Suprachoroidal Delivery of Investigational Surabgene Lomparvovec (Sura-vec*, ABBV-RGX-314): Results in NPDR at 2.5 Years

The Phase II ALTITUDE® study

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*Sura-vec is an investigational product that has not been approved by any regulatory authority. No conclusions regarding the safety and efficacy of the product can be made.

Disclosures

4DMT: C
Adverum Biotech: C
AiViva: C
Alcon: C, G
Aldeyra: C
Alimera: C
Alkahest: C
Allegro: C, O
Allergan: C, G
Allgenesis: C
Amydis: C
Annexon: C
Apellis: C
AGTC: C
AsclepiX: C
Ashvattha: C
Aviceda: C
Bausch + Lomb: C
Bayer: C
Biovisics: C
Boehringer Ingelheim: C
Cell Care: C
Chengdu Kanghong: C
Clearside Bio: C
Curacle: C
Delsitech: C
EyePoint: C
Genentech: C, G
Glaukos: C
jCyte: C
IvericBio: C
Kriya: C
Kyowa Kirin: C
Lineage Cell: C
LumiThera: C
Nanoscope: C
Neurotech: G
NGM Bio: C
Novartis: C, G
Ocular Therapeutix: C
Ocugen: C
Oculis: C
Ocuphire: C
OcuTerra: C
Ocutrx: C
Opthea: C
Optigo: C
Optos: C
Oxurion: C
Palatin: C
Pfizer: C, G
REGENXBIO, Inc.: C
Regeneron: C, G
RetinAI Medical AG: C
Ripple: C
Roche: C
Sanofi: C
Santen: C, G
Stealth Bio: C
Surrozen: C
Syneso : C
Thea Labs: C
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Vitranu: C
Vitro Bio: C
ViviVision: C

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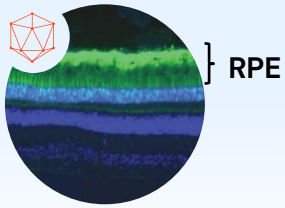
Investigational In-office Surabgene Lomparvovec (sura-vec) for the Treatment of Diabetic Retinopathy (DR)

Sura-vec Product Candidate

NAV® VECTOR AAV8



- Efficient gene delivery to the RPE[1]
- Improved AAV vector technology

+

Sura-vec transgene anti-VEGF mAb fragment (fab)

FDA-approved anti-VEGF mAb fabs are current standard of care for DR complications

=

Sura-vec
AAV8 encoding anti-VEGF fab

Potential for long-term therapeutic anti-VEGF expression

Mechanism of Action

Reducing leaky blood vessel formation by giving ocular cells the ability to produce an anti-VEGF fab

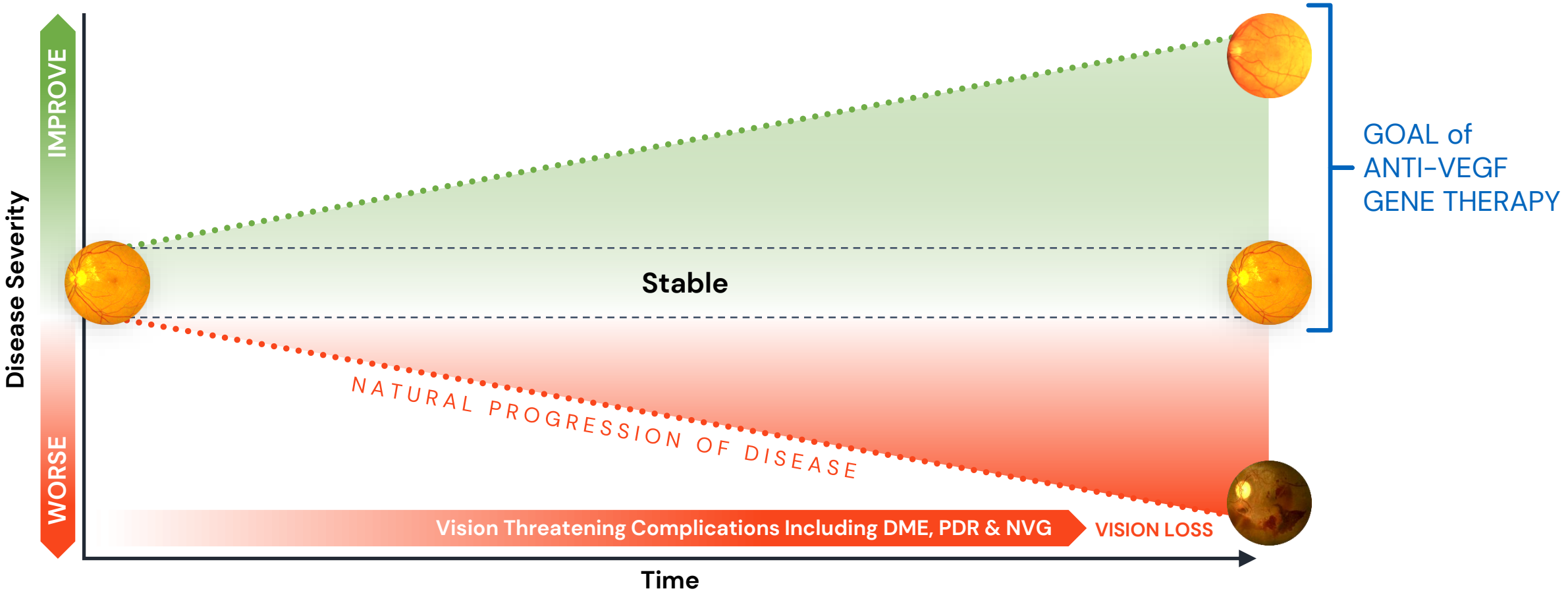
Suprachoroidal Administration[2](SCS)

