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ORIGINAL RESEARCH

One-Year Outcomes of Faricimab in Treatment-Naïve Neovascular Age-Related Macular Degeneration: A Swiss Retina Research Network Report

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ABSTRACT

***Introduction*:** This study evaluates the efficacy and safety of faricimab in a real-world cohort of treatment-naïve patients with neovascular age-related macular degeneration (nAMD). Data were retrospectively collected from 130 eyes of 118 patients across 11 centers of the Swiss Retina Research Network, all treated with faricimab using a treat-and-extend regimen and followed for 12 months between May 2022 and October 2024.

***Methods*:** Demographic data, visual and anatomical outcomes, treatment intervals, and adverse events were extracted from the electronic medical records over a 12-month follow-up period. Main outcomes included change in best corrected visual acuity (BCVA), central retinal thickness (CRT), presence of intra- and subretinal fluid, retinal pigment epithelial detachment (PED), injection intervals, and safety. Data are presented as mean ± standard deviation.

***Results*:** Twelve months after the initiation of faricimab therapy, mean BCVA improved from 64.6 ± 14.1 to 69.2 ± 20.3 ETDRS (Early Treatment of Diabetic Retinopathy Study) letters ($p < 0.001$),

Anne Tillmann and Richard Stillenmunkes share the first authorship.

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while mean CRT decreased from 386.3 ± 172.3 to 246.6 ± 90.4 µm ($p < 0.001$). An early anatomical response to faricimab was observed in 34.6% of eyes achieving complete retinal fluid resolution after the first injection and in 55.6% after 12 months. The mean treatment interval was extended to 10.5 ± 4.3 weeks, with 26.2% of eyes achieving intervals of 8–11 weeks and 39.2% achieving intervals of ≥ 12 weeks after 12 months. Intraocular inflammation occurred in 0.77% of eyes ($n = 1$, anterior uveitis); serious adverse events were not reported.

***Conclusion*:** Faricimab demonstrates favorable anatomical and functional outcomes with extended treatment intervals in a majority of patients with treatment-naïve nAMD, offering the potential of reduced treatment burden and the absence of retinal fluid in more than half of the subjects during the first year, while maintaining safety in a real-world setting.

Keywords: Age-related macular degeneration; Faricimab; Real-world; Swiss Retina Research Network; Treatment-naïve

Key Summary Points

Why carry out this study?

Neovascular age-related macular degeneration (nAMD) is a leading cause of vision loss in older adults, with real-world patients often undertreated compared to those in clinical trials, highlighting an unmet need for therapies that reduce treatment burden while maintaining efficacy.

Faricimab, a bispecific antibody targeting vascular endothelial growth factor (VEGF)-A and angiopoietin-2 (Ang-2), offers the potential for enhanced durability and less frequent dosing, but clinical trial results may not reflect outcomes in broader, real-world populations.

This multicenter, retrospective study assessed 1-year efficacy, safety, and durability of faricimab in 130 treatment-naïve nAMD eyes treated with a treat-and-extend regimen in routine clinical practice.

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What was learned from the study?
Faricimab resulted in significant visual and anatomical improvements with more than half of eyes achieving a dry macula and nearly 39% reaching ≥ 12-week treatment intervals after 1 year, along with a low incidence of ocular adverse events.
The findings support faricimab as an effective and safe treatment for nAMD in real-world settings, though fewer patients achieved very extended intervals compared to clinical trials, emphasizing the value of real-world evidence for clinical decision-making.

INTRODUCTION

Neovascular age-related macular degeneration (nAMD) is a leading cause of vision loss in older adults, its prevalence increasing globally as populations age [1]. Over the past two decades, intravitreal injections of anti-vascular endothelial growth factor (anti-VEGF) agents have revolutionized nAMD treatment, yielding significant improvements in both visual and anatomical outcomes [2]. However, real-world evidence shows that patients often receive fewer injections than in clinical trials, potentially contributing to poorer visual and structural outcomes in routine care settings [3, 4]. The logistical challenges of frequent monitoring and regular injections may partly explain this undertreatment, besides the financial challenge [5, 6]. Consequently, there is an urgent need for alternative therapies that maintain efficacy while reducing the treatment burden.

Faricimab (Vabysmo®, Roche, Basel, Switzerland), a bispecific antibody targeting vascular endothelial growth factor-A (VEGF-A) and angiopoietin-2 (Ang-2), offers a novel approach to nAMD management. By addressing two pro-angiogenic pathways, faricimab may provide enhanced durability and improved fluid resolution compared to existing anti-VEGF therapies [7]. Phase III trials (TENAYA and LUCERNE) were conducted worldwide and demonstrated that faricimab achieved visual outcomes non-inferior to aflibercept 2 mg, with less frequent dosing. By the end of the first year, 45% of patients extended their dosing intervals to 16 weeks, highlighting its potential for sustained efficacy [8].

