# Extended Treatment Outcomes and the Potential for Q20W Dosing With Faricimab in nAMD: A Post Hoc Analysis of the TENAYA/LUCERNE Trials

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## Key Clinical Questions

- What is the efficacy of extended faricimab dosing (every 12 weeks [Q12W] or Q16W) in patients with neovascular age-related macular degeneration (nAMD) from the phase 3 TENAYA/LUCERNE studies?
- How many patients potentially could have extended to Q20W dosing?

## Conclusions

Patients with nAMD from the TENAYA/LUCERNE trials on ≥ Q12W faricimab dosing intervals exhibited stable disease control with robust anatomic and vision outcomes through 2 years

56% of faricimab treat-and-extend (T&E) patients met extension criteria and could potentially extend to Q20W

These data support the potential for dual angiopoietin-2 (Ang-2)/vascular endothelial growth factor (VEGF)-A inhibition with faricimab to extend treatment durability with stable disease control for patients with nAMD

### Financial Disclosures

- PJP: Consultant: Bayer UK, Boehringer Ingelheim; Roche UK
- LH: Consultant: Alimera, Genentech, Inc., PolyPhotonix, RecensMedical
- AS, PM: Employee: F. Hoffmann-La Roche Ltd.
- AK: Employee: Roche Products Ltd.

### Study 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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- Roche conducted a factual accuracy check on the final article but any decision to incorporate comments was made solely at the discretion of the authors

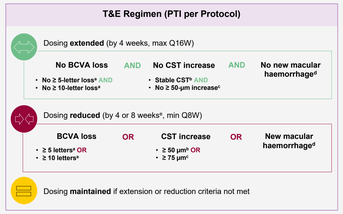
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## Background

- Faricimab is the first bispecific antibody for intraocular use that independently binds and neutralises both Ang-2 and VEGF-A with high specificity and potency[1]
- Anti-VEGF treatment for nAMD can be burdensome for physicians, patient, and caregivers[2]
- In the phase 3 TENAYA/LUCERNE trials, a personalised T&E–based regimen evaluated the potential of faricimab to reduce treatment burden while maintaining clinical efficacy in patients with nAMD[3]

## Methods

- TENAYA (NCT03823287) and LUCERNE (NCT03823300) were randomised phase 3 trials that enrolled treatment-naïve nAMD patients. Patients (pooled N = 1329) were randomised to faricimab 6.0 mg up to Q16W (n = 665) after 4 initial Q4W doses or aflibercept 2.0 mg Q8W after 3 initial Q4W doses (n = 664)
- Following protocol-defined disease activity assessments at weeks 20 and 24, patients treated with faricimab received fixed dosing up to Q16W until week 60 followed by a T&E–based regimen[3]
- After week 60, faricimab treatment intervals could be adjusted as shown below[4]
- Efficacy and safety were assessed at monthly visits through week 112



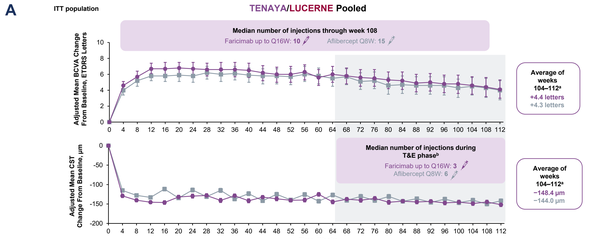

[a] vs average BCVA over previous 2 scheduled visits. [b] vs average CST over previous 2 scheduled visits. [c] vs lowest CST recorded at either of previous 2 scheduled visits. [d] Per the investigator and attributable to nAMD. [e] If ≥ 2 of the reduction criteria were met or 1 criterion includes new macular haemorrhage, the interval was reduced to an 8-week interval. BCVA, best-corrected visual acuity; CST, central subfield thickness; max, maximum; min, minimum; nAMD, neovascular age-related macular degeneration; PTI, personalised treatment interval; Q8W, every 8 weeks; Q16W, every 16 weeks; T&E, treat-and-extend.

