Robust Vision Gain and Anatomic Improvement With Faricimab in Patients With Polypoidal Choroidal Vasculopathy: Week 48 Results From SALWEEN

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This analysis evaluated vision, anatomical, durability and safety outcomes up to week 48 of SALWEEN with faricimab in patients with PCV from Asia

Introduction

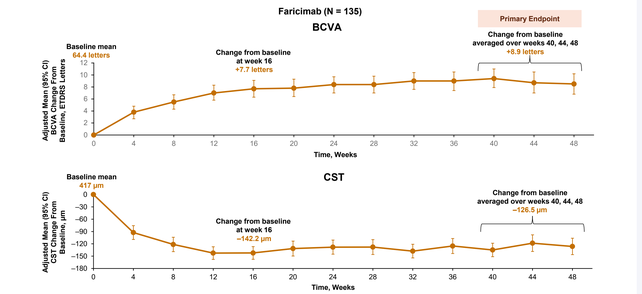
- PCV is a subtype of nAMD that is frequently underdiagnosed and reflects a more difficult-to-treat subtype[1]
- Week 16 results from the SALWEEN trial in patients with PCV from Asia demonstrated that patients treated with faricimab, a dual Ang-2/VEGF-A inhibitor, experienced robust vision and anatomic improvements[2]

Methods

- SALWEEN (ISRCTN69073386) is a phase 3b/4 multicentre, open-label, single-arm study that evaluated the efficacy, safety and durability of faricimab in PCV in Asia
- Patients with symptomatic macular PCV (N = 135) received 4 initial Q4W doses of faricimab 6 mg, followed by faricimab Q8W, Q12W or Q16W based on disease activity assessments at weeks 20/24
- From week 44/48 to week 104, faricimab dosing followed a T&E-based regimen, with treatment intervals ranging from Q8W to Q20W
- The primary endpoint was change from baseline in BCVA averaged over weeks 40, 44 and 48
- Other endpoints included change from baseline in CST, central choroidal thickness, proportion of patients with absence of IRF and SRF, resolution of polypoidal lesions, durability and safety

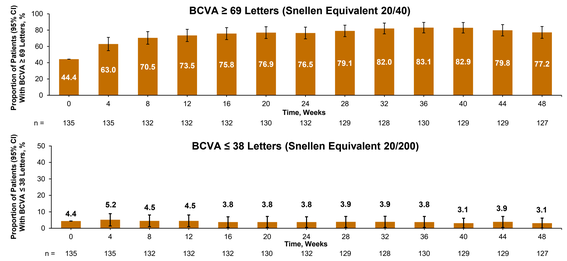
Results

1. Robust BCVA and CST Improvements From Baseline Through Week 48



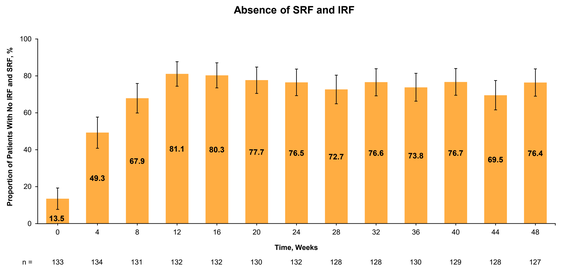
Results were based on an MMRM analysis, adjusted for visit, baseline BCVA or CST (continuous). An unstructured covariance structure was used. Treatment policy strategy was applied to intercurrent events, except for death. Missing and unmeasurable outcomes after death were implicitly imputed by MMRM. Baseline was defined as the last available measurement obtained on or prior to first exposure to study drug. CST was defined as the distance between ILM and BM. Invalid BCVA values were excluded from analysis. Includes measurements with onset up to day 346 (last day of week 48 of the time window). 95% CIs are shown.

2. Patients With BCVA ≥ 69 Letters (Snellen 20/40) Increased Through Week 48; Low Proportion of Patients With ≤ 38 Letters (Snellen 20/200) Through Week 48



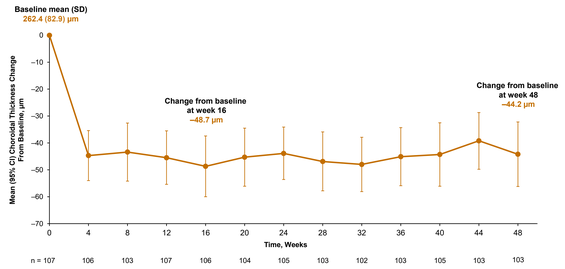
95% CI was computed following Wald's method. 95% CI limits below 0% or above 100% were imputed as 0% or 100%, respectively. Treatment policy strategy was applied to intercurrent events, except for death. Missing and unmeasurable outcomes after death were not imputed. Invalid BCVA values are excluded from analysis. Baseline was defined as the last available measurement obtained on or prior to first exposure to study drug.

3. 76% of Patients Had Absence of Retinal Fluid at Week 48



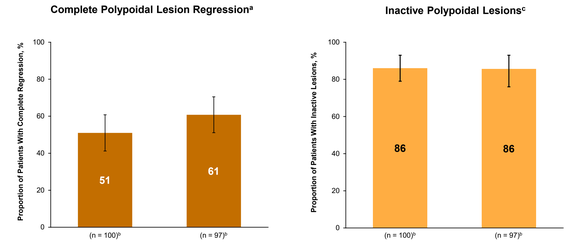
IRF and SRF were measured in the central subfield (centre 1 mm); if this was missing, then the result from whole field of view assessment was considered. Treatment policy strategy was applied to intercurrent events, except for death. Missing and unmeasurable outcomes after death were not imputed. 95% CI was computed following Wald's method. 95% CI limits below 0% or above 100% were imputed as 0% or 100%, respectively. Baseline was defined as the last available measurement obtained on or prior to first exposure to study drug. Includes measurements with onset up to day 346 (last day of week 48 of the time window). 95% CIs are shown.