Despite these promising results, clinical trials often exclude patients with complex comorbidities or extreme baseline visual acuities, as in the TENAYA and LUCERNE studies. This limits their applicability to real-world settings. Furthermore, the fixed regimens used in trials do not reflect the treatment regime and flexibility required in everyday practice. Thus, real-world studies are critical to assess faricimab's efficacy, safety, and durability in broader, more representative patient populations.

To date, multiple real-world studies have evaluated the use of faricimab in nAMD, predominantly including previously treated eyes or mixed cohorts of treatment-naïve and pretreated patients. A systematic review from real-world settings—encompassing both treatment-naïve ($n=234$) and pretreated ($n=1438$) nAMD cases—revealed outcomes consistent with phase III trial findings [9]. The follow-up duration ranged from 1 to 12 months. The included real-life studies demonstrated significant improvements in both visual and anatomical outcomes, with faricimab being generally well tolerated and reducing the overall treatment burden in clinical practice. Importantly, no major safety concerns were reported.

In Japan, several studies have focused specifically on patients with treatment-naïve nAMD. While these data provide valuable insights, the majority of studies were small and included only short observation periods [10–14]. Notably, the studies by Matsumoto et al. and Mukai et al. are the only ones with a follow-up of 12 months [12, 15], whereas the remaining studies tracked outcomes for 3–4 months only, leaving gaps in long-term outcomes. European studies on faricimab in nAMD including mixed populations of treatment-naïve and pretreated eyes are scarce and often limited in scale, typically featuring single-center cohorts and short follow-up periods [16–20]. To date, a few small European studies have focused exclusively or at least included the subgroup of patients with treatment-naïve nAMD, underscoring the urgent need for more comprehensive research [17, 21].

The Swiss Retina Research Network, founded in 2024, is a national consortium of hospital and private retina centers providing real-world data. This study used the network to assess 1-year outcomes of faricimab in patients with treatment-naïve nAMD, aiming to provide insights into its efficacy, safety, and clinical applicability.

METHODS

This retrospective, non-comparative, multicenter case series draws on data from 11 specialized ophthalmic centers in Switzerland: Berner Augenklinik, Bern (JGG); Vista Augenklinik, Binningen (KH); Augenarzt Praxisgemeinschaft Gutblick, Pfäffikon, Switzerland (MRM, AT, RS); Eye Clinic of the Institute of Clinical Neurosciences of Southern Switzerland (INSI), Ospedale Regionale di Lugano, Lugano, Switzerland (GG, MM); Kantonsspital St. Gallen (AE); Jules Gonin Eye Hospital, University Hospital Lausanne, Lausanne (CE, JC); University Hospital Basel, Basel (JF); Stadtspital Triemli, Zürich (TS, GS); University Hospital Zürich, Zürich (MC, SZ); Pallas Kliniken, Olten (AW); and Swiss Visio Retina Research Center, Lausanne (AA). The study was approved by all participating ethics committees, led by the ethics committee of the canton of Berne (registration no. 2024-01026). Coded patient data were included on the basis of general or specific informed consent, in line with ICH-GCP E6, the Declaration of Helsinki, and Swiss law.

We enrolled patients with treatment-naïve nAMD with active disease (intra-/subretinal fluid, exudates, or hemorrhages) who began faricimab after Swissmedic approval in May 2022 and completed 12 ± 1 months of follow-up by October 2024. Patient selection for faricimab was not systematic but rather based on individual physician discretion and real-world clinical practice. Both eyes were included if eligible. Exclusion criteria were prior photodynamic or radiotherapy, macular damage with no visual potential, and active systemic disease (e.g., uncontrolled rheumatic disease or vasculitis needing immunosuppression). Further exclusions included significant ocular opacities, intraocular surgery within 3 months (except YAG), or corticosteroid use within 6 months. All patients received a treat-and-extend regimen with an initial loading dose, typically three monthly injections. Thereafter, intervals were adjusted by approximately 2 weeks according to disease activity, at physician discretion.

In our multicenter study, each participating site based treatment decisions on optical coherence tomography (OCT) imaging performed at the time of each visit. The presence or absence of intraretinal or subretinal fluid on OCT was assessed by the treating ophthalmologist, who was always a fully licensed specialist; residents participated only under supervision. As this reflects real-world routine practice in Switzerland, OCT grading was not centralized. In instances where more than one physician was involved in patient management, any potential discrepancies were resolved by joint review and consensus during clinical rounds or direct discussion, ensuring a consistent assessment and treatment decision.

