

Suprachoroidal Delivery of Investigational Surabgene Lomparvovec (Sura-vec^{*}, ABBV-RGX-314): Results in NPDR at 3 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.

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Disclosures

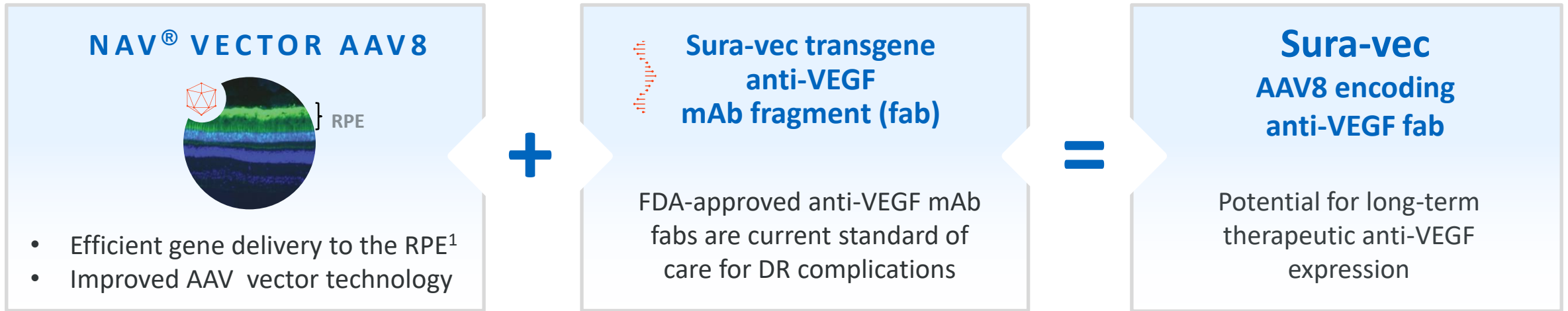
4D Molecular Therapeutics: I
Abbvie: I, C
AdaptDx: I
Adverum: I
Amgen: I
Apellis Pharmaceuticals Inc: I, C
Astellas: I, C
Boehringer Ingelheim: I
Eyepoint: I
i-Lumen Scientific, Inc: I
Genentech/Roche: I, C
Janssen Pharmaceuticals: I
Johnson & Johnson: I
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Outlook Pharmaceuticals: I
Oxurion: I
OcuTerra Therapeutics: I
Perceive Bio: I
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Investigational In-office Surabgene Lomparovvec (sura-vec) for the Treatment of Diabetic Retinopathy (DR)

SURA-VEC PRODUCT CANDIDATE



MECHANISM OF ACTION

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

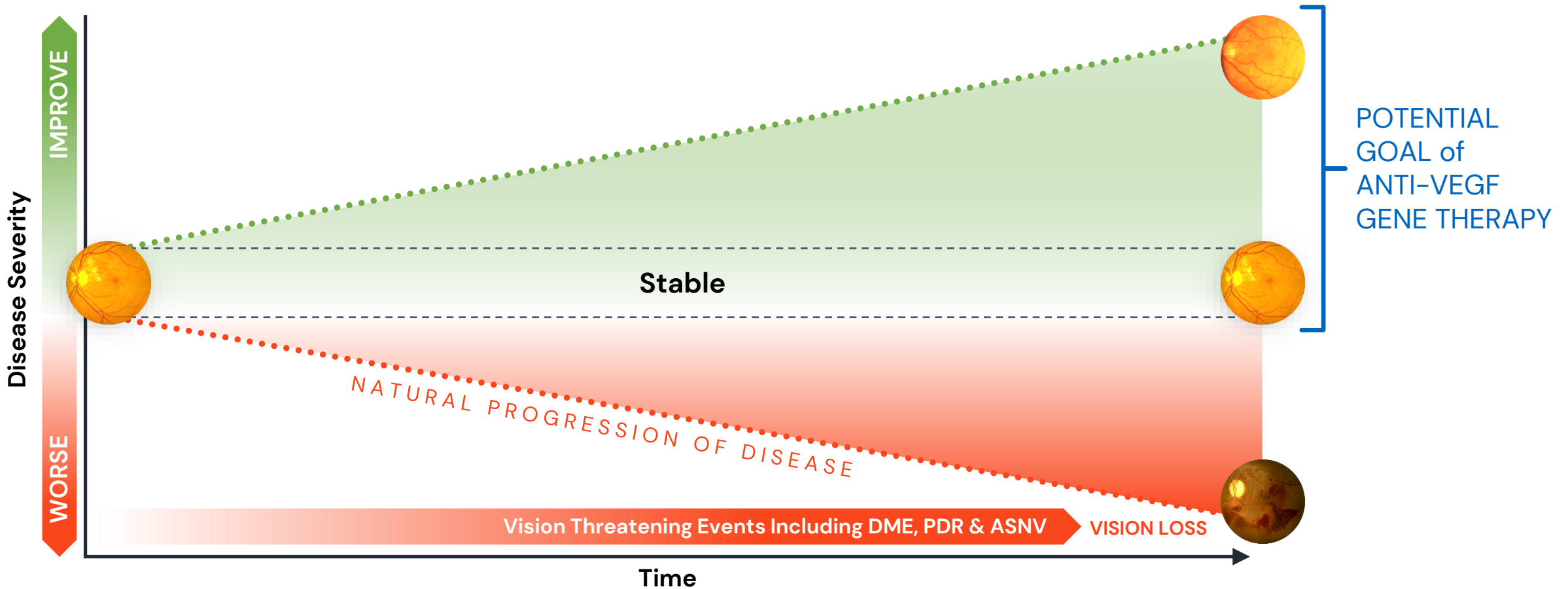
SUPRACHOROIDAL ADMINISTRATION²(SCS)

