Precigen, Inc.

24 January 2023

PRGN-2012 AdenoVerse™ Immunotherapy

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Forward-looking Statements

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Forward-looking Statements (cont.)

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R&D Day Participants

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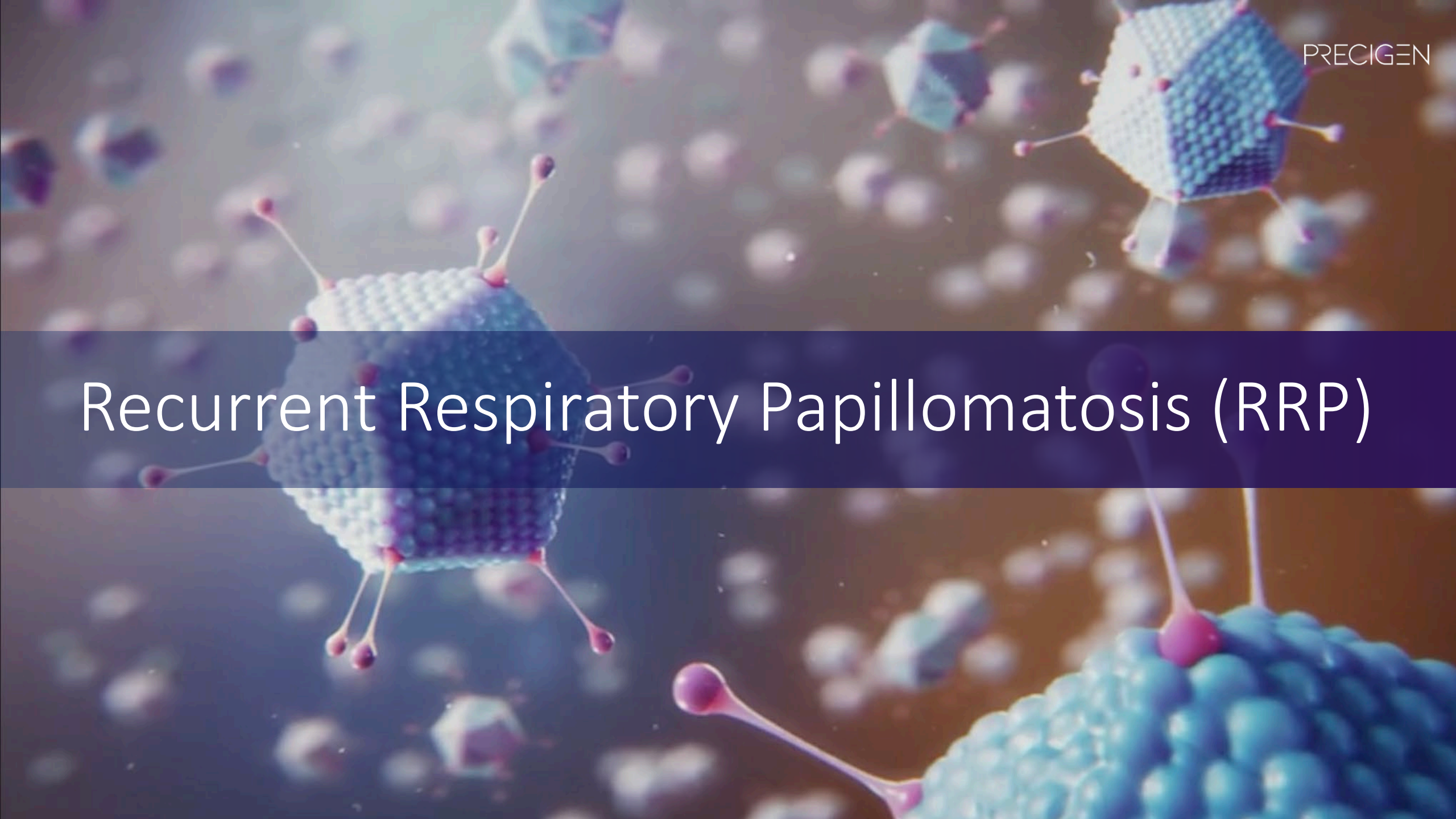
Precigen



Recurrent Respiratory Papillomatosis (RRP)

Recurrent Respiratory Papillomatosis (RRP): Need for Safe and Effective Treatment