Data were collected retrospectively from medical records and imaging per protocol. Recorded parameters included diagnosis date, baseline characteristics, and follow-ups at 1, 3, 6, and 12 months. Parameters recorded included Snellen best corrected visual acuity (BCVA), intraocular pressure (IOP), central retinal thickness (CRT), and the presence of intraretinal fluid (IRF), subretinal fluid (SRF), or both (RF) within the central 6 mm of the Early Treatment of Diabetic Retinopathy Study (ETDRS) grid on OCT. In addition, the presence and maximum height of pigment epithelial detachment (PED) on OCT was recorded. BCVA was determined using a Snellen scale and converted to ETDRS letter scores for analysis, with a Snellen BCVA of 1.0 corresponding to 85 ETDRS letters [22]. Hand motion and finger counting vision were categorized according to Schulze-Bonsel and colleagues [23]. Injection intervals, the total number of injections, and the proportion of eyes achieving a dry macula (absence of RF) were also analyzed.

Primary outcomes were changes in BCVA, CRT, and injection intervals over 12 months. Secondary outcomes included the proportion of eyes with dry macula (absence of RF in central 6 mm^2 ETDRS grid) after the first injection (rapid drying) and at 12 months, the proportion remaining on faricimab without

switching, morphological changes (IRF/SRF), and adverse events, particularly intraocular inflammation (IOI). As a result of the limited sample size, safety analysis was descriptive, covering ocular and systemic adverse events with focus on IOI. Eyes switched to another anti-VEGF were censored at the time of switch. Those who stopped treatment remained in the analysis if follow-up data were available. Eyes with no data beyond baseline or patient death were excluded. For eyes that underwent cataract surgery after switching to faricimab, post-surgery BCVA measurements were censored, but these eyes remained included in all other analyses wherever applicable.

Percentages for anatomical outcomes as well as treatment interval distributions at follow-up visits were calculated using the baseline cohort (n = 130 eyes) as denominator. Missing data at specific time points were not re-normalized to the number of eyes with available observations, reflecting real-world data completeness.

Descriptive statistics summarized baseline characteristics and longitudinal changes. Subgroup analyses examined outcomes by baseline fluid status or visual acuity. Correlation and regression explored associations between injection intervals, CRT reduction, and BCVA improvement. Regression results are reported as *r* (degrees of freedom) and *p* value.

Non-parametric tests were used due to non-normal distribution (Shapiro–Wilk). The Wilcoxon signed-rank test assessed paired changes; the Friedman test was used for repeated measures.

Statistics were performed using SPSS v27 (IBM, Chicago, IL) and R v3.2.4 (R Foundation, Vienna). Data are presented as mean ± SD or median (IQR).

RESULTS

A total of 130 treatment-naïve eyes with nAMD (118 patients) were included in this retrospective analysis. Of these, 12 patients (9.2%) received bilateral treatment. The mean age at baseline was 80.0 ± 8.0 years. Demographic and baseline data, including laterality, are summarized in Table 1. An in-label loading dose (defined as three injections within 4 months) was performed in 122

Table 1 Baseline and demographic data

	Number (%)[a]
Patient demographics	
Total eyes (patients)	130 (118)
Sex	
Male	35 (29.7%)
Female	83 (70.3%)
Laterality	
Right	58 (44.6%)
Left	72 (55.4%)
Age (years), median [IQR]	80 [76, 86]
Baseline clinical features	
Lens status	
Pseudophakic	62 (47.7%)
Phakic (until last visit)	48 (36.9%)
Phakic (cataract surgery during study time)	19 (14.6%)
Unknown	1 (0.8%)
BCVA (ETDRS)	64.6 ± 14.1
Central retinal thickness (μm)	386.3 ± 172.3
Presence of PED	86 (66.2%)
Maximal PED height in the central 3 mm (μm)	918.0 ± 175.4
Presence of macular fluid	127 (97.7%)
Subretinal	42 (32.3%)
Intraretinal	27 (20.8%)
Both SRF/IRF	60 (46.2%)

BCVA best corrected visual acuity, *ETDRS* Early Treatment Diabetic Retinopathy Study, *IQR* interquartile range, *PED* pigment epithelium detachment, *SRF* subretinal fluid, *IRF* intraretinal fluid

[a]Data are presented as *n* (%) unless otherwise specified

eyes (93.8%). Only 25 eyes (19.2%) received four monthly loading injections as per label.

