SALWEEN 1-Year Results Deep Dive

SALWEEN

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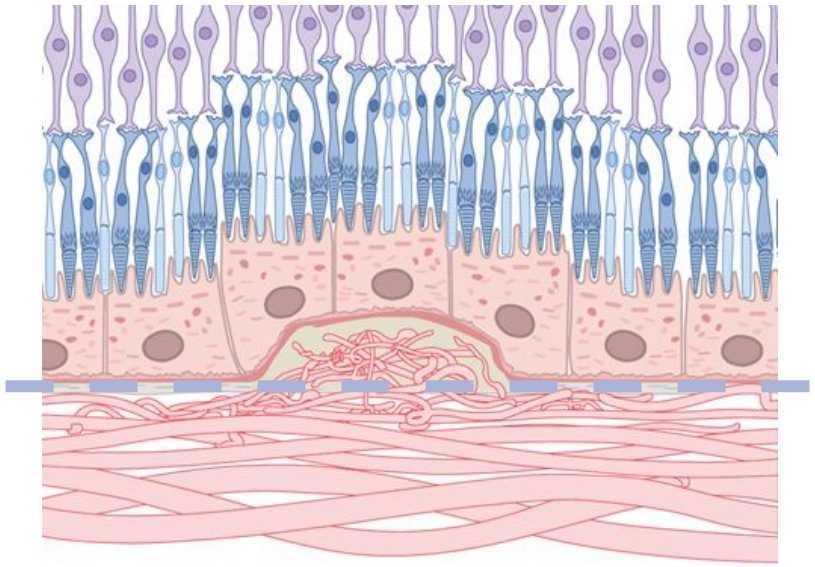
PCV is a subtype of nAMD

Polypoidal lesions are located under the Bruch's membrane and RPE [3–6]

nAMD



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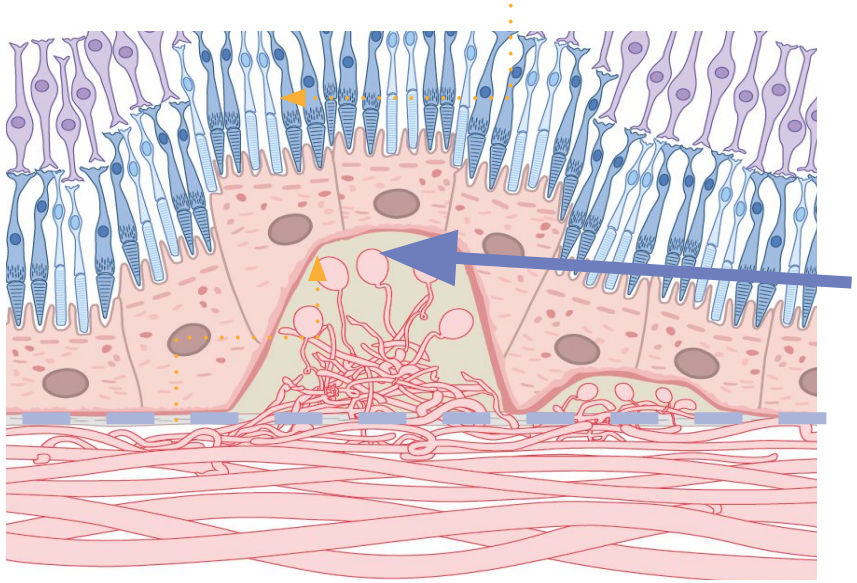

POLYPS in PCV

*PCV is diagnosed based on early subretinal ICG-A hyperfluorescence and must include at least one characteristic as described by the EVEREST II guidelines[6]

BVN, branching vascular network; CNV, choroidal neovascularisation; ICG-A, indocyanine green angiography; MNV, macular neovascularisation; nAMD, neovascular age-related macular degeneration; OCT, optical coherence tomography; PCV, polypoidal choroidal vasculopathy; PED, pigment epithelial detachment; RPE, retinal pigment epithelium

1. Spaide RF, et al. Ophthalmology. 2020;27:616–36; 2. American Academy of Ophthalmology. Choroidal neovascularization: OCT angiography findings. http://eyewiki.aao.org/Choroidal_Neovascularization%3A_OCT_Angiography_Findings [last accessed June 2022]; 3. American Academy of Ophthalmology. Polypoidal choroidal vasculopathy. http://eyewiki.aao.org/Polypoidal_Choroidal_Vasculopathy [last accessed June 2022]; 4. Schmidt-Erfurth U, et al. Br J Ophthalmol. 2014;98:1144–67; 5. Chang YS, et al. Korean J Ophthalmol. 2016;30:198–205; 6. Tan CS, et al. Br J Ophthalmol. 2015;99:624–28

Prevalence of PCV:

PCV a subtype of nAMD is highly prevalent in Asian populations (22.3–61.6%) [1] compared to Caucasians (8–13%) [3,4,5]

- PCV accounts for up to 50% of all nAMD cases among Asian patients (e.g., India: 49.7%, Singapore: 33–61%, Japan: 23–55%, Taiwan/China: 24.5–49%, South Korea: 24.6%) [2,6]

1.Asia Pacific J of Ophthalmology. 2020;9;260–8; 2. PLoS One. 2020 Apr 28;15(4):e0231901. doi: 10.1371/journal.pone.0231901. eCollection 2020.
3.Ophthalmology. 2018;125:708–24; 4.Acta Ophthalmol. 2013;91:e578–9
5.Br J Ophthalmol. 2014;98:188–94; 6. https://www.aao.org/education/topic-detail/polypoidal-choroidal-vasculopathy-pcv--asia-pacifi

Substantial unmet need exists with current treatments for PCV [1,2]

Treatment type	Disadvantages
Anti-VEGF	• Limited polyp regression (25–40%) • Multiple injections may be needed
Laser photocoagulation	• Laser limited to extrafoveal polypoidal lesions: Treating BVN may result in large scar and paracentral scotoma • High recurrence rate
PDT	• Repeated PDT may cause cumulative damage to the normal choroidal vasculature and RPE • Rare cases of acute vision loss resulting from subretinal haemorrhage, choroidal infarct and RPE tear • High cost and availability of PDT is quite challenging.

BVN, branching vascular network; ICG-A, indocyanine green angiography; PCV, polypoidal choroidal vasculopathy; PDT, photodynamic therapy; RPE, retinal pigment epithelium; VEGF, vascular endothelial growth factor

1. Ophthalmology. 2018;125:708–24 2. Ophthalmol Ther (2022) 11:1175–1186

Polypoidal Choroidal Vasculopathy (PCV) Is a Highly Prevalent Subtype of nAMD in Asia[1]

The phase 3 TENAYA/LUCERNE trials demonstrated that **individualised faricimab** dosing **controls anatomic outcomes** and **maintains vision,** with **fewer injections than aflibercept,** through 2 years in patients with **nAMD**

Patients with PCV **comprised a small proportion of the population** in the phase 3 TENAYA/LUCERNE trials

SALWEEN is evaluating the **efficacy, durability and safety** of **dual Ang-2/VEGF-A inhibition** with **faricimab** in patients with **PCV** in **Asia**

TENAYA (NCT03823287); LUCERNE (NCT03823300); SALWEEN (ISRCTN69073386). Ang-2, angiopoietin-2; nAMD, neovascular age-related macular degeneration; PCV, polypoidal choroidal vasculopathy; VEGF, vascular endothelial growth factor. 1. Chaikitmongkol V et al. *Asia Pac J Ophthalmol (Phila)*. 2020;9;260-268.

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TENAYA and LUCERNE Trial Design

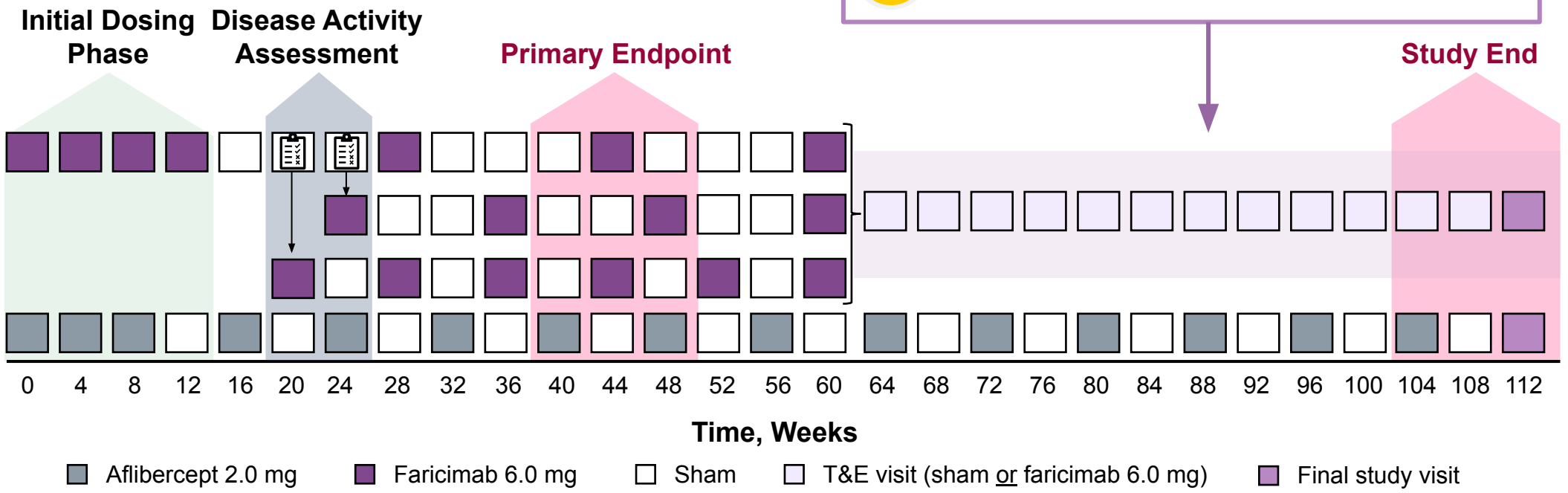
Faricimab nAMD Trials Use Disease Criteria Reflective of Clinical Practice