- Targeted access and broad transduction of the retinal cells observed in preclinical studies
- Compartmentalized AAV delivery
- Minimal exposure to the vitreous and anterior segment

1. Vandenberghe et al. 2011 Science Translational Medicine. 2 Ding, K., et al. 2019 Journal of Clinical Investigation.
AAV: Adeno-associated virus; RPE: Retinal pigment epithelium; VEGF: Vascular endothelial growth factor; SCS: Suprachoroidal Space.

The Goal of a One-time, In-office SCS-injection of Gene Therapy

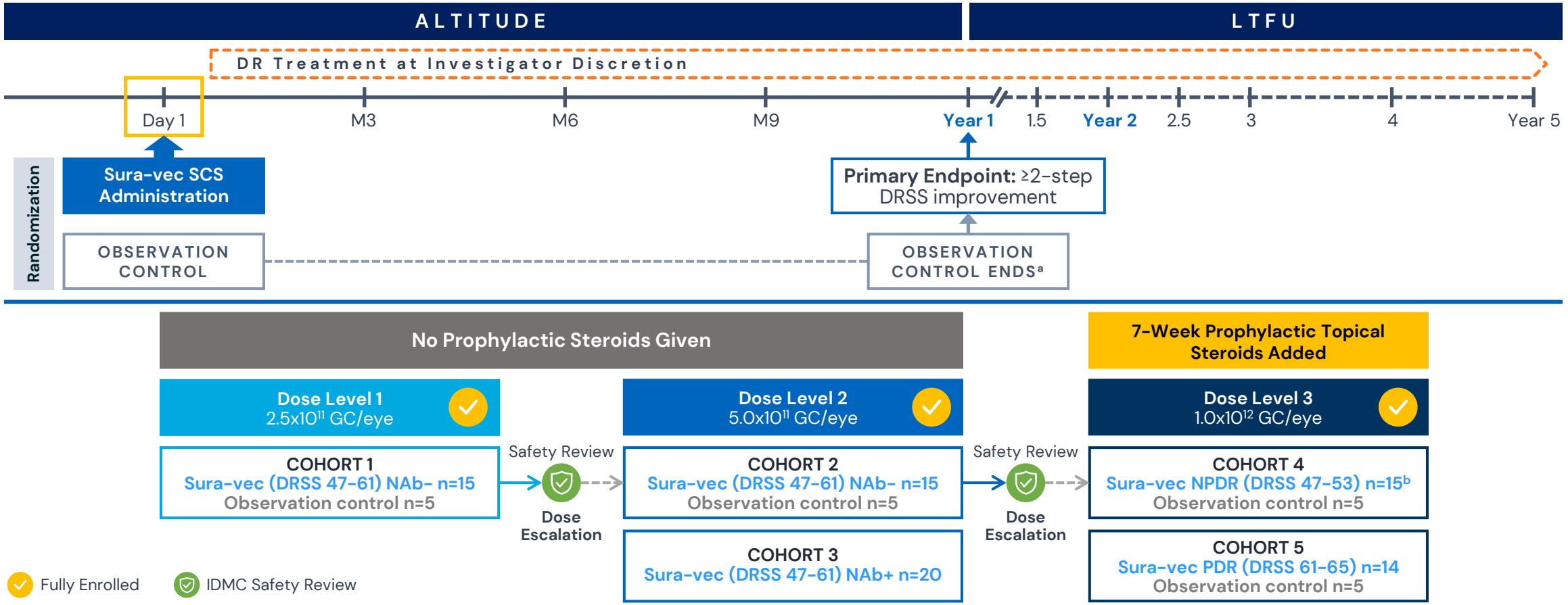
To Provide Long-lasting Improvement in DR Severity and Reduce Risk of Vision-threatening Complications



DR = Diabetic Retinopathy.
DME = Diabetic Macular Edema.
NVG = Neovascular Glaucoma.
PDR = Proliferative Diabetic Retinopathy.
VEGF = Vascular Endothelial Growth Factor.