Functional Outcomes

BCVA improved from baseline 64.6 ± 14.1 (median 65.1 [IQR 54.9–75.0]) to 69.2 ± 20.3 (median 75.0 [IQR 65.1–80.2]) ETDRS letters (mean change + 4.5 ± 17.1 ETDRS letters, Wilcoxon signed rank test, $p < 0.001$) at the end of the 12-month follow-up. At baseline, BCVA ranged in 67 eyes (51.5%) ≤0.4 (equivalent 65.1 ETDRS letters), while 63 eyes (48.5%) had a BCVA ≥0.5 (equivalent to 69.9 ETDRS letters). BCVA at 12 months correlated significantly with BCVA at baseline ($r(129) = 0.56$, $p < 0.01$) and early drying ($r(98) = 0.29$, $p = 0.005$) after the first faricimab injection. Conversely, the persistence of IRF after the first injection was negatively correlated with BCVA at 12 months ($r(98) = -0.24$, $p = 0.02$). During the 1-year follow-up, 19 eyes (14.6%) underwent cataract surgery. To minimize an inherent bias, BCVA data for these eyes were censored from baseline on. The evolution of BCVA is shown in Fig. 1a.

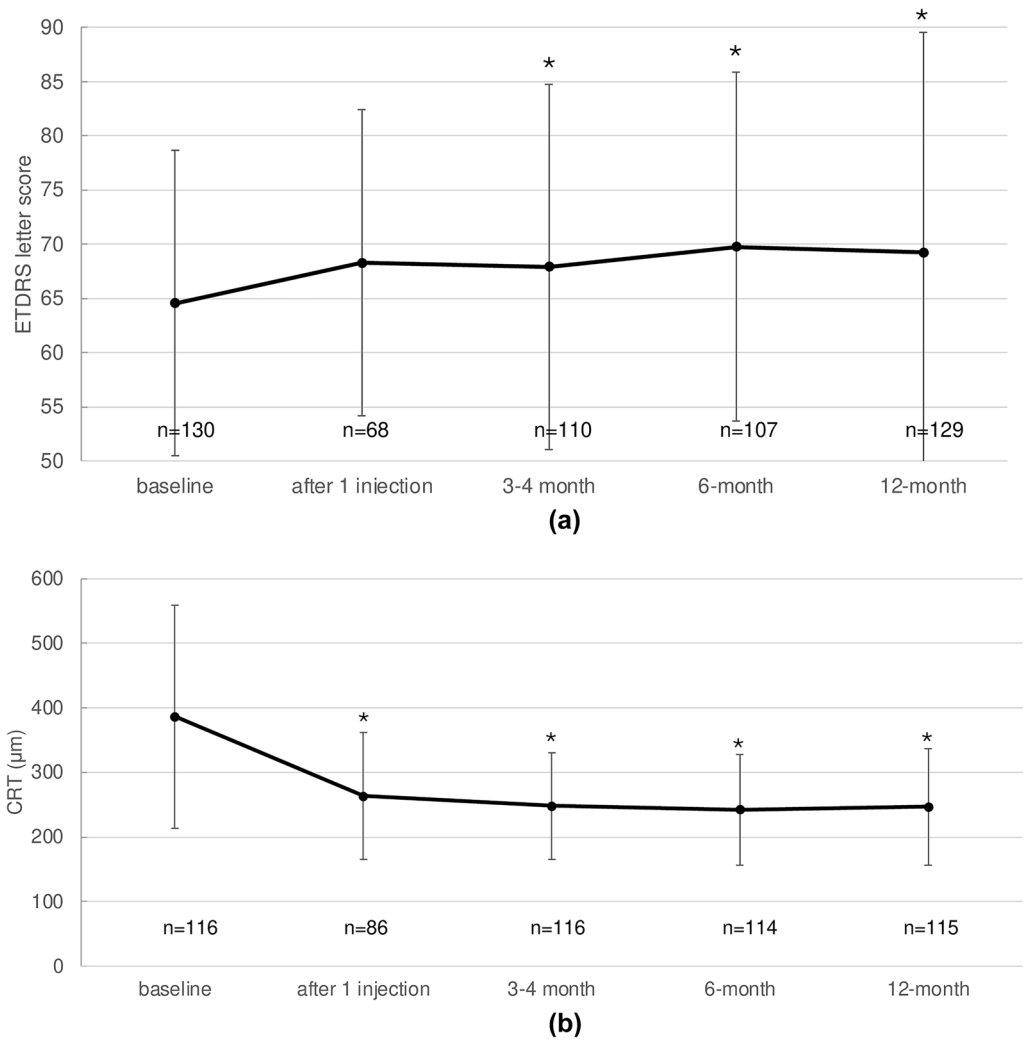

Fig. 1 Changes in mean best corrected visual acuity (BCVA) and central retinal thickness (CRT) from baseline to 12-month follow-up. After treatment with faricimab, significant changes in BCVA (**a**) and CRT (**b**) at 12 months are observed. *Significant time points

