Poster #213

Real-world Use of Faricimab to Treat DME Patients in the UK (FARWIDE Study)

Richard P. Gale, BSc, MBChB, FRCP, FRCOphth, MEd, PhD[1]; Tunde Peto, MD, PhD[2]; James Talks, FRCOphth[3]; Gabriella De Salvo, MD, FRCOphth[4]; Andrew Lotery, MD, FRCOphth[5]; Ian Pearce, MB, ChB, BSc, FRCOphth[6]; Christine Kiire, MA(Oxon), MRCP, DM, FRCOphth[7]; Clare Bailey, MD, FRCOphth[8]; Louise Downey, MBChB, BSc, PhD, FRCOphth[9]; Rhianon Reynolds, BSc, PhD, FRCOphth[10]; Sobha Sivaprasad, FRCOphth[11]; Natalee James, MBBS[12]; Gloria Chi, PhD, MPH[13]; Amanda Downey, PhD(c), MBA[14]; Parth Shah, MBBS, BSc, MRes, FRCOphth[12]; Melanie Dodds, BSc[15]; Sarah McGrory, BSc, PhD[15]; and Parul Dayal, MS, PhD[13]

[1] Hull York Medical School, University of York, York, UK; [2] Queen's University Belfast, Belfast, UK; [3] NHS Foundation Trust, Newcastle Upon Tyne, UK; [4] University Hospital Southampton NHS Foundation Trust, Southampton, UK; [5] University of Southampton, Southampton, UK; [6] Royal Liverpool University Hospital, Liverpool, UK; [7] Oxford Eye Hospital, John Radcliffe Hospital, Oxford, UK; [8] Bristol Eye Hospital, University Hospitals Bristol, NHS Foundation Trust, Bristol, UK; [9] Hull University Teaching Hospital/Northern Lincolnshire and Goole NHS Foundation Trust, Hull, UK; [10] Cardiff University School of Vision Science, Aneurin Bevan University Health Board, Cardiff, UK; [11] NIHR Moorfields Biomedical Centre, Moorfields Eye Hospital, London, UK; [12] Roche Products Ltd, Welwyn Garden City, UK; [13] Genentech, Inc., South San Francisco, CA, USA; [14] Hoffmann-La Roche Limited, Mississauga, ON, Canada; [15] Medisoft Limited, Leeds, UK

Patient Selection

Extraction Criteria and Cohort

Patient-eye received ≥ 1 intravitreal injection of faricimab on or after June 1, 2022

↓

Patient-eye with diagnosis of DME on or prior to index date

↓

Patient-eye does not have concomitant nAMD

↓

Total study population (age ≥ 18 years)
Patients, n = 951 (92.6%), Eyes, n = 1309 (93.0%)

↓

Previously treated eyes
n = 886 (67.7%)

Treatment-naïve eyes
n = 423 (32.3%)

Conclusions

- FARWIDE is a multicenter, real-world study underway to evaluate faricimab uptake, patient characteristics, treatment frequency, and visual acuity outcomes
- Data from 951 patients and 1309 eyes, evaluated during the first 9 months of faricimab launch, showed that:
- Patient demographics were generally as expected for a cohort with DME
- A majority of the faricimab patient-eyes with DME were switched from another anti-VEGF treatment
- Most eyes had less than 3 months of follow-up and received 4 or fewer faricimab injections
- 52% previously treated eyes and 61% treatment-naïve eyes received ≥ 4 injections in the first 18 weeks after initiating faricimab
- Treatment-naïve eyes achieved visual gains

Limitations

- This is an observational, noncontrolled study with no standardized measurements of visual acuity, no anatomical outcomes to fully understand the treatment response, and a lack of physician dosing frequency rationale
- These results report the patterns of early faricimab use; additional data on treatment frequency and visual acuity change will be reported as the follow-up on faricimab accrues over time

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Results

1. Baseline Patient Demographics

Baseline Characteristics	Patients (n = 951)
Age at first faricimab injection, mean (SD)	63.35 (11.6)
Sex	
Female	368 (38.7%)
Ethnicity	
White British	502 (52.8%)
White Irish	5 (0.5%)
Asian or Asian British	77 (8.1%)
Black or Black British	27 (2.8%)
Chinese	3 (0.3%)
Any other White background	23 (2.4%)
Any other mixed background	3 (0.3%)
Any other ethnic group	10 (1.1%)
Not stated	301 (31.7%)
Index of Multiple Deprivation Decile (composite SES measure)	
1–2 (most deprived)	211 (22.2%)
3–4	221 (23.2%)
5–6	188 (19.8%)
7–8	180 (18.9%)
9–10 (least deprived)	137 (14.4%)
Not stated	14 (1.5%)

