

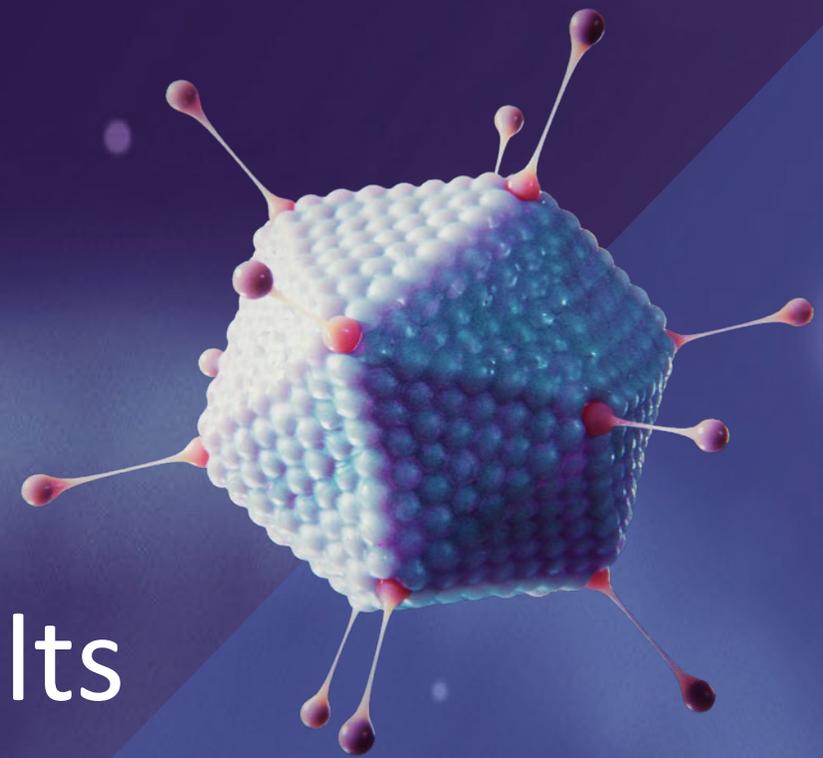


PRECIGEN

ADVANCING MEDICINE WITH PRECISION™

# PRGN-2012 Pivotal Study Results and Update Call

June 3, 2024



Nasdaq: PGEN

# Forward-looking Statements

Some of the statements made in this presentation are forward-looking statements. These forward-looking statements are based upon Precigen's current expectations and projections about future events and generally relate to plans, objectives, and expectations for the development of the company's business, including the timing and progress of preclinical studies, clinical trials, discovery programs, product candidate approval and commercialization, and related milestones, the promise of Precigen's portfolio of therapies, and in particular its AdenoVerse and CAR-T therapies. Although management believes that the plans and objectives reflected in or suggested by these forward-looking statements are reasonable, all forward-looking statements involve risks and uncertainties, including the possibility that the timeline for Precigen's clinical trials, product candidate approvals or plans for commercial launch of products might be impacted by economic conditions, industry developments, or other factors, and actual future results may be materially different from the plans, objectives and expectations expressed in this presentation. Precigen has no obligation to provide any updates to these forward-looking statements even if its expectations change. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. For further information on potential risks and uncertainties, and other important factors, any of which could cause Precigen's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the company's most recent Annual Report on Form 10-K and subsequent reports filed with the Securities and Exchange Commission.

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This presentation contains market data and industry statistics and forecasts based on studies and clinical trials sponsored by third parties, independent industry publications and other publicly available information. Although Precigen believes these sources are reliable, it does not guarantee the accuracy or completeness of this information and has not verified this data.

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# Today's Agenda and Participants

## AGENDA

- AdenoVerse Gene Therapy Platform
- PRGN-2012 Pivotal Study Results
- PRGN-2012 Opportunity
- Q&A

## PARTICIPANTS



**Helen Sabzevari, PhD**

President and CEO  
Precigen



**Harry Thomasian Jr.**

CFO  
Precigen



**Scott M. Norberg, DO**

Center for Immuno-Oncology, Center for Cancer Research,  
National Cancer Institute, NIH



**Clint T. Allen, MD**

Senior Investigator, Surgical Oncology Program, Center for Cancer  
Research, National Cancer Institute, NIH

# AdenoVerse<sup>®</sup> Platform

Novel gene therapy platform to train and amplify the immune system *in vivo* (from WITHIN the body)