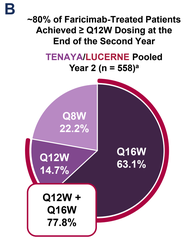
### References

1. Regula JT et al. *EMBO Mol Med*. 2016;8(11): 1265-1288, with erratum in Regula JT et al. *EMBO Mol Med*. 2019;11(5):e10666.
2. Giocanti-Auregan A et al. *Patient Prefer Adherence*. 2022;16:587-604.
3. Heier JS et al. *Lancet*. 2022;399(10326):729-740.
4. Khanani AM et al. *Ophthalmology*. 2024; 19:S0161-6420(24)00134-9.

## Results

### 1. Patients in the Faricimab Arm Achieved Disease Control With Fewer Injections Over 2 Years

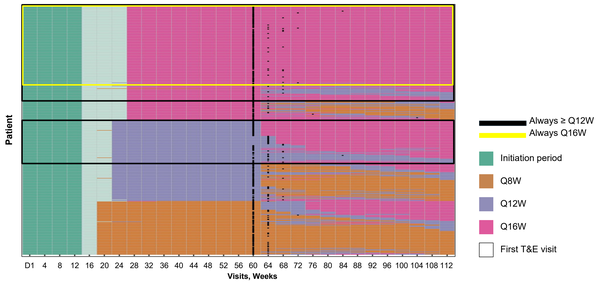



Results are based on an MMRM analysis in the ITT population. For the MMRM analysis, the model is adjusted for treatment group, visit, visit-by-treatment group interaction, baseline BCVA (continuous), baseline BCVA (≥ 74, 73–55 and ≤ 54 letters), baseline LLD (< 33, ≥ 33 letters), region (US and Canada, Asia and the rest of the world) and study (TENAYA vs LUCERNE). Treatment policy strategy and hypothetical strategy were applied to non-COVID-19–related and COVID-19–related intercurrent events, respectively. Missing data were implicitly imputed by MMRM. The median number of injections is based on the safety-evaluable population. 95% CIs are shown. CST is measured as ILM-RPE, as graded by a central reading centre. [a] Adjusted mean change from baseline at 2 years, averaged over weeks 104, 108 and 112. [b] T&E phase refers to the protocol-driven personalised treatment interval. After week 60 to week 112, faricimab T&E phase vs aflibercept Q8W fixed dosing. Based on study design, aflibercept 2.0 mg was not allowed to extend beyond Q8W dosing. T&E dosing regimen was delayed in some patients due to dose holds or missed visits. BCVA, best-corrected visual acuity; CI, confidence interval; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; ILM, internal limiting membrane; ITT, intent to treat; LLD, low luminance deficit; MMRM, mixed model for repeated measures; Q8W, every 8 weeks; Q16W, every 16 weeks; RPE, retinal pigment epithelium; T&E, treat-and-extend.

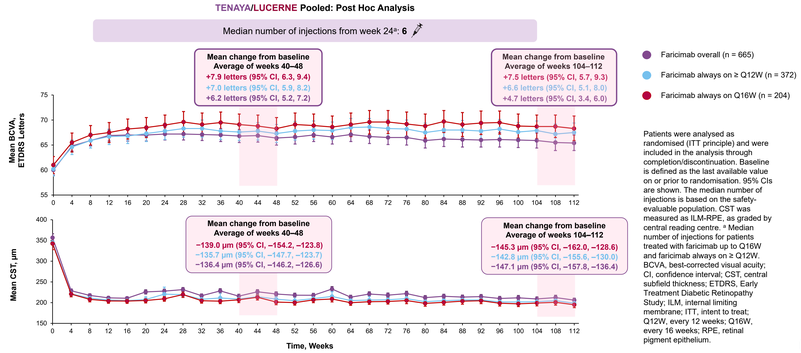
Proportion of patients in the pooled faricimab T&E arms on Q4W, Q8W, Q12W or Q16W dosing at week 96 (year 2), among those who had not discontinued the study at that visit. Treatment interval at week 96 (year 2) is defined as the treatment interval decision at week 92. [a] Percentages are based on number of patients randomised to the faricimab arm who had not discontinued the study at that visit. Treatment interval at week 112 (year 2) is defined as the treatment interval decision at week 108. Q4W, every 4 weeks; Q8W, every 8 weeks; Q12W, every 12 weeks; Q16W, every 16 weeks; T&E, treat-and-extend.