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



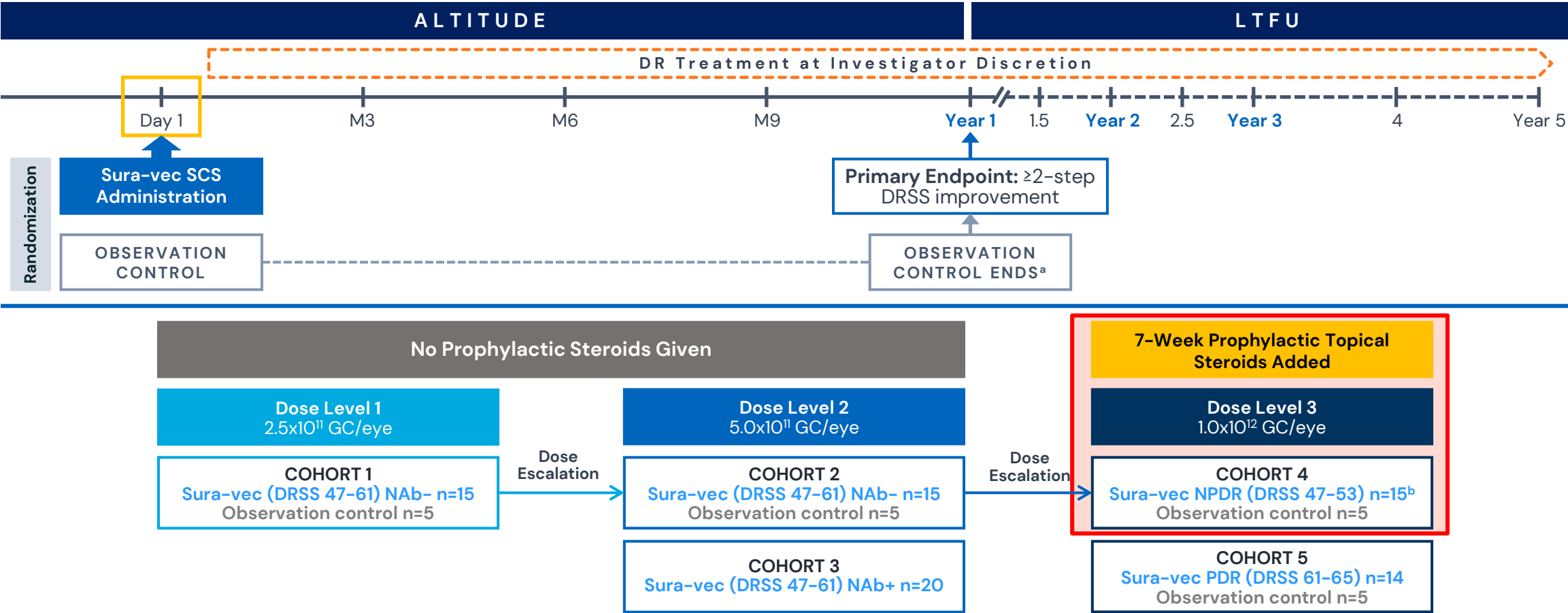
The Goal of a One-time, In office SCS injection of Gene Therapy

To Provide Long-lasting Improvement in DR Severity and Reduce Risk of Vision Threatening Events