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Large payload capacity

Low seroprevalence in humans

Ability for repeat administration

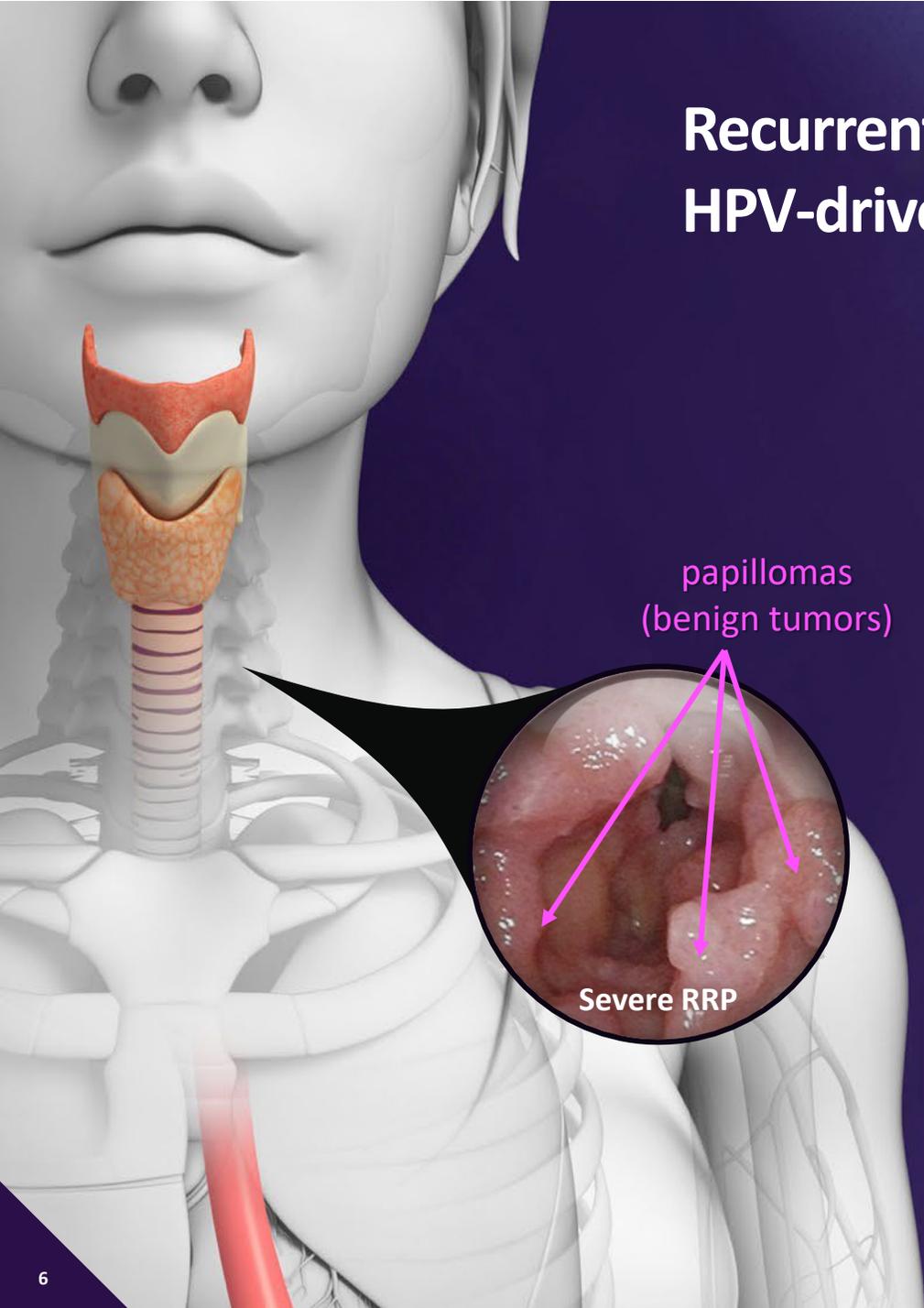
Durable antigen-specific immune response

