Real-World VOYAGER Study of Faricimab in nAMD and DMO: Baseline and 3-Month Data

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Purpose

To present preliminary data from the VOYAGER study

Conclusions

Mean visual acuity increased and central subfield thickness showed a rapid decrease from baseline at 3 months among patients with neovascular age-related macular degeneration (nAMD) and diabetic macular oedema (DMO) who switched from an anti–vascular endothelial growth factor (VEGF) to faricimab

No new safety concerns were identified

Physician fluid tolerance was disease dependent and treat-and-extend regimens were preferred for both nAMD and DMO

Upcoming analyses will include data from more countries, and more diverse populations and clinicians in terms of experiences and practices

Financial Disclosures

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- RG: Consultant: Apellis, Bayer, Novartis, Roche/Genentech, Inc.

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 includes research conducted on human subjects
- Institutional Review Board approval was obtained prior to study initiation
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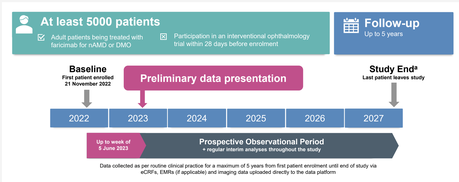
Background

- Vision outcomes with anti-VEGF agents are often poorer in clinical practice than in clinical trials, possibly due to:
  - Differences in access to anti-VEGF treatment and patient populations[1-3]
  - Lack of long-term data to inform treatment strategies[4]
  - Inability to replicate complex treatment algorithms and imaging protocols from clinical trials
  - Variation in clinical assessment and management[5-7]
- The VOYAGER (NCT05476926) study will gather robust long-term clinical data among patients receiving faricimab for nAMD or DMO in routine clinical practice globally to address this disparity

Methods

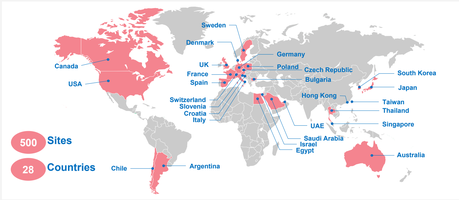
- The objectives of this analysis were to describe:
  - Prior anti-VEGF treatment
  - Changes in visual acuity and central subfield thickness from baseline at month 3
  - Physician preferences regarding treatment management
- These preliminary results include data from United States, Canada and Japan involving 220 eyes from 174 patients with nAMD and 107 eyes from 69 patients with DMO, and 22 physicians

VOYAGER: A Non-Interventional, Prospective, Multinational, Multicentre Study



VOYAGER clinical trial [NCT05476926]. [a] Study end: date on which the last entry of the last patient is recorded in the database. DMO, diabetic macular oedema; eCRF, electronic case report form; EMR, electronic medical record; nAMD, neovascular age-related macular degeneration.

The VOYAGER Study Will Obtain Data From a Variety of Practice Settings and Clinician Experience



UAE, United Arab Emirates; UK, United Kingdom; USA, United States of America. Guymer R et al. *Ophthalmol Science*. Published online 3 December 2023, 100442.

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Results

Patient Baseline Demographic Characteristics

Characteristic	Faricimab for nAMD N = 174[a]	Faricimab for DMO N = 69[a]
Age, years, mean (SD)	79.7 (7.9)	65.3 (12.2)
Female, n (%)	95 (54.6)	27 (39.1)
Current country of residence, n (%)		
Canada	17 (9.8)	12 (17.4)
Japan	1 (0.6)	5 (7.2)
USA	156 (89.7)	52 (75.4)
Race, n (%)		
American Indian or Alaska Native	0	1 (1.5)
Asian	3 (1.7)	6 (8.8)
Black or African American	0	3 (4.4)
White	160 (93.0)	54 (79.4)
Other	1 (0.6)	1 (1.5)
Missing	2	1
Ethnicity, n (%)		
Hispanic or Latino	2 (1.2)	2 (2.9)
Not Hispanic or Latino	144 (83.7)	58 (85.3)
Unknown/not reported/missing	28	9

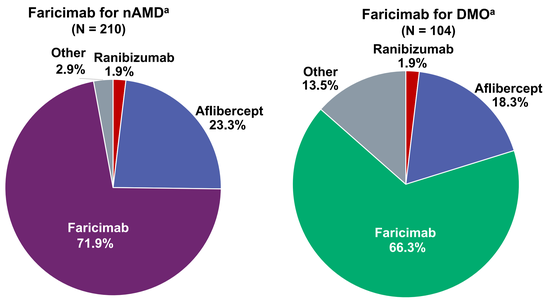
[a] N value reflects patient numbers; patients with ≥ 1 eye being treated are counted once. The data points are still subject to data cleaning and data collection (missing values), and the results may change when the final analysis is performed. DMO, diabetic macular oedema; nAMD, neovascular age-related macular degeneration; SD, standard deviation.

