Two-Year Effectiveness, Durability and Safety of Faricimab in Eyes With Diabetic Macular Oedema: Results From the UK FARWIDE-DMO Study

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This analysis evaluated patient characteristics, effectiveness, safety and durability of faricimab treatment in eyes with DMO with ≥ 24 months of follow-up

Introduction

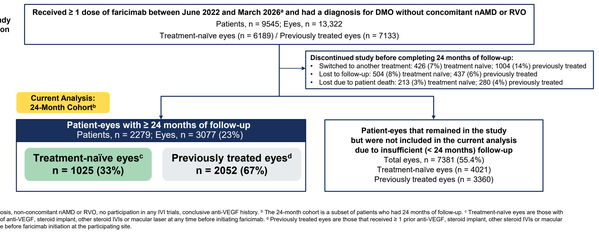
- FARWIDE is an observational study leveraging Medisoft EMR data from 34 National Health Service sites
- FARWIDE is the largest real-world study evaluating faricimab treatment patterns and outcomes outside the United States, providing insights into faricimab effectiveness and safety

Methods

- Data analysed included patient-eyes that initiated faricimab between June 2022 and March 2026 and had:
  - Documented diagnosis for DMO
  - Non-concomitant nAMD or RVO
  - No participation in any IVI trials
  - Conclusive anti-VEGF history
  - ≥ 1 faricimab injection on or after June 2022
- Ophthalmic assessment, treatment and diagnostic information were obtained from the EMR
- Analyses are descriptive
- Limitations:
  - Data capture was limited to what was collected in routine clinical practice
  - Data are specific to the United Kingdom and may not be readily generalisable to other countries

Results

1. 24-Month Outcomes Were Analysed in 3077 Eyes of 2279 Patients



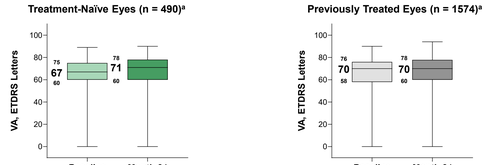
[a] DMO diagnosis, non-concomitant nAMD or RVO, no participation in any IVI trials, conclusive anti-VEGF history. [b] The 24-month cohort is a subset of patients who had 24 months of follow-up. [c] Treatment-naïve eyes are those with no evidence of anti-VEGF, steroid implant, other steroid IVIs or macular laser at any time before initiating faricimab. [d] Previously treated eyes are those that received ≥ 1 prior anti-VEGF, steroid implant, other steroid IVIs or macular laser any time before faricimab initiation at the participating site.

2. Baseline Patient Demographics of 24-Months Cohort

Characteristics at Index Injection (Patient Level)	n = 2279
Age at index (first) faricimab injection, mean (SD), years	62.5 (11.5)
Sex, n (%)[a]	
Female	777 (34.1)
Race, n (%)	
White/White British/White Irish	989 (43.4)
Asian/Asian British	211 (9.3)
Black/Black British	58 (2.5)
Chinese	5 (0.2)
Other[b]	129 (5.7)
Unknown	887 (38.9)
Index of Multiple Deprivation deciles), n (%)	
1–2 (most deprived)	557 (24.4)
3–4	465 (20.4)
5–6	425 (18.6)
7–8	417 (18.3)
9–10 (least deprived)	359 (15.8)
Unknown	56 (2.5)

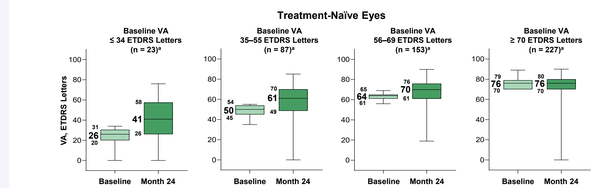
[a] Male, n = 1204 (52.8%); sex not stated, n = 298 (13.1%). [b] Includes any other White or mixed background or other ethnic group.