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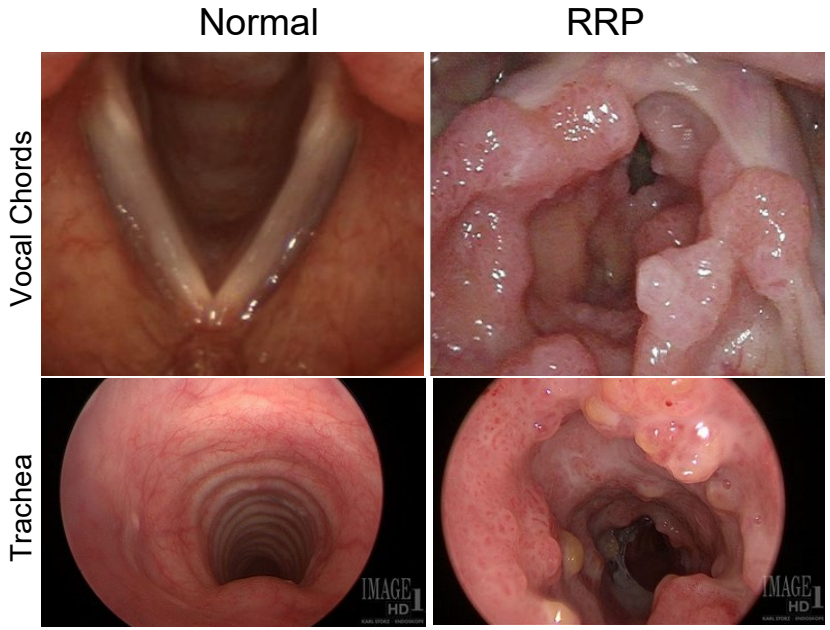
RRP IS CAUSED BY HPV6 OR HPV11 INFECTION[1,2]

- A rare disease in which benign tumors called papillomas grow in the respiratory tract
- RRP can cause severe voice disturbance, airway compromise, fatal pulmonary lesions, and invasive cancers
- Affects both children and adults

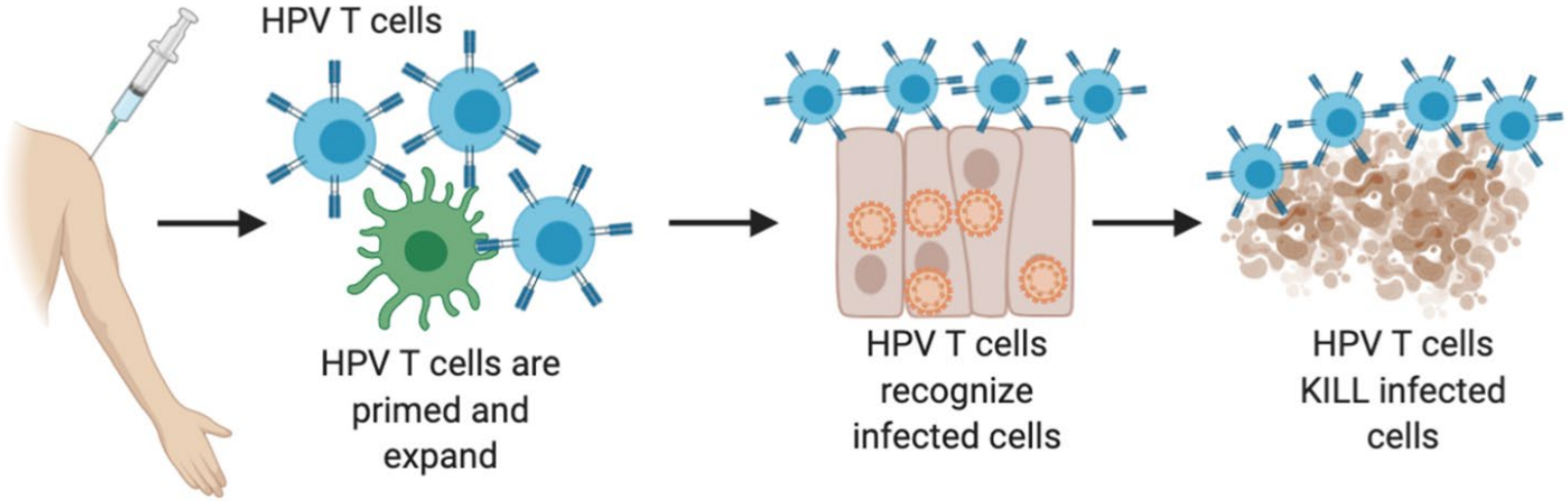


SIGNIFICANT UNMET MEDICAL NEED IN RRP

- **There are no approved therapeutics for RRP**
- Current standard-of-care treatment is repeat surgical debulking of papilloma[3,4]
  - Surgery does not treat underlying cause of RRP
  - Surgery is not curative but palliative and therefore only treats RRP symptoms
- Some RRP patients will require hundreds of lifetime surgeries
  - High economic burden of repeat surgeries for patients and healthcare system