Disease activity assessment criteria
(at weeks 20 and 24) based on
CST OR BCVA OR new macular hemorrhage[a]

T&E Regimen (PTI per Protocol)

- Dosing **extended** (by 4 weeks, max Q16W) based on **CST AND BCVA AND macular hemorrhage[a]**
- Dosing **reduced** (by 4 or 8 weeks[b], min Q8W) based on **CST OR BCVA OR macular hemorrhage[a]**
- Dosing **maintained** if extension or reduction criteria not met

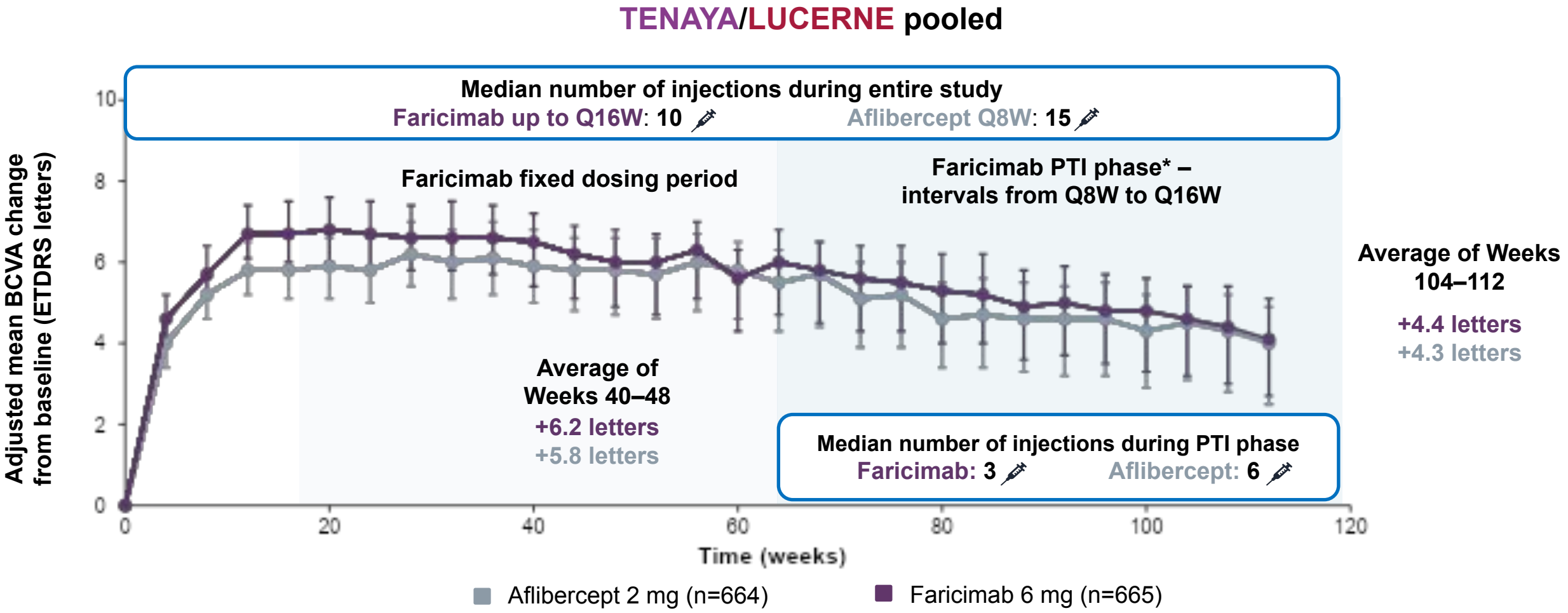
Treatment-naïve CNV secondary to nAMD
N = 1329[a]



T&E regimen in TENAYA (NCT03823287) and LUCERNE (NCT03823300) uses different criteria than those used in the YOSEMITE and RHINE clinical trials. [a] Per the investigator. [b] if ≥ 2 of the reduction criteria were met or 1 criterion includes new macular hemorrhage, 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, personalized treatment interval; Q8W, every 8 weeks; Q16W, every 16 weeks; T&E, treat-and-extend.

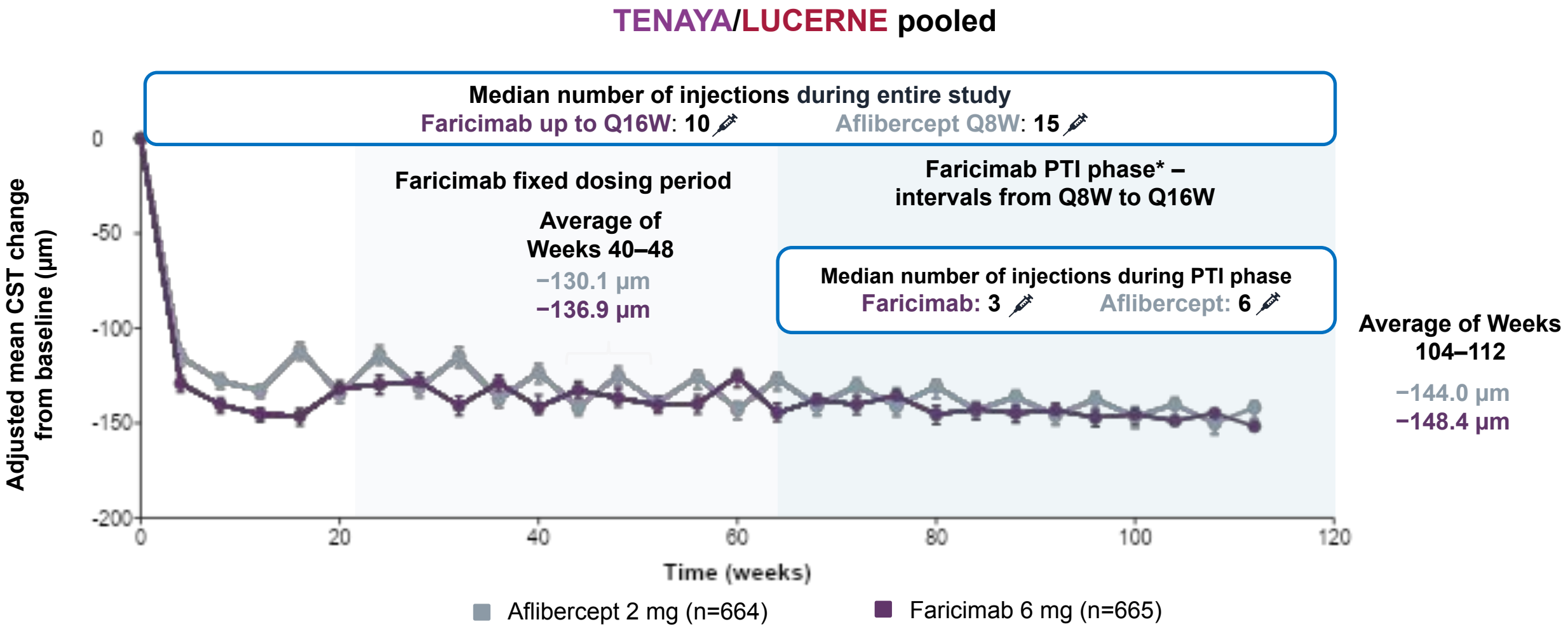
TENAYA LUCERNE

Vision gains from baseline with faricimab up to Q16W were noninferior to aflibercept Q8W at Week 48



*Lines reflect treatment interval assigned at Weeks 20/24; after Week 60, actual dosing intervals vary depending on disease activity (Q8W–Q16W)
Results are based on a Mixed-Model Repeated-Measures (MMRM) analysis, using the primary estimand strategy
BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; PTI, personalised treatment interval; QxW, every x weeks

Comparable reductions in CST through Week 112 with faricimab and aflibercept



*Lines reflect treatment interval assigned at Weeks 20/24; after Week 60, actual dosing intervals vary depending on disease activity (Q8W–Q16W)
Results are based on a Mixed-Model Repeated-Measures (MMRM) analysis, using the primary estimand strategy; CST is measured as ILM-RPE, as graded by central reading centre
CST, central subfield thickness; ILM, internal limiting membrane; PTI, personalised treatment interval; QxW, every x weeks; RPE, retinal pigment epithelium