Highly productive manufacturing process

# PRGN-2012 for the Treatment of RRP



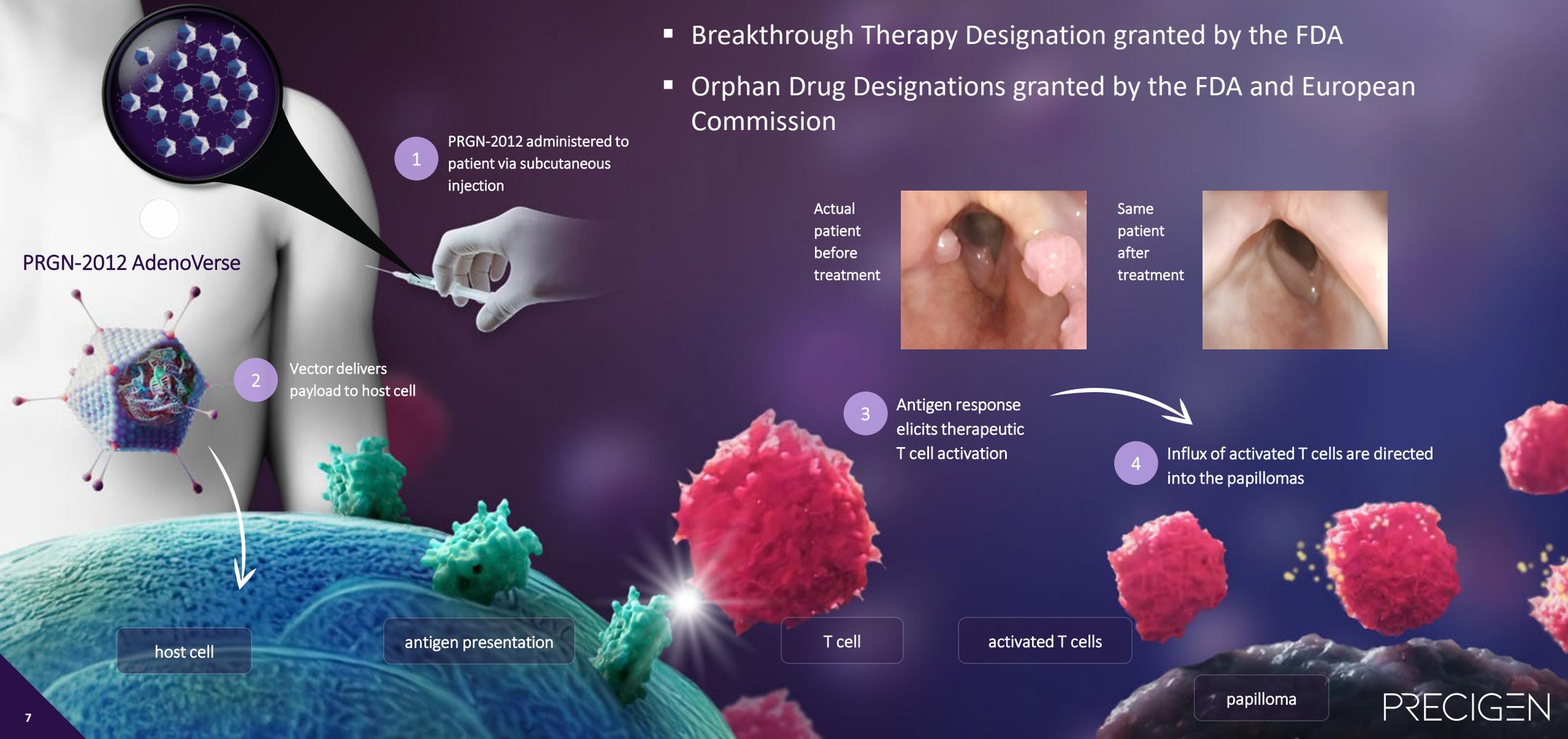
# Recurrent Respiratory Papillomatosis (RRP) is a Rare HPV-driven Disease with No FDA-approved Therapeutic



- RRP is a recurring benign HPV-mediated tumor on the larynx that is mainly treated surgically
- HPV6 and HPV11 infections are the drivers of the disease
- Adult onset RRP is driven by sexual transmission and juvenile onset RRP is typically transmitted during birth
- RRP is potentially life-threatening especially if pulmonary or malignant transformation occurs
- RRP can cause severe voice disturbance, airway compromise, fatal pulmonary lesions, and invasive cancers

