

Predictors of Outcomes at Year 1 in Patients Treated With Faricimab in TENAYA/LUCERNE

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Disclosures

Financial Disclosures

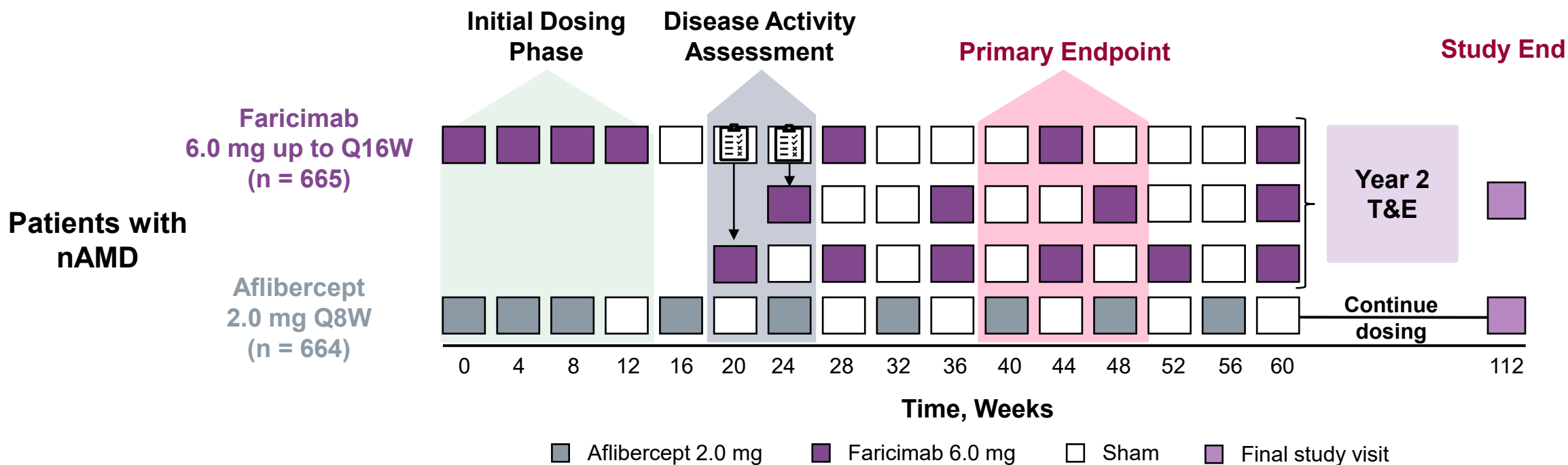
- ▶ DSD: Consultant: Alimera Science, Allergan, Apellis, Bayer, Biocryst, Coherus, Eyepoint, Genentech, Inc, Iveric Bio, Neurotech, Ocular Therapeutix, Outlook Therapeutics, Oxular, Regeneron, RegenXBio, Roche, Novartis; Stockholder: Outlook Therapeutics, Vortex Surgical
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- ▶ IS, MY: Employee: Genentech, Inc.
- ▶ LH: Consultant: Alimera, Genentech, Inc., PolyPhotonix, Recens Medical