Most Patient Eyes had Long-Standing Disease (41–46 months) and had Received a Large Number of Prior Treatments With Anti-VEGF and/or Faricimab
More Than 65% of Patient Eyes Were Last Treated With Faricimab Before Enrolment

Prior Treatment With Anti-VEGF and/or Faricimab

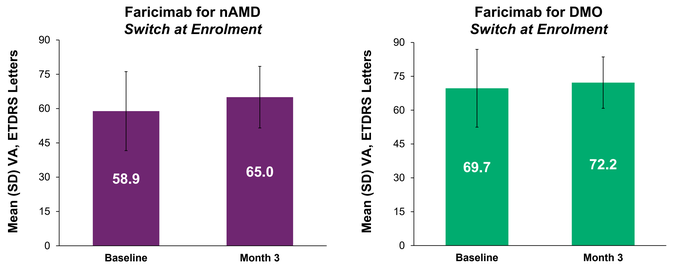
	Faricimab for nAMD N = 220[a]	Faricimab for DMO N = 107[a]
Eyes that received anti-VEGF and/or faricimab before enrolment, n (%)		
Yes	210 (97.7)	104 (98.1)
No	5 (2.3)	2 (1.9)
Missing	5	1
Total number of anti-VEGF and/or faricimab injections per eye before enrolment, n (%)		
0	5	2
1–5	20 (9.5)	16 (15.4)
6–10	32 (15.2)	17 (16.3)
11–15	22 (10.5)	10 (9.6)
16–20	19 (9.0)	9 (8.7)
21–25	15 (7.1)	9 (8.7)
> 25	102 (48.6)	43 (41.3)
Missing	5	1
Duration of prior anti-VEGF and/or faricimab treatment, months[b]		
Mean (SD)	46.4 (39.66)	41.3 (32.64)
Time from last anti-VEGF and/or faricimab treatment before enrolment, months[c]		
Mean (SD)	2.0 (3.8)	2.5 (6.1)

Last Treatment Received Before Enrolment



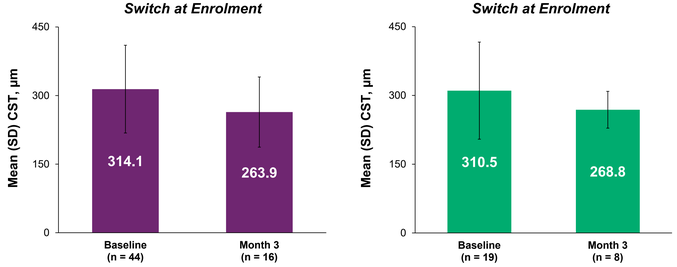
[a] Treated eyes were considered separately and were included in their respective cohort by treatment and disease state. [b] Duration of prior anti-VEGF treatment (months) = (Date of last treatment before enrolment – Date of first anti-VEGF treatment + 1) / 30.4375. [c] Time from last anti-VEGF and/or faricimab treatment before enrolment (months) = (Date of informed consent – Date of last treatment before enrolment + 1) / 30.4375. The data points are still subject to data cleaning and data collection (missing values) and the results may change when the final analysis is performed. DMO, diabetic macular oedema; nAMD, neovascular age-related macular degeneration; SD, standard deviation; VEGF, vascular endothelial growth factor.

Visual Acuity Increased in nAMD and DMO Switch Patients Who Initiated Faricimab at Enrolment From Baseline to Month 3



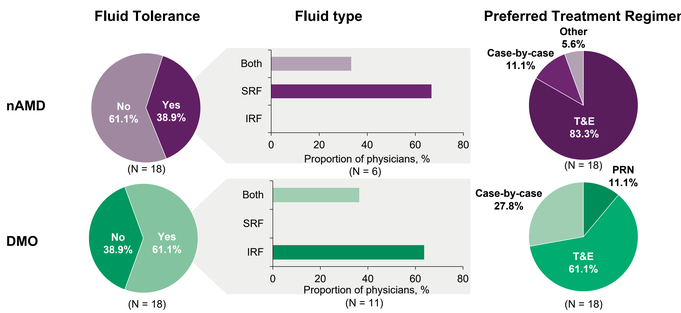
VA, collected as measured per local practice, was converted to approximate ETDRS score automatically in the eCRF.[8] Switch at enrolment reflects patients who were switched from anti-VEGF (ranibizumab, aflibercept, brolucizumab, other) to faricimab at enrolment into VOYAGER. N values reflect the number of patient eyes that data were collected from at the analysis time points. For post-baseline VA measurements, patient eyes with VA measurements outside the analysis time window were not considered. The data points are still subject to data cleaning and data collection (missing values) and the results may change when the final analysis is performed. DMO, diabetic macular oedema; eCRF, electronic case report form; ETDRS, Early Treatment Diabetic Retinopathy Study; nAMD, neovascular age-related macular degeneration; SD, standard deviation; VA, visual acuity; VEGF, vascular endothelial growth factor.

Rapid CST Reductions in nAMD and DMO Switch Patients Who Initiated Faricimab at Enrolment From Baseline to Month 3



CST was collected as measured in local practice. Switch at enrolment reflects patients who were switched from anti-VEGF (ranibizumab, aflibercept, brolucizumab, other) to faricimab at enrolment into VOYAGER. N values reflect the number of patient eyes that data were collected from at the analysis time points. For post-baseline CST measurements, patient eyes with a CST measurements outside the analysis time window were not considered. The data points are still subject to data cleaning and data collection (missing values) and the results may change when the final analysis is performed. CST, central subfield thickness; DMO, diabetic macular oedema; nAMD, neovascular age-related macular degeneration; SD, standard deviation; VEGF, vascular endothelial growth factor.

Investigator Tolerance of Fluid Was Disease Dependent: T&E Regimens Were Preferred



22 physicians completed the survey. Data were collected at the baseline visit. Tolerance to fluid refers to if a physician will allow a limit of retinal fluid before considering additional medication doses. The data points are still subject to data cleaning and data collection (missing values) and the results may change when the final analysis is performed. DMO, diabetic macular oedema; IRF intraretinal fluid; nAMD, neovascular age-related macular degeneration; PRN, pro re nata; SRF, subretinal fluid; T&E, treat-and-extend.