[1]What is RRP? Recurrent Respiratory Papillomatosis Foundation, Accessed 2023. https://rrpf.org/what-is-rrp/; https://rrpf.org/pulmonary-rrp/
[2]Venkatesan, N.N., et al., Otolaryngologic Clinics of North America (2012)
[3]https://www.nidcd.nih.gov/health/recurrent-respiratory-papillomatosis
[4]Allen, C.T., et al. j. immunotherapy cancer (2019)

A Therapeutic Vaccine Designed To Induce HPV-specific T-cells may Cure RRP



RATIONALE FOR HPV6/11 THERAPEUTIC VACCINE

- Immune-mediated clearance of HPV is likely the only way to potentially cure RRP[1]
- T cells are the only immune cells that can specifically detect and kill HPV infected cells
- Data demonstrates a lack of HPV-specific T cells in RRP patients

[1]Bai L., et al., Laryngoscope (2021)

PRGN-2012 AdenoVerse Immunotherapy

PRGN-2012: Investigational Off-the-shelf AdenoVerse Immunotherapy for RRP

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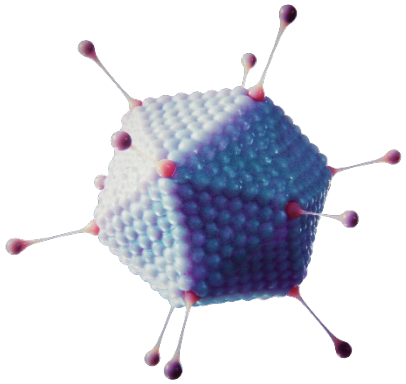
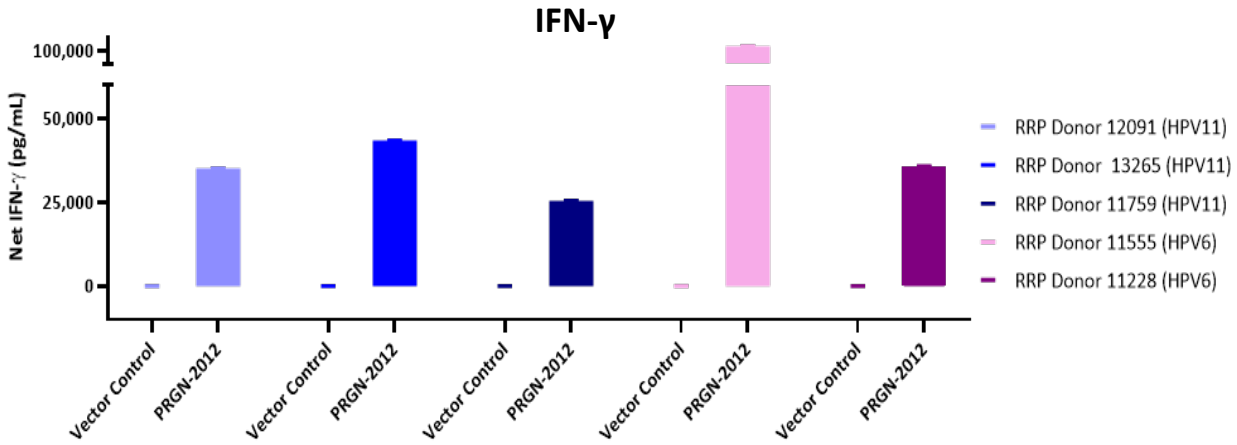
PRGN-2012 TARGETS HPV6/11 INFECTED CELLS



- 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
- Orphan Drug Designation (ODD) granted by the FDA

PRGN-2012 INDUCES ROBUST HPV6 AND HPV11 SPECIFIC T-CELL RESPONSE IN RRP PATIENT SAMPLES *IN VITRO*



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AdenoVerse™ Immunotherapy Explained


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Phase 1 Clinical Trial

PRGN-2012: Phase 1 Clinical Trial Design

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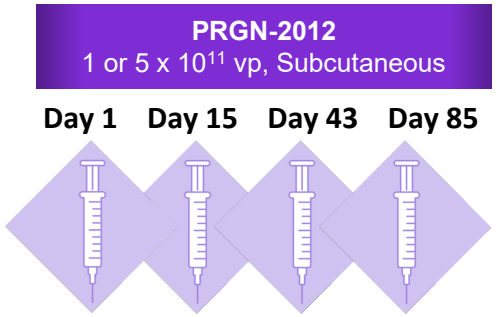
FIRST-IN-HUMAN STUDY TO EVALUATE SAFETY & EFFICACY OF PRGN-2012

- **Adult patients with severe, aggressive RRP (≥ 3 surgeries in prior 12 months before treatment) are eligible**



Dose Level (DL)	Subjects	Dose
DL1	N=3	1x10^{11} viral particles
DL2	N=12	5x10^{11} viral particles

STUDY ENDPOINTS

Efficacy:

