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

Effectiveness and Safety of Faricimab in Eyes With nAMD in the United Kingdom: 18-Month Results From the FARWIDE-nAMD Study

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- AD: Employee: F. Hoffmann-La Roche Ltd.
- MD: Employee: Medisoft Ltd.

Study and Product 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
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References

1. Regula JT et al. *EMBO Mol Med*. 2016;8(11):1265-1288. Erratum in: Regula JT et al. *EMBO Mol Med*. 2019;11(5):e10666.
2. FDA. Vabysmo [prescribing information]. Updated 2024. Accessed 30 April 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761235s005lbl.pdf
3. EMA. Vabysmo EPAR 2024. Accessed 30 April 2025. https://www.ema.europa.eu/en/documents/overview/vabysmo-epar-medicine-overview_en.pdf
4. Data on file
5. Sivaprasad I et al. Presented at: Macula Society Annual Meeting; 12–25 February 2025, Charlotte Harbor; FL.
6. UK Ministry of Housing, Communities & Local Government. The English Indices of Deprivation 2019. Accessed 30 April 2025. https://assets.publishing.service.gov.uk/media/5dfb3d7ce5274a3432700cf3/IoD2019_FAQ_v4.pdf
7. Scottish Government. Scottish Index of Multiple Deprivation (SIMD) 2020. Accessed 30 April 2025. https://www.spatialdata.gov.scot/geonetwork/srv/eng/catalog.search#/metadata/0286f6b0b-66e5-46ab-9b1c-d433dc3c2fae
8. Wong TY et al. *Ophthalmology*. 2024;131(6):708-723.
9. Khanani AM et al. *Ophthalmology*. 2024;131(8):914-926.

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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 effectiveness, durability and safety outcomes for patient-eyes in the FARWIDE-nAMD cohort with ≥ 18 months of follow-up are reported

Methods

- The FARWIDE study includes data from 35 UK National Health Service sites using the Medisoft or MediSIGHT electronic medical record system
- The 18-month FARWIDE-nAMD cohort included patient-eyes with nAMD and no concomitant DMO or retinal vein occlusion, who initiated faricimab from June 2022 and had ≥ 18 months of follow-up as of July 2024
- Treatment-naïve eyes had no prior anti-VEGF treatment. Previously treated eyes switched to faricimab from another anti-VEGF treatment
- Baseline characteristics, visual acuity (VA) and injection frequency were assessed in the 18-month cohort
- Presumed infectious endophthalmitis (PIE) and intraocular inflammation (IOI) events were identified amongst eyes with nAMD or DMO with any duration of follow-up
- Analyses are descriptive

Results

1. Patient Attrition

- Diagnosis of nAMD on or prior to the index (first) faricimab injection date
- Patient age of ≥ 50 years at index date
- No concomitant diagnosis of DMO or RVO
- No known participation in IVI trials
- Patient-eye does not have inconclusive anti-VEGF history at the index date

Total Study Population

Patients, n = 15,821; Eyes, n = 19,036

- Treatment-naïve eyes[a]: n = 7999 (42.0%)
- Previously treated eyes[b]: n = 11,037 (58.0%)

18-Month Cohort[c]

Patients, n = 1404; Eyes, n = 1667

- Treatment-naïve eyes[a]: n = 332 (19.9%)
- Previously treated eyes[b]: n = 1335 (80.1%)

[a] Treatment-naïve eyes are those with no evidence of anti-VEGF injections at any time prior to initiating faricimab. [b] Previously treated eyes are defined as those that received ≥ 1 prior anti-VEGF treatment any time prior to faricimab initiation at the participating site. [c] The 18-month cohort is a subset of eyes that had ≥ 18 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. Patient Demographics at Index Faricimab Injection (Baseline), 18-Month Cohort

Characteristics at Index Injection (Patient-Level)	n = 1404
Age at index (first) faricimab injection, mean (SD)	79.2 (7.6)
Sex, n (%)[a]	
Female	848 (60.4)
Race, n (%)	
White/White British/White Irish	985 (70.2)
Asian/Asian British	11 (0.8)
Black/Black British	3 (0.2)
Chinese	1 (0.1)
Other[b]	49 (3.5)
Unknown	355 (25.3)
Index of Multiple Deprivation deciles, n (%)[c,6,7]	
1–2 (most deprived)	173 (12.3)
3–4	269 (19.2)
5–6	288 (20.5)
7–8	301 (21.4)
9–10 (least deprived)	361 (25.7)
Unknown	12 (0.9)