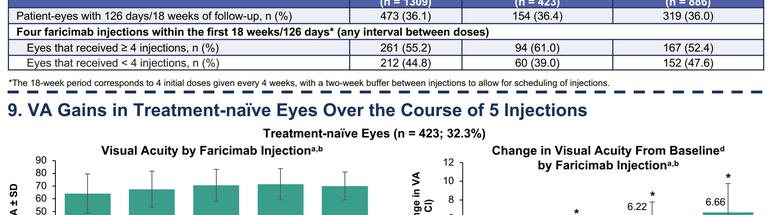
SD, standard deviation; SES, socio-economic status.

2. Baseline Eye Characteristics

Characteristics	Treatment-naïve Eyes (n = 423; 32.3%)	Previously Treated Eyes (n = 886; 67.7%)
Left eye, n (%)	219 (51.8%)	436 (49.2%)
Right eye, n (%)	204 (48.2%)	450 (50.8%)
Baseline ocular conditions[a]		
Glaucoma	0	11 (1.2%)
Cataract	57 (13.5%)	77 (8.7%)
Amblyopia	2 (0.5%)	1 (0.1%)
Diabetic retinopathy[b]	248 (58.6%)	423 (47.7%)
Retinal vein occlusion	1 (0.2%)	5 (0.6%)

[a] Diagnosis within the 12 months (365 days) prior to the index date, including the index date.
[b] Diabetic retinopathy data included here based on the Electronic Health Record.

3. A High Proportion of Eyes had a Baseline VA[a] of 70 or More ETDRS Letters (20/40 or Better)[b]



[a] Most recently recorded VA measurement within 28 days prior to or on the index date; [b] Among eyes with a baseline VA.
ETDRS, Early Treatment of Diabetic Retinopathy Study; VA, visual acuity.

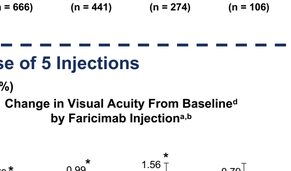
4. Previously Treated Patients: Prior Anti-VEGF Treatment

- Most previously treated patients switched from aflibercept
- Switched eyes were on treatment for an average (mean) of 3 years before switching to faricimab
- Mean anti-VEGF injection frequency in prior treatment was 17 injections, approximately 10 weeks apart

Prior Anti-VEGF Treatment (n = 886)

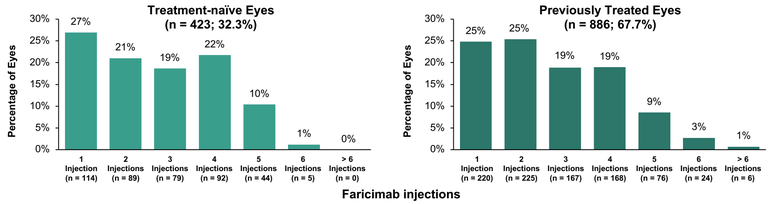
Duration (years)	
Mean (SD)	3.1 (2.6)
Median (Q1, Q3)	3.3 (1.6, 5.4)
Number of injections	
Mean (SD)	17.2 (13.3)
Median (Q1, Q3)	13.5 (8, 23)
Last anti-VEGF treatment interval (weeks)	
Mean (SD)	9.7 (16.5)
Median (Q1, Q3)	6.4 (4.9, 9.3)

Percentage of Eyes Treated With Anti-VEGF Agent Prior to Faricimab (n = 886)



[a] Bevacizumab (Avastin), brolucizumab (Beovu), pegaptanib (Macugen), ranibizumab (Byooviz), ranibizumab (Lucentis), and ranibizumab (Ongavia).
Q1, 25th percentile; Q3, 75th percentile; SD, standard deviation; VA, vision acuity; VEGF, vascular endothelial growth factor.