Phase II ALTITUDE® Part 1 Study Design

Sura-vec for the Treatment of Diabetic Retinopathy



Presentation will focus on DL3 in the NPDR Subpopulation, which was Selected as Pivotal Dose

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; 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
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Baseline Characteristics

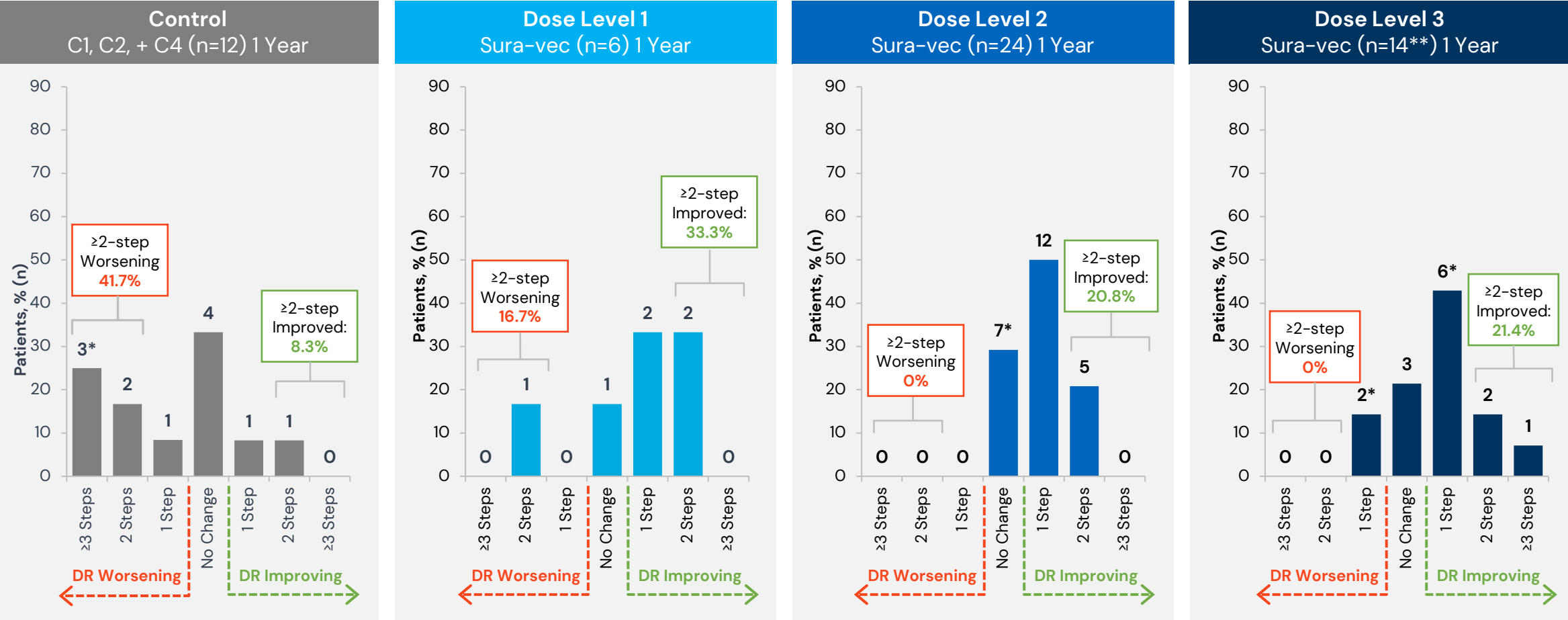
NPDR (DRSS 47–53)

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)	12 (100.0%)	4 (66.7%)	21 (87.5%)	10 (71.4%)	47 (83.9%)
	DRSS 53 (Severe NPDR)	0	2 (33.3%)	3 (12.5%)	4 (28.6%)	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: May 25, 2026.
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
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Change in DRSS at 1 Year