# PRGN-2012 Targets HPV6/11 Infected Cells

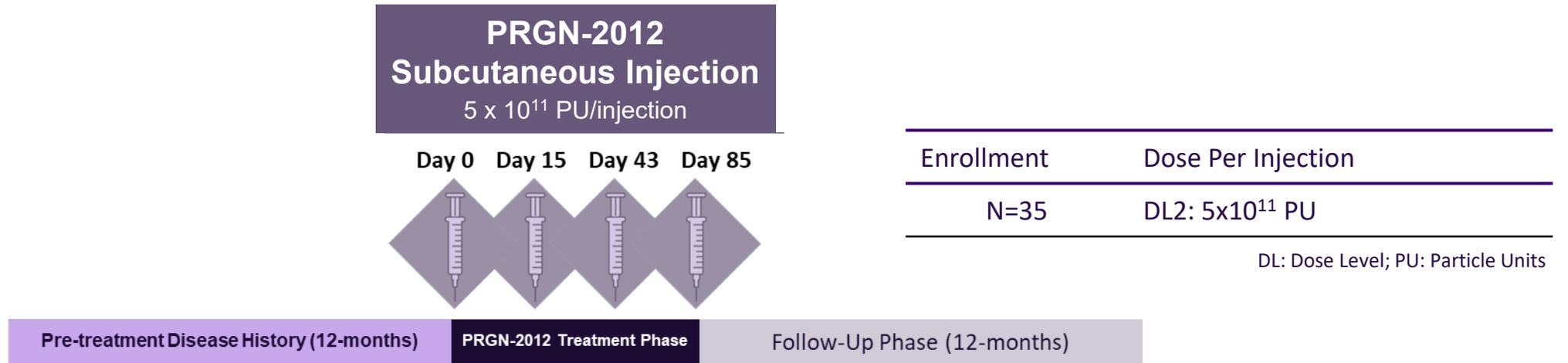
- Gorilla adenoviral vector with the ability for repeat injections
- Designed to elicit T cell mediated immune responses against papilloma cells infected with HPV6 or HPV11
- Breakthrough Therapy Designation granted by the FDA
- Orphan Drug Designations granted by the FDA and European Commission





# PRGN-2012 Pivotal Study Results

# PRGN-2012 Pivotal Study Design



## PRIMARY ENDPOINTS

- Safety
- **Complete Response Rate:** Patients with no surgeries required to control RRP in the 12 months following completion of treatment

## KEY SECONDARY ENDPOINTS

- HPV 6/11–specific immune responses
- Extent of papilloma growth (Derkey scores) and quality of life (Vocal Handicap Index: VHI-10)

# PRGN-2012 Pivotal Study Patient Demographics

	5x10 <sup>11</sup> PU / dose (N=35)
Mean age (range), years	49.3 (20-88)
Male/Female	20 (57%) / 15 (43%)
<b>Patient Characteristics</b>	
Age at diagnosis (years)	1-68
Juvenile onset	12 (34%)
Adult onset	23 (66%)
Mean age at diagnosis	29 (1-68)
Mean years since diagnosis	20 (1-65)
<b>Baseline Disease</b>	
Surgeries in last 12 months	Mean 4.5 (range 3-10)
Derkay score	Mean 10.6 (range 3-31)
VHI-10	Mean 23.5 (range 6-40)

# PRGN-2012 Treatment was Well-tolerated with No DLTs

## TREATMENT RELATED TREATMENT EMERGENT ADVERSE EVENTS OCCURRING IN MORE THAN 1 PATIENT

Event	5x10 <sup>11</sup> PU / dose (N=35)	
	Grade 1 (N, %)	Grade 2 (N, %)
Chills	25 (71%)	-
Fatigue	28 (80%)	2 (6%)
Fever	24 (69%)	-
Headache	2 (6%)	-
Hyperhidrosis	2 (6%)	-
Injection site reaction	34 (97%)	-
Myalgia	9 (26%)	2 (6%)
Nausea	8 (23%)	-
Vomiting	2 (6%)	-

### SAFETY SUMMARY

- TRAEs were Grade 1-2, no Grade > 2 TRAEs
- The most common TRAEs were injection site reactions, chills, fatigue and fever
- TRAEs were mostly mild, with no DLTs or treatment related serious adverse events
- No treatment discontinuations; all patients received four doses of PRGN-2012