Phase II ALTITUDE® Part 1 Study Design

Sura-vec for the Treatment of Diabetic Retinopathy



Presentation will focus on NPDR Population

a. Control subjects were encouraged to cross over to receive sura-vec. b. One subject in Dose Level 3 was randomized and dosed but was later found to have disease at baseline that confounded efficacy outcome assessment.
CI-DME: Center-involved diabetic macular edema; DR: Diabetic Retinopathy; DRSS: Diabetic Retinopathy Severity Scale; GC: genome copies; IDMC: Independent Data Monitoring Committee LTFU: long-term follow-up; M: month; NAb+: AAV8 neutralizing antibody positive; NAb–: AAV8 neutralizing antibody negative/low; NPDR: non-proliferative diabetic retinopathy; PDR: proliferative diabetic retinopathy; SCS: suprachoroidal space; Year 1 = 48 weeks; Sura-Vec: surabgene lomparvovec.

Adapted from Wykoff, AAO 2025

Baseline Characteristics

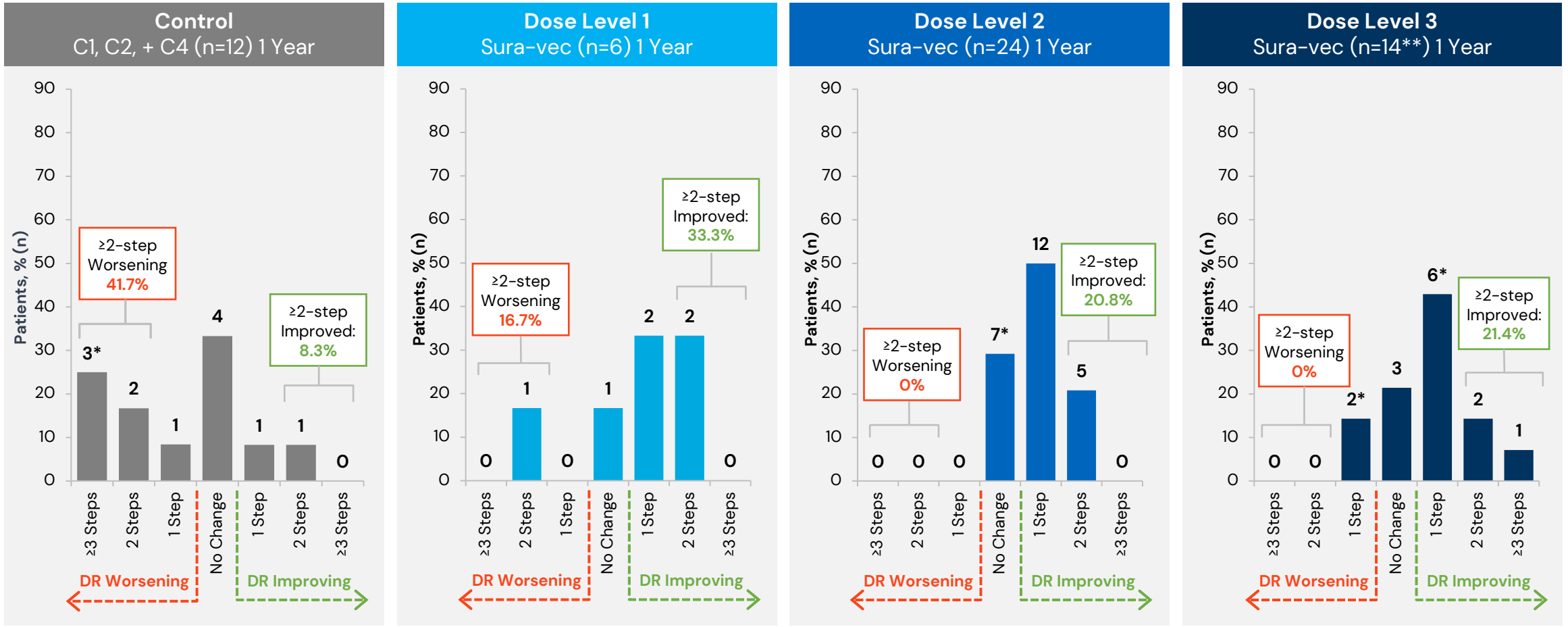
NPDR (DRSS 47–53)

	VARIABLE	Observational Control (N=12)	Dose Level 1 (N=6)	Dose Level 2 (N=24)	Dose Level 3 (N=14[b])	Total (N=56)
BASELINE[a]	**Mean Age** (Years)	54.9	57.2	60.1	54.4	**57.2**
	Gender – Female	3 (25.0%)	4 (66.7%)	10 (41.7%)	4 (28.6%)	**21 (37.5%)**
	Hemoglobin A1c- Mean	7.7	7.9	7.8	7.7	**7.7**
	DR Category at Baseline DRSS 47 (Moderately Severe NPDR) DRSS 53 (Severe NPDR)	 12 (100.0%) 0	 4 (66.7%) 2 (33.3%)	 21 (87.5%) 3 (12.5%)	 10 (71.4%) 4 (28.6%)	 **47 (83.9%)** **9 (16.1%)**
	Screening BCVA (ETDRS letters)	85.3	74.7	83.0	80.1	**81.9**
	Screening OCT CRT (µm)	273.7	250.5	272.2	279.4	**272.0**
	Lens Status – Phakic n (%)	10 (83.3%)	5 (83.3%)	15 (62.5%)	13 (92.9%)	**43 (76.8%)**
	Subjects That Completed the Study (1Y)	12	6	24	14[b]	**56**
	Subjects That Entered LTFU	n/a	6	20	12	**38**