Anatomical Outcomes

CRT decreased from 386.3 ± 172.3 µm (median 336.0 [IQR 268.3–481.5]) at baseline to 246.6 ± 90.4 µm (median 230.0 [IQR 198.0–261.0]) at 12 months (mean change −137.8 ± 146.4 µm, $p < 0.001$). Of the 130 eyes with intra- and/or subretinal fluid at baseline, 45 (34.6%) had a completely dry macula after the first faricimab injection, and 72 eyes (55.6%) after 12 months. Of the 55 eyes with remaining fluid, 21 (38.2%) had SRF, 28 (50.9%) IRF, and 6 (10.9%) both SRF and IRF. The presence of a PED at baseline had no effect on fast drying, but significantly correlated with the presence of retinal fluid at 12 months ($r(126) = 0.20$, $p = 0.027$). An overview of CRT reductions and fluid dynamics throughout the treatment period is visualized in Figs. 1b and 2.

Treatment Intervals and Increments

After 12 months, the mean treatment interval was 10.5 ± 4.3 (median 10.6 [IQR 7.0–13.0]; range 3.6–22) weeks. Twenty-nine eyes (22.3%) had a treatment interval of < 8 weeks, while 51 eyes (39.2%) achieved a treatment interval of ≥ 12 weeks. During the first year after diagnosis, patients received a mean of 7.8 ± 2.0 (median 8.0 [IQR 6.0–9.0]; range 4–13) injections. No correlation was observed between fast-drying and longer treatment intervals at year 1 ($r(88) = 0.10$ $p = 0.37$). Regression analysis revealed that rapid drying after the first injection was not associated with longer treatment intervals at 1 year (adjusted $R^2 = -0.2\%$). The distribution of treatment intervals during the follow-up period is shown in Fig. 3.

Safety and Discontinuation Rate

Safety signs were observed in 5 eyes (3.8%), including one case of anterior uveitis, two cases of retinal pigment epithelium tear, and one case of minor bleeding close to the macula (Table 2). The anterior uveitis case was mild and successfully treated with topical corticosteroids. Within a total of 922 injections, no cases of occlusive vasculitis or endophthalmitis were reported during the study. A total of 17 eyes (13.1%) discontinued treatment with faricimab during the 12-month follow-up period. Six eyes (4.6%) discontinued intravitreal therapy, while 7 eyes

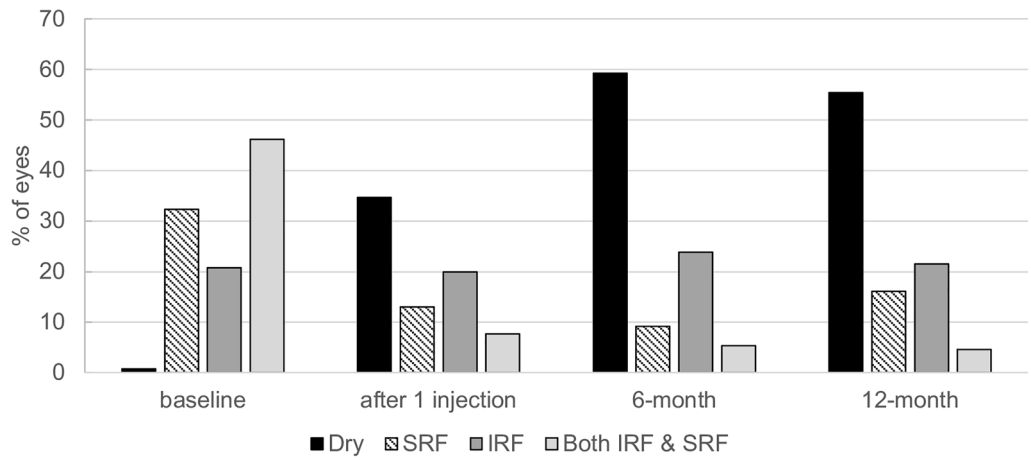

Fig. 2 Macular fluid status at baseline and during follow-up after faricimab initiation. The proportion of eyes displaying a dry macula on optical coherence tomography increases over time, from 0.8% at baseline to 55.4% at Month 12. Percentages are calculated relative to the baseline cohort (n = 130 eyes). The number of eyes with available OCT data was n = 130 at baseline, n = 98 after the first injection, n = 127 at Month 6, and n = 127 at Month 12. One eye classified as dry at baseline (0.8%) showed pigment epithelial detachment. IRF: intraretinal fluid; SRF: subretinal fluid.