### 2. Patients on Always ≥ Q12W and Always Q16W Dosing Through Year 2 Visualised on a Heatmap



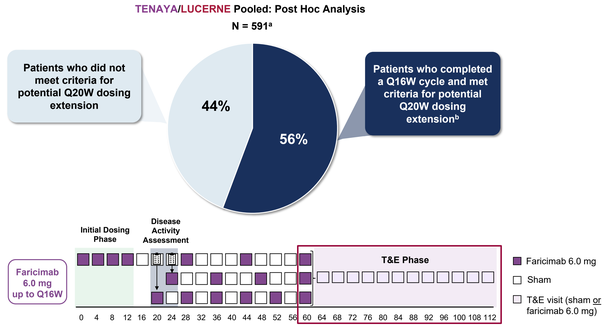

D, day; Q8W, every 8 weeks; Q12W, every 12 weeks; Q16W, every 16 weeks; T&E, treat-and-extend.

### 3. Patients Always on ≥ Q12W Dosing and Always on Q16W Dosing Achieved Stable BCVA Gains and CST Reductions Through 2 Years




Patients were analysed as randomised (ITT principle) and were included in the analysis through completion/discontinuation. Baseline is defined as the last available value on or prior to randomisation. 95% CIs are shown. The median number of injections is based on the safety-evaluable population. CST was measured as ILM-RPE, as graded by central reading centre. [a] Median number of injections for patients treated with faricimab up to Q16W and faricimab always on ≥ Q12W. BCVA, best-corrected visual acuity; CI, confidence interval; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; ILM, internal limiting membrane; ITT, intent to treat; Q12W, every 12 weeks; Q16W, every 16 weeks; RPE, retinal pigment epithelium.

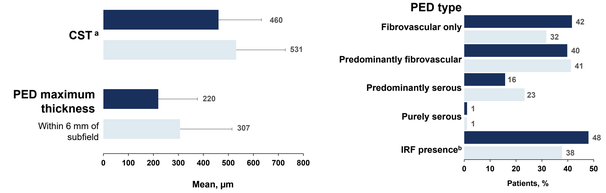
### 4. > 50% of Faricimab-Treated Patients Met Criteria for Potential Q20W Dosing Intervals During the T&E Phase




[a] Limited to patients on Q16W dosing who had ≥ 1 faricimab dose during the T&E phase. [b] The same protocol-defined extension criteria for personalised T&E were used in this analysis. Q16W, every 16 weeks; Q20W, every 20 weeks; T&E, treat-and-extend.

### 5. Baseline Characteristics of Faricimab-Treated Patients Who Met Criteria for Potential Q20W Dosing

- Patients who met the criteria for potential Q20W dosing displayed numerically lower CST and PED thickness and higher rates of fibrovascular PEDs and IRF at baseline




[a] Limited to patients on Q16W dosing who had ≥ 1 faricimab dose during the T&E phase. [b] The same protocol-defined extension criteria for personalised T&E were used in this analysis. CST, central subfield thickness; IRF, intraretinal fluid; PED, pigment epithelial detachment; Q16W, every 16 weeks; Q20W, every 20 weeks; T&E, treat-and-extend.

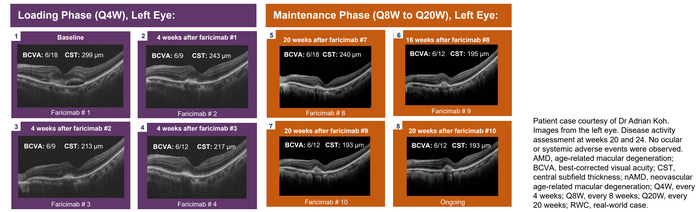
### 6. RWC: Patient With Treatment-Naïve nAMD Extended to Q20W

**Treatment History:** 10 Faricimab (ongoing)

**Patient History:**

| | |
|---|---|
| Age | 68 years |
| Sex | Female |
| Disease | Choroidal neovascularisation, AMD |
| Duration | 1-week metamorphopsia |

| | |
|---|---|
| Affected eye(s) | Left eye |
| Ocular history | Pseudophakic |
| Patient background | No significant medical history |
| Baseline BCVA | 6/18 |




Patient case courtesy of Dr Adrian Koh. Images from the left eye. Disease activity assessment at weeks 20 and 24. No ocular or systemic adverse events were observed. AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; CST, central subfield thickness; nAMD, neovascular age-related macular degeneration; Q4W, every 4 weeks; Q8W, every 8 weeks; Q20W, every 20 weeks; RWC, real-world case.