Data cut: Jun 09, 2025.
a. Ocular variables refer to study eye only.
b. One subject in Dose Level 3 was randomized and dosed but was later found to have disease at baseline that confounded efficacy outcome assessment.
BCVA: best corrected visual acuity; CRT: central retinal thickness; DR: Diabetic retinopathy; DRSS: Diabetic Retinopathy Severity Scale: ETDRS: Early Treatment Diabetic Retinopathy Study; NPDR: non-proliferative diabetic retinopathy; OCT: optical coherence tomography; LTFU: long-term follow-up; Y: year.
This is an interim analysis performed by REGENXBIO for an ongoing trial.

Change in DRSS at 1 Year

Dose Level 2 and 3 Sura-vec Treated Subjects Outperform Control with Similar Outcomes at 1 Year



Data cut: June 09, 2025. LOCF (Last Observation Carried Forward) data.
*Includes one subject who received on-study anti-VEGF. **One subject in Dose Level 3 was found to have confounding disease at baseline and their data was excluded.
One subject each in Dose Levels 1 and 2 missed their 1-Year visit, so their 6-month results were used.
C: Cohort; DR: diabetic retinopathy; DRSS: Diabetic Retinopathy Severity Scale; Sura-Vec: surabgene lomparvovec; VEGF: vascular endothelial growth factor; Y: year.
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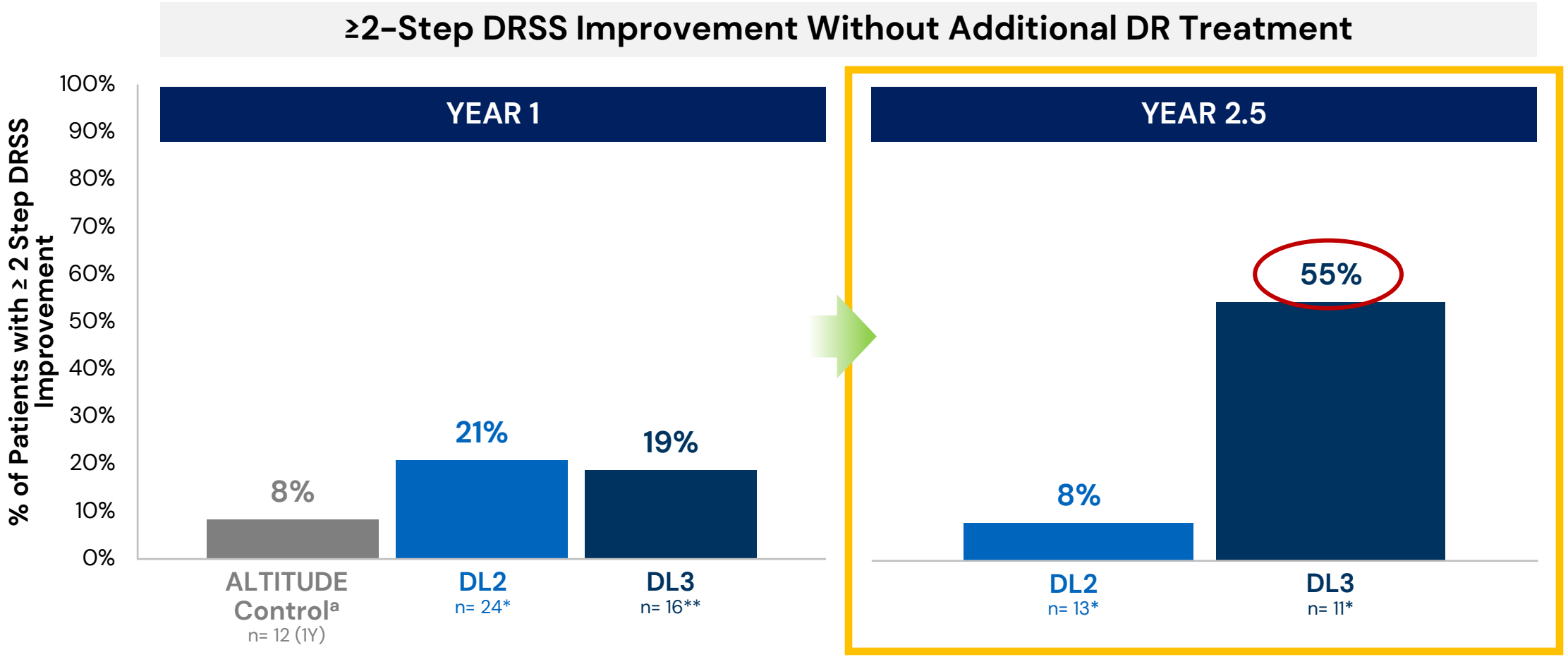
Adapted from Wykoff, AAO 2025

