



SUMMARY OF RESEARCH

Summary of Research: Four-Year Outcomes of Faricimab in Diabetic Macular Edema: Results From the RHONE-X Extension Trial

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ABSTRACT

This is a summary of the original article “Four-Year Outcomes of Faricimab in Diabetic Macular Edema: Results From the RHONE-X Extension Trial.” RHONE-X was a phase 3, multicenter, nonrandomized, 2-year open-label extension of the YOSEMITE/RHINE clinical trials. RHONE-X assessed the long-term safety (primary endpoint) and efficacy (exploratory) of faricimab using a treat-and-extend (T&E) protocol in patients with diabetic macular edema (DME). Patients in YOSEMITE/RHINE who received faricimab 6.0 mg every 8 weeks (Q8W), faricimab 6.0 mg T&E, or aflibercept 2.0 mg Q8W received faricimab 6.0 mg up to Q16W T&E (based on prespecified vision and anatomic criteria) for

a further 2 years in RHONE-X. Faricimab was well tolerated through 2 years of RHONE-X, and adverse events reported were consistent with the known safety profile of faricimab. Vision and anatomical improvements achieved during YOSEMITE/RHINE were maintained through RHONE-X. In patients treated with aflibercept during YOSEMITE/RHINE, the proportion achieving absence of DME (CST < 325 μ m) increased after switching to faricimab. Approximately 80% of patients were on a faricimab dosing interval of $\geq$ Q12W at the end of 4 years. These findings demonstrated the long-term safety, efficacy, and durability of faricimab T&E in patients with DME.

Keywords: Diabetic macular edema; Faricimab; Long-term; RHONE-X

SUMMARY OF RESEARCH

This is a summary of the original article “Four-Year Outcomes of Faricimab in Diabetic Macular Edema: Results From the RHONE-X Extension Trial” (Fig. 1) [1]

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Summary of Research: Four-Year Outcomes of Faricimab in Diabetic Macular Edema: Results From the RHONE-X Extension Trial

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- RHONE-X was a global, phase 3, multicenter, 2-year open-label extension of the YOSEMITE/RHINE trials, providing a total of 4 years of follow-up data on faricimab in DME
- RHONE-X evaluated the long-term safety and tolerability (primary endpoints) and efficacy (exploratory endpoints) of faricimab, a dual Ang-2/VEGF-A inhibitor, and is the largest long-term extension study in DME to date

Study design

Eligible patients:

Patients with DME who completed YOSEMITE or RHINE without discontinuation of study treatment

YOSEMITE/RHINE 2 years

1891 patients

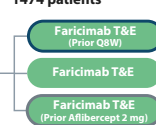


Faricimab T&E

- Extend by 4 weeks up to Q16W, if stable CST and BCVA
- Reduce by 4 or 8 weeks to as low as Q4W, if worsening CST ± BCVA
- Maintain dosing if extension or reduction criteria not met

RHONE-X 2 years

1474 patients



Patients transitioned to faricimab T&E in RHONE-X without requiring monthly initiation doses. All received faricimab T&E up to Q16W based on BCVA and CST per YOSEMITE/RHINE criteria.

* Of 1622 patients who completed YOSEMITE/RHINE.

Results



Faricimab was well tolerated through 2 years of RHONE-X, with a safety profile consistent with the YOSEMITE/RHINE trials

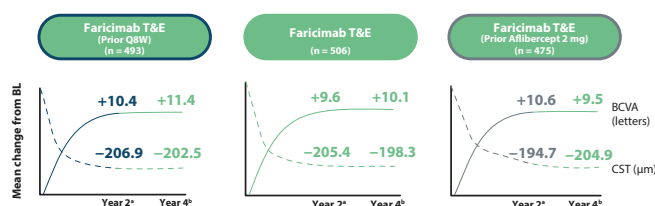
Patients with ≥ 1 event, % (n):	Faricimab T&E (Prior Q8W) (n = 491)	Faricimab T&E (n = 500)	Faricimab T&E (Prior Aflibercept 2 mg) (n = 473)
Ocular AEs	44.6%	37.6%	41.6%
Serious ocular AEs	6.3%	3.0%	5.5%
Intraocular inflammation	1.4%	1.4%	1.1%

No cases of retinal vasculitis or retinal occlusive vasculitis were reported

Data are presented for the safety-evaluable population, which is defined as patients who received at least 1 dose of faricimab in RHONE-X.



Robust improvements in BCVA and CST were maintained in RHONE-X with faricimab T&E dosing



^a Mean at year 2, end of YOSEMITE/RHINE (week 100). ^b Mean at year 4, end of RHONE-X (average of weeks 192–204).