- Number of surgeries required to control RRP in the 12 months following completion of treatment with RRP
- Extent of papilloma growth at 6 months (Derkay scores)
- Vocal function at 6 months (Vocal Handicap Index: VHI-10)

Safety:

- Incidence and severity of adverse events

Mechanistic correlates:

- Effect of PRGN-2012 on HPV-specific immune responses

ClinicalTrials.gov Identifier: NCT04724980

PRGN-2012 Phase 1 Study: Patient Characteristics

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	N=15
Median age (range), years	51 (30-73)
Male	10 (67%)
Female	5 (33%)
Age at diagnosis	
▪ Range (years)	1-68
▪ Juvenile onset	2 (13%)
▪ Adult onset	13 (87%)
▪ Years since diagnosis	15 (1-43)
Baseline disease	
▪ Surgeries in last 12 months	Mean 6.2 (range 3-10)

Phase 1 Study Population

- Adult patients with severe, aggressive RRP
- ≥ 3 surgeries per year prior to enrollment

Dose Level (DL)	Subjects	Dose
DL1	N=3	$1x10^{11}$ viral particles
DL2	N=12	$5x10^{11}$ viral particles

- 100% patient compliance through treatment phase
- 15/15 subjects have evaluable data through 52 weeks

Presentation Data cutoff: 12 January 2023

PRGN-2012 Phase 1 Study: Safety Summary

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PRGN-2012 Treatment-related Adverse Events (TRAEs)

	Dose Level 1 1×10^{11} vp (N=3)		Dose Level 2 5×10^{11} vp (N=12)		All Subjects (N=15)	
	Subjects (N, %)	Events (N)	Subjects (N, %)	Events (N)	Subjects (N, %)	Events (N)
Grade 1	3 (100%)	7	12 (100%)	105	15 (100%)	112
Grade 2	0 (0%)	0	2 (16.7%)	4	2 (13.3%)	4
Grades 3 -5	**0 (0%)**	0	**0 (0%)**	0	**0 (0%)**	0

- PRGN-2012 administrations were well-tolerated
- All Treatment-related AEs were ≤ Grade 2
- No DLTs or SAEs were observed

- TRAEs were all mild and reduced in frequency over the treatment interval
- Most common AE was injection site reaction (100% subjects)
- Majority of adverse events occurring in > 1 subject were similar to seasonal vaccines^ (i.e., chills, fatigue, fever)

^https://www.cdc.gov/flu/prevent/flushot.htm

PRGN-2012 Phase 1 Study: Safety Summary

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PRGN-2012 Treatment-related Adverse Events by Grade

Total Subjects (N=15)

	Grade 1		Grade 2	
	Subjects (N, %)	Events (N)	Subjects (N, %)	Events (N)
Chills	10/15 (66.7%)	14	0 (0%)	0
Diarrhea	1/15 (6.7%)	1	0 (0%)	0
Shortness of breath (Dyspnea)	1/15 (6.7%)	1	0 (0%)	0
Excessive sweating (Hyperhidrosis)	2/15 (13.3%)	2	0 (0%)	0
Fatigue	9/15 (60.0%)	20	2/15 (13.3%)	2
Fever	9/15 (60.0%)	17	0 (0%)	0
Injection site reaction	15/15 (100%)	46	0 (0%)	0
Muscle aches (Myalgia)	2/15 (13.3%)	2	2/15 (13.3%)	2
Nausea	4/15 (26.7%)	6	0 (0%)	0
Skin itching (Pruritus)	1/15 (6.7%)	1	0 (0%)	0
Vomiting	2/15 (13.3%)	2	0 (0%)	0

All Treatment-related AEs were ≤ Grade 2

PRGN-2012 Treatment at Dose Level 1 Reduced the Need for Surgeries in Patients with Severe, Aggressive RRP