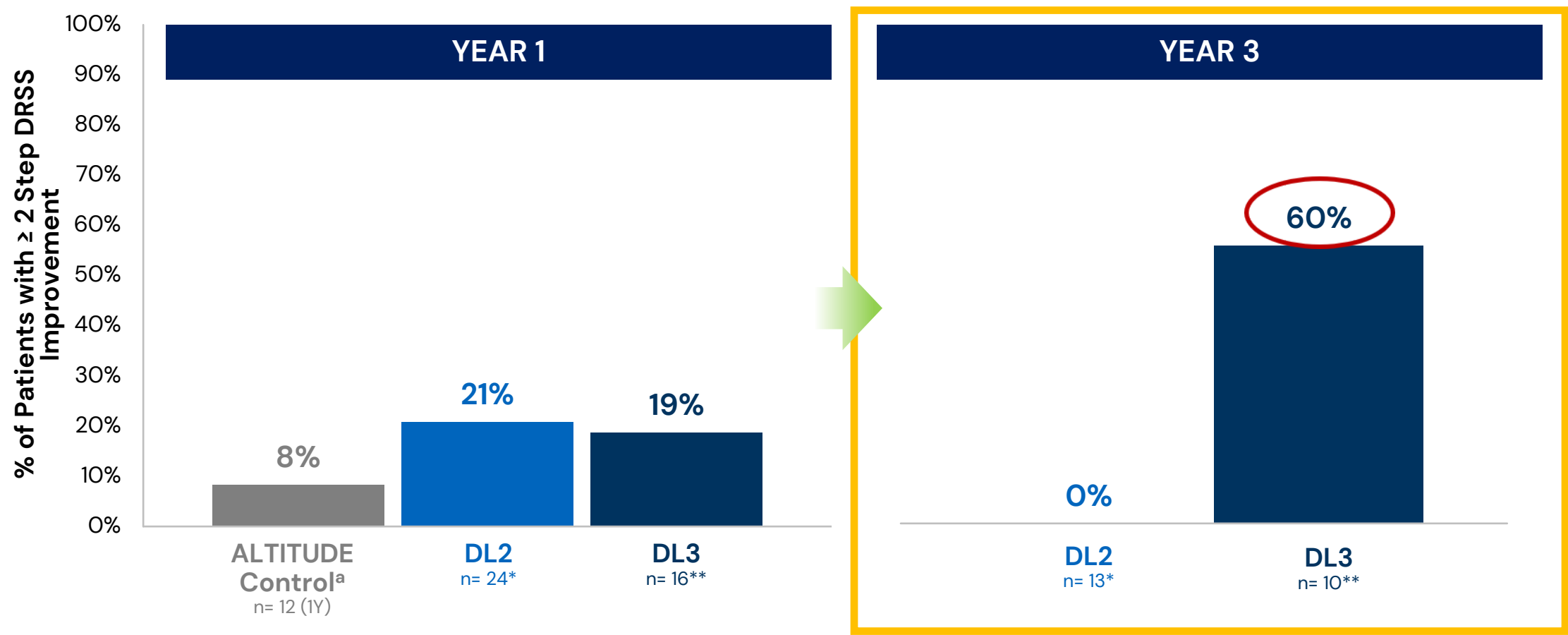
Dose Level 2 and 3 sura-vec treated subjects outperform control with similar outcomes at 1 yr



Data cut: June 09, 2025. Includes NPDR (DRSS 47-53). 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 lomparovec; VEGF: vascular endothelial growth factor; Y: year
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A Single Injection of Sura-vec at Pivotal Dose Shows Continued DRSS Improvements through 3 Years

60% achieved ≥ 2 -Step Improvement Without Additional DR Treatment



Data cut: Aug 17, 2026. Includes NPDR (DRSS 47-53).
*Includes 1 subject who crossed over from control; **Includes 2 subjects who crossed over from control.
a. Control arm ended at 1 year. 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.
DL: Dose Level; DR: diabetic retinopathy; DRSS: Diabetic Retinopathy Severity Scale; Sura-vec: surabgene lomparvovec; Y: year.
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A Single Injection of Sura-vec at Pivotal Dose Shows Continued DRSS Improvements at 3 Years

60% (6/10) Improved 2-Steps without Vision Threatening Events or Additional Treatment for DR

		ALTITUDE		LTFU		
Baseline DRSS		Dose Level 3 Sura-vec		Year 1	Year 3	Total IVT through Year 3
NO VTE	53			2 Steps Better	2 Steps Better	0
	47			2 Steps Better	2 Steps Better	0
	47			1 Step Better	2 Steps Better	0
	53			No Change	2 Steps Better	0
	47			1 Step Better	2 Steps Better	0
	47			1 Step Better	2 Steps Better	0
	53 (crossover)*			1 Step Better	Expected Q4 2026	0
	47 (crossover)*			1 Step Better	Expected Q4 2026	0
	53			3 Steps Better	No Data ^a	
	47			No Change		
	47			1 Step Worse		
	47			1 Step Better	Lost to Follow Up ^b	2
VTE	47			1 Step Better	2 Steps Better	8
	47			1 Step Better	2 Steps Better	17
	47			No Change	2 Steps Better	12
	53			1 Step Worse	1 Step Worse	14