3. Median VA Improved in Treatment-Naïve Eyes From Baseline to 24 Months and Remained Stable in Previously Treated Eyes



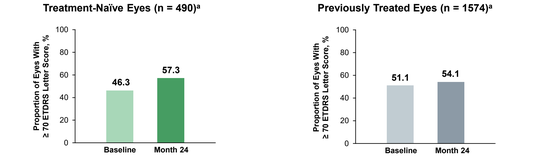
[a] Among eyes with VA at baseline and at 24 months, VA at baseline is the most recent recorded VA measurement within 28 days before the first faricimab injection, including the injection date. VA at 24 months is the closest VA measurement 24 months after the first faricimab injection, within a window of 56 days before and after the 24-month time point. Count fingers, hand motion, perception of light and no perception of light were assigned as 0 ETDRS letters.

4. Median VA Improved at 24 Months in Treatment-Naïve Eyes With Baseline VA < 70 Letters and Was Maintained in Eyes With Baseline VA ≥ 70 Letters



[a] Among eyes with VA at baseline and at 24 months. VA at baseline is the most recent recorded VA measurement within 28 days before the first faricimab injection, including the injection date. VA at 24 months is the closest VA measurement 24 months after the first faricimab injection, within a window of 56 days before and after the 24-month time point. Count fingers, hand motion, perception of light and no perception of light were assigned as 0 ETDRS letters.

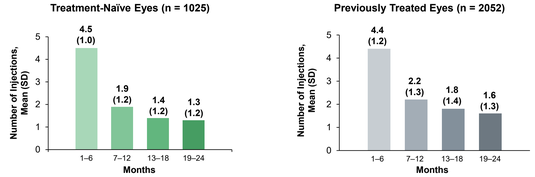
5. The Proportion of Eyes With Driving-Level VA Improved in Treatment-Naïve Eyes and Remained Stable in Previously Treated Eyes at 24 Months vs Baseline



- **40% of eyes attained** and **79% maintained** driving-level vision at 24 months
- **29% of eyes attained** and **78% maintained** driving-level vision at 24 months

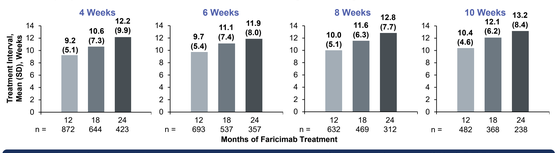
[a] Among eyes with VA at baseline and at 24 months.

6. Mean Number of Faricimab Injections Declined Sharply After 6 Months and Continued to Decline Steadily Up to 24 Months



At the start of FARWIDE, the posology in the United Kingdom for faricimab recommended a loading dose of 4 injections. On 19 December 2024, the posology was updated to recommend a minimum of 3 injections.

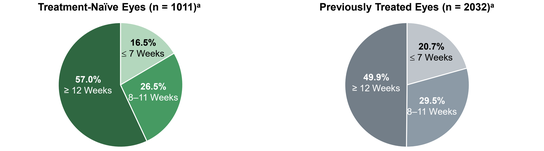
7. Sustained Interval Extension With Faricimab Achieved in Previously Treated Eyes



- Prior to faricimab initiation, previously treated eyes received anti-VEGF treatment for a mean (SD) of **3.6 (3.0)** years
- **67%** switched to faricimab from **aflibercept 2 mg**[b]

[a] Pre-index anti-VEGF treatment interval: average of the last 2 pre-index treatment intervals. Patient-eyes are only included if this average was ≤ 77 days. 4 weeks: > 0 to ≤ 5 weeks, 1–35 days; 6 weeks: > 5 to ≤ 7 weeks, 36–49 days; 8 weeks: > 7 to ≤ 9 weeks, 50–63 days; ≥ 10 weeks: > 9 to ≤ 11 weeks, 64–77 days. [b] Other last treatment prior to faricimab initiation included bevacizumab (2.7%), ranibizumab (13.7%), dexamethasone (5.2%), macular laser (10.1%), fluocinolone acetonide (0.4%) and triamcinolone (0.5%).