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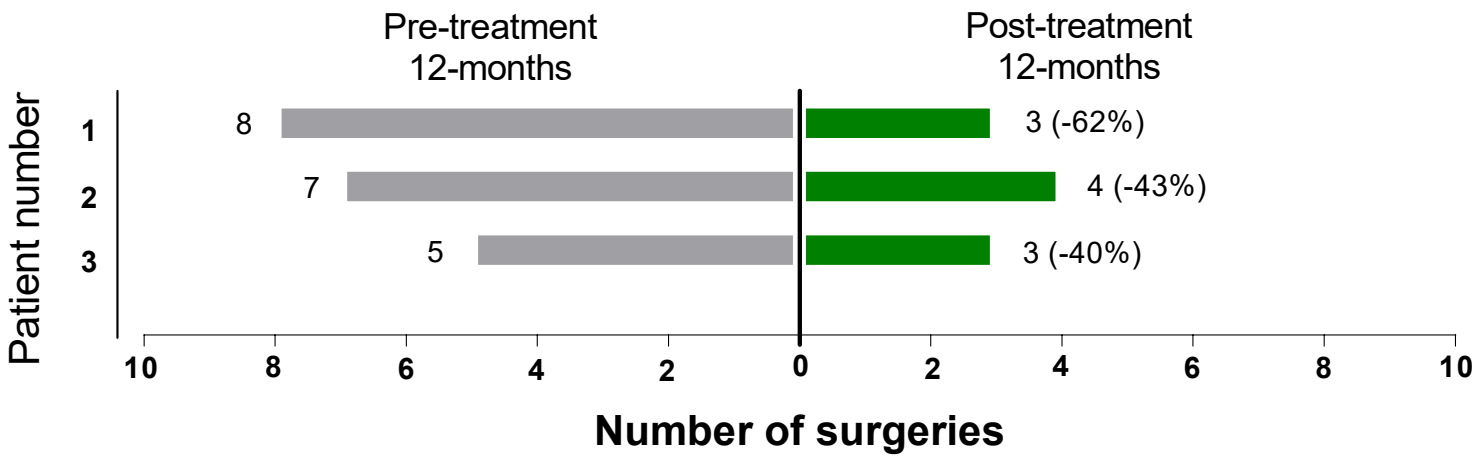
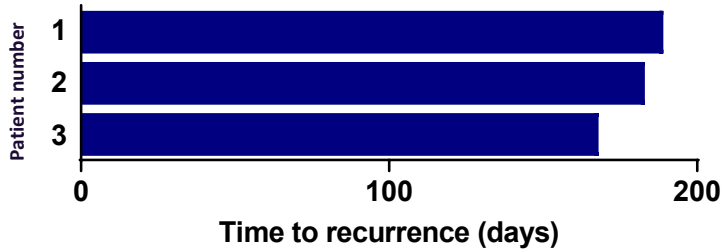
Number of Surgeries in the 12-months Prior to PRGN-2012 Treatment Compared to Surgeries in the 12-months Post PRGN-2012 Treatment



- PRGN-2012 treatment at Dose Level 1 reduced need for surgeries for severe, aggressive RRP patients
  - Patients in Dose Level 1 had an average of 6.6 surgeries in the prior year
  - During the 12 months following treatment with PRGN-2012, patients required an average of 3.3 surgeries
- PRGN-2012 at Dose Level 1 was well-tolerated with no incidence of dose limiting toxicities, severe adverse events

Time to Recurrence (TTR) after PRGN-2012 Treatment at Dose Level 1



Average Time to Recurrence Following PRGN-2012 Treatment

Pre-treatment Interval[#]	Post-treatment Interval[Ψ]	Change in TTR
55 Days	180 Days	125 Days

[#] average surgery-free interval during prior 12 months
[Ψ] Time from start of treatment to first surgery

PRGN-2012 Treatment at **Dose Level 2** Eliminated Need for Any Surgeries in 50% of RRP Patients#