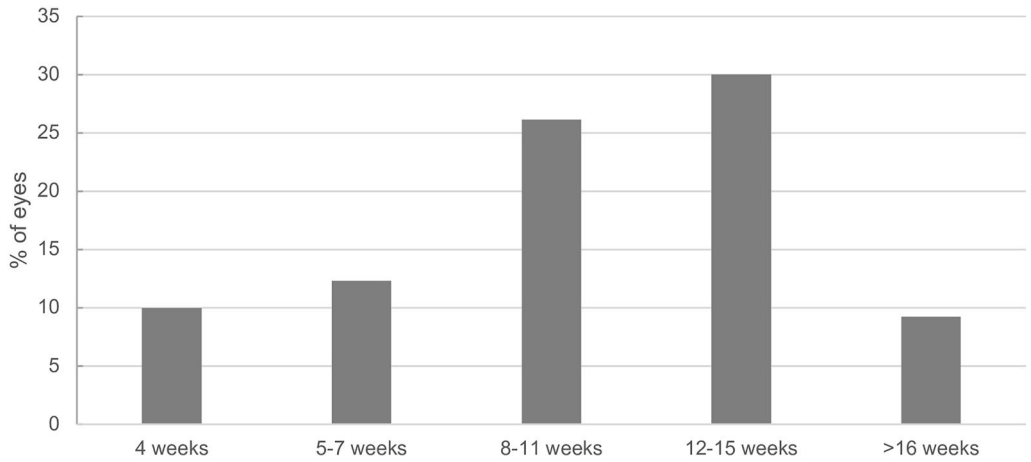

Fig. 3 Distribution of treatment intervals at Month 12 after faricimab initiation. Percentages are shown relative to the baseline cohort (n = 130 eyes). At Month 12, treatment interval data were available for 114 eyes. Eyes treated at ≥12-week intervals represent a markedly greater proportion compared with eyes on 4-week intervals.

Table 2 Ocular and non-ocular adverse events reported with faricimab treatment ($n = 5$, 3.8%)

Adverse event	Cases (*n*)
Anterior uveitis	1
Minor macular bleeding	1
Retinal pigment epithelium tear	2
Subconjunctival cyst	1

Table 3 Reasons for discontinuation of treatment with faricimab ($N = 17$, 13.1%)

Reason	*n* (%)
Switch to alternative anti-VEGF therapy	7 (5.4%)
Persistent macular fluid	3 (2.3%)
Inability to extend interval beyond 8 weeks	4 (3.1%)
Intravitreal treatment cessation	6 (4.6%)
Absence of disease activity	4 (3.1%)
No functional potential	2 (1.5%)
Patient's death	1 (0.8%)
Unknown	3 (2.3%)

(5.4%) were switched to alternative anti-VEGF therapies, mainly aflibercept 8 mg ($n = 6$). Reasons for discontinuation included inadequate response and intravitreal treatment cessation due to disease control or no functional potential. Details are shown in Table 3.

DISCUSSION

In this real-world cohort of patients with treatment-naïve nAMD, we analyzed the anatomical and functional outcomes of faricimab over a 12-month period. During this period, more than 55% of eyes achieved complete drying indicating disease stability after a median of eight injections. There is a growing need for real-world evidence in the management of macular diseases, particularly as novel therapies such as faricimab continue to emerge. Understanding the efficacy and limitations of these treatments in routine clinical practice is essential to optimize patient care. This initiative aligns with broader efforts by specialized retinal centers, such as the Swiss Retina Research Network, to systematically collect and evaluate real-world data on innovative therapies for macular disease.

Faricimab was approved by the US Food and Drug Administration (FDA) in January 2022 and

has since been the focus of extensive real-world studies worldwide, providing important insights into its use in the treatment of nAMD [9]. As the pivotal randomized clinical trials (RCTs) TENAYA and LUCERNE have focused on patients with treatment-naïve nAMD, this study offers a unique opportunity to directly compare their outcomes to real-world data [8].