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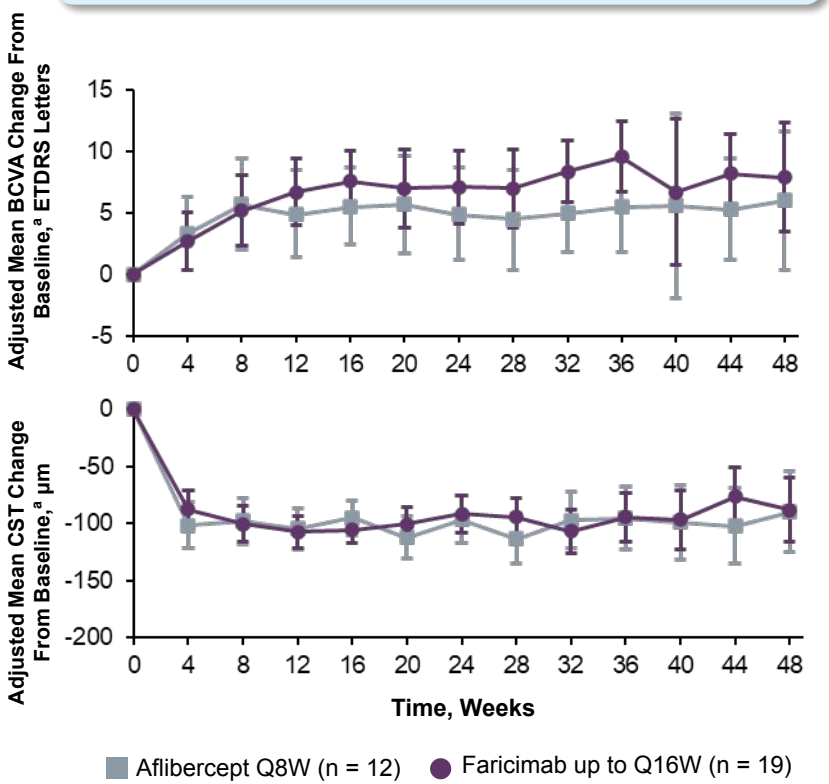
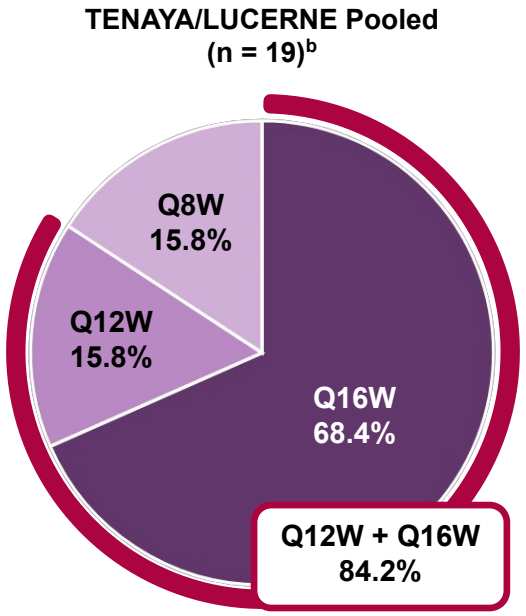
Results in patients with PCV: Efficacy of Faricimab in the PCV Subgroup of TENAYA/LUCERNE Was Consistent With the Global Results in Year 1 (Post Hoc Analysis)

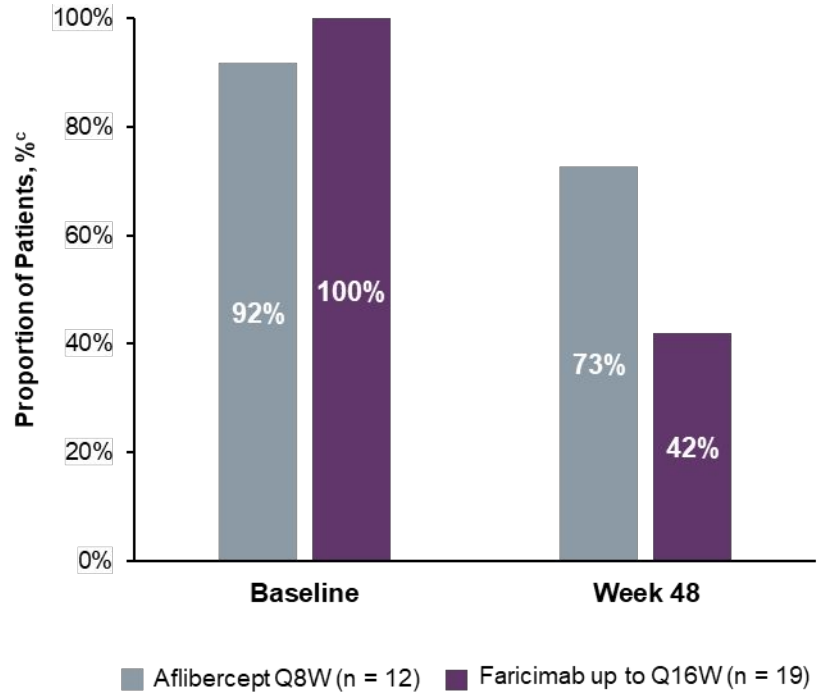
Visual Acuity and Anatomic Outcomes in PCV Subgroup



Durability in PCV Subgroup



Presence of Polypoidal Lesions in PCV Subgroup



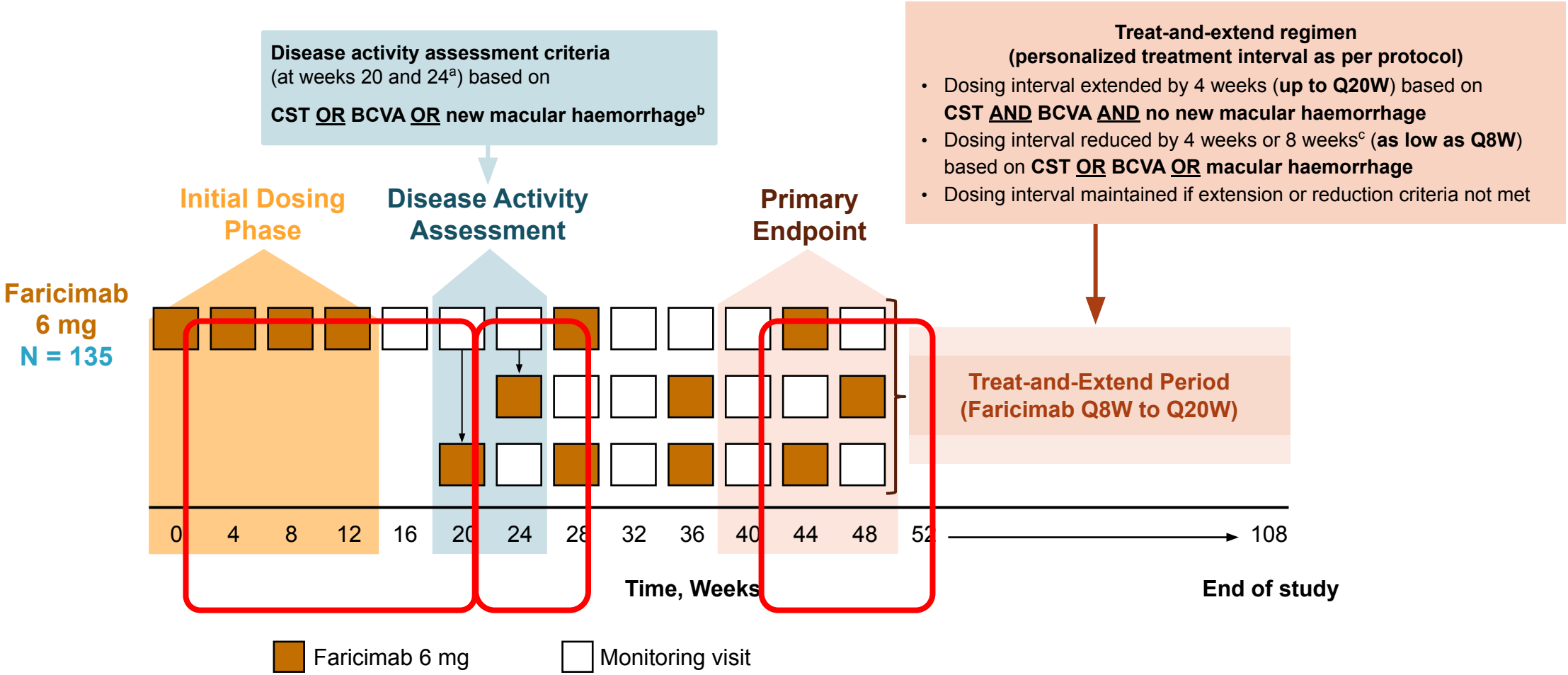
Patients with PCV composed a small proportion of the patients in the phase 3 TENAYA/LUCERNE trials (n = 31)

Includes patients from the global TENAYA/LUCERNE trials and the Japan extension study and includes Japanese, Korean and Chinese patients. [a] Adjusted mean change from baseline at 1 year. ITT population, pooled TENAYA, including Japan extension study, and LUCERNE studies. PCV status "Yes" defined per ICGA. Invalid BCVA values excluded from analysis. Assessments were censored following COVID-19–related intercurrent events. Baseline is defined as the last available value on or before randomisation. Results are based on a mixed model for repeated measures analysis. 95.00% CIs are shown. [b] Percentages are based on number of patients randomised to the faricimab arm who have not discontinued the study at week 48. [c] Judgement of PCV was made by the central reading centre. Percentages are based on the total number of patients assessed at the given time point. BCVA, best-corrected visual acuity; CST, central subfield thickness; COVID-19, coronavirus disease 2019; ETDRS, Early Treatment Diabetic Retinopathy Study; ICG-A, indocyanine green-angiography; ITT, intent-to-treat; PCV, polypoidal choroidal vasculopathy; Q8W, every 8 weeks, Q12W, every 12 weeks, Q16W, every 16 weeks.