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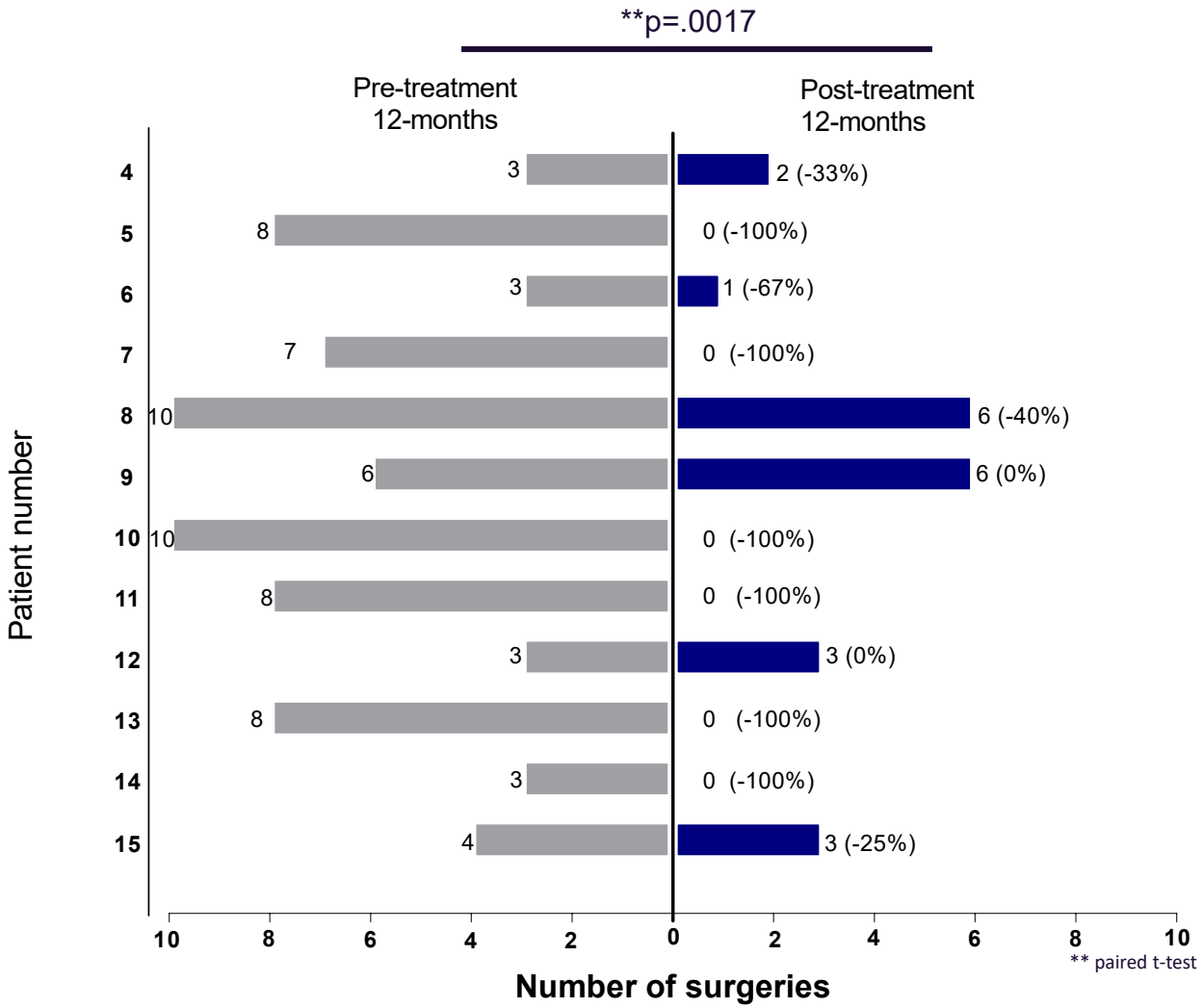
Number of Surgeries in the 12-months Prior to PRGN-2012 Treatment Compared to Surgeries in the 12-months Post PRGN-2012 Treatment



- **PRGN-2012 treatment significantly reduced need for surgeries for severe, aggressive RRP patients**
- **50% (6 out of 12) Complete Response (CR)#** rate in patients treated at Dose Level 2
- Patients in Dose Level 2 needed an average of 6 surgeries in the prior year
- **58% (7 out of 12) Overall Response Rate (ORR)Ψ** in patients treated at Dose Level 2
- **83% (10 out of 12)** patients demonstrated reduction in need for surgeries compared to pre-treatment

#CR: Complete Response; No need for surgeries after PRGN-2012 treatment completion during the 12-month follow up period

ΨORR: Overall Response Rate; ≥50% reduction in surgeries in the 12-month period after PRGN-2012 treatment completion compared to the 12-month period prior to treatment initiation

PRGN-2012 Treatment at Dose Level 2 Significantly Enhances Time to Recurrence in RRP