Dose Level 3 Sura-vec Outperforms Dose Level 2 at 2.5 Years

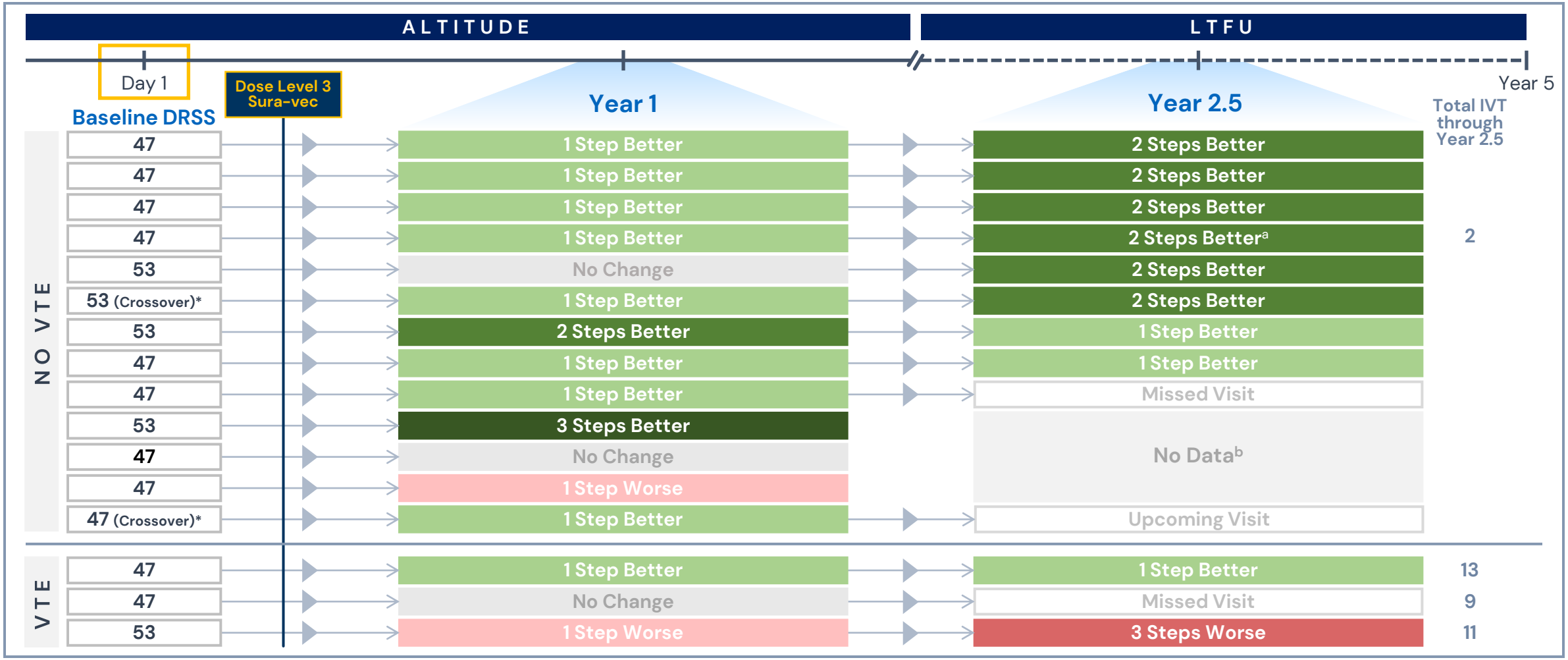
Dose Level 3 Advances as the Pivotal Dose



Data cut: May 25, 2026.
*Includes 1 subject who crossed over from control; **Includes 2 subjects who crossed over from control.
Control subjects were eligible to cross over to receive sura-vec at Year 1. Subjects who were DRSS 47 and 53 at crossover are included in the treatment arm analyses.
One subject in Dose Level 2 missed their 1-Year visit. One subject in Dose Level 3 was found to have confounding disease at baseline and their data was excluded. One subject In Dose Level 3 without IVT missed their 2Y visit but had a 2-Step DRSS improvement at their 2.5Y visit. DL: Dose Level; DR: diabetic retinopathy; DRSS: Diabetic Retinopathy Severity Scale; IVT: intra-vitreal therapy; Sura-Vec: surabgene lomparvovec; Y: year.
This is an interim analysis performed by REGENXBIO for an ongoing trial.

55% Achieved ≥2-Step Improvement without Additional DR Treatment at 2.5 Years

> 70% of Pivotal Dose Subjects Did Not Experience a VTE



Data cut: May 25, 2026. *Control subjects were eligible to cross over to receive sura-vec at Year 1. Subjects who were DRSS 47 and 53 at crossover are included in the treatment arm analyses (n=2).
a. Subject received 2 IVT after Y2 for DME, but OCT showed dry retina at the time of injection. Subject was receiving IVT for FE DME. b. One subject enrolled in long-term follow-up and had no return visits. One subject in Dose Level 3 was found to have confounding disease at baseline and their data was excluded.
VTEs = VTCs + CI-DME; VTCs could include PDR or ASNV ; DR: diabetic Retinopathy; DRSS: Diabetic Retinopathy Severity Scale; FE: Fellow eye; IVT: intra-vitreal therapy: Sura-Vec: surabgene lomparvovec.
This is an interim analysis performed by REGENXBIO for an ongoing trial.