Study and Product Disclosures

- ▶ Faricimab is approved for the treatment of neovascular age-related macular degeneration, diabetic macular edema, and retinal vein occlusion in multiple countries worldwide. Faricimab is not currently approved for use outside these indications
- ▶ This study includes research conducted on human subjects
- ▶ Institutional Review Board approval was obtained prior to study initiation
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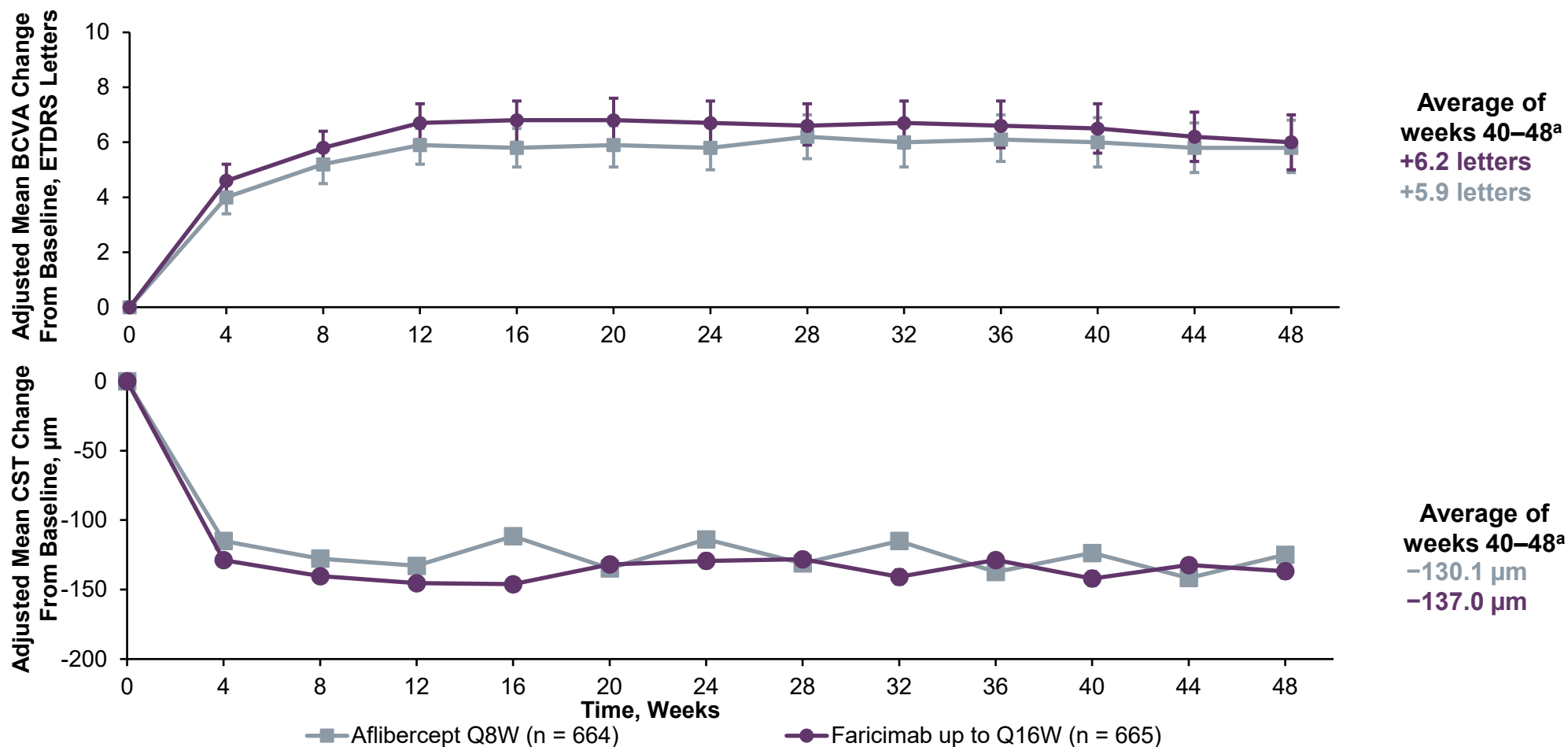


TENAYA and LUCERNE Trial Design



TENAYA/LUCERNE Year 1 Faricimab Outcomes: Improved BCVA, CST Reduction

TENAYA/LUCERNE Pooled (ITT Population)



^a Adjusted mean change from baseline at 1 year, averaged over weeks 40, 44, and 48. Results are based on a mixed model for repeated measures analysis in the ITT population. 95% CIs are shown. CST is measured as ILM-RPE, as graded by central reading center.
^b Percentages are based on number of patients randomized to the faricimab arm who have not discontinued the study at week 48. Treatment interval at week 48 is defined as the treatment interval decision followed at that visit. BCVA, best-corrected visual acuity; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; ILM, internal limiting membrane; ITT, intent to treat; Q8W, every 8 weeks; Q16W, every 16 weeks; RPE, retinal pigment epithelium.



