FARWIDE-DMO demonstrates the real-world effectiveness, durability and safety of faricimab for the treatment of DMO in the UK

Effectiveness and Safety of Faricimab in Eyes With DMO in the United Kingdom: 1-Year Results From the FARWIDE-DMO Study

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- IP: Advisory Board/Consulting/Honoraria/Travel Expenses: Roche
- GCC, PD: Employee: Genentech, Inc. Stocks and options: Roche
- NJ: Employee: Roche Products Ltd
- AD: Employee: F. Hoffmann-La Roche Ltd.
- MD: Employee: Medisoft Ltd.

Study Disclosures

- In the UK, faricimab is approved for the treatment of neovascular age-related macular degeneration, diabetic macular oedema and macular oedema secondary to retinal vein occlusion. 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
- Funding was provided by F. Hoffmann-La Roche Ltd. for the study and third-party writing assistance, which was provided by Christopher A. Lamb, PhD, of Envision Pharma Group
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Introduction

- Faricimab is the only approved intraocular bispecific antibody that inhibits angiopoietin-2 and vascular endothelial growth factor-A (VEGF-A)[1–3]
- To date, > 7 million doses have been distributed in > 100 countries[4]
- Faricimab Real-World Evidence (FARWIDE) is a multicentre, retrospective, observational study evaluating the effectiveness and safety of faricimab for the treatment of neovascular age-related macular degeneration (nAMD) and diabetic macular oedema (DMO) in the United Kingdom (UK)[5]
- Baseline characteristics, key effictiveness, durability and safety outcomes for patient-eyes in the FARWIDE-DMO cohort with ≥ 12 months of follow-up are reported

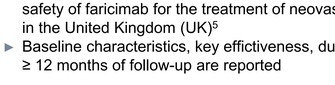
Methods

- Data from 35 UK NHS sites using the Medisoft or MediSIGHT electronic medical records (EMR) were included
- Patient-eyes had diagnosed DMO, no diagnosed nAMD or RVO, initiated faricimab after June 2022 and had ≥ 12 months of follow-up as of June 2024
- Treatment-naïve eyes had no prior anti-VEGF or steroid implant treatment. Previously treated eyes switched to faricimab from an anti-VEGF or steroid implant treatment
- Baseline characteristics, visual acuity (VA) and injection frequency were assessed in the 12-month cohort
- Presumed infectious endophthalmitis (PIE) and intraocular inflammation (IOI) events were identified amongst eyes with nAMD or DMO and any duration of follow-up
- Analyses are descriptive

Results

1. > 2000 Eyes Had ≥ 12 Months of Follow-Up and 32% Were Treatment-Naïve

- Diagnosis of DMO on or prior to the index (first) faricimab injection date
- Patient age of ≥ 18 years at the index date
- No concomitant diagnosis of nAMD or RVO
- No known participation in IVI trials
- No inconclusive anti-VEGF history at index date



[a] Treatment-naïve eyes are those with no evidence of anti-VEGF injections or steroid implants at any time prior to initiating faricimab. [b] Previously treated eyes are defined as those that received ≥ 1 prior anti-VEGF treatment or steroid implant any time prior to faricimab initiation at the participating site. [c] The 12-month cohort is a subset of patients who had ≥ 12 months of follow-up. DMO, diabetic macular oedema; IVI, intravitreal injection; nAMD, neovascular age-related macular degeneration; RVO, retinal vein occlusion; VEGF, vascular endothelial growth factor.