Faricimab for Polypoidal Choroidal Vasculopathy: 1-Year Results From the Phase 3b/4 SALWEEN Trial

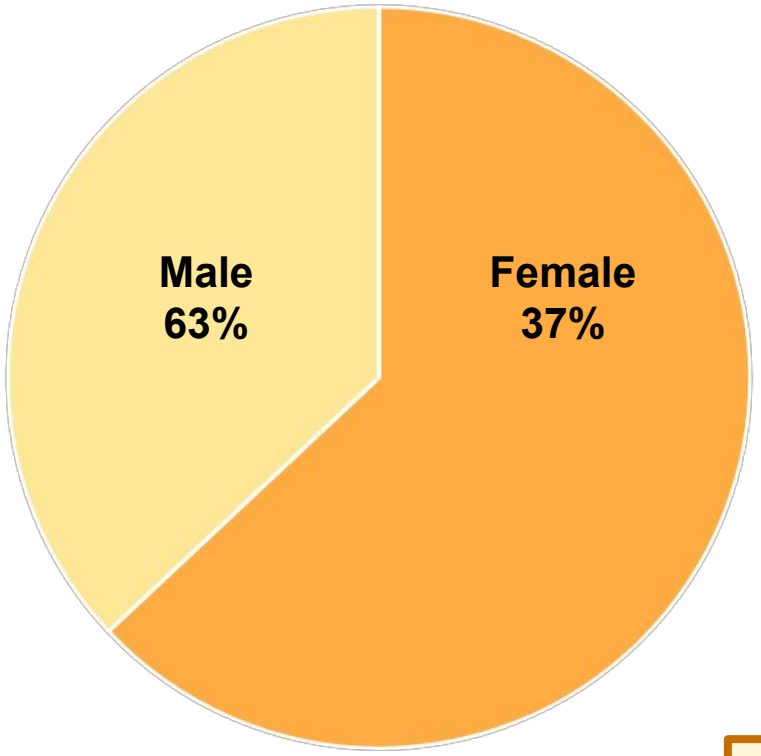
Timothy Y. Y. Lai, MD et al, Presented at the 25th EURETINA Congress | Paris, France | 4–7 September 2025

SALWEEN Study Design Is Adapted From TENAYA/LUCERNE Trial Design

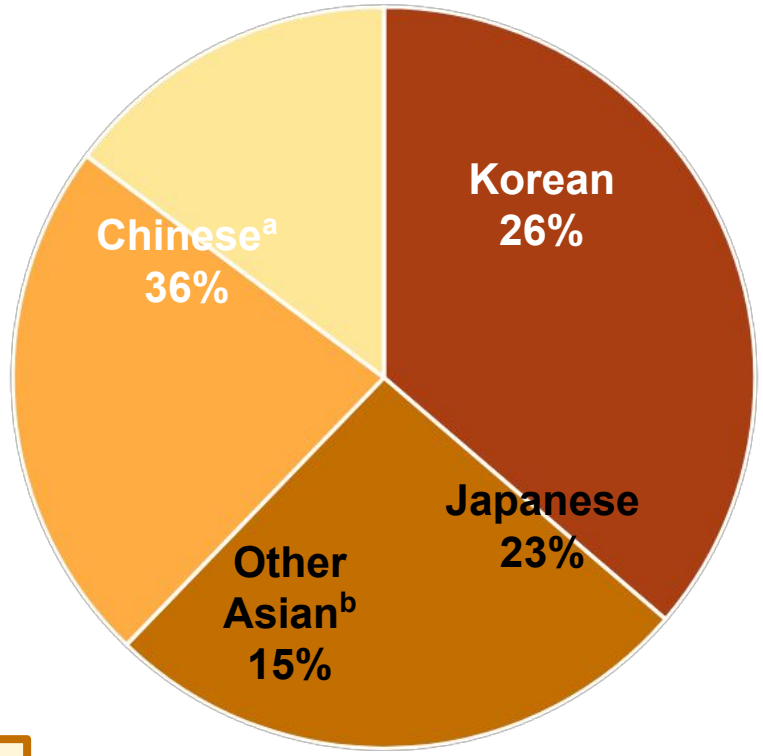


SALWEEN (ISRCTN69073386). During weeks 20–104, investigators may have the possibility to temporarily increase the frequency of study treatment to Q4W, where permitted by the local label, for patients with persistent polypoidal lesion activity who have been dosed Q8W and meet ≥ 2 criteria for treatment interval reduction. [a] Investigator opinion of significant PCV disease activity at week 24 that requires immediate treatment. [b] Due to PCV activity, as determined by the investigator. [c] If ≥ 2 of the reduction criteria are met, the interval will be reduced by 8 weeks. BCVA, best-corrected visual acuity; CST, central subfield thickness; PCV, polypoidal choroidal vasculopathy; QXW, every X weeks.

Most Patients Enrolled in SALWEEN Are Chinese, Korean or Japanese



N = 135



Age, years, mean (SD): 68.6 (8.3)

SD, standard deviation. [a] Ethnic Chinese participants from mainland China, Taiwan, Hong Kong, Malaysia and Singapore. [b] Other Asian ethnicities: Indian, Malay and Thai.

SALWEEN Key Eligibility Criteria

General inclusion criteria

- **Age ≥ 50 years**

Key ocular inclusion criteria

- **Confirmed diagnosis <u>by the investigator</u> of active symptomatic macular PCV defined by:**
  - Macular **polypoidal lesion shown by ICGA AND** presence of **exudative** or **haemorrhagic** features involving the **macula**
- **BCVA of 78–24 ETDRS letters (20/32 to 20/320 approximate Snellen equivalent)**
  - Recruitment of participants with **BCVA > 73 letters** will be **capped at 20%**

Key ocular exclusion criteria

- **Any prior or concomitant treatment** for PCV or other retinal diseases
- **Subretinal haemorrhage** of > 4 **MPS disc area** and/or that **involves the fovea**
- **Fibrosis** or **atrophy** of > 50% of the total lesion area and/or that **involves the fovea**
- **History** or **presence of macular pathology unrelated** to PCV
- **Any intraocular condition** that could **reduce** the **potential** for **visual improvement** or **require medical** or **surgical intervention** during the study

BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; ICGA, indocyanine green angiography; MPS, Macular Photocoagulation Study; PCV, polypoidal choroidal vasculopathy; Q8W, every 8 weeks; Q12W, every 12 weeks; Q16W, every 16 weeks, Q20W, every 20 weeks.

More Than 90% of Patients Completed Treatment Through Week 48

135 patients enrolled and treated with faricimab 6 mg

126 (93.3%) Completed treatment through week 48	**9 (6.7%) discontinued treatment**

9 (6.7%) discontinued treatment
- 3 adverse event
- 1 lack of efficacy
- 2 protocol deviation
- 1 withdrawal by patient
- 2 physician decision

Includes disposition events with onset up to day 346 (last day of week 48 of the time window).

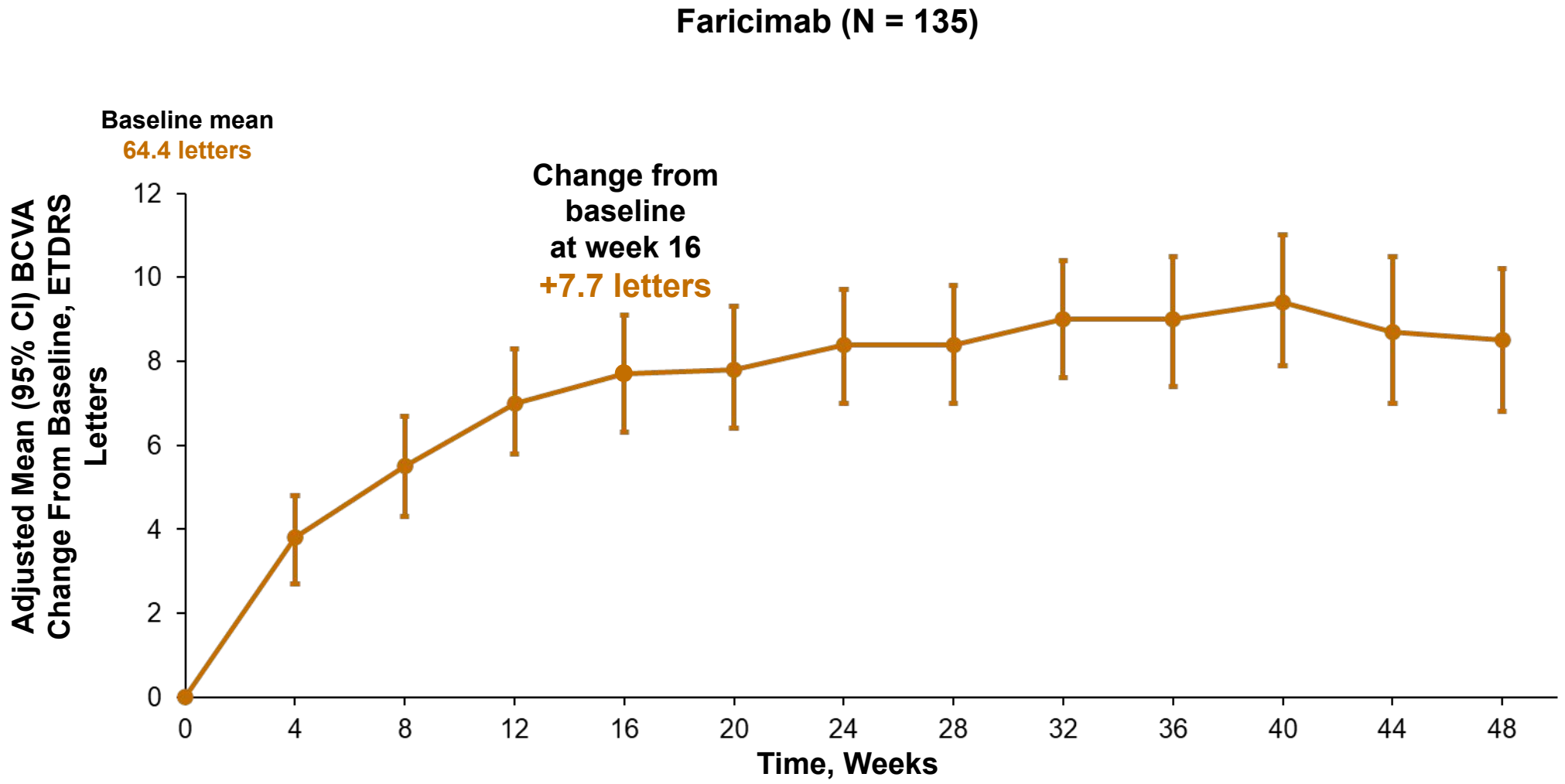
SALWEEN (ISRCTN60073886). Vector: Shutterstock used with permission. Image ID: 351089861. [a] Ethnic Chinese participants from mainland China, Taiwan, Hong Kong, Malaysia, and Singapore. [b] Other Asian ethnicities: Indian, Malay, and Thai. PCV, polypoidal choroidal vasculopathy; SD, standard deviation.