Data cut: Aug 17, 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). One subject in Dose Level 3 was found to have confounding disease at baseline and their data was excluded. a. One subject enrolled in long-term follow-up and had no return visits; b. Patient received 2 IVT after Y2 for DME, but OCT showed dry retina at the time of injection. Subject was receiving IVT for DME in FE. VTEs = VTCs + CI-DME; VTCs could include PDR or ASNV. DR: diabetic Retinopathy; DRSS: Diabetic Retinopathy Severity Scale; FE: Fellow eye; IVT: intra-vitreous therapy; LTFU: long-term follow-up; Sura-vec: surabgene lomparovvec; VTC: Vision Threatening Complication; VTE: Vision Threatening Event. This is an interim analysis performed by REGENXBIO for an ongoing trial.

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Cumulative Safety Summary

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

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

- 34 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: <i>Common Ocular TEAEs^a in the Study Eye through 3 Years</i>	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: Aug 17, 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=3, DL3 n=2).

a. Common TEAEs include AEs for total group ≥10% + intraocular inflammation, with onset through the 3-year visit. Includes one subject in DL3 without available 3-year data, for whom safety data through 2.5 years are included. 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.

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A Single In-office Suprachoroidal Injection Of Sura-vec

3-Year Results in NPDR Subjects from the Phase II ALTITUDE® Study

Safety at Dose Levels 1, 2, and 3

- ✓ 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 Pivotal Dose subjects **3 years after a single injection**

- ✓ **Majority of subjects achieved ≥ 2 -step DRSS improvement** without additional DR treatment
- ✓ **60% did not experience a VTE**

NAAVIGATE Pivotal Trial in NPDR – Enrollment Ongoing

Data cut: Aug 17, 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=1 in DL2, n=2 in DL3).

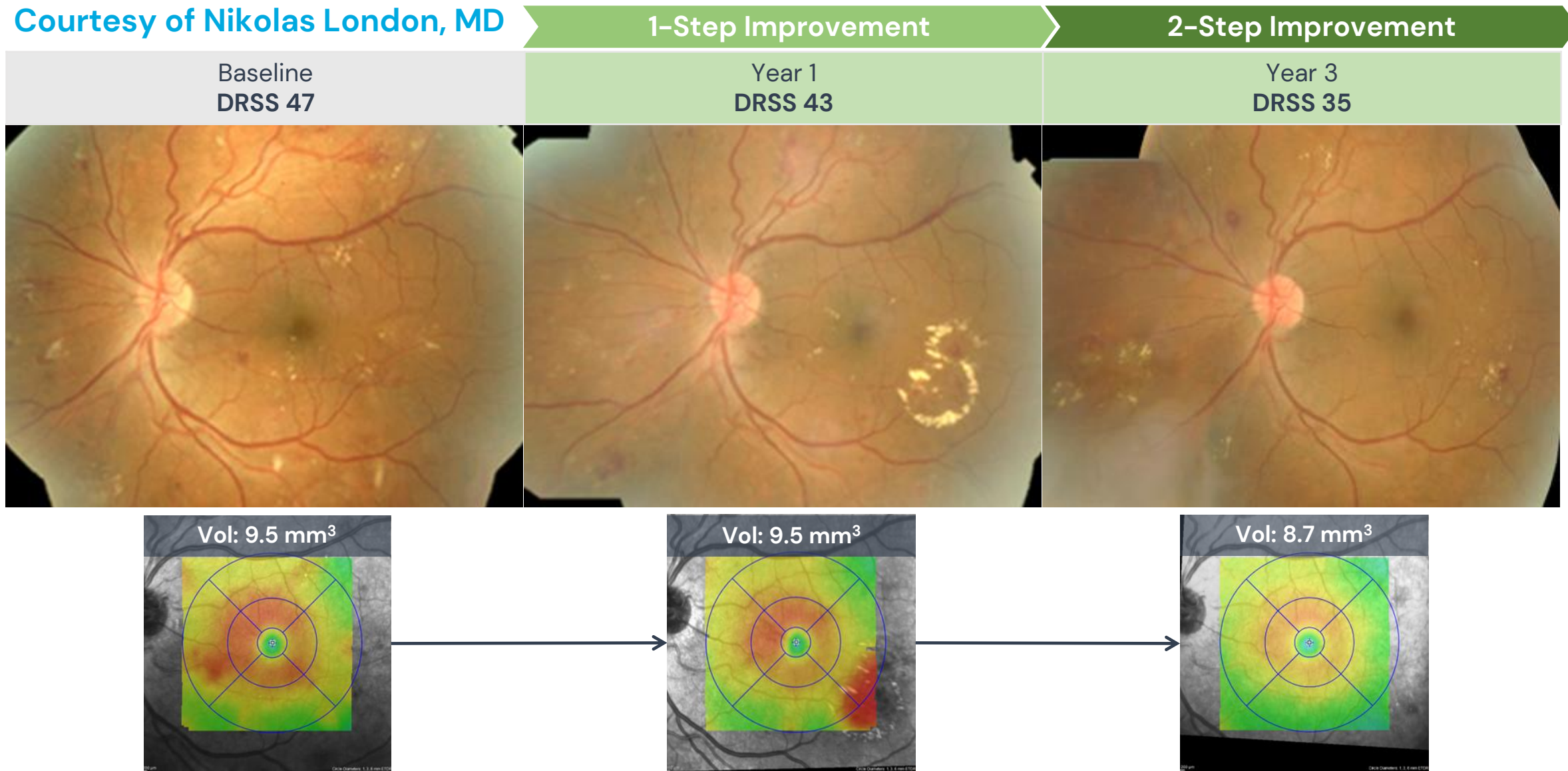
VTEs = VTCs + CI-DME; VTCs could include PDR or ASNV