The results of this study provide valuable evidence to demonstrate its therapeutic potential in the treatment of patients with treatment-naïve nAMD. Given the absence of a study population selection bias, the functional response in real life does not completely reach that of RCTs. This is also the case in our cohort with a mean gain of 4.6 letters compared to 5.8 letters in TENAYA and 6.6 letters in LUCERNE. Moreover, baseline BCVA was lower in TENAYA and LUCERNE (approximately 60 EDTRS letters) than in our study, which may have contributed to a potential ceiling effect in our population. Early visual improvements were positively correlated with baseline BCVA and rapid drying ($r=0.29$, $p=0.005$). Moreover, our cohort experienced distinct anatomical improvements as evidenced by a mean CRT reduction of 138 µm over 1 year. This confirms the strong drying effect of faricimab in the TENAYA and LUCERNE trials (−137 µm) [8], which is critical for disease control. In addition, 34.6% of eyes showed a "fast drying" response already after the first injection. However, it should be emphasized that a "fast drying" response is not indicative of longer treatment intervals, suggesting that early response to treatment is not predictive of long-term response.

Following a treat-and-extend (T&E) protocol, 39.2% of our patients achieved a treatment interval of ≥12 weeks at the end of the first year of treatment. This is evidently lower than in the two pivotal trials where 79.7% (TENAYA) and 77.8% (LUCERNE) achieved a treatment interval of ≥12 weeks at week 48 [8]. This discrepancy can largely be attributed to differences in treatment protocols. In the pivotal trials, patients received four loading injections followed by a protocol-driven extension to q12 or q16 intervals, resulting in an average of approximately six injections during the first year. Post-loading intervals were fixed during the first year in the RCTs, which may have led to an overestimation of treatment efficacy. In contrast, our cohort received 7.8 injections in year 1, reflecting more frequent monitoring and adjustments aimed at maximizing visual outcomes. Furthermore, the pivotal trials prioritized demonstrating maximal durability with non-inferior visual outcomes, whereas in daily clinical practice, treatment decisions are primarily driven by achieving the best possible visual function. Additionally, fluid and morphological activity assessment focused on the central 1 mm in the phase 3 trials, while clinicians usually assess the whole OCT scan and aggressively treat signs of fluid when present foveally or parafoveally. Thus, disease activity criteria in clinical trials do not reflect the criteria usually employed in a real-world setting. These points highlight the limitations when attempting to compare our results to the pivotal randomized controlled trials.

Two Japanese research groups, Matsumoto et al. and Mukai et al., have reported 1-year outcomes of faricimab in patients with treatment-naïve nAMD, offering valuable insights for comparison [12, 15]. Both Matsumoto et al. ($n=40$) and Mukai et al. ($n=57$) investigated treatment-naïve nAMD eyes following a loading phase of three monthly faricimab injections and maintenance therapy using a T&E regimen with intravitreal administration of faricimab. Their findings align closely with ours, demonstrating significant BCVA improvements after 12 months: Matsumoto et al. reported an increase from 0.32 ± 0.40 to 0.17 ± 0.33 logMAR, while Mukai et al. observed a change from 0.44 ± 0.46 logMAR to 0.34 ± 0.48 logMAR ($p<0.01$). Similarly, both studies documented substantial CRT reductions: Matsumoto et al. from 215 ± 97 to 184 ± 89 µm ($p<0.001$) and Mukai et al. from 326 ± 149 to 195 ± 82 µm ($p<0.0001$). The number of injections during the year was comparable across studies: 6.6 ± 0.7 and 6.8 ± 0.9 in the Matsumoto and Mukai cohorts, respectively, versus 7.8 ± 1.9 in our cohort. While our mean treatment interval at the final visit was 10.5 weeks (± 4.3), Matsumoto et al. reported a longer interval of 12.7 ± 3.3 weeks. Probably based on differences in lesion types, which we have not assessed in our cohort, 43.3% of Matsumoto's patients and 44% of Mukai's patients

achieved a treatment interval of ≥ 16 weeks by the end of the first year, closely mirroring the results from the TENAYA and LUCERNE trials, in which 45% of patients reached this interval. In contrast, only 10.5% of our cohort achieved a 16-week interval, although 44.7% reached an interval of ≥ 12 weeks, underscoring promising real-world durability. The differences in outcomes between these Japanese cohorts and our study may also be confounded by remarkable differences in patient retention. Matsumoto et al. reported a relatively high dropout rate of 25%, with 12.5% of patients switching to brolucizumab because of persistent exudative changes despite an 8-week interval with faricimab. Mukai et al. noted a lower switch rate of 7.1%, primarily to aflibercept, due to insufficient response to faricimab, a factor that could have led to an overestimation of faricimab's efficacy in their cohort. In contrast, our study reported a switch rate of only 5.4%. The high prevalence of polypoidal choroidal vasculopathy, a common subtype in Asian populations—43.3% in Matsumoto's cohort and 35% in Mukai's—may have added to the differences in the outcomes. The distinct patient profile, along with higher discontinuation and switch rates, likely contributed to the more favorable outcomes observed in those who completed the 1-year follow-up.