Baseline Ocular Characteristics

Characteristic	Investigator-Confirmed PCV[a] N = 135
BCVA, mean (SD), letters	64.4 (11.3)
BCVA category, n (%)	
≤ 54 (20/80 or worse)	26 (19.3)
55–73 (between 20/80 and 20/40)	86 (63.7)
≥ 74 letters (20/32 or better)	23 (17.0)
CST,[b] mean (SD), µm	417.0 (155.2)
IRF[c] present, n (%)	25 (18.5)
SRF[c] present, n (%)	105 (77.8)
PED[d] present, n (%)	132 (97.8)
Reading center–confirmed PCV, n (%)	104 (77.0)
Polypoidal lesion area,[a] mean (SD), mm^2	n = 104; 0.25 (0.26)
Branching neovascular network area, mean (SD), mm^2	n = 99; 3.28 (2.74)
Total lesion area by FFA, mean (SD), mm^2	n = 123; 8.1 (6.8)

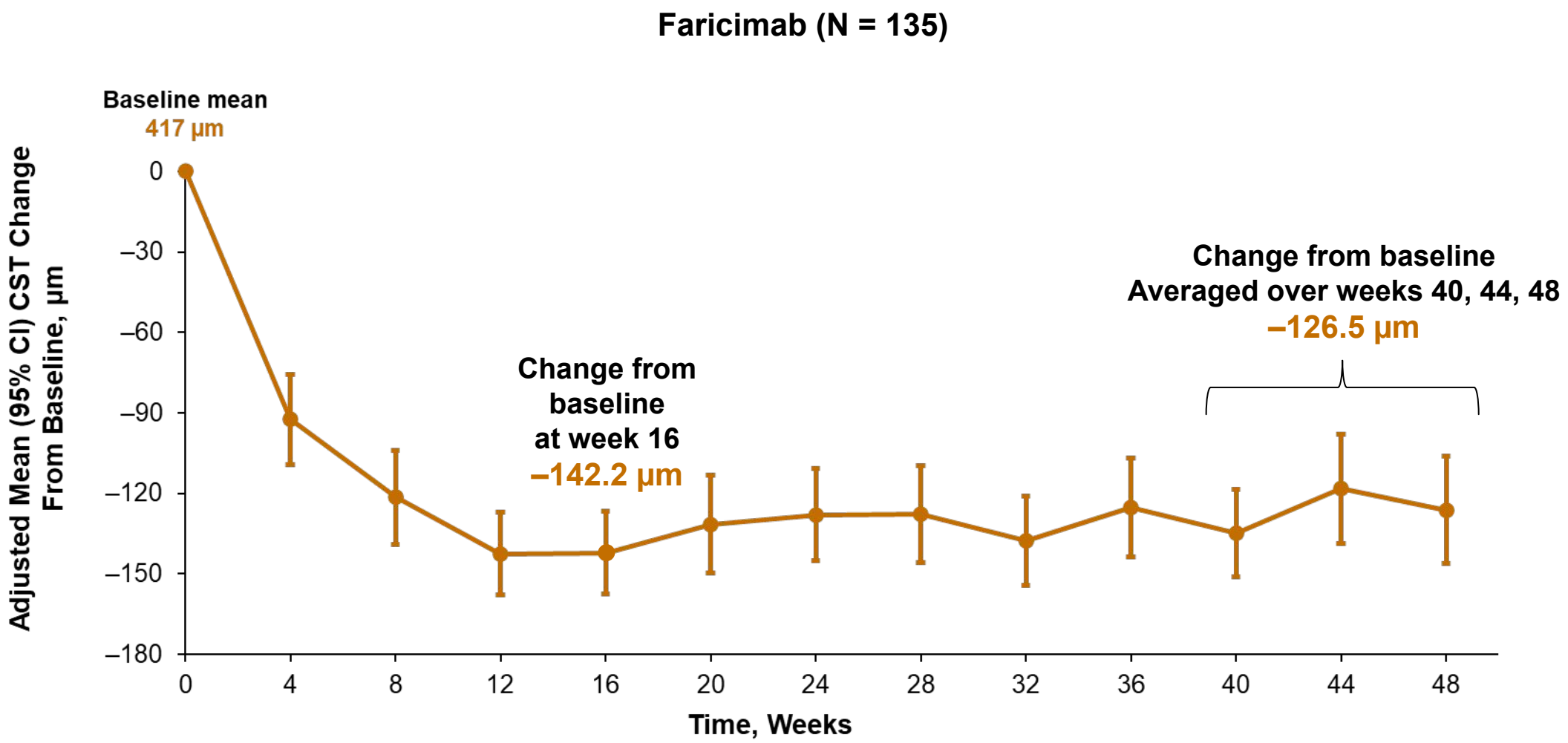
[a] Confirmed diagnosis by the investigator of active symptomatic macular PCV defined by macular polypoidal lesion shown by ICGA AND presence of exudative or haemorrhagic features involving the macula. Months since PCV diagnosis in the study eye, mean (SD): 0.67 (1.31). [b] CST is measured from ILM to BM. [c] Measured in the central subfield (centre 1 mm). [d] Measured in whole field of view. BCVA, best-corrected visual acuity; BM, Bruch's membrane; CST, central subfield thickness; FFA, fundus fluorescein angiography; ICGA, indocyanine green angiography; ILM, internal limiting membrane; IRF, intraretinal fluid; PCV, polypoidal choroidal vasculopathy; PED, pigment epithelial detachment; SD, standard deviation; SRF, subretinal fluid.

Robust BCVA Increase From Baseline Through Week 48



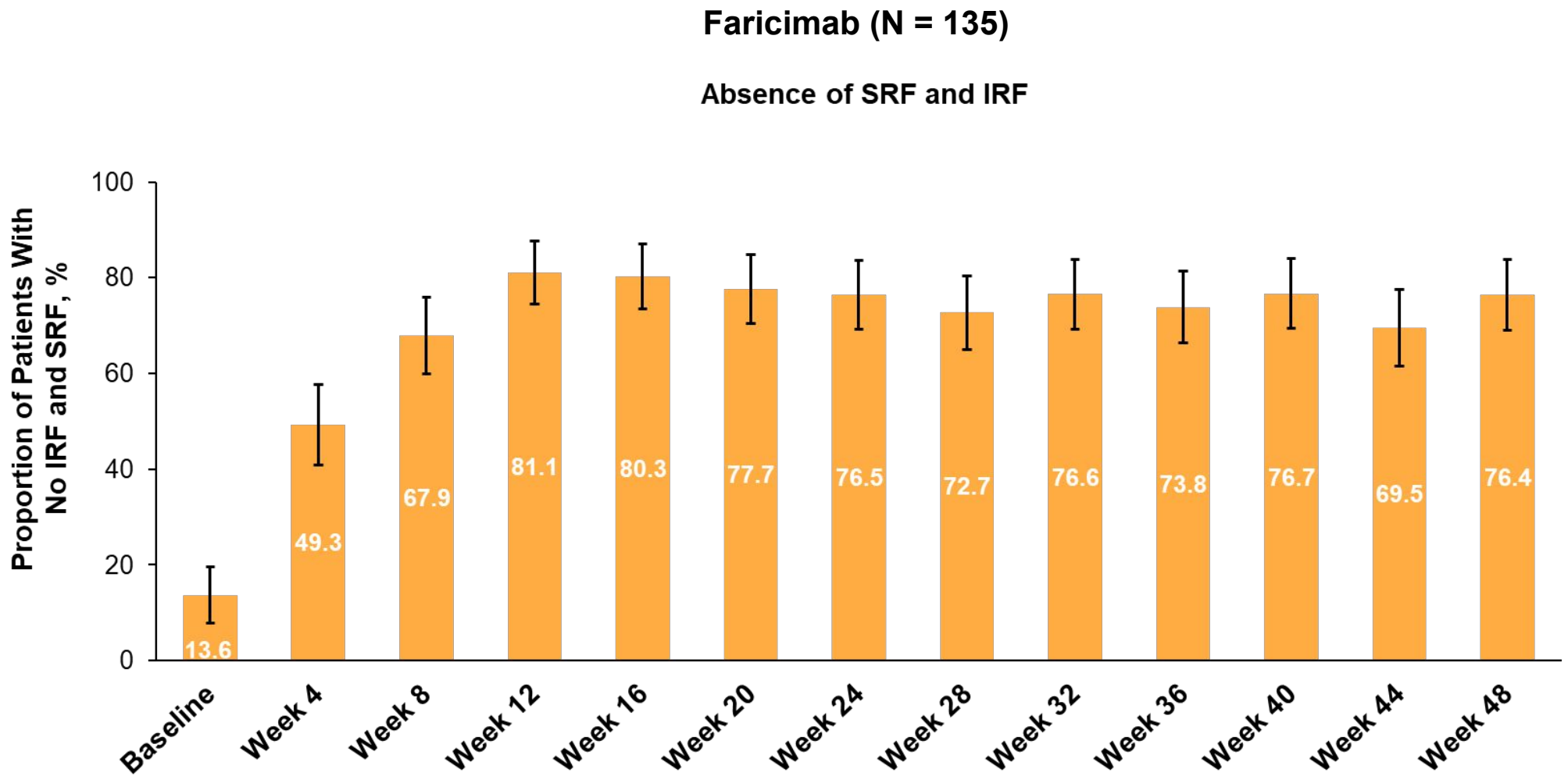
Results are based on an MMRM analysis, adjusted for visit, baseline BCVA (continuous). An unstructured covariance structure was used. Treatment policy strategy was applied to intercurrent events, except for death. Missing and unmeasurable outcomes after death were implicitly imputed by MMRM. Baseline is defined as the last available measurement obtained on or prior to first exposure to study drug. 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. BCVA, best-corrected visual acuity; CI, confidence interval; ETDRS, Early Treatment Diabetic Retinopathy Study; MMRM, mixed-effect model with repeated measures.