Cumulative Safety Summary

Dose Levels 1–3 Through 2.5 Years: NPDR (DRSS 47–53)

Sura-vec safety in Dose Levels 1, 2 and 3 NPDR subjects (n=50)*

- 29 SAEs: none considered drug-related
- No cases of vasculitis, occlusion, hypotony, or chorioretinitis
- Zero IOI with short course of prophylactic topical steroids

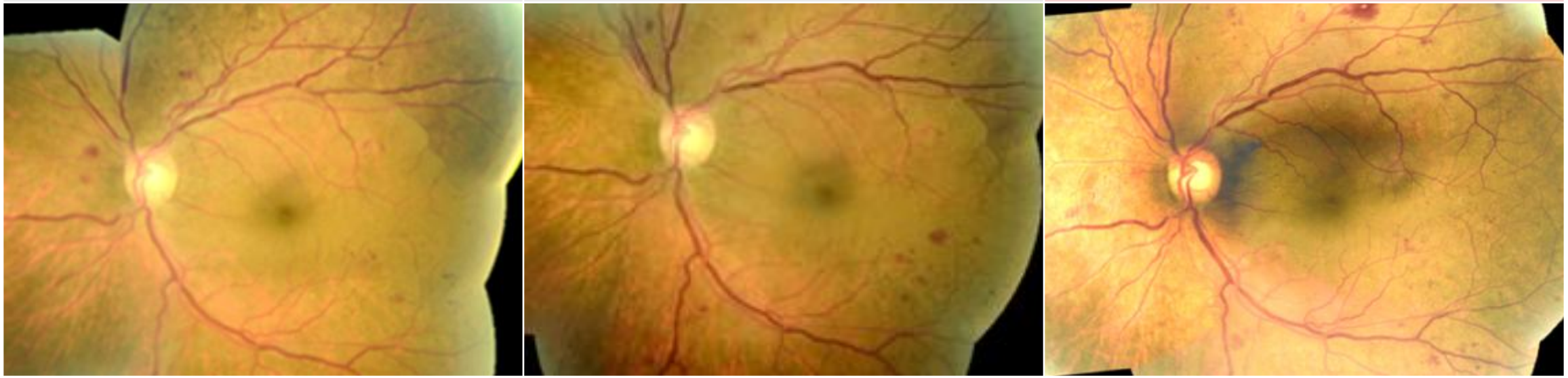
DOSE LEVELS 1–3: *Common Ocular TEAEs[a] in the Study Eye through 2.5 Years*	No prophylactic steroids		Prophylactic 7-week topical steroids
	Dose Level 1 $2.5x10^{11}$ DRSS 47–53 (N=6)	Dose Level 2 $5x10^{11}$ DRSS 47–53 (N=27)*	Dose Level 3 $1x10^{12}$ DRSS 47–53 (N=17)*
Conjunctival hyperemia	1 (16.7%)	8 (29.6%)	0 (0%)
Conjunctival hemorrhage	1 (16.7%)	5 (18.5%)	3 (17.6%)
Cataract	2 (33.3%)	3 (11.1%)	1 (5.9%)
Episcleritis[b]	0 (0.0%)	3 (11.1%)	3 (17.6%)
IOP increase[c]	0 (0.0%)	2 (7.4%)	3 (17.6%)
Intraocular inflammation[d]	1 (16.7%)	2 (7.4%)	0 (0%)