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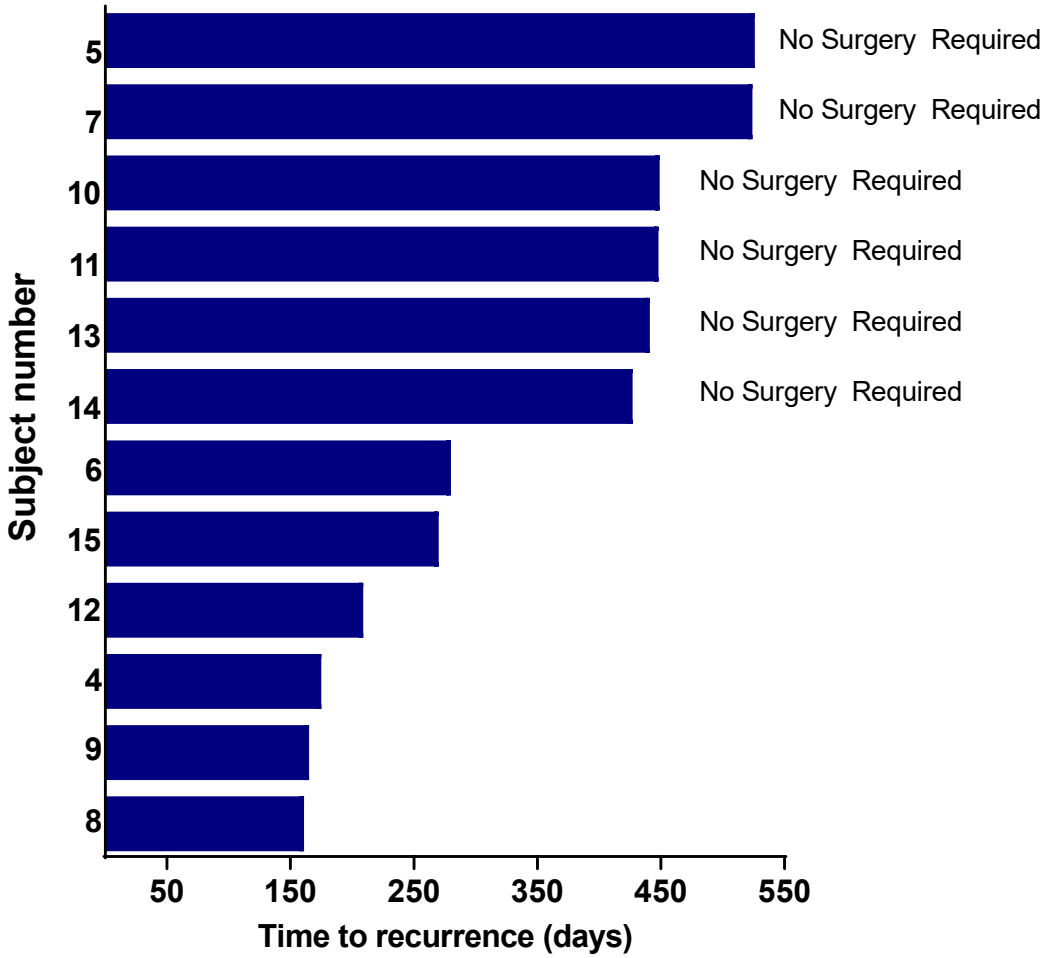
Time to Recurrence (TTR) after PRGN-2012 Treatment at Dose Level 2 (N=12)



Average Time to Recurrence Following PRGN-2012 Treatment

Pre-treatment Interval[#]	Post-treatment Interval[Ψ]	Change in TTR
68 Days	338 Days	270 Days

[#] average surgery-free interval during prior 12 months
[Ψ] Time from start of treatment to first surgery

- **6/12 (50%) subjects treated at Dose Level 2 do not have RRP recurrence and have not required any surgery post-treatment to date**

Clinical Efficacy Summary

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PRGN-2012 AdenoVerse Immunotherapy Clinical Efficacy Summary

	Dose Level 1 (N=3)	Dose Level 2 (N=12)
Complete Response (CR) No surgeries needed during 12-months post-treatment	**0% (0/3)**	**50% (6/12)**
Overall Response Rate (ORR) ≥ 50% reduction in surgeries during 12-months post-treatment compared to 12-months pre-treatment	**33% (1/3)**	**58% (7/12)**
Decrease in rate of surgery 12-months post-treatment compared to 12-months pre-treatment	**100% (3/3)**	**83% (10/12)**

Derkay Scoring

1. How long since the last papilloma surgery	
2. Counting today's surgery, how many papilloma surgeries in the past 12 months?	
3. Describe the patient's voice today	0=normal 1=abnormal 2 = aphonic
4. Describe the patient's stridor today	0=absent 1=present with activity 2 = present at rest
5. Describe the urgency of today's intervention	0=scheduled 1=elective 2 = urgent 3= emergent
6. Describe today's level of respiratory distress	0=none 1=mild 2 = moderate 3= severe 4=extreme

Total score for questions 3-6:

For each site below, score as 0=none, 1=surface lesion, 2= raised lesion, 3=bulky lesion

Epiglottis – lingual surface	Right arytenoid	Right bronchus
Epiglottis – laryngeal surface	Left arytenoid	Left bronchus
Right aryepiglottic fold	Anterior commissure	Tracheostomy stoma
Left aryepiglottic fold	Posterior commissure	Nose
Right false vocal fold	Subglottis	Pharynx
Left false vocal fold	Trachea – upper one third	Esophagus
Right true vocal fold	Trachea – middle one third	Lungs
Left true vocal fold	Trachea – lower one third	Other

- A Derkay Scoring is performed at screening and at every treatment and follow-up study visits (up to 24 weeks) based on endoscopic exam by Study Investigators
- The Derkay score is a tool used for research purposes only to **quantify recurrent respiratory papillomatosis (RRP) severity based on involvement of laryngeal structures**
- The Derkay score is not used in routine clinical practice to make determination for surgical intervention
- Patient-reported symptoms are used for surgical treatment decisions by the patient local physician