Clinically Relevant CST Decrease From Baseline Through Week 48



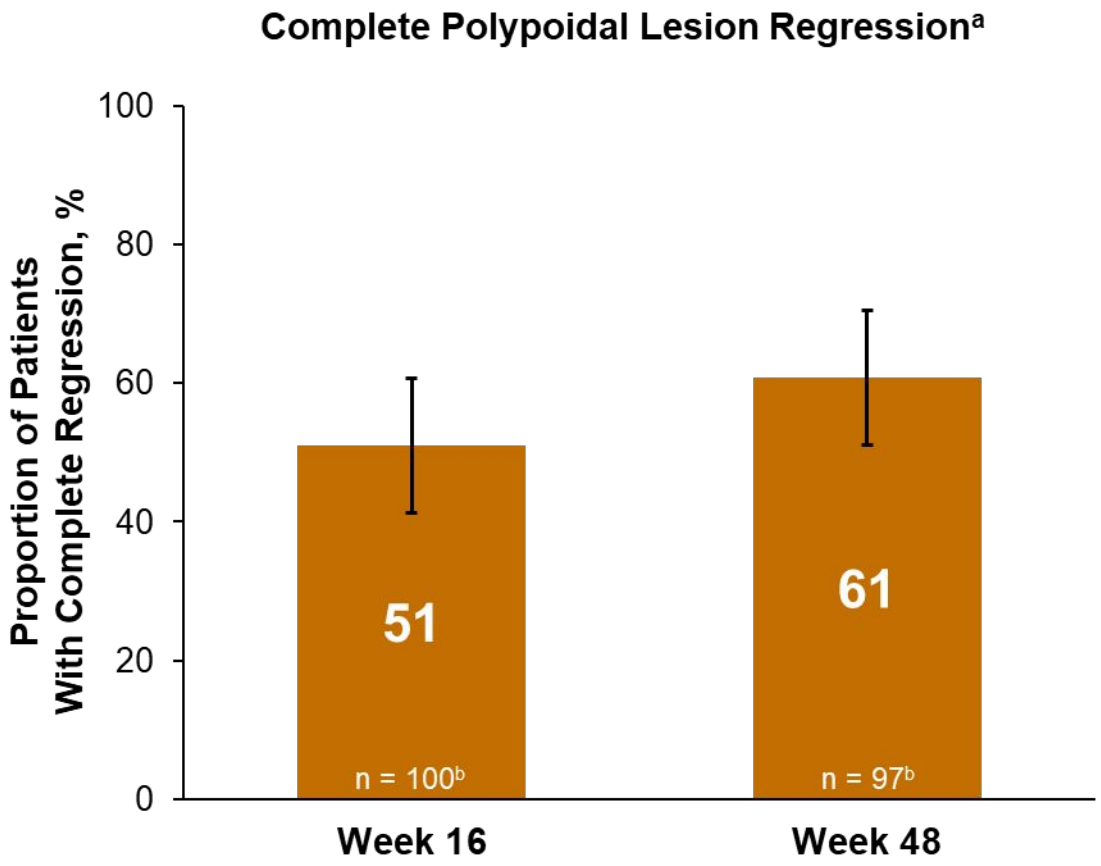
CST is defined as the distance between ILM and BM. For the MMRM analysis, the model adjusted for visit, and baseline CST (continuous). An unstructured covariance structure was used. Treatment policy strategy was applied to intercurrent events, except for death. Missing and unmeasurable outcomes after death were implicitly imputed by MMRM. Baseline was defined as the last available measurement obtained on or prior to first exposure to study drug. Includes assessments with onset up to day 346 (last day of week 48 of the time window). 95% CIs are shown. BM, Bruch's membrane; CI, confidence interval; CST, central subfield thickness; ILM, internal limiting membrane; MMRM, mixed-effect model with repeated measures.

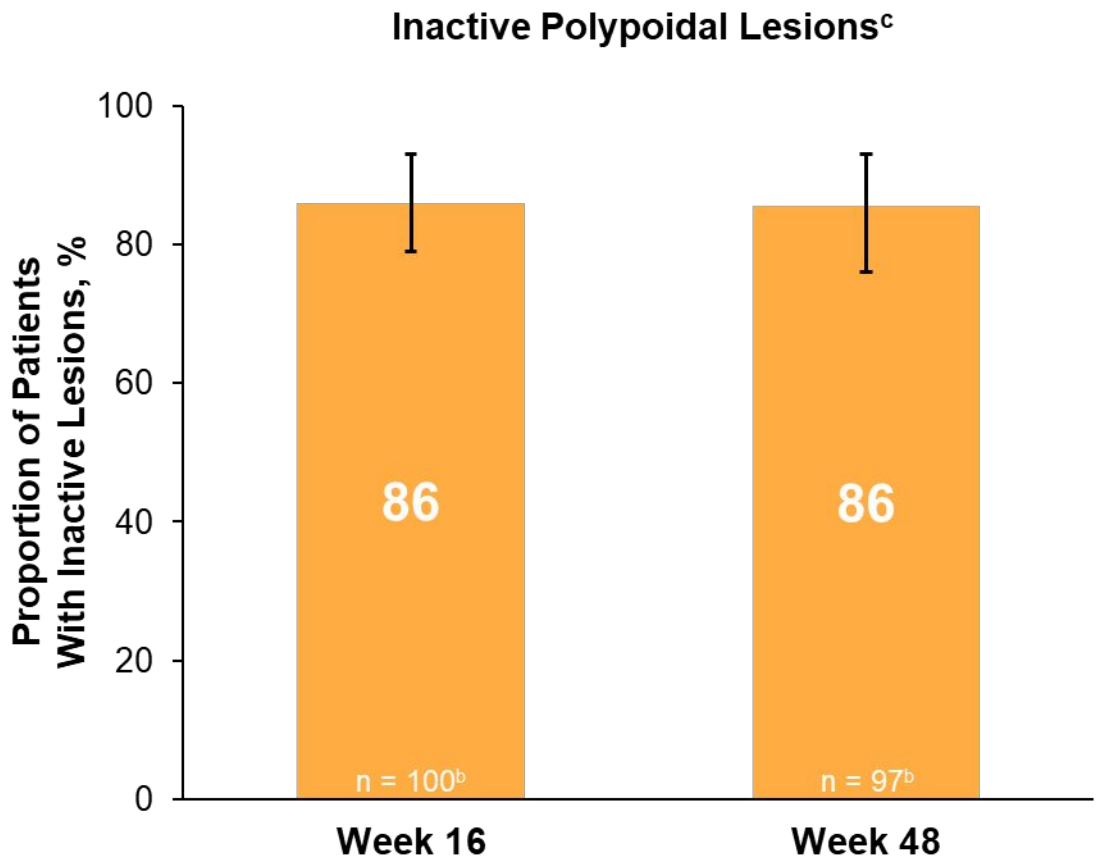
76% of Patients With Absence of Retinal Fluid at Week 48



IRF and SRF were measured in the central subfield (center 1 mm); if this is missing then the result from whole field of view assessment will be 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% are imputed as 0% or 100% respectively. Baseline is 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.
CI, confidence interval; IRF, intraretinal fluid; SRF, subretinal fluid.