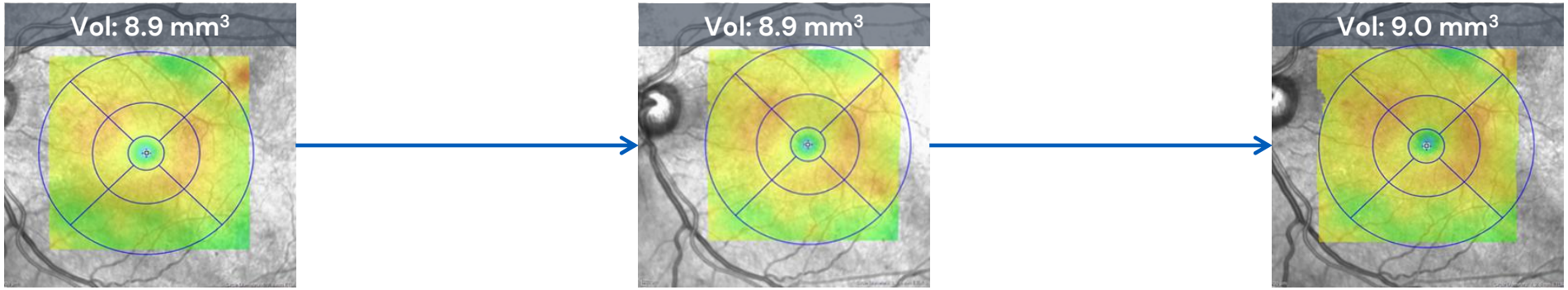
Data cut: May 25, 2026.
*Control subjects were eligible to cross over to receive sura-vec at Year 1. Subjects who were DRSS 47 and 53 at crossover are included in the treatment arm analyses (DL2 n=1, DL3 n=2).
a. Common TEAEs include AEs for total group ≥10% + intraocular inflammation, with onset through the 2-year visit; includes 2 subjects who missed the 2-year visit but had data at 2.5 years.
b. All cases were mild to moderate (grade 1 - 2) and have resolved on topical corticosteroids based on slit lamp examination.
c. All cases were mild to moderate (grade 1 - 2) and resolved after steroid discontinuation and are off IOP lowering medications, except one case of bilateral Primary Angle Closure Glaucoma (grade 2) unrelated to drug which was treated with bilateral iridectomy.
d. All cases were mild (range +0.5 to +1) and most presented 2-6 weeks post injection, predominantly as anterior cells on slit lamp examination. Resolved on topical corticosteroids.
AE: adverse event; DRSS: Diabetic Retinopathy Severity Scale; IOI: intraocular inflammation; IOP: intraocular pressure; NPDR: non-proliferative diabetic retinopathy; SAE: serious adverse event; Sura-Vec: surabgene lomparvovec.; TEAE: treatment emergent adverse event.
This is an interim analysis performed by REGENXBIO for an ongoing trial.

Case #1: ALTITUDE Observation Control: 1-Step Worse

Courtesy of David Boyer, MD

	No Change	1-Step Worsening
Screening **DRSS 47**	Week 24 **DRSS 47**	Week 48 **DRSS 53**



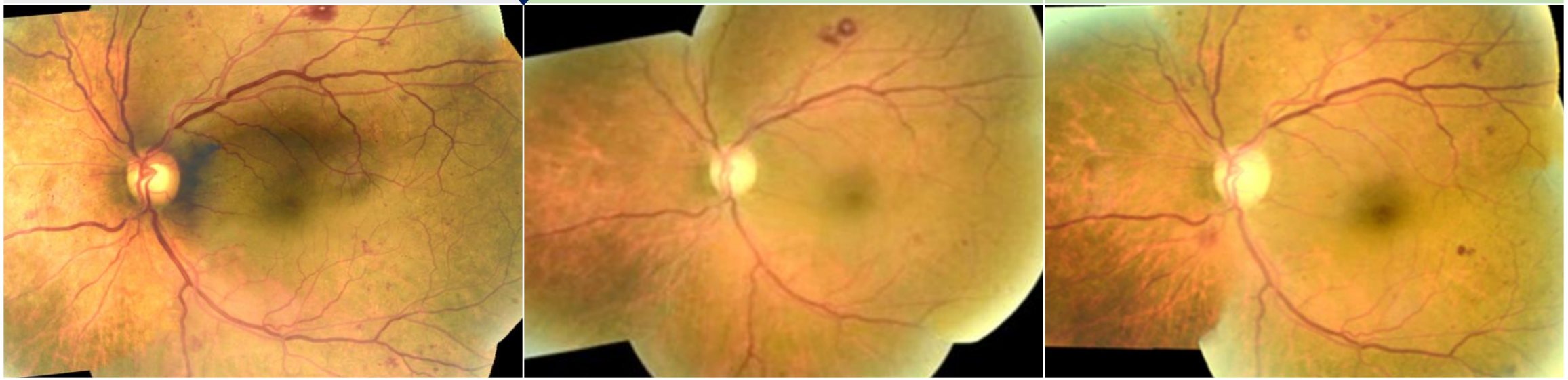


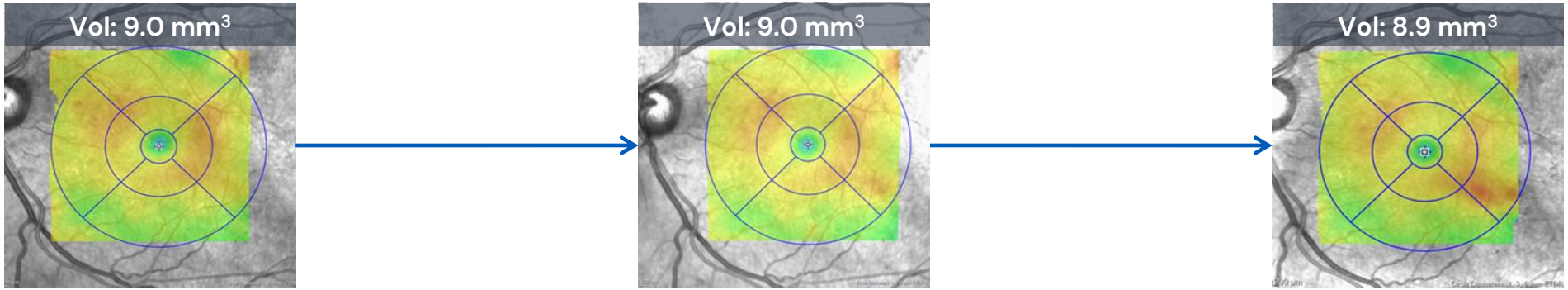
Data cut: March 19, 2026. This slide presents results from individual participants and is not indicative of outcomes experienced by all subjects in this trial.
DRSS: Diabetic Retinopathy Severity Scale; Vol: volume.
This is an interim analysis performed by REGENXBIO for an ongoing trial.

