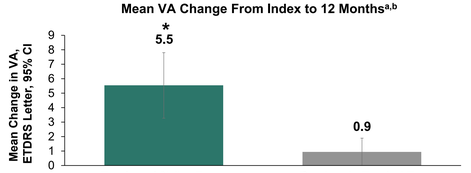
[a] Eyes with VA data at 12 months. ETDRS, Early Treatment Diabetic Retinopathy Study; VA, visual acuity.

8. Percentage of Previously Treated Eyes With VA ≥ 70 ETDRS Letters Remained Stable From Index to 12 Months



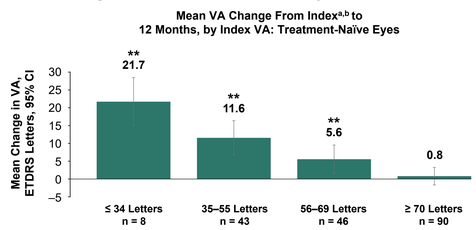
[a] Eyes with VA data at 12 months. ETDRS, Early Treatment Diabetic Retinopathy Study; VA, visual acuity.

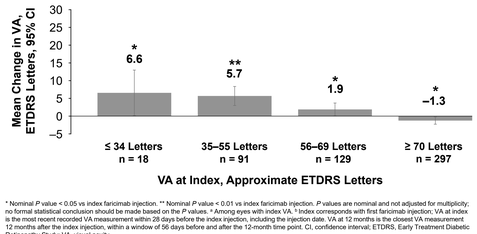
9. VA Improved on Average in Treatment-Naïve Eyes at 12 Months



[a] Nominal *P* value < 0.001 vs index faricimab injection. *P* values are nominal and not adjusted for multiplicity; no formal statistical conclusion should be made based on the *P* values. [b] Among eyes with index VA. [c] Index corresponds with first injection; VA at index is the most recent recorded VA measurement within 28 days before the index injection, including the injection date. VA at 12 months is the closest VA measurement 12 months after the index injection, within a window of 56 days before and after the 12-month time point. CI, confidence interval; ETDRS, Early Treatment Diabetic Retinopathy Study; VA, visual acuity.

10. VA Change From Index to 12 Months by Index VA





[a] Nominal *P* value < 0.05 vs index faricimab injection. ** Nominal *P* value < 0.01 vs index faricimab injection. *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 index VA. [b] Index corresponds with first faricimab injection; VA at index is the most recent recorded VA measurement within 28 days before the index injection, including the injection date. VA at 12 months is the closest VA measurement 12 months after the index injection, within a window of 56 days before and after the 12-month time point. CI, confidence interval; ETDRS, Early Treatment Diabetic Retinopathy Study; VA, visual acuity.

11. IOI and PIE Among nAMD and DMO Eyes

Event Type	Statistic	Previously Treated Eyes (No. Injections = 68,111)	Treatment-Naïve Eyes (No. Injections = 31,457)
IOI	Number of distinct events[a]	101	37
	% Events per injection (95% CI)[b]	0.15 (0.12, 0.18)	0.12 (0.08, 0.16)
PIE	Number of distinct events[a]	54	28
	% Events per injection (95% CI)[b]	0.08 (0.06, 0.10)	0.09 (0.06, 0.13)

- IOI and PIE were assessed among all 6709 naïve and 11,611 previously treated eyes meeting the eligibility criteria of the FARWIDE-nAMD/DMO studies
- IOI and PIE events were not mutually exclusive; 51 records could not be identified as IOI or PIE separately and have been included in both sets of results
- IOI and PIE events were identified using the post-operative complications, diagnoses or clinical examination findings on a patient's electronic medical record (EMR). PIE events were additionally identified using surgical records of vitreous biopsy or anterior chamber tap, or intravitreal injections of ceftazidime or vancomycin on a patient's EMR

[a] Adverse events are included if they are within 180 days after a faricimab injection and prior to a subsequent anti-VEGF injection. If adverse events of the same type occur within 30 days of each other, then only the first is included. Fourteen records of IOI and 18 records of PIE were identified from multiple sources in the EMR. [b] The exact *p*' method was used to calculate the 95% CI for the rates. CI, confidence interval; DMO, diabetic macular oedema; IOI, intraocular inflammation; nAMD, neovascular age-related macular degeneration; PIE, potentially infectious endophthalmitis; VEGF, vascular endothelial growth factor.