Aim: To determine if baseline characteristics and/or early treatment response predict year 1 treatment interval, visual acuity, and anatomic outcomes among patients in the faricimab arm



Variables Included in Analyses

Predictors

Baseline Characteristics

Anatomic

- CST (ILM-BM)
- PED^a (presence)
- SRF^b (thickness, presence)
- IRF^b (presence)
- CNV lesion type
- CNV lesion size

Demographics

- Ethnicity
- Race
- Sex
- Age
- BMI
- Smoking status

Vision

- BCVA
- LLD

Disease Risk Factors

- Cardiac disease
- Vascular disease

Early Response

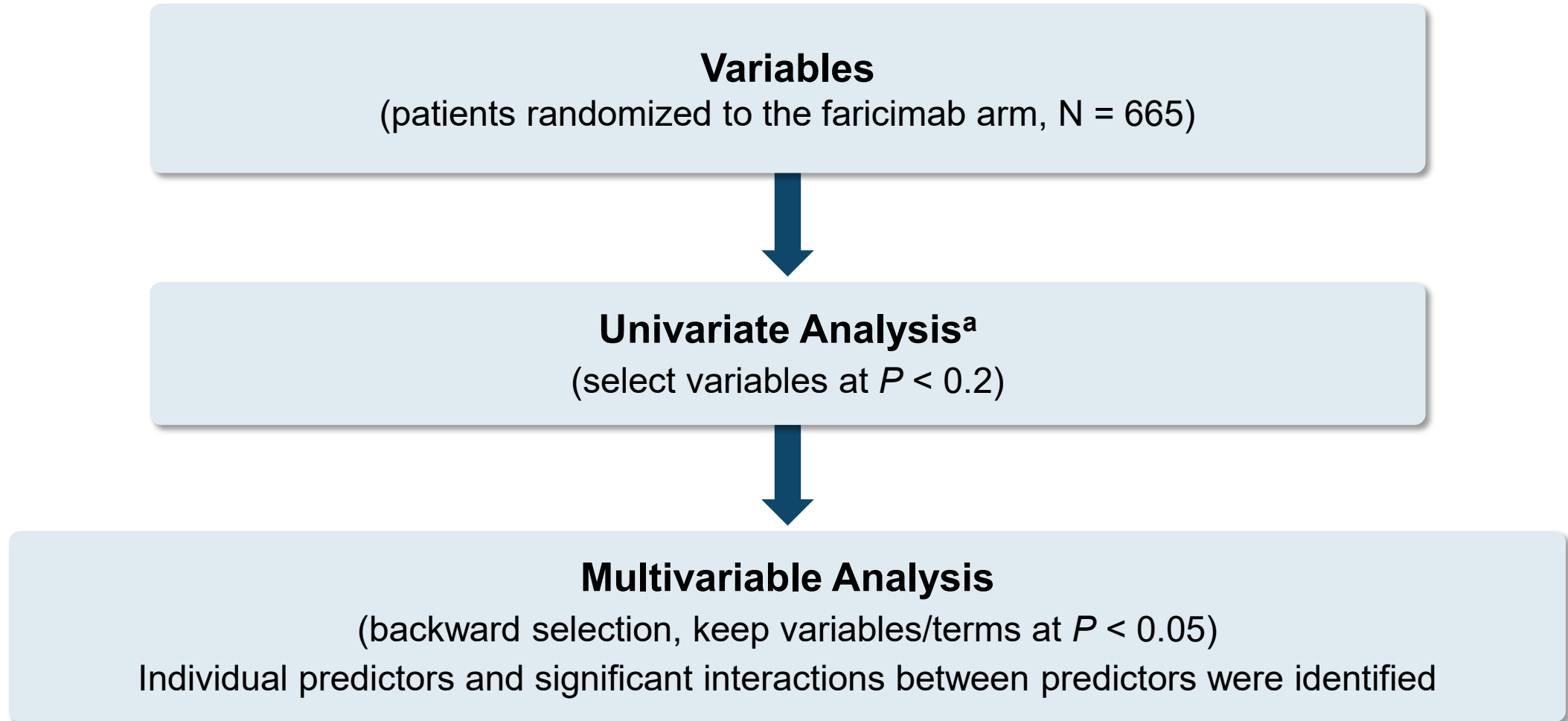
- BCVA \geq 76 and CST \leq 350 μ m at week 4