Case #1: Post Sura-vec Cross Over: 2-Steps Better

Courtesy of David Boyer, MD

Baseline at Cross Over	Sura-vec Injection	1-Step Improvement	2-Step Improvement
DRSS 53		Year 1 Post **DRSS 47**	Year 2.5 Post **DRSS 43**





Data cut: March 19, 2026. This slide presents results from individual participants and is not indicative of outcomes experienced by all subjects in this trial.
DRSS: Diabetic Retinopathy Severity Scale; Vol: volume.
This is an interim analysis performed by REGENXBIO for an ongoing trial.

Sura-vec 2.5 Year Results in NPDR Subjects from the Phase II ALTITUDE® Study

Single In-office Suprachoroidal Injection of Sura-vec

Safety at Dose Levels 1, 2, and 3[a]

- **No IOI** in Dose Level 3 NPDR subjects with **short-course topical steroids**
- No drug-related serious adverse events.
- No cases of vasculitis, occlusion, hypotony or cases of chorioretinitis.

Durable, long-term efficacy observed in Dose Level 3[b]

- **Majority** of subjects achieved **DRSS improvement**
  - **55%** achieved **≥2-step** improvement
- **>70%** of Pivotal Dose subjects treated with a single dose did not experience a VTE

NAAVIGATE Phase IIb/III Study in NPDR – Enrollment Ongoing

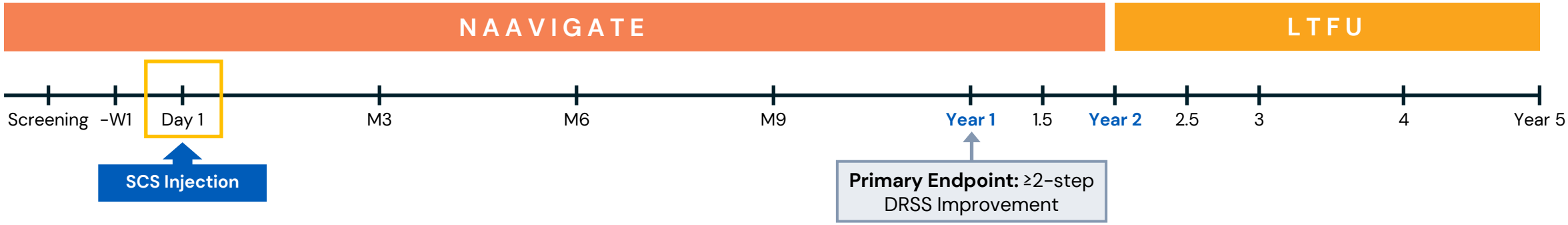
Data cut: May 25, 2026.
DRSS: Diabetic Retinopathy Severity Scale: IOI: intraocular inflammation; NPDR: non-proliferative diabetic retinopathy; Sura-Vec: surabgene lomparvovec.
a. Control subjects were eligible to cross over to receive sura-vec at Year 1. Subjects who were DRSS 47 and 53 at crossover are included in the treatment arm analyses (n=1 in DL2, n=2 in DL3).
b. One crossover subject missed their 2.5 year visit.
This is an interim analysis performed by REGENXBIO for an ongoing trial.

NAAVIGATE

NAAVIGATE Study Overview

NAAVIGATE Pivotal Study Design

Sura-vec for the Treatment of NPDR (DRSS 47-53)



Phase 2b

Phase 3*

Bilateral Substudy

Prophylactic Topical Steroids
1 Week Pre and 12 Weeks Post

- Sura-vec (n=90) $1.0x10^{12}$ GC/eye
- Sura-vec (n=205) $1.0x10^{12}$ GC/eye
- Sura-vec (n=30) ~ 60 eyes $1.0x10^{12}$ GC/eye

VS

VS

Artificial Tears
1 Week Pre and 12 Weeks Post

- Sham Control (n=46)
- Sham Control (n=205)

Other Key Endpoints at Years 1 and 2:

- Stable to Improved DRSS
- Ocular safety
- Development of vision threatening events (CI-DME, PDR, and ANSV)

*A second Phase 3 global study will be initiated in parallel

CI-DME: center-involved diabetic macular edema; DRSS: Diabetic Retinopathy Severity Scale; GC: genome copies; LTFU: long-term follow-up; NPDR: non-proliferative diabetic retinopathy; PDR: proliferative diabetic retinopathy; SCS: suprachoroidal space.