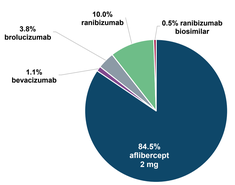
[a] Male, n = 546 (38.9%); not stated, n = 10 (0.7%). [b] Includes any other ethnic group and any other mixed background. [c] The deciles are calculated per nation by ranking the 32,844 LSOAs in England and 6976 data zones in Scotland from most deprived to least deprived and dividing them into 10 equal 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 2.6 Years of Prior Anti-VEGF Treatment With 23 Injections, on Average

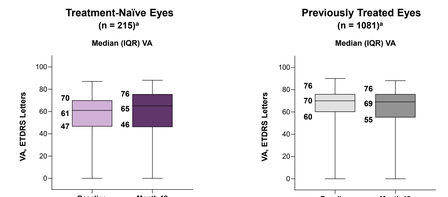
Duration of Anti-VEGF Treatment Before Faricimab Initiation (Years)[a]	
Mean (SD)	2.6 (2.2)
Total Number of Injections Before Faricimab Initiation	
Mean (SD)	23.0 (16.9)
Median (Q1, Q3)	19 (10, 31)
Number of Distinct Anti-VEGF Agents Before Faricimab Initiation, n (%)	
1	976 (73.1)
2	321 (24.0)
3	36 (2.7)
> 3	2 (0.2)

[a] Number of years between the first anti-VEGF injection and the first faricimab injection. nAMD, neovascular age-related macular degeneration; Q, quartile; SD, standard deviation; VEGF, vascular endothelial growth factor.

Percentage of nAMD Previously Treated Eyes by Prior Anti-VEGF Agent (n = 1335): 18-Month Cohort

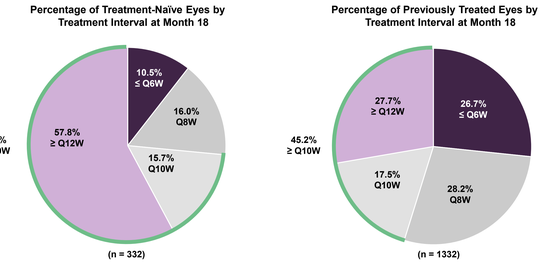


4. VA Improved in Treatment-Naïve Eyes and Remained Stable in Previously Treated Eyes From Baseline at 18 Months



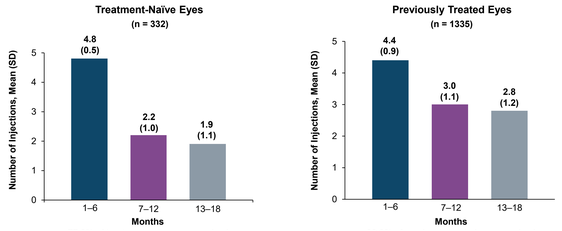
[a] Amongst eyes with VA at baseline and at 18 months. VA at baseline is the most recent recorded VA measurement within 28 days before the first faricimab injection, including the injection date. VA at 18 months is the closest VA measurement 18 months after the first faricimab injection, within a window of 56 days before and after the 18-month time point. ETDRS, Early Treatment Diabetic Retinopathy Study; IQR, interquartile range; VA, visual acuity; VEGF, vascular endothelial growth factor.

5. 74% of Treatment-Naïve nAMD Eyes Reached a Treatment Interval ≥ 10 Weeks by Month 18



The treatment interval included is the interval preceding the last faricimab injection received before the 18-month time point. Included eyes had received more than 1 faricimab injection during the 18-month follow-up period. nAMD, neovascular age-related macular degeneration; QXW, every X weeks.

6. Fewer Faricimab Injections Observed in the Second and Third 6 Months of Treatment



[a] Amongst eyes with at least 4 injections of faricimab; n = 330 treatment-naïve and n = 1325 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 3 injections. SD, standard deviation.

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

Pooled AEs[a] Across nAMD and DMO

	Treatment-Naïve Eyes	Previously Treated Eyes
	n = 11,139 eyes (57,641 injections)	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

- The majority of previously treated eyes switched from aflibercept 2 mg had been on anti-VEGF treatment for 3 years and received 23 injections before switching to faricimab
- Over 18 months, median VA improved in treatment-naïve eyes and was maintained in previously treated eyes
  - The percentage of eyes with VA ≥ 70 Early Treatment Diabetic Retinopathy Study letters increased from baseline (29.8%) to 18 months (40.9%) in treatment-naïve eyes and remained stable in previously treated eyes
- By 18 months, 74% of treatment-naïve patient-eyes reached a treatment interval of ≥ 10 weeks
- Mean faricimab injection count declined steadily from treatment months 1–6 through treatment months 7–12 and 13–18, suggesting extension of treatment intervals in year 1 and further extension into year 2
- IOI and PIE rates were low and did not exceed rates observed in phase 3 faricimab clinical trials[8,9]