Year 1 Outcomes

- Faricimab treatment interval
 - Q8W, Q12W, or Q16W
- Change from baseline in BCVA^c
- Change from baseline in CST^c



Predictor Analysis Flow Chart



^a Logistic regression or linear regression was used for treatment interval at year 1, as were change from baseline in BCVA and CST, respectively. BCVA, best-corrected visual acuity; CST, central subfield thickness.



Predictors of Treatment Interval at Year 1

Univariate Analysis (variables significant at $P < 0.2$)

- Early response ($P = 0.04$)
- BCVA ($P = 0.005$)
- CNV lesion size ($P = 0.0004$)
- CST ($P < 0.0001$)
- SRF full form ($P = 0.10$)
- SRF thick foveal center full form ($P = 0.01$)
- LLD ($P = 0.08$)



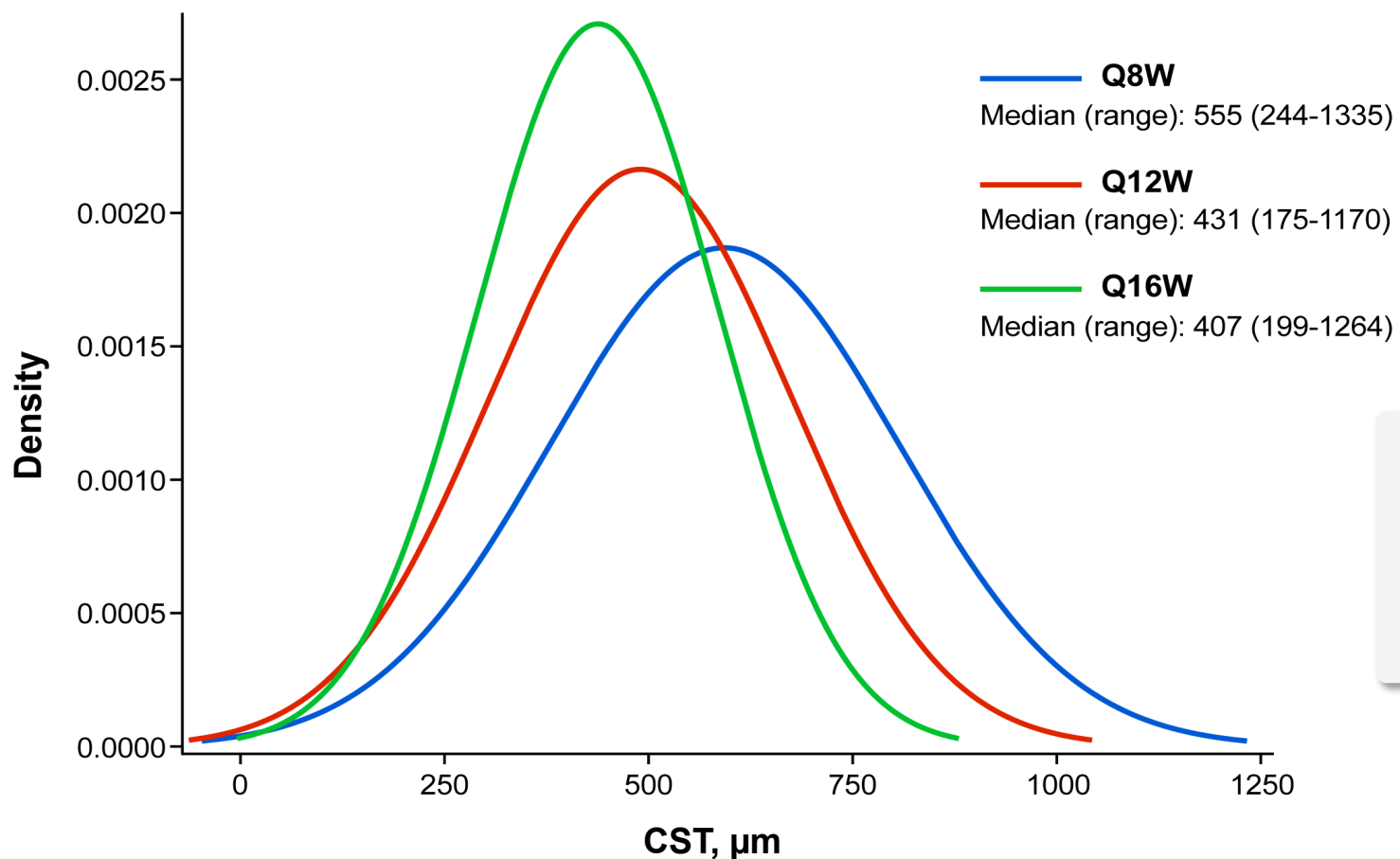
Multivariable Analysis (variables significant at $P < 0.05$)