DLT: Dose Limiting Toxicity  
TRAE: Treatment Related Adverse Event

# Clinical Efficacy Summary

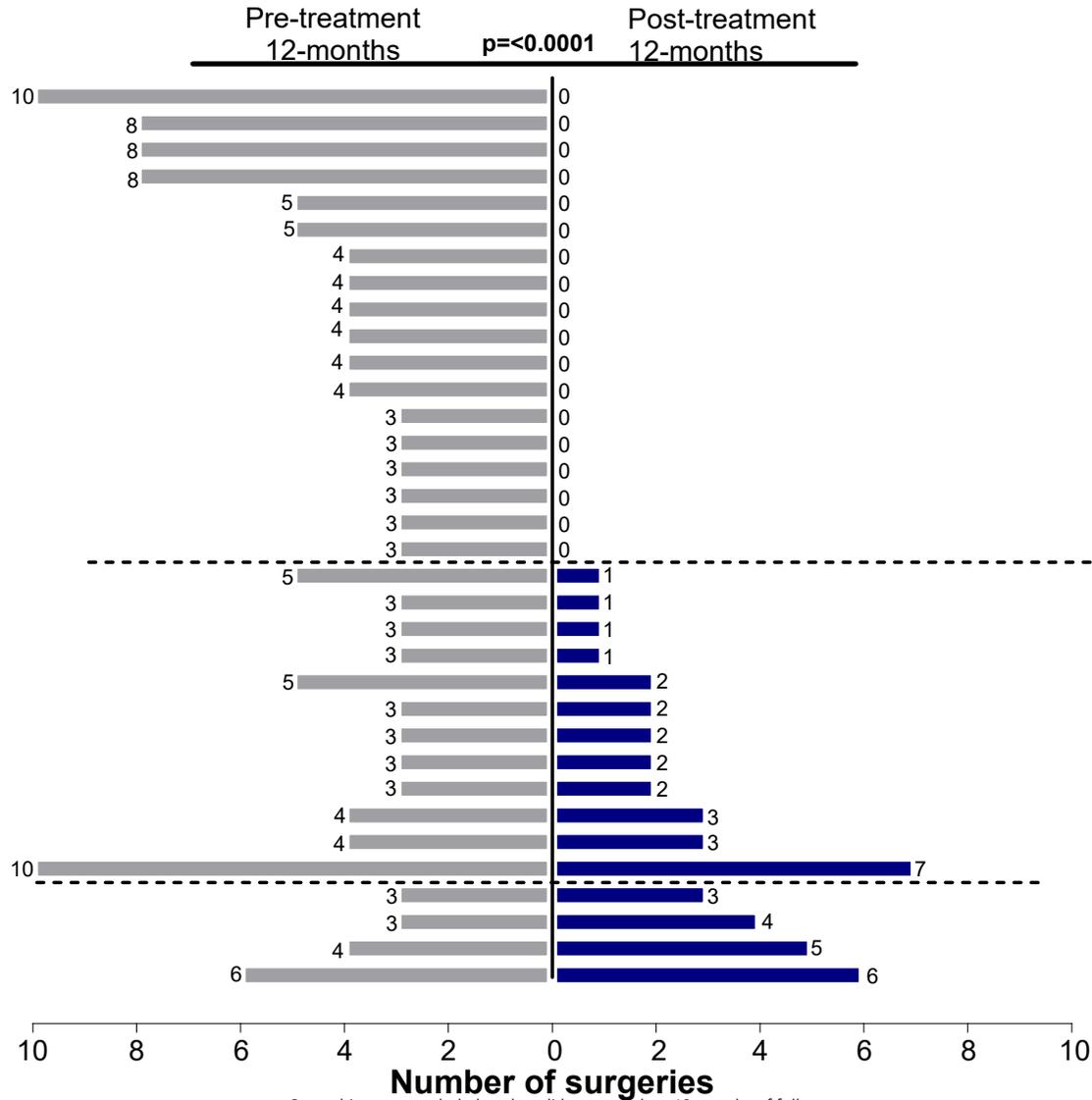
## *Consistent Results in Phase 1 and Phase 2 Portions of the Pivotal Study*

	Phase 1 (N=12)	Phase 2 (N=23)	Phase 1/2 Total (N=35)
<b>Complete Response Rate</b> No surgeries needed during 12-months post-treatment	<b>50% (6/12)</b>	<b>52% (12/23)</b>	<b>51% (18/35)</b>
<b>Decrease in number of surgery</b> 12-months post-treatment compared to 12-months pre-treatment	<b>83% (10/12)</b>	<b>87% (20/23)</b>	<b>86% (30/35)</b>