PRGN-2012 Treatment Improved Derkay Scores in RRP Patients

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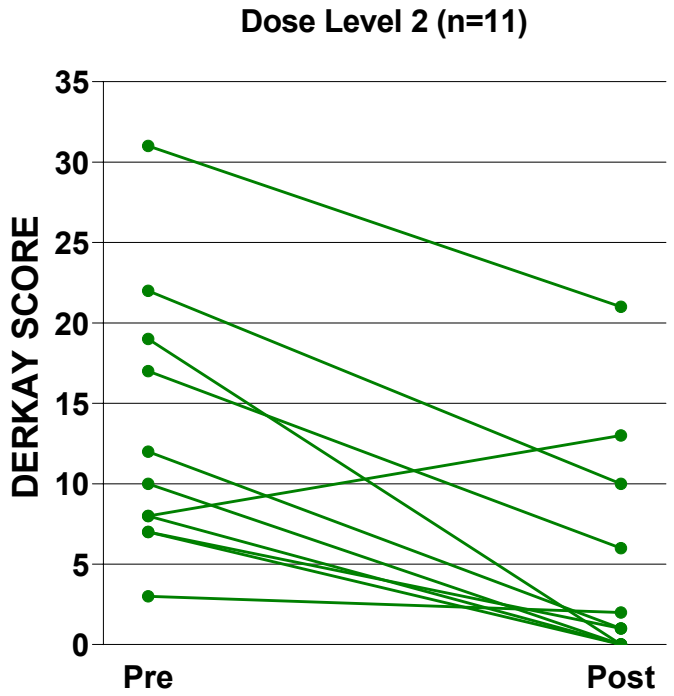
Change in Derkay Scores following treatment with PRGN-2012



RRP patients had significant# improvement in Derkay score at 24 week follow up compared to baseline

p=0.0014; paired t-test

One subject (subject # 9) had an increase in Derkay Score at 24 week follow up compared to baseline
One subject did not have Derkay score assessment at 24 week follow-up interval

Vocal Handicap Index-10 (VHI-10)

	Score				
1. My voice makes it difficult for people to hear me	0	1	2	3	4
2. People have difficulty understanding me in a noisy room	0	1	2	3	4
3. My voice difficulties restrict my personal & social life	0	1	2	3	4
4. I feel left out of the conversations because of my voice.	0	1	2	3	4
5. My voice problem causes me to lose income.	0	1	2	3	4
6. I feel as though I have to strain to produce voice	0	1	2	3	4
7. The clarity of my voice is unpredictable.	0	1	2	3	4
8. My voice problem upsets me	0	1	2	3	4
9. My voice makes me feel handicapped	0	1	2	3	4
10. People ask, "What's wrong with your voice?"	0	1	2	3	4

0= Never; 1 = Almost never; 2 = Sometimes; 3 = Almost always; 4 = Always
Rosen, C. A., et al. (2004). "Development and validation of the voice handicap index-10." Laryngoscope 114(9): 1549-1556

- The Vocal Handicap Index-10 is collected at screening and at every treatment and follow-up study visits (up to 24 weeks)
- The VHI-10 has been **validated** as meeting the criteria for reliability, validity, and availability of normative data and is established as a valuable outcome measure for voice disorders

PRGN-2012 Treatment Improved Voice Function in RRP Patients

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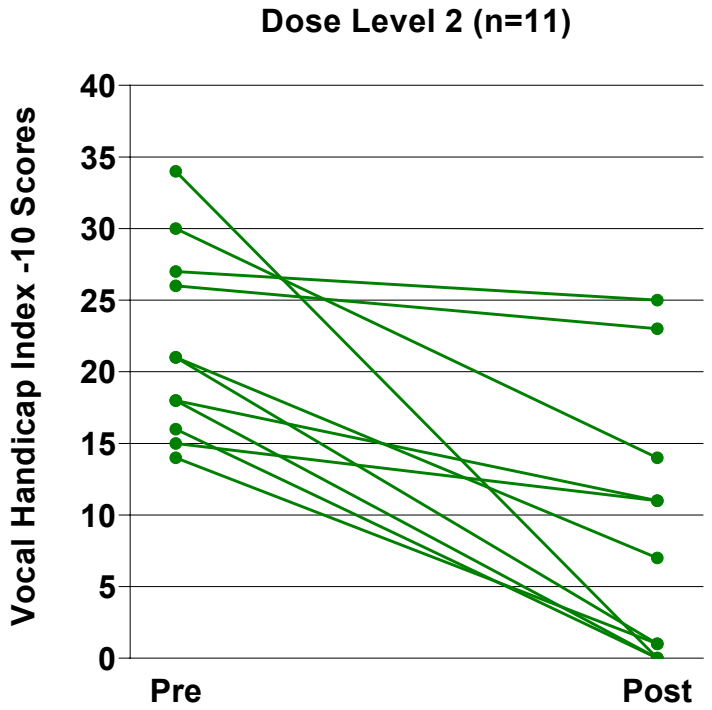
Change in VHI-10 Scores following PRGN-2012 treatment