- CST ($P = 0.0382$)



On Average, Eyes on Q8W Dosing at Year 1 Had Higher Baseline CST vs Eyes on Q12W or Q16W

Baseline CST Distribution by Treatment Interval at Year 1



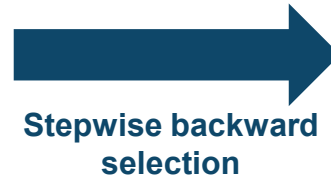
- Odds ratio (95% CI) for 50-µm increase in baseline CST:
 - Q8W vs Q12W: 1.13 (1.07, 1.20)
 - Q8W vs Q16W: 1.26 (1.18, 1.34)



Predictors of BCVA Change From Baseline at Year 1

Univariate Analysis (variables significant at $P < 0.2$)

- Pigment epithelial detachment
- Cardiac disease risk factor
- Early response
- BCVA
- CNV lesion type
- CNV lesion size
- LLD
- CST

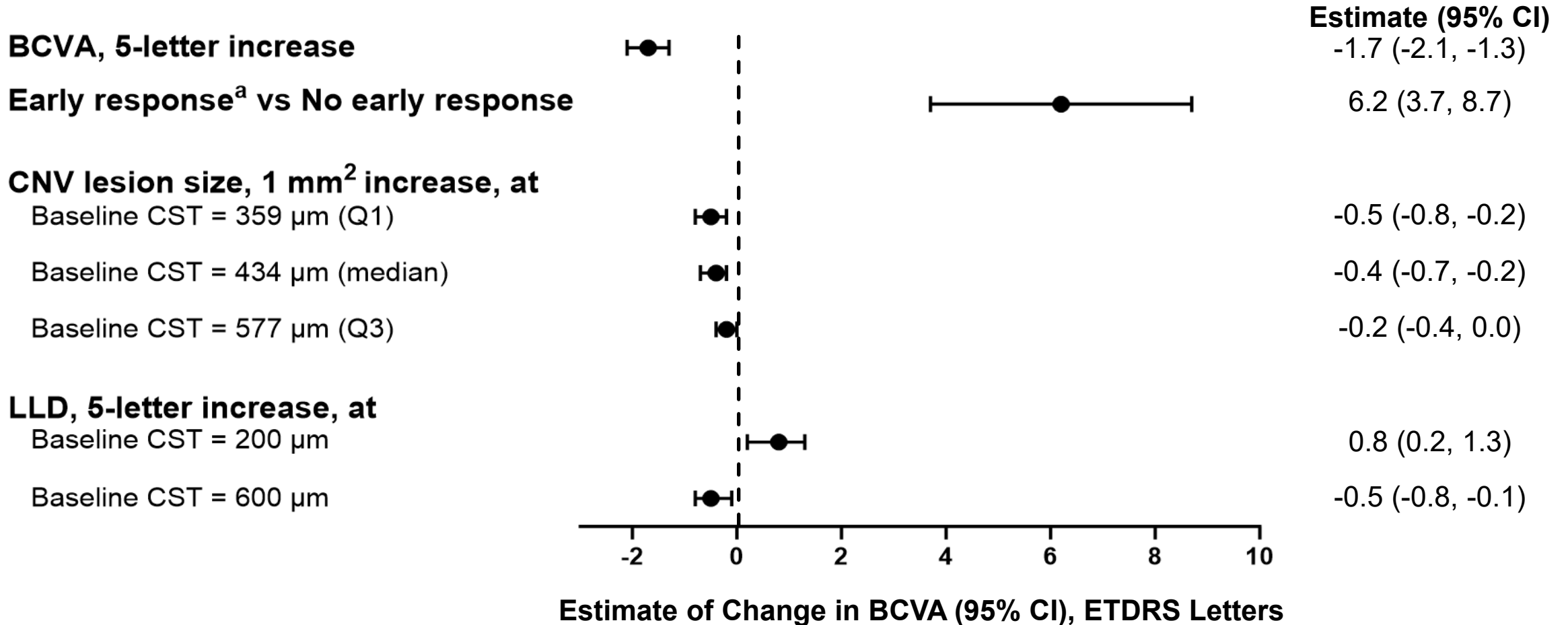


Multivariable Analysis (variables significant at $P < 0.05$)

- Early response
- BCVA
- CNV lesion size
- LLD
- Interaction between CST and:
 - LLD
 - CNV lesion size



Predictors of BCVA Change From Baseline at Year 1



^a Defined as BCVA ≥ 76 and CST ≤ 350 μm at week 4 (ie, after 1 injection).

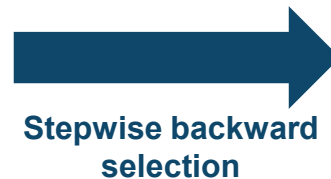
BCVA, best-corrected visual acuity; CI, confidence interval; CNV, choroidal neovascularization; CST, central subfield thickness; Early Treatment Diabetic Retinopathy Study; LLD, low luminance deficit; Q, quartile.



Predictors of CST Reduction From Baseline at Year 1

Univariate Analysis (variables significant at $P < 0.2$)

- Sex
- Age
- Ethnicity
- Pigment epithelial detachment absence
- Vascular disease risk factor
- Early response
- BCVA
- CNV lesion type
- CNV lesion size
- CST
- IRF presence
- IRF absence
- SRF absence
- LLD