# Pivotal Study Met Primary Efficacy Endpoint

*51% Complete Response Rate*

*86% Patients had a Reduction in Number of Surgeries*



■ **51% Complete Response (CR) Rate (95% CI [34-69%])**

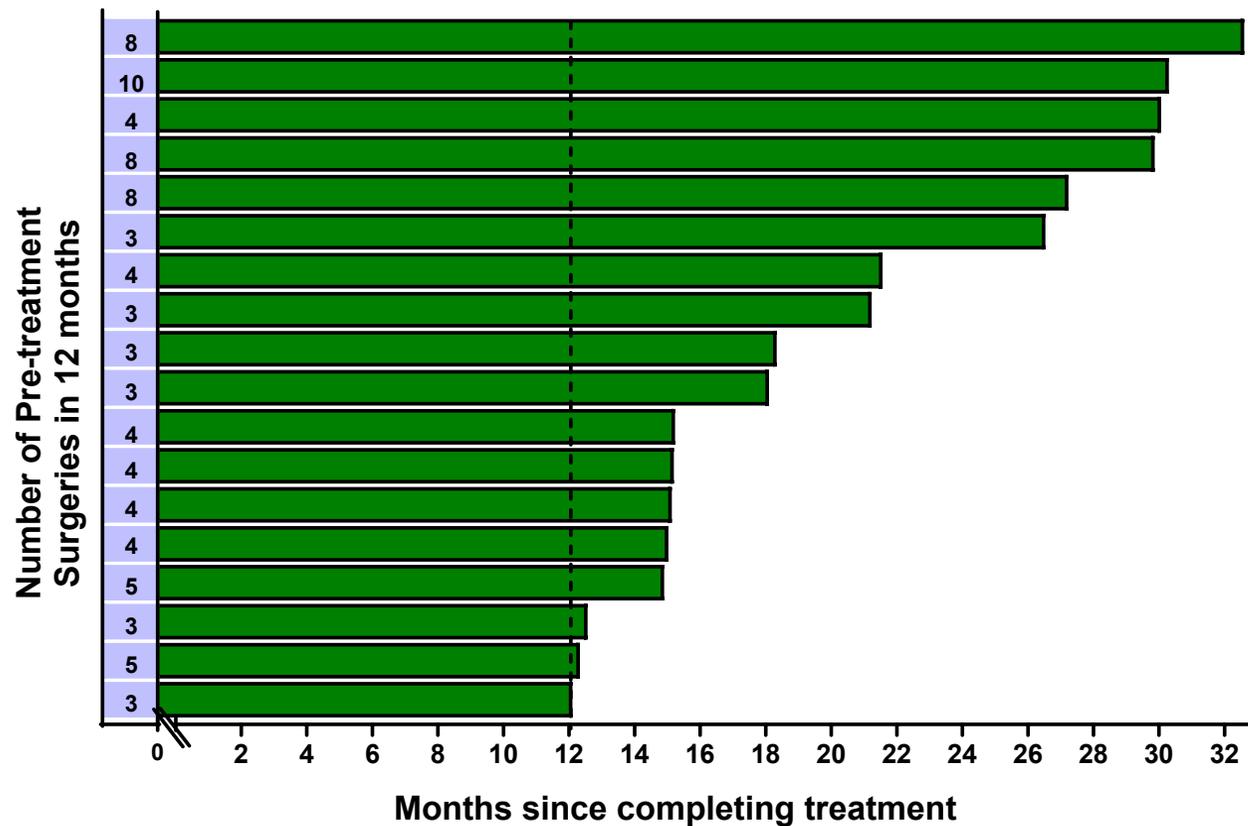
Complete Response = No need for surgery for 12 months after PRGN-2012 treatment completion

■ **86% of patients demonstrated a reduction in need for surgeries (95% CI [70-95%])**

Number of surgeries required during the 12 months after PRGN-2012 treatment completion was reduced compared to 12 months prior to treatment