ASNV: Anterior Segment Neovascularization; DR = Diabetic Retinopathy; CI-DME: Center-involved Diabetic Macular Edema; DRSS: Diabetic Retinopathy Severity Scale; IOI: intraocular inflammation; NPDR: non-proliferative diabetic retinopathy; PDR = Proliferative Diabetic Retinopathy; Sura-vec: surabgene lomparovvec; VTC: Vision Threatening Complication; VTE: Vision Threatening Event. This is an interim analysis performed by REGENXBIO for an ongoing trial.

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Case #1: Dose Level 3

Courtesy of Nikolas London, MD



This slide presents results from individual participants and is not indicative of outcomes experienced by all participants in this trial.

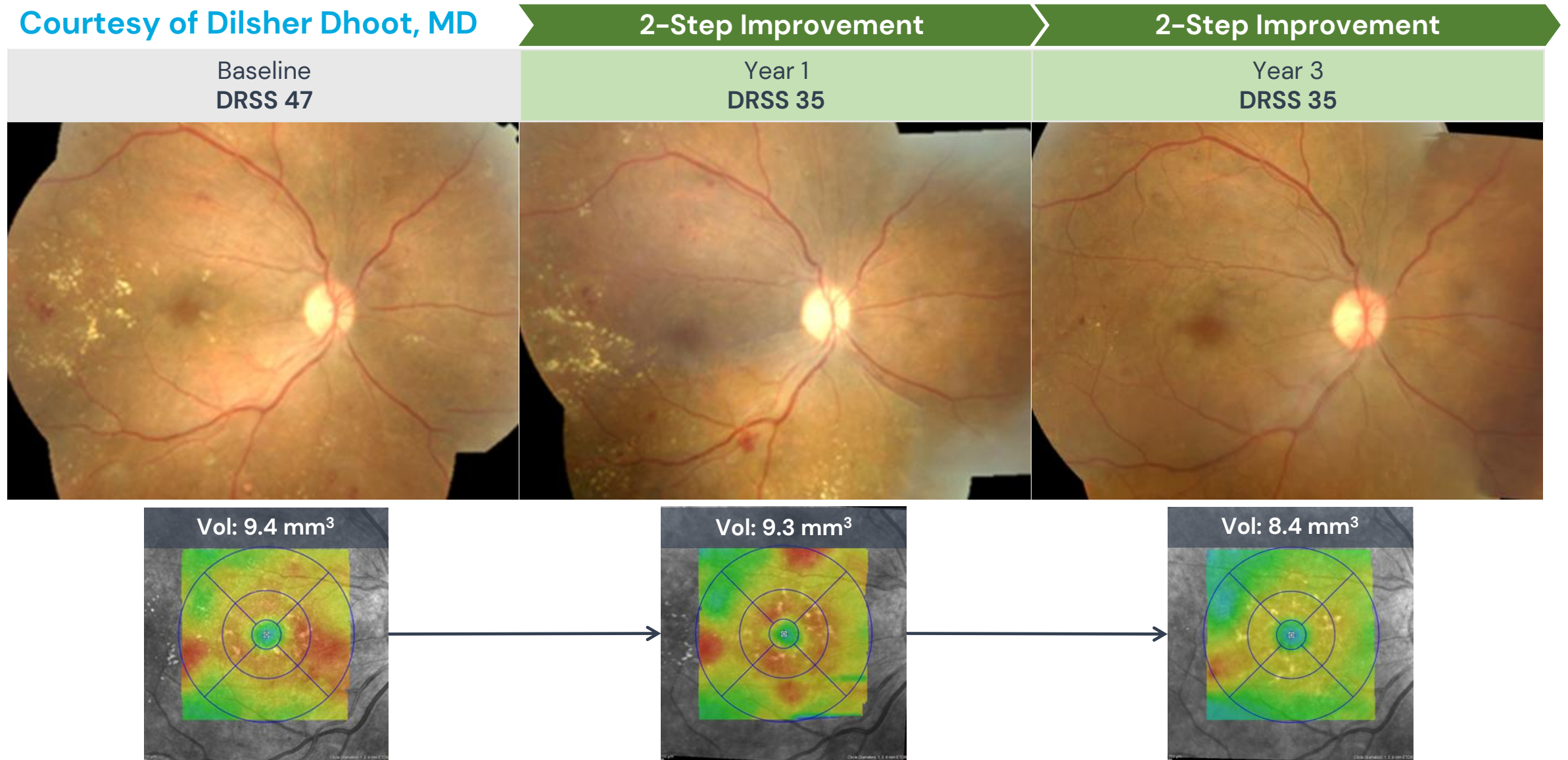
DRSS: Diabetic Retinopathy Severity Scale; Vol: volume.