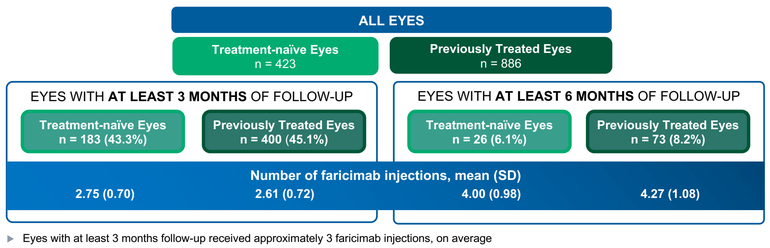
5. Most Eyes Received up to 4 Injections



- Mean (SD) number of faricimab injections per eye was 2.7 (1.4) for both treatment-naïve and previously treated eyes over a mean of 2.5 (2.0) and 2.6 (2.1) months, respectively

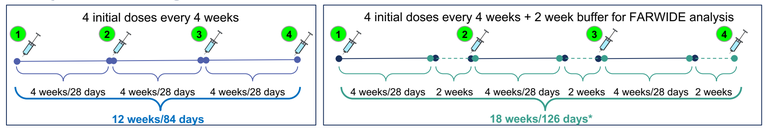
Data are from entire follow-up period and were extracted on March 13, 2023.
SD, standard deviation.

6. Most Eyes Treated With Faricimab Had < 3 Months of Follow-up



- Eyes with at least 3 months follow-up received approximately 3 faricimab injections, on average

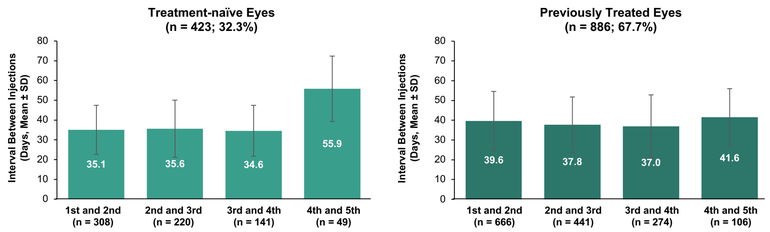
7. Almost Half of Previously Treated Eyes and 39% of Treatment-naïve Eyes Received < 4 Injections During the First 18 Weeks



	All eyes (n = 1309)	Treatment-naïve Eyes (n = 423)	Previously Treated Eyes (n = 886)
Patient-eyes with 126 days/18 weeks of follow-up, n (%)	473 (36.1)	154 (36.4)	319 (36.0)
Four faricimab injections within the first 18 weeks/126 days* (any interval between doses)			
Eyes that received ≥ 4 injections, n (%)	261 (55.2)	94 (61.0)	167 (52.4)
Eyes that received < 4 injections, n (%)	212 (44.8)	60 (39.0)	152 (47.6)

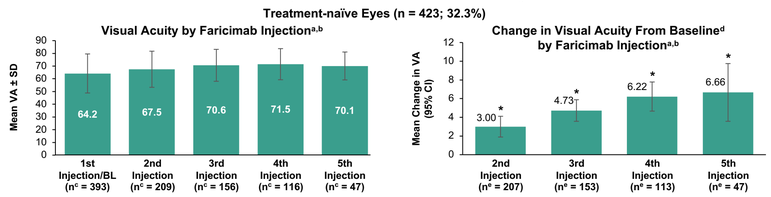
*The 18-week period corresponds to 4 initial doses given every 4 weeks, with a two-week buffer between injections to allow for scheduling of injections.

8. Average Treatment Interval Extended After the 4th Injection in Treatment-Naïve Eyes



SD, standard deviation.

9. VA Gains in Treatment-naïve Eyes Over the Course of 5 Injections



[a] Among eyes with a baseline VA; [b] VA at each injection is the most recent recorded VA measurement within 14 days prior to the injection (28 days for injection 1), including the injection date; [c] Eye counts that had VA at that injection alone, independent from having baseline VA; [d] Baseline corresponds with 1st injection; [e] Eye counts with VA at 1st and the respective injection number
* Nominal *P*-value < 0.001; *P* values are nominal and not adjusted for multiplicity; no formal statistical conclusion should be made based on the *P* values.
BL, baseline; CI, confidence interval; BL, baseline; SD, standard deviation; VA, visual acuity.