4. Choroidal Thickness Decreased From Baseline Through Week 48



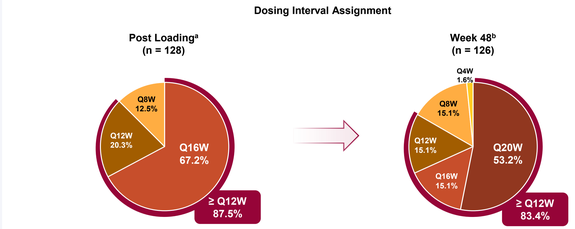
Treatment policy strategy was applied to intercurrent events, except for death. Missing and unmeasurable outcomes after death were not imputed. Baseline was defined as the last available measurement obtained on or prior to first exposure to study drug. Includes measurements with onset up to day 346 (last day of week 48 of the time window).

5. 61% of Polypoidal Lesions Had Completely Regressed and 86% Were Inactive at Week 48



[a] Based on ICGA. Complete polypoidal lesion regression was defined as patients with no polypoidal lesions at the corresponding visit. Treatment policy strategy was applied to intercurrent events, except for death. Missing and unmeasurable outcomes after death were not imputed. [b] Number of patients with polypoidal lesions at screening who did not discontinue treatment before week 16/48. [c] Includes patients with no polypoidal lesions in study eye at week 16/48 and patients with polypoidal lesions at week 16/48 with no IRF and no SRF at week 16/48. IRF and SRF were measured in the central subfield (centre 1 mm). Poypoidal lesions were assessed by ICGA, OCT and FFA.

6. More Than 50% of Patients Were Assigned to Faricimab Q20W Dosing Intervals at Week 48



Patients (n = 135) received a **median**[c] of **6.0 faricimab injections** through week 48

Percentages were based on the number of patients enrolled who had not discontinued the study at the specified visit. Treatment interval at a given visit was defined as the treatment interval decision followed at that visit. [a] Assessed at weeks 20, 24 and 28; patients received faricimab Q4W up to week 16 and underwent protocol-defined disease activity assessments at weeks 20 and 24. Patients with no evidence of active disease at weeks 20 and 24 received study treatment at week 28 and continued to receive study treatment every Q16W; those with active disease at week 20 received Q8W dosing; patients with active disease only at week 24 received Q12W dosing. [b] Assessed at weeks 44 and 48; only patients who entered the T&E phase were included. [c] Lower and upper quartiles were 6.0 and 7.0, respectively.

Conclusions

Dual Ang-2/VEGF-A inhibition with faricimab for PCV at week 48:

- **Was associated with robust BCVA improvements (+8.9 letters) and clinically relevant anatomic improvements**
- **Was associated with complete regression (61%) and inactivation of polypoidal lesions (86%) in the majority of eyes**
- **Allowed > 50% of patients to be assigned to Q20W dosing**

Faricimab was well tolerated; safety was consistent with the known safety profile of faricimab

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1. Spindler J et al. *J Clin Med*. 2026;15(4):1492.
2. Lee J et al. *Invest Ophthalmol Vis Sci*. 2025;66(8):1859.

Financial Disclosures

- IP: Advisory Board/Consulting/Honoraria/Travel Expenses: Allergan, Apellis, Bayer, Boehringer Ingelheim, Novartis, Roche
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- GC: Consultant: Allergan, Bayer, Boehringer Ingelheim, Novartis, Roche, Samsung, Topcon
- S-JC: Consultant: Roche; Funding: Allergan, Bayer, Novartis
- TI: Consultant: Bayer, Boehringer Ingelheim, Chugai/Roche, Novartis, Senju
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- XL: Nothing to disclose
- PR: Consultant: Bayer, Novartis, Roche; Funding: Bayer, Roche
- XS: Consultant: Alcon, Allergan, Bayer, Innovent, Kanghong, Novartis, Roche, ZEISS
- YY: Funding: Alcon Japan, SanBio, Santen
- RB: Employee: Roche Products Ltd.
- AND, PM: Employee: F. Hoffmann-La Roche Ltd.

Study and Product Disclosures

- In the UK, faricimab is approved for the treatment of neovascular age-related macular degeneration, visual impairment due to diabetic macular oedema and visual impairment due to macular oedema secondary to retinal vein occlusion
- This study includes research conducted on human subjects
- Institutional Review Board approval was obtained prior to study initiation
- Funding was provided by F. Hoffmann-La Roche Ltd. for the study and third-party writing assistance, which was provided by Nicole Tom, PhD, and Luke Carey, PhD, CMPP, of Envision Pharma Group

Abbreviations

Ang-2, angiopoietin-2; BCVA, best-corrected visual acuity; BM, Bruch's membrane; CI, confidence interval; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; FFA, fundus fluorescein angiography; ICGA, indocyanine green angiography; ILM, internal limiting membrane; IRF, intraretinal fluid; MMRM, mixed-effect model with repeated measures; nAMD, neovascular age-related macular degeneration; OCT, optical coherence tomography; PCV, polypoidal choroidal vasculopathy; QXW, every X weeks; SD, standard deviation; SRF, subretinal fluid; T&E, treat-and-extend; VEGF-A, vascular endothelial growth factor-A.