# PRGN-2012 Treatment Induced Durable Complete Responses

## DURATION OF COMPLETE RESPONSES

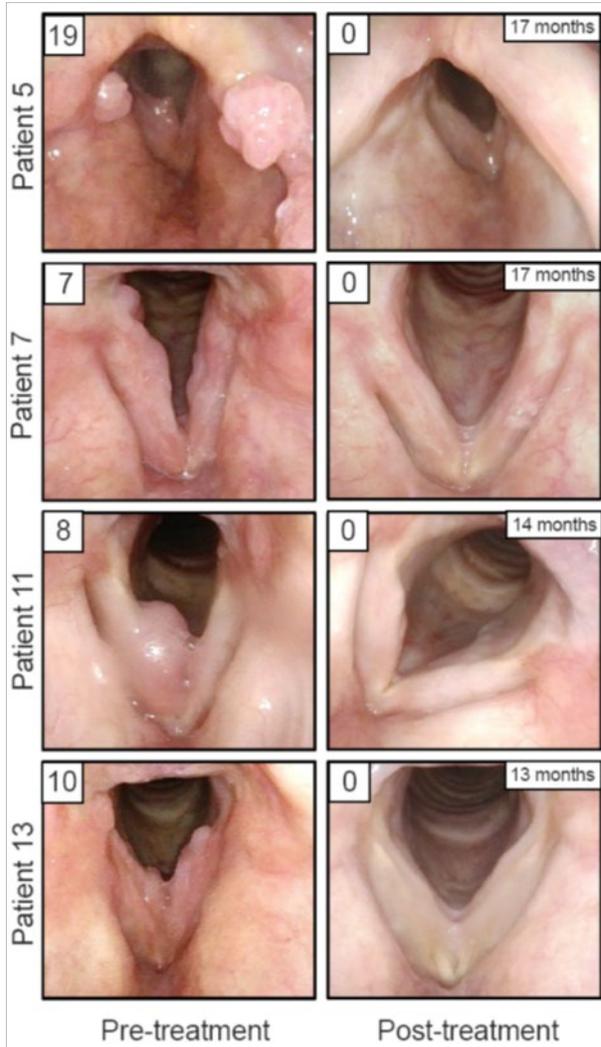


- Median duration of follow up 20 months
- Median duration of complete response has not yet been reached