10. Stable VA in Previously Treated Eyes Over the Course of 5 Injections

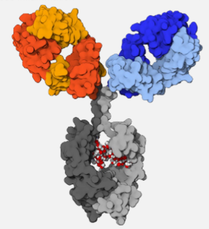
[a] Among eyes with a baseline VA; [b] VA at each injection is the most recent recorded VA measurement within 14 days prior to the injection (28 days for injection 1), including the injection date; [c] Eye counts that had VA at that injection alone, independent from having baseline VA; [d] Baseline corresponds with 1st injection; [e] Eye counts with VA at 1st and the respective injection number
* Nominal *P*-value < 0.05; *P* values are nominal and not adjusted for multiplicity; no formal statistical conclusion should be made based on the *P* values.
BL, baseline; CI, confidence interval; SD, standard deviation; VA, visual acuity.

Background

- Faricimab (Vabysmo®) is the first bispecific antibody for intraocular use that independently binds and neutralizes both angiopoietin-2 and VEGF-A with high specificity and potency[1]
- Faricimab was approved in GB on May 17, 2022, for the treatment of DME[2]
- Faricimab Real-World Evidence (FARWIDE) is a retrospective observational study taking place from 2022 to 2024 to evaluate:
  - Faricimab uptake
  - Patient characteristics
  - Treatment frequency
  - Visual acuity outcomes

Anti–Ang-2 Fab
Stabilizes vessels
Reduces vascular leakage
Reduces inflammation

Anti–VEGF-A Fab
Reduces vascular leakage
Inhibits neovascularization



Modified Fc
Reduces systemic exposure
Reduces inflammatory potential

Methods

- FARWIDE-DME includes patients receiving faricimab for the treatment of DME at 14 participating National Health Service sites using the Medisoft ophthalmic electronic medical record system
- Site recruitment currently underway; plan to recruit 25 sites in total
- Preliminary data up to the week of March 13, 2023 are presented, with an observation period of approximately 9 months, from June 2022 to February 2023

Abbreviations

BL, baseline; CI, confidence interval; DME, diabetic macular edema; ETDRS, Early Treatment of Diabetic Retinopathy Study; nAMD, neovascular age-related macular degeneration; Q1, 25th percentile; Q3, 75th percentile; SD, standard deviation; SES, socio-economic status; VA, visual acuity; VEGF, vascular endothelial growth factor.

References

1. VABYSMO Summary of Product Characteristics. Available at https://www.medicines.org.uk/emc/product/13741 (Accessed June 2023).
2. National Institute for Health and Care Excellence (NICE) Documents TA799; 2022. Available at https://www.nice.org.uk/guidance/TA799 (Accessed June 2023).

Financial Disclosures

- RPG: Consultant: AbbVie, Allergan, Bayer, Biogen, Boehringer Ingelheim, Novartis, Roche. Research: Bayer, Novartis, Roche
- TP: Consultant: Alimera Sciences Ltd, Allergan (AbbVie), Apellis, Boehringer Ingelheim, Heidelberg Engineering, Novartis, Optos, Oxurion, Roche
- JT: Research, advisory boards, and travel: Bayer, Novartis, Roche
- GDS: Advisory boards: Apellis, Teva; Advisory boards, speaker, travel: AbbVie, Bayer, Novartis; Advisory boards, travel, consultant: Roche; Consultant: Boehringer Ingelheim; Speaker, travel: Heidelberg Engineering
- AL: Travel: Equity in Eyebio, Roche
- IP: Consultant: Alimera Sciences Ltd; Consultant and speaker: Allergan, Apellis, Bayer, Biogen, Novartis, Roche
- CK: Advisory boards: Alimera Sciences Ltd, Bayer; Speaker: Quantel Medical; Chair: Roche
- CB: Advisory board, meetings, lecture, travel: Alimera Sciences Ltd, Apellis, Bayer, Boehringer Ingelheim, Janssen, Novartis, Roche
- SS: Funding/fees: AbbVie, Apellis, Bayer, Biogen, Boehringer Ingelheim, EyeBiotech, Novartis, Optos, Roche
- LD, RR: Nothing to disclose
- NJ, PS: Employee: Roche Products Ltd.
- AD: Employee: Hoffmann-La Roche Ltd.
- MD; SM: Employee: Medisoft Limited
- GC,PD: Employee: Genentech, Inc.

Study and Product Disclosures

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