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Case #2: Dose Level 3

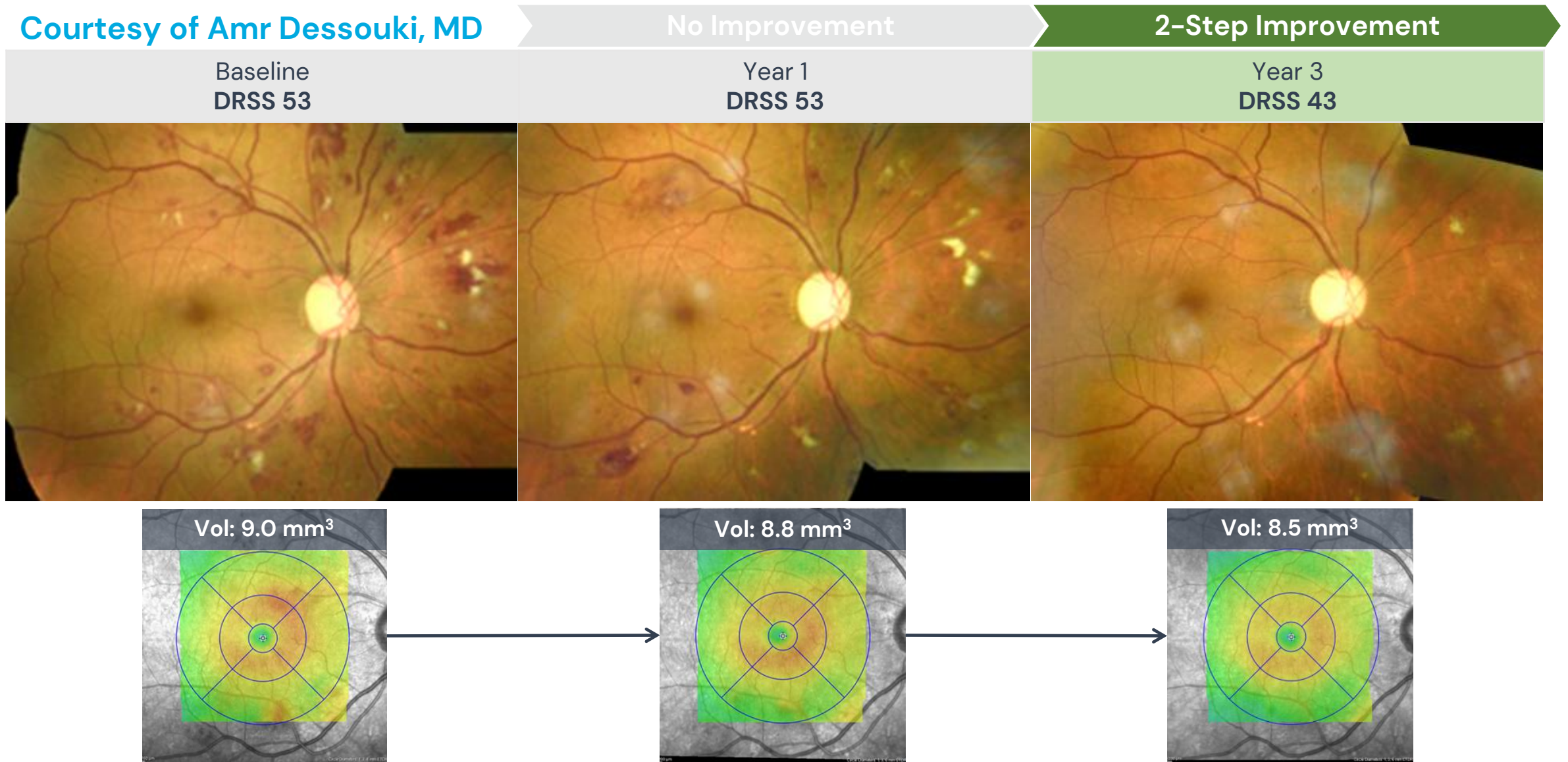
Courtesy of Dilsher Dhoot, MD



This slide presents results from individual participants and is not indicative of outcomes experienced by all participants in this trial.
DRSS: Diabetic Retinopathy Severity Scale; Vol: volume.
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Case #3: Dose Level 3

Courtesy of Amr Dessouki, MD



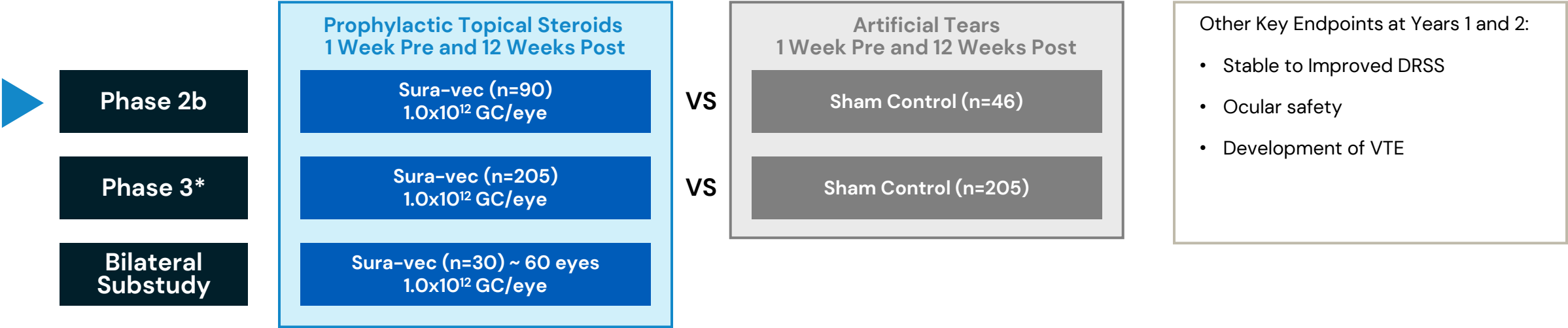
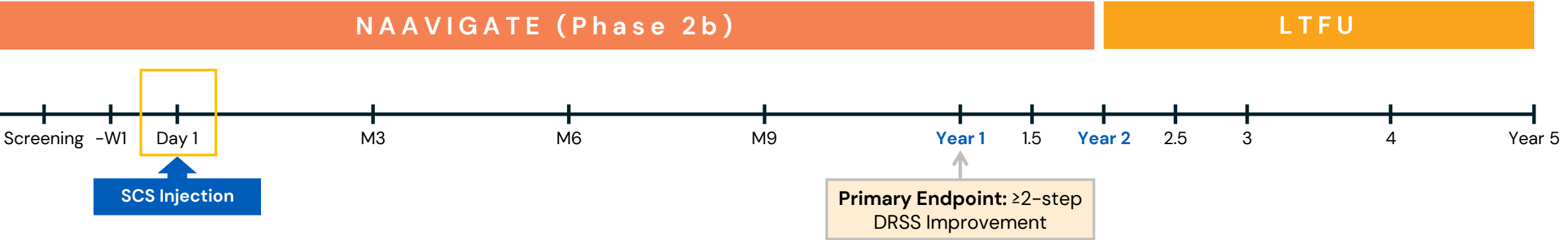
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DRSS: Diabetic Retinopathy Severity Scale; Vol: volume.
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NAAVIGATE Study Overview

NAAVIGATE Pivotal Study Design

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



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

VTEs = VTCs + CI-DME; VTCs could include PDR or ASNV. ASNV: anterior segment neovascularization; 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; VTC: Vision Threatening Complication; VTE: Vision Threatening Event.
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