The safety results of this study confirm a good safety profile of faricimab. Ocular adverse events were observed in 3.8% of eyes and included anterior uveitis, retinal pigment epithelial tears, and subconjunctival cysts. Importantly, no cases of endophthalmitis or occlusive vasculitis were reported. These findings are consistent with previous real-world studies and clinical trials highlighting the tolerability of faricimab in diverse patient populations [12, 24, 25]. In addition, the low discontinuation rate (13.1%) further supports the safety and efficacy of faricimab in the treatment of treatment-naïve nAMD. However, this study is not powered to detect differences in endophthalmitis or vasculitis rates.

A primary limitation of our study is the relatively modest sample size. Beyond the formal exclusion criteria, the most decisive factors limiting inclusion were sufficient follow-up time and the presence of a general consent for the use of coded patient data. Additional parameters influencing the sample size, without introducing selection bias, included the timing of reimbursement in Switzerland, data lock at September 1, 2024, and a focus on first experiences with switcher eyes. Furthermore, the inherent limitations of a retrospective design and minor differences in re-treatment criteria between centers may have introduced bias. Variations in treatment protocols—such as three vs. four loading injections and differing follow-up strategies—limit comparability with pivotal trials and other retrospective studies. Moreover, the lack of lesion type data and standardized imaging reduces generalizability. These factors should all be considered when interpreting our findings and their applicability to broader patient populations.

A larger sample size and longer follow-up would enhance both statistical robustness and the generalizability of our findings. Our present analysis was specifically designed to provide timely, real-world 1-year outcome data after the approval of faricimab in Switzerland, as such annual results are clinically meaningful and provide critical early guidance for practitioners and health systems. While it would be possible to substantially increase our cohort by revisiting data collection for a future 2-year analysis, we believe that early annual outcomes hold distinct value for benchmarking real-world efficacy, informing clinical adoption, and enabling direct comparison with pivotal trials.

This study was conceived as a non-comparative observational series to provide homogeneous, practice-based data on faricimab in routine clinical settings. Inclusion of a parallel control group on aflibercept 2 mg could have introduced significant selection bias, since randomization was not feasible in our real-world design. Furthermore, aflibercept 8 mg was not available at any participating center during our inclusion window. We therefore determined that reporting on a focused real-world population would deliver the most reliable insights for this first-year analysis.

CONCLUSION

In this real-world, multicenter cohort of patients with treatment-naïve nAMD, faricimab demonstrated significant functional

and anatomical benefits over 1 year, with a favorable safety profile and considerable reduction in treatment burden for many patients. While fewer eyes achieved very extended injection intervals compared to pivotal randomized trials, the results affirm faricimab's effectiveness and tolerability in routine clinical practice. These data support the clinical utility of faricimab as a first-line therapy for nAMD and highlight the need for further prospective, long-term studies to optimize treatment regimens and assess outcomes in broader, more diverse patient populations.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Gabriela Grimaldi: consultant for Apellis, Bayer, Roche. Lecturer for Abbvie, Apellis, Bayer, Roche. Grant support from Bayer and Roche. Gábor M. Somfai: consultant for Apellis, Allergan, Bayer, Novartis, Roche. Lecturer for Apellis, Allergan, Bayer, Novartis, Roche, Carl Zeiss Meditec. Justus G. Garweg: Consultancies and Lectures for AbbVie, Apellis, Bayer. Novartis, Roche Andreas Ebneter: Consultant for Apellis, Bayer, Roche, former employee of F. Hoffmann-La Roche Ltd. Andreas Weinberger: Consultancies and Lectures for Apellis, Bayer. Novartis, Roche Marion R. Munk: consultant for Apellis, Abbvie, Acuccela, Bayer, Roche, Lumithera, Novartis, Oculterra, Alimera, Zeiss, Ocular therapeutix, Isarna, RetinAI, Dandelion, Optos, Oculis, Lumithera, Kubota, Eyepoint, Avecida Therapeutics, Astellas, Genesight Therapeutics. Anne Tillmann, Richard Stillenmunkes, Jennifer Cattaneo, Nicolò Bartolomeo, Tahm Spitznagel, Eva C De Oliveira Figueiredo, Aude Ambresin, Moreno Menghini, Sandrine Zweifel, Jacqueline Fröhlich, Dmitri Artemiev, Katja Hatz, Isabel B. Pfister, Chiara Eandi, Christin Schild has nothing to disclose.

Ethical Approval. The study was approved by all participating ethics committees, led by the ethics committee of the canton of Berne (registration no. 2024-01026). Coded patient data were included on the basis of general or specific informed consent, in line with ICH-GCP E6, the Declaration of Helsinki, and Swiss law.

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