8. 57% of Treatment-Naïve Eyes and ~50% of Previously Treated Eyes Had Latest Treatment Intervals of ≥ 12 Weeks at Month 24



Mean (SD) treatment interval at 24 months was **14.4 (10.6) weeks**

Mean (SD) latest treatment interval was **7.9 (3.3)** weeks pre faricimab and **13.3 (5.8)** weeks at 24 months

[a] Among eyes that received > 1 faricimab injection. 4 weeks: > 0 to ≤ 5 weeks, 1–35 days; 6 weeks: > 5 to ≤ 7 weeks, 36–49 days; 8 weeks: > 7 to ≤ 9 weeks, 50–63 days; ≥ 10 weeks: > 9 to ≤ 11 weeks, 64–77 days; ≥ 12 weeks: > 11 weeks, 78 days and above.

9. Low Rates of IOI and Endophthalmitis Among nAMD, DMO and RVO Eyes With Any Duration of Follow-Up

Pooled AEs[a] Across nAMD, DMO and RVO

	Treatment-Naïve Eyes n = 22,853	Previously Treated Eyes n = 23,965
IOI % of events per injection	**0.20%** (335 events from 169,233 injections)[b]	**0.17%** (395 events from 229,156 injections)[b]
Endophthalmitis % of events per injection	**0.02%** (40 events from 169,233 injections)[b]	**0.03%** (73 events from 229,156 injections)[b]

[a] Among eyes meeting the eligibility criteria of the FARWIDE-nAMD/DMO/RVO studies. Eyes were included in the safety analysis if they had no evidence of IOI or endophthalmitis in the 12 months prior to faricimab initiation. AEs are included if they are within 180 days after a faricimab injection and before a subsequent anti-VEGF injection. If AEs of the same type occur within 30 days of each other, then only the first is included. Only 1 event per injection is counted. [b] IOI and endophthalmitis events were identified using the post-operative complications, diagnoses or clinical examination findings on a patient's EMR. Endophthalmitis events were additionally identified using surgical records of vitreous biopsy or anterior chamber tap or IVIs of ceftazidime or vancomycin on a patient's EMR.

Conclusions

FARWIDE-DMO 24-month results demonstrate effectiveness, durability and safety that are consistent with phase 3 trials

Effectiveness
- **VA improved in treatment-naïve eyes and remained stable in previously treated eyes**

Durability
- **Mean number of faricimab injections declined sharply after the initial 6 months and further declined up to 24 months**
- **Previously treated eyes had notable extensions in their treatment intervals with faricimab at 24 months**
- **57% of treatment-naïve eyes and ~50% of previously treated eyes had a latest treatment interval of ≥ 12 weeks by month 24**

Safety
- **Rates of IOI and endophthalmitis were low and consistent with the phase 3 faricimab trials and other faricimab real-world studies[1–4]**

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3. Sheth V. Presented at: EURETINA; September 19–22, 2024; Barcelona, Spain.
4. Lim J. Presented at: EURETINA; September 19–22, 2024; Barcelona, Spain.

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- IP: Advisory Board/Consulting/Honoraria/Travel Expenses: Allergan, Apellis, Bayer, Boehringer Ingelheim, Novartis, Roche
- GCC, PD: Employee: Genentech, Inc.
- AD: Employee: Roche Products Ltd.
- MD: Employee: Medisoft Ltd.

Study and Product Disclosures
- In the UK, faricimab is approved for the treatment of neovascular age-related macular degeneration, visual impairment due to diabetic macular oedema and visual impairment due to macular oedema secondary to retinal vein occlusion
- This study is a non-interventional, retrospective secondary data use study, leveraging data from the Medisoft EMR systems
- 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 F. Hoffmann-La Roche Ltd. for the study and third-party writing assistance, which was provided by Hannah Chatfield, PhD, of Envision Pharma Group

Abbreviations
AE, adverse event; DMO, diabetic macular oedema; EMR, electronic medical record; ETDRS, Early Treatment Diabetic Retinopathy Study; IOI, intraocular inflammation; IVI, intravitreal injection; nAMD, neovascular age-related macular degeneration; RVO, retinal vein occlusion; SD, standard deviation; VA, visual acuity; VEGF, vascular endothelial growth factor.