2. Mean Cohort Age Was 62 Years, With the Majority Being Male and White British

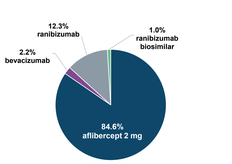
Characteristics at Index Injection (Patient-Level)	n = 1564
Age at index (first) faricimab injection, mean (SD)	62.5 (11.6)
Sex, n (%)[a]	
Female	591 (37.8)
Race, n (%)	
White/White British/White Irish	813 (52.0)
Asian/Asian British	130 (8.3)
Black/Black British	35 (2.2)
Chinese	5 (0.3)
Other[b]	48 (3.1)
Unknown	533 (34.1)
Index of Multiple Deprivation deciles, n (%)[c,6,7]	
1–2 (most deprived)	369 (23.6)
3–4	330 (21.1)
5–6	285 (18.2)
7–8	279 (17.8)
9–10 (least deprived)	259 (16.6)
Unknown	42 (2.7)

[a] Male, n = 958 (61.3%); not stated, n = 15 (1.0%). [b] Includes any other ethnic group and any other mixed background. [c] The deciles are calculated per nation by ranking the 32,844 LSOAs in England and 6976 data zones in Scotland from most deprived to least deprived and dividing them into 10 equal groups, respectively. Areas in decile 1 fall within the most deprived 10% and areas in decile 10 fall within the least deprived 10% of LSOAs/data zones per nation. LSOA, Lower Layer Super Output Area; SD, standard deviation.

3. Previously Treated Eyes Initiating Faricimab Had Received 3 Years of Prior Anti-VEGF Treatment With 16 Injections, on Average

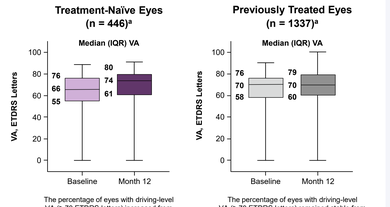
Duration of Anti-VEGF Treatment Before Faricimab Initiation (Years)[a]	
Mean (SD)	2.8 (2.3)
Total Number of Injections Before Faricimab Initiation	
Mean (SD)	16.2 (11.7)
Median (Q1, Q3)	13 (7, 22)
Number of Distinct Anti-VEGF Agents at Any Time Before Faricimab Initiation, n (%)	
1	1100 (76.8)
2	301 (21.0)
3	32 (2.2)

Percentage of DMO Previously Treated Eyes by Prior Anti-VEGF Agent (n = 1564)



[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. VA Improved in Treatment-Naïve Eyes and Remained Stable in Previously Treated Eyes From Baseline at 12 Months



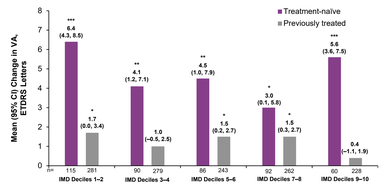
The percentage of eyes with driving-level VA (≥ 70 ETDRS letters) increased from **46.9%** at baseline to **63.2%** by month 12

The percentage of eyes with driving-level VA (≥ 70 ETDRS letters) remained stable from **53.0%** at baseline to **58.1%** at month 12

[a] Amongst eyes with VA at baseline and 12 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 12 months is the closest VA measurement 12 months after the first injection, within a window of 56 days before and after the 12-month time point. ETDRS, Early Treatment Diabetic Retinopathy Study; IQR, interquartile range; VA, visual acuity.

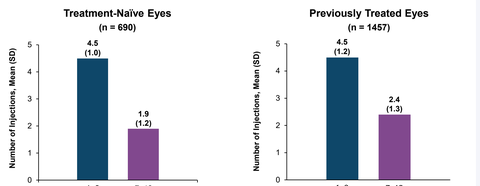
5. Treatment-Naïve Patient-Eyes Showed Improved Mean VA Changes From Baseline to 12 Months Across IMD Deciles

Mean VA Change From Index[a,b] to 12 Months by IMD Decile



[a] Nominal *P* value < 0.05 vs baseline. ** Nominal *P* value ≤ 0.01 vs baseline. *** Nominal *P* value < 0.001 vs baseline. *P* values are nominal and not adjusted for multiplicity; no formal statistical conclusion should be made based on the *P* values. * Amongst eyes with VA at index. [b] Index corresponds with the 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; IMD, Index of Multiple Deprivation; VA, visual acuity.