Fig. 1 The Phase 3 RHONE-X extension trial demonstrated the safety, efficacy, and durability of faricimab treat-and-extend in the long-term management of diabetic macular edema

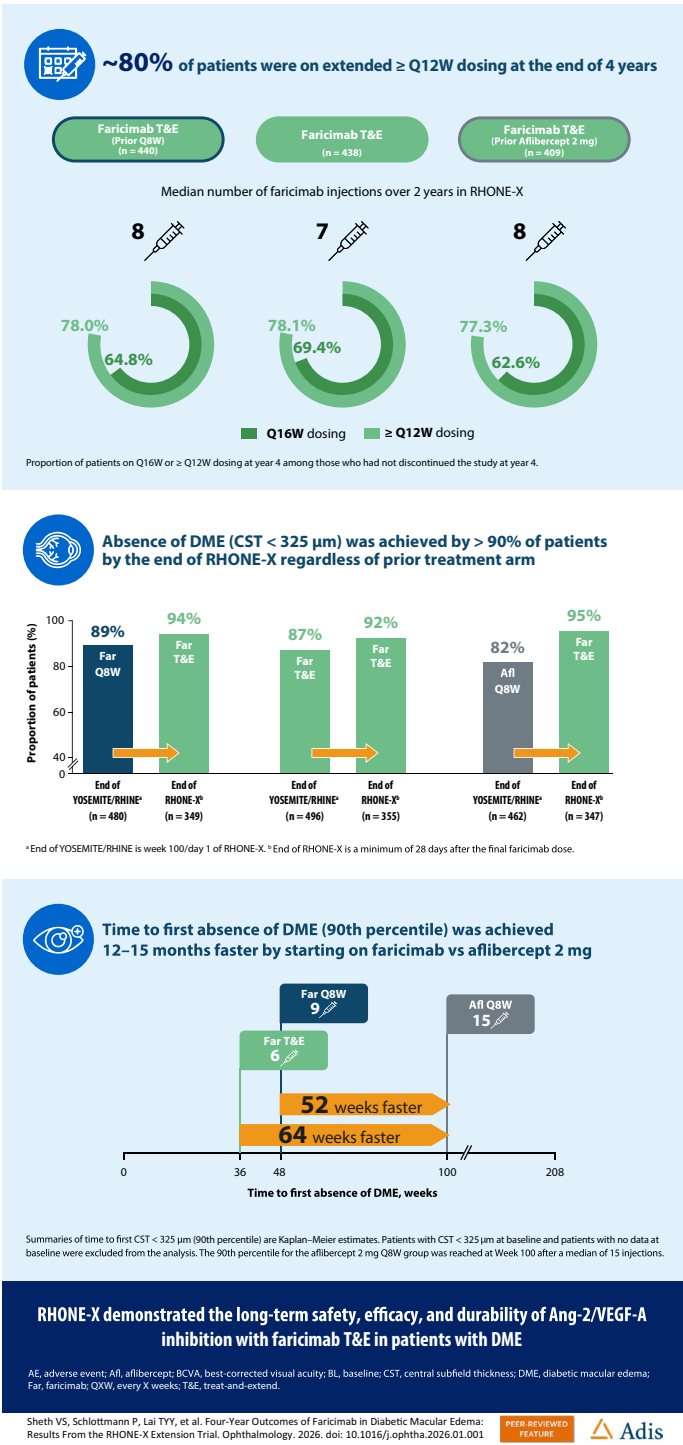


Fig. 1 continued

LIMITATIONS

The RHONE-X trial had some limitations, as described in the original article. As RHONE-X was an open-label, non-comparator-controlled trial, it may have been vulnerable to selection bias, although this bias may have been reduced by high patient retention from the YOSEMITE/RHINE trials. During the T&E phase, data were only collected during treatment visits rather than monthly, limiting available data points. Efficacy analysis included only observed patients, which may have overestimated outcomes if patients who discontinued had poorer outcomes.

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Declarations

Conflict of Interest. Please see original article for full author disclosures. Veeral S. Sheth: Speaker: Genentech, Inc./Roche; Consultant: Alkeus, Apellis, Boehringer Ingelheim, EyePoint, Genentech, Inc., Iveric Bio, Janssen, Kriya, Novartis, Ocular Therapeutix, Oculis, Ocuphire, Ollin, Opthea, Regeneron, RevOpsis, Unity, Vial; Contracted Research: 4DMT, AbbVie, Adverum, Alimera, Ashvattha, Astellas, Aviceda, Chengdu

Kanghong, Eluminex, EyeBio, EyePoint, Genentech, Inc., Gyroscope, i-Lumen, Ionis, Iveric Bio, Janssen, NGM, Novartis, Ocugen, Ocular Therapeutix, Oculis, OcuTerra, OliX, Opthea, Outlook, Oxular, Oxurion, Perfuse, RecensMedical, Regeneron, Regenxbio, Rezolute, Roche, SalutarisMD, SamChungDang, Santen, Smile Biotech, Unity, Vanotech; Stela Vujosevic: Consultant: AbbVie/ Allergan, Adverum, Alimera, Apellis, Bayer, Boehringer Ingelheim, Novartis, RetinAI, Roche, ZEISS; Alex Kotak, Aachal Kotecha, and Kara Gibson: Employee: Roche Products Ltd.

Ethics approval, Consent to participate, Consent to publish, Availability of data and material. Not applicable.

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