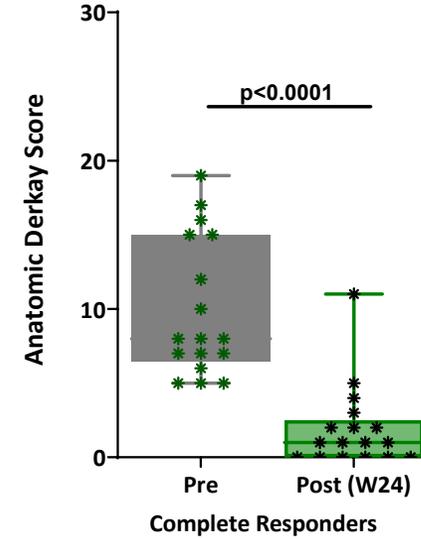
Data cutoff: May 20, 2024

# Significant Improvement in Derkey Anatomic Scores and Vocal Function (VHI-10) in Complete Responders

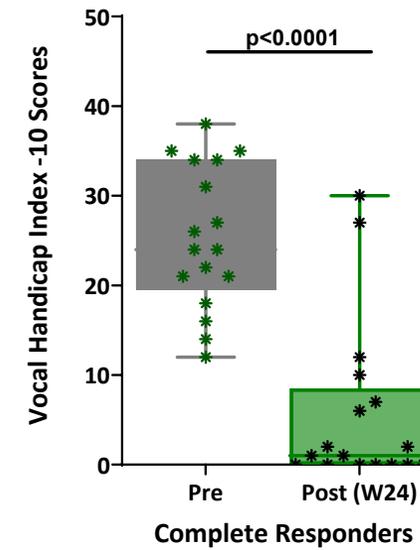
REPRESENTATIVE IMAGES OF COMPLETE RESPONDERS



DERKEY SCORE: REDUCTION IN PAPILLOMA SEVERITY

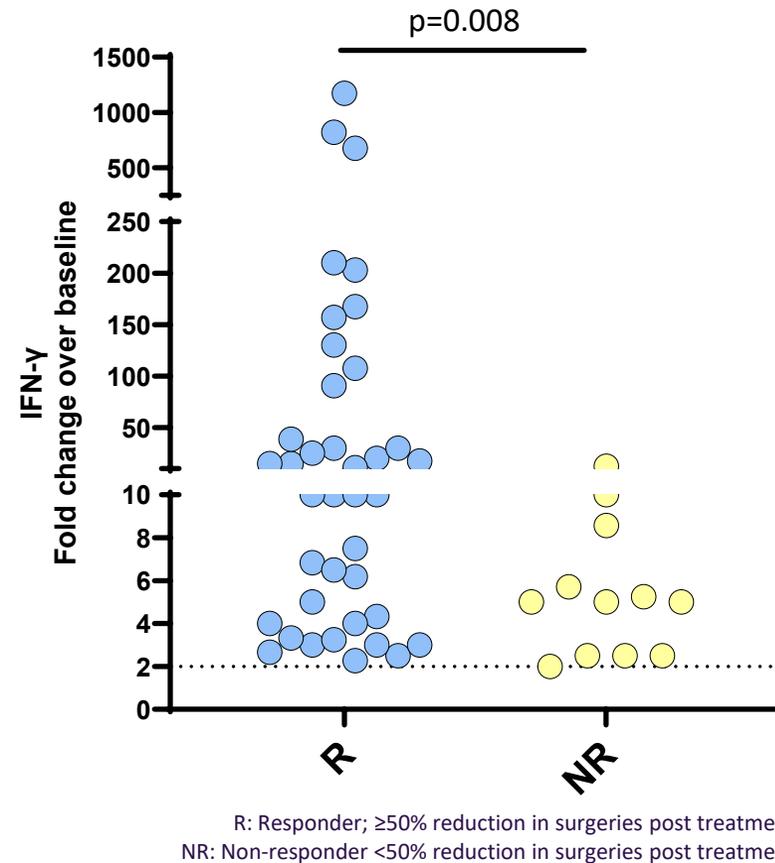


VHI-10 INDEX: IMPROVED VOICE QUALITY



# PRGN-2012 Induced HPV 6/11-specific T Cell Immune Response

*Significantly greater expansion of peripheral HPV-specific T cells in responders compared to non-responders*



Peripheral blood samples of patients were analyzed in IFN- $\gamma$  ELISpot Assay  
Each dot represents T cell response against specific HPV6/11 epitopes that were at least two-fold higher than baseline

# Pivotal Study Results Summary

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	N=35
<b>Complete Response Rate</b> No surgeries needed during 12 months post-treatment	<b>51% (18/35)</b>
<b>Decrease in number of surgery</b> 12 months post-treatment compared to 12 months pre-treatment	<b>86% (30/35)</b>

- **The Primary Safety and Efficacy endpoints of the pivotal study were met**
- PRGN-2012 treatment was well-tolerated with only mild (grade 1-2) adverse events
  - No meaningful anti-drug antibody response with repeat administrations of PRGN-2012
- PRGN-2012, a novel gene therapy that can elicit HPV 6/11-specific T cell immune responses, resulted in complete response rate of 51% in RRP patients
  - This response rate is much higher than the statistical threshold for the study
  - Complete responses are durable beyond 12 months and patients continue to be followed



# PRGN-2012 Opportunity

# PRGN-2012 is On Track for Potential Commercial Launch in 2025

## Preparing for BLA submission

- Rolling BLA submission under an accelerated approval pathway planned for 2H 2024
- Potential commercial launch in 2025

## Significant potential market opportunity

- ~15-20K US RRP patients



- >125K ex-US RRP patients



- Concentrated prescriber base (laryngologists)



## Preparing for commercial launch in 2025

- **Marketing**
  - Market research with clinicians, patients and caregivers
- **Medical Affairs**
  - Engaging with KOLs and patient support groups
- **Market Access/Distribution**
  - Payer engagement
  - Establishing specialty distribution

Sources: Derkay et al. Task Force on recurrent respiratory papillomas. 1995; Armstong et al. Incidence and Prevalence of Recurrent Respiratory Papillomatosis among Children. 2000; Marsico et al. Estimating the Incidence and Prevalence of Juvenile-Onset Recurrent Respiratory Papillomatosis. 2014, accessed October 2023; Discussions with Laryngologists, General Otolaryngologists & Pediatric Otolaryngologists, Precigen commissioned research in Nov-Dec 2023; RRP Foundation website. World Health Organization. HPV vaccination coverage database; World Bank; Yin et al. A national cross-sectional study on the influencing factors of low HPV vaccination coverage in mainland China. 2022.

# PRGN-2012 has Potential to be the First- and the Best-in-Class RRP Treatment

Groundbreaking efficacy demonstrated in RRP

Favorable safety profile

Ease of SQ administration is preferred by HCPs

Established mechanism of action with strong HPV 6/11-specific T cell immune response

Lack of meaningful anti-drug neutralizing antibodies with repeated dosing

Orphan Drug Designation from the FDA and European Commission

Breakthrough Therapy Designation from the FDA

Rolling BLA submission anticipated for 2H 2024 under accelerated approval pathway



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