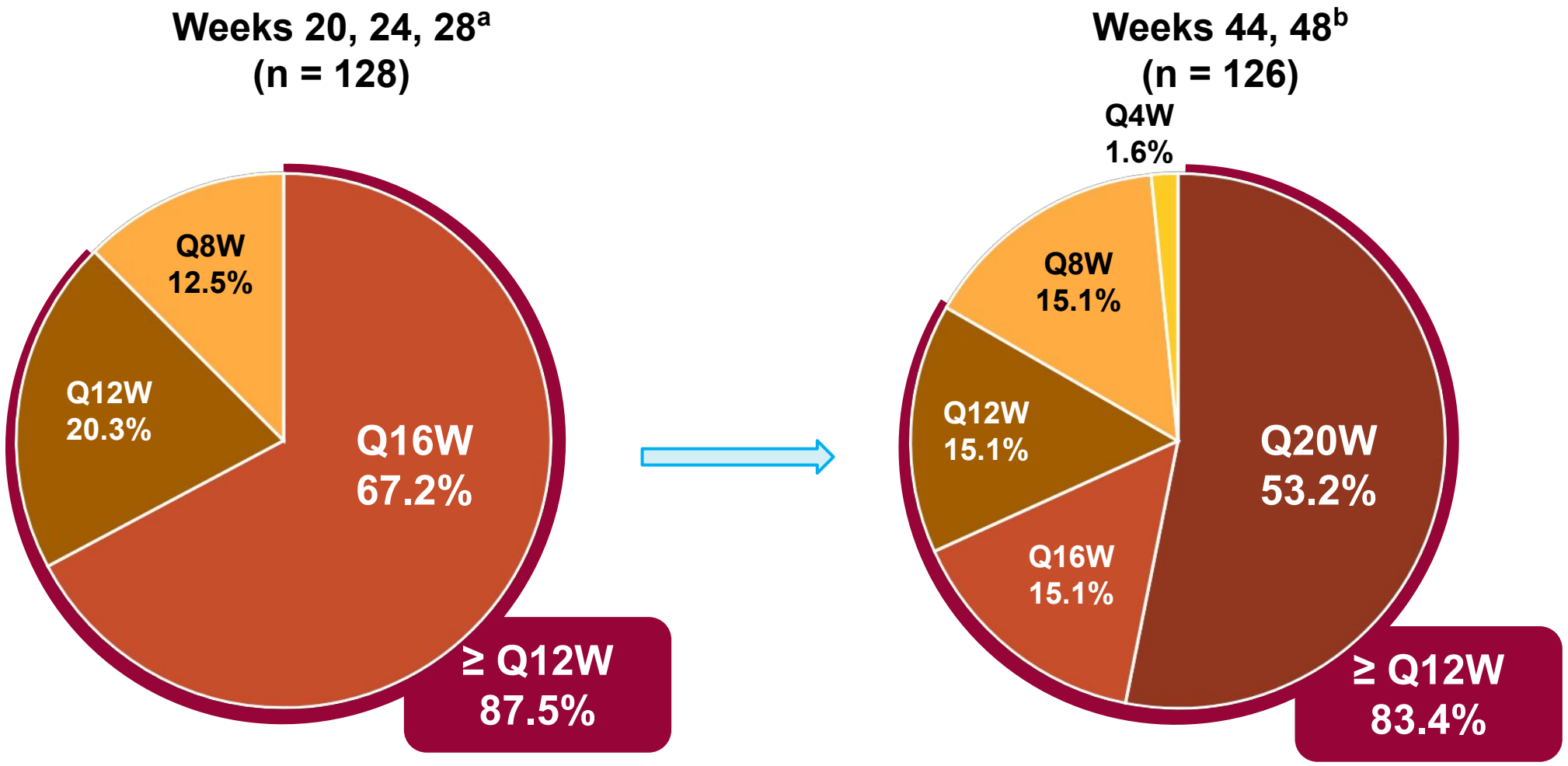
61% of PLs Had Completely Regressed and 86% Were Inactive at Week 48





[a] Based on ICGA. Complete polypoidal lesion regression is defined as patient with no polypoidal lesion at 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 lesion at screening who did not discontinued treatment before week 16/48. [c] Included patients with no polypoidal lesion in study eye at week 16/48 and patients with polypoidal lesion at week 16/48 with no IRF and no SRF at week 16/48. IRF and SRF were measured in the central subfield (center 1 mm). PL were assessed by ICGA, OCT, and FFA. FFA, fundus fluorescein angiography; ICGA, indocyanine green angiography; IRF, intraretinal fluid; OCT, optical coherence tomography; SRF, subretinal fluid.

More Than 50% of Patients Were Assigned To Faricimab Q20W Dosing Intervals at Weeks 44/48



Percentages are based on number of patients enrolled who had not discontinued the study at the specified visit. Treatment interval at a given visit is defined as the treatment interval decision followed at that visit. [a] 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] Only patients who entered the treat-and-extend phase were included. Q4W, every 4 weeks; Q8W, every 8 weeks; Q12W, every 12 weeks; Q16W, every 16 weeks; Q20W, every 20 weeks..

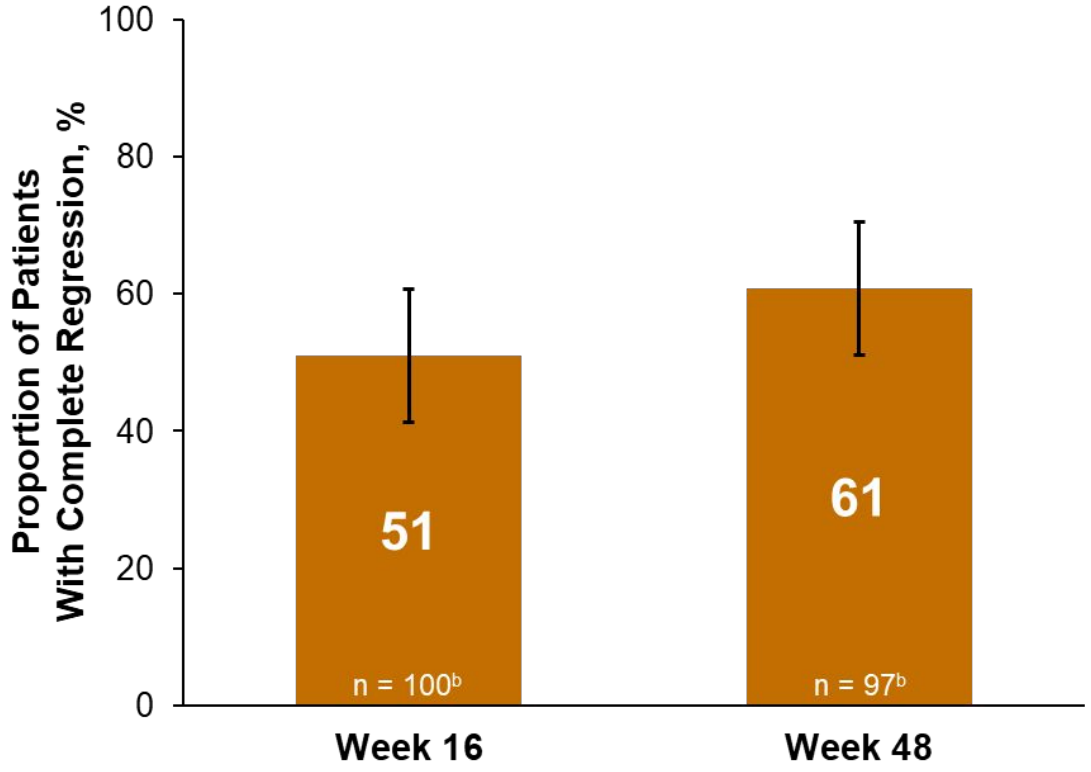
Faricimab Was Well Tolerated Through Week 48