6. Faricimab Injection Count Declined Steadily During the First 12 Months of Treatment



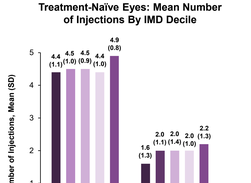
61.0% of treatment-naïve eyes received at least **4 loading doses** of faricimab[a]

47.7% of previously treated eyes received **4 loading doses** of faricimab[a]

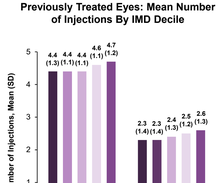
[a] Amongst eyes with 4 injections of faricimab; n = 667 treatment-naïve and n = 1395 previously treated. Loading doses are defined as the number of consecutive faricimab injections that had a treatment interval of 28 (14) days, up to the fourth injection. At the time of data extraction (July 2024), the posology in the UK for faricimab recommended a loading dose of 4 injections. On 19 December 2024, the posology was updated to recommend a minimum of ≥ 3 injections. SD, standard deviation.

7. Injection Frequency Declined in the Second 6 Months of Treatment Across All IMD Deciles

Treatment-Naïve Eyes: Mean Number of Injections By IMD Decile



Previously Treated Eyes: Mean Number of Injections By IMD Decile

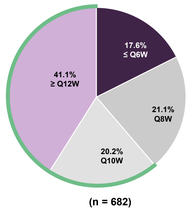


IMD deciles 1–2 | IMD deciles 3–4 | IMD deciles 5–6 | IMD deciles 7–8 | IMD deciles 9–10

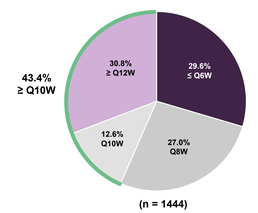
[a] Eyes with data at 12 months. 1 = most deprived decile, 10 = least deprived decile. IMD, Index of Multiple Deprivation; SD, standard deviation.

8. 61% of Treatment-Naïve Eyes Reached a Treatment Interval of ≥ Q10W

Percentage of Treatment-Naïve Eyes by Treatment Interval



Percentage of Previously Treated Eyes by Treatment Interval



Treatment interval included was the interval on or prior to completing 12 months of follow-up. Included eyes had received more than 1 faricimab injection during the 12-month follow-up period. QXW, every X weeks.

9. Low Rates of IOI and PIE Amongst nAMD and DMO Eyes With Any Duration of Follow-Up

Pooled AEs[a] Across nAMD and DMO

	Treatment-Naïve Eyes n = 11,139 eyes (57,641 injections)	Previously Treated Eyes n = 15,013 eyes (100,741 injections)
Percentage of Events per Injection	IOI: 0.14% (81 events)[b] PIE: 0.03% (16 events)[b]	IOI: 0.14% (137 events)[b] PIE: 0.04% (44 events)[b]

[a] Amongst all eyes meeting the eligibility criteria of the FARWIDE-nAMD/DMO studies. 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. Endophthalmitis was considered PIE per FARWIDE protocols. [b] IOI and PIE events were identified using the post-operative complications, diagnoses or clinical examination findings on a patient's 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. AE, adverse event; DMO, diabetic macular oedema; EMR, electronic medical record; IOI, intraocular inflammation; nAMD, neovascular age-related macular degeneration; PIE, presumed infectious endophthalmitis; VEGF, vascular endothelial growth factor.

Conclusion

- FARWIDE is the largest real-world study of faricimab treatment patterns and outcomes outside the United States[8]
- Over 12 months, VA improved in treatment-naïve eyes by approximately 1 line and was maintained in previously treated eyes
  - The proportion of patients with driving-level VA increased over 12 months in treatment-naïve eyes and remained stable in previously treated eyes
  - Treatment-naïve eyes in the most deprived Index of Multiple Deprivation deciles (1–2) achieved similar mean VA change to those in the least deprived deciles (9–10) at 12 months
- Faricimab injections reduced from month 6, suggesting extension of treatment intervals after the initial loading phase through to year 2
  - Fewer injections were received in the second 6 months of follow up compared with the first 6 months across all IMD deciles
  - 61% of treatment-naïve eyes reached a faricimab treatment interval of ≥ 10 weeks at or before 12 months
- Safety data evaluated were consistent with phase 3 trials[9,10]