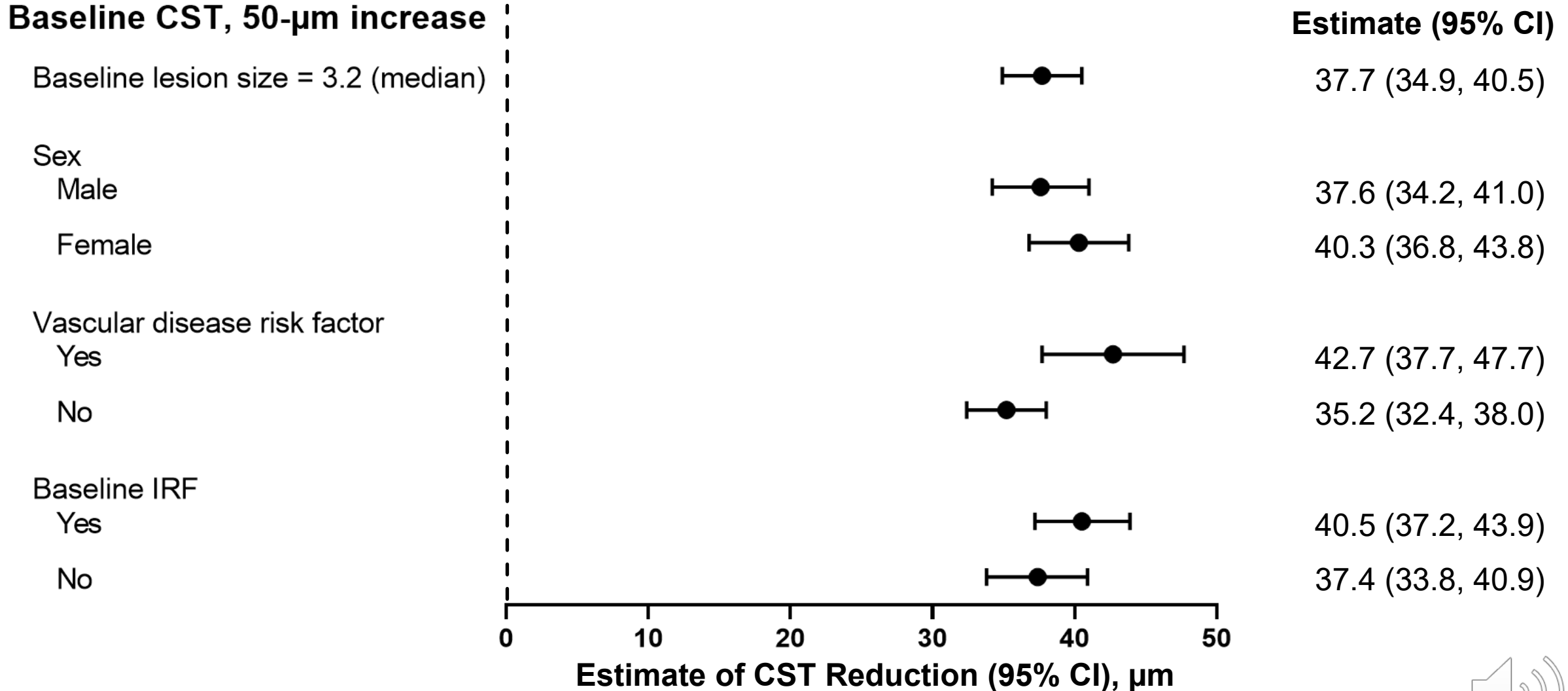


Multivariable Analysis (variables significant at $P < 0.05$)

- **CST**
- **CNV lesion size**
- **Interaction between CST and:**
 - **Sex**
 - **CNV lesion size**
 - **Vascular disease risk factor**
 - **IRF absence**
- **Interaction between BCVA and vascular disease risk factor**



Predictors of CST Reduction From Baseline at Year 1



Select Baseline Characteristics and Early Treatment Response Predicted Year 1 Outcomes in nAMD Faricimab Patients

Treatment Interval



- ▶ Baseline CST was the only identified predictor

BCVA Change



- ▶ Baseline BCVA
- ▶ Lesion size and LLD (dependent on CST)
- ▶ Good early response to treatment^a predicted better vision

CST Reduction



- ▶ Baseline CST (dependent on sex, vascular disease risk, IRF)

Patients with thicker retinas at baseline or those who respond early may have better outcomes

^a BCVA \geq 76 and CST \leq 350 μ m at week 4.

BCVA, best-corrected visual acuity; CST, central subfield thickness; IRF, intraretinal fluid; LLD, low luminance deficit; nAMD, neovascular age-related macular degeneration.