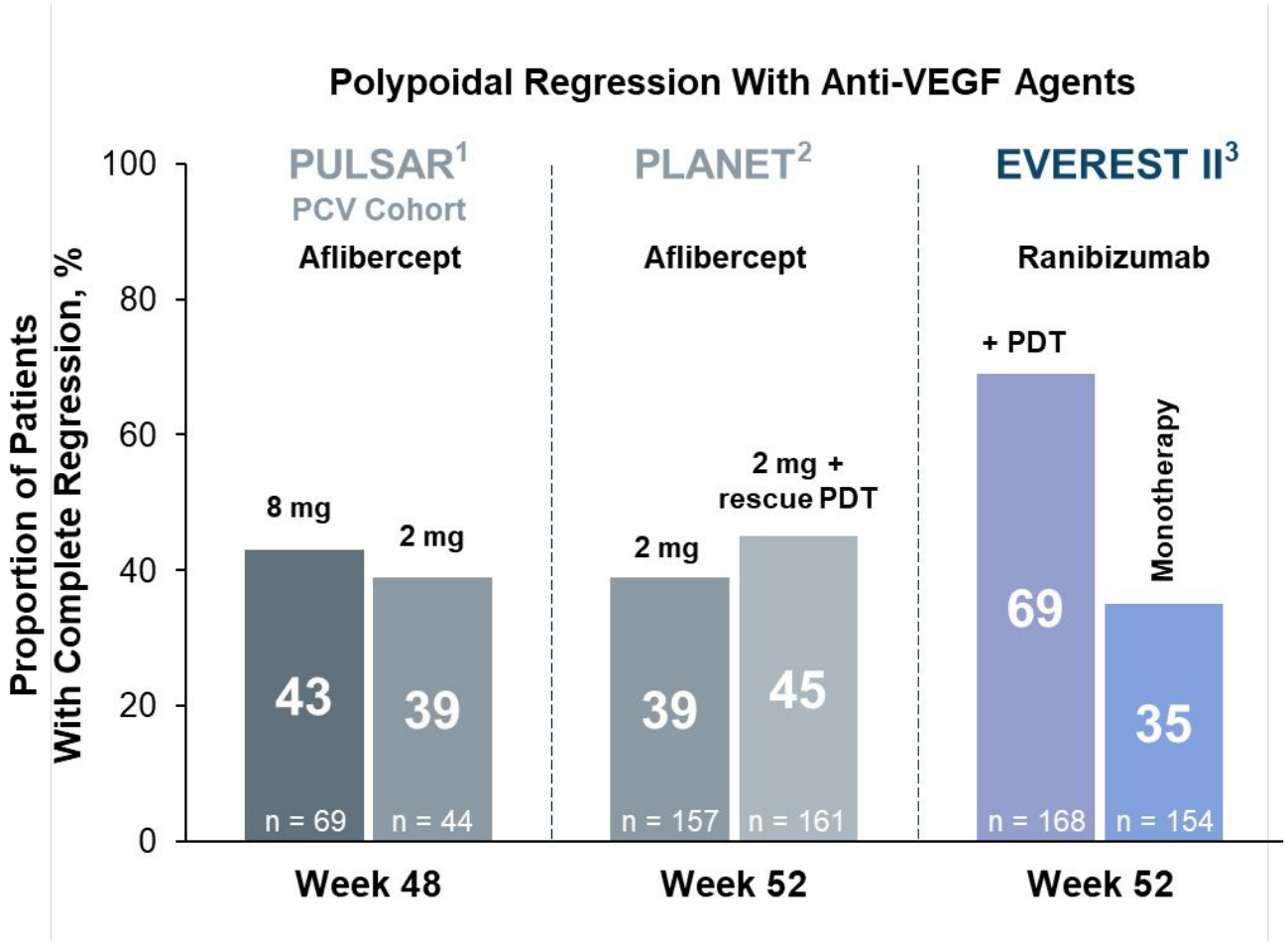
Patients With ≥ 1 Event Through Week 48, n (%)[a]	N = 135
Ocular AEs[b]	40 (29.6)
Serious ocular AEs[b]	5 (3.7)
Ocular AEs of special interest[c]	5 (3.7)
Intraocular inflammation[b,d]	4 (3.0)
Iridocyclitis	2 (1.5)
Iritis	1 (0.7)
Retinal occlusive vasculitis (diagnosis not confirmed on review by independent RC)[e]	1 (0.7)
Endophthalmitis	1 (0.7)
Retinal pigment epithelial tear	1 (0.7)
Retinal vascular occlusion	0
Serious nonocular AEs	9 (6.7)
Arterial thromboembolic events	2 (1.5)[f]
Deaths	0
Withdrawal from study due to an AE	0
Withdrawal from study treatment due to an AE	3 (2.2)

[a] Percentages are based on n values in the column headings; multiple occurrences of the same AE in an individual are counted only once. Includes AEs with onset up to day 346 (last day of week 48 of the time window). Results are based on all enrolled participants who received any amount of study medication. [b] Ocular AEs in the study eye only are presented. [c] Ocular AEs of special interest were defined as events associated with severe intraocular inflammation, events requiring surgical or medical intervention to prevent permanent loss of sight, or events associated with BCVA loss of ≥ 30 letters for > 1 hour. [d] Includes serious and nonserious IOI events; excludes endophthalmitis events. [e] On independent Duke RC image review, there was no evidence of retinal occlusive vasculitis or intraocular inflammation. [f] lacunar infarction and peripheral artery disease. AE, adverse event; BCVA, best-corrected visual acuity; RC, reading center.

Unprecedented polypoidal lesion regression for intravitreal injections after 1 year of Faricimab treatment in PCV

Cross-trial comparisons are limited by differences in trial design and definitions

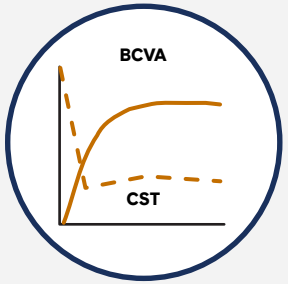




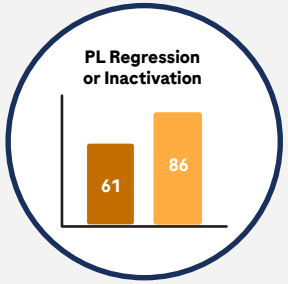
[a] Based on ICGA. Complete polypoidal lesion regression is defined as patient with no polypoidal lesion at corresponding visit. Treatment policy strategy was applied to intercurrent events, except for death. Missing and unmeasurable outcomes after death were not imputed. [b] Number of patients with polypoidal lesion at screening who did not discontinued treatment before week 16/48. ICGA, indocyanine green angiography; PCV, polypoidal choroidal vasculopathy; PDT, photodynamic therapy; VEGF, vascular endothelial growth factor. 1. Silva R et al. Presented at: 24th EURETINA Congress; September 19–22, 2024; Barcelona, Spain. 2. Lee WK et al. *JAMA Ophthalmol.* 2018;136(7):786-793. 3. Koh A et al. *JAMA Ophthalmol.* 2017;135(11):1206-1213.

Faricimab in PCV: Robust Disease Improvement Through Week 48

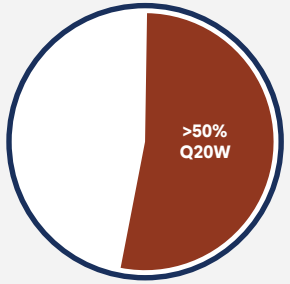
Dual Ang-2/VEGF-A inhibition with faricimab for PCV at week 48:



Showed **robust improvement in BCVA** (+8.9 letters) and **clinically relevant CST reduction**



Was associated with **complete regression** (61%) and **inactivation of polypoidal lesions** (86%) in the **majority** of eyes



Allowed **more than 50%** of patients to be assigned to **Q20W dosing**

Was **well tolerated** and consistent with the known safety profile of faricimab

Ang-2, angiopoietin-2; BCVA, best-corrected visual acuity; CST, central subfield thickness; PCV, polypoidal choroidal vasculopathy; VEGF-A, vascular endothelial growth factor-A.

Common Abbreviations and full forms

- OS- oculus sinister
- OD- oculus dexter
- OU- oculus uterque
- HM- hand movement
- CNVM- choroidal neovascular membrane
- OCT- optical coherence tomography
- OCT-A- OCT angiography
- CSME- central submacular edema
- IV- intravitreal
- MTH- month
- IOP- intraocular pressure
- VA- visual acuity
- IRF/SRF- intraretinal fluid/subretinal fluid
- HRF- hyper reflective foci
- H Ex- hard exudates
- BVN- branched vascular networks
- SR- sub retinal
- BCVA- best corrected visual acuity
- CR- central retinal
- PED- pigment epithelial detachment
- PCV- polypoidal choroidal vasculopathy
- IOL- intraocular lens
- SHRM- subretinal hyper reflective material
- FA- fluoresceine angiography
- FFA- fundus fluoresceine angiography
- DRIL – disruption of retinal inner layers
- DROL- disruption of retinal outer layers
- HAEM- haemorrhage
- ERM- epiretinal membrane
- VEGF- vascular endothelial growth factor
- DME- diabetic macular edema
- DR- diabetic retinopathy
- Ang, angiopoietin;
- nAMD, neovascular age-related macular degeneration;
- Tie2, tyrosine kinase with immunoglobulin-like domains 2;
- Yr- years
- M/F- Male/female
- HT- hypertension
- POAG- primary open angle glaucoma
- Eylea- aflibercept
- Avastin- Bevacizumab
- Vabysmo- faricimab
- NVI- neovascularization of iris
- ICG-(A)- Indocyanine green (angiography)
- HbA1c- hemoglobin A1c
- PCIOL- post chamber IOL
- NPDR- non proliferative DR
- PDR- proliferative DR
- HNRR stands for Healthy Neuro Retinal Rim
- CDR- cup disc ratio

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Input Code: M-IN-00006402
Valid Upto: 08/09/2026

Doing Now What Patients Need Next

Thank You to the Investigators and Participants at All Study Sites

- Kozawa Eye Hospital and Diabetes Center
- Kyorin University Hospital
- Nihon University Hospital
- University of the Ryukyus Hospital
- Osaka Metropolitan University Hospital
- Tokyo Medical University Hachioji Medical Center
- Nagoya City University Hospital
- Tokyo Women's Medical University Hospital
- Kagawa University Hospital
- Hyogo Medical University Hospital
- Fukushima Medical University Hospital
- Hyogo Prefectural Amagasaki General Medical Centre (Hyogo AGMC)
- West China Hospital of Sichuan University
- Tianjin Medical University Eye Hospital
- Shanghai First People's Hospital
- Shanghai Ninth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine
- Beijing Hospital of Ministry of Health
- Xiamen Eye Center of Xiamen University
- Singapore Eye Research Institute
- Tan Tock Seng Hospital
- Asan Medical Center
- Nune Eye Hospital
- Yeungnam University Medical Center
- Severance Hospital (Yonsei University Health System)
- Kim's Eye Hospital
- Kyung Hee University Hospital
- Hospital Selayang
- Hospital Shah Alam
- Taipei Veterans General Hospital
- China Medical University Hospital
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- Maharaj Nakorn Chiang Mai Hospital
- Hong Kong Eye Hospital
- Queen Mary Hospital
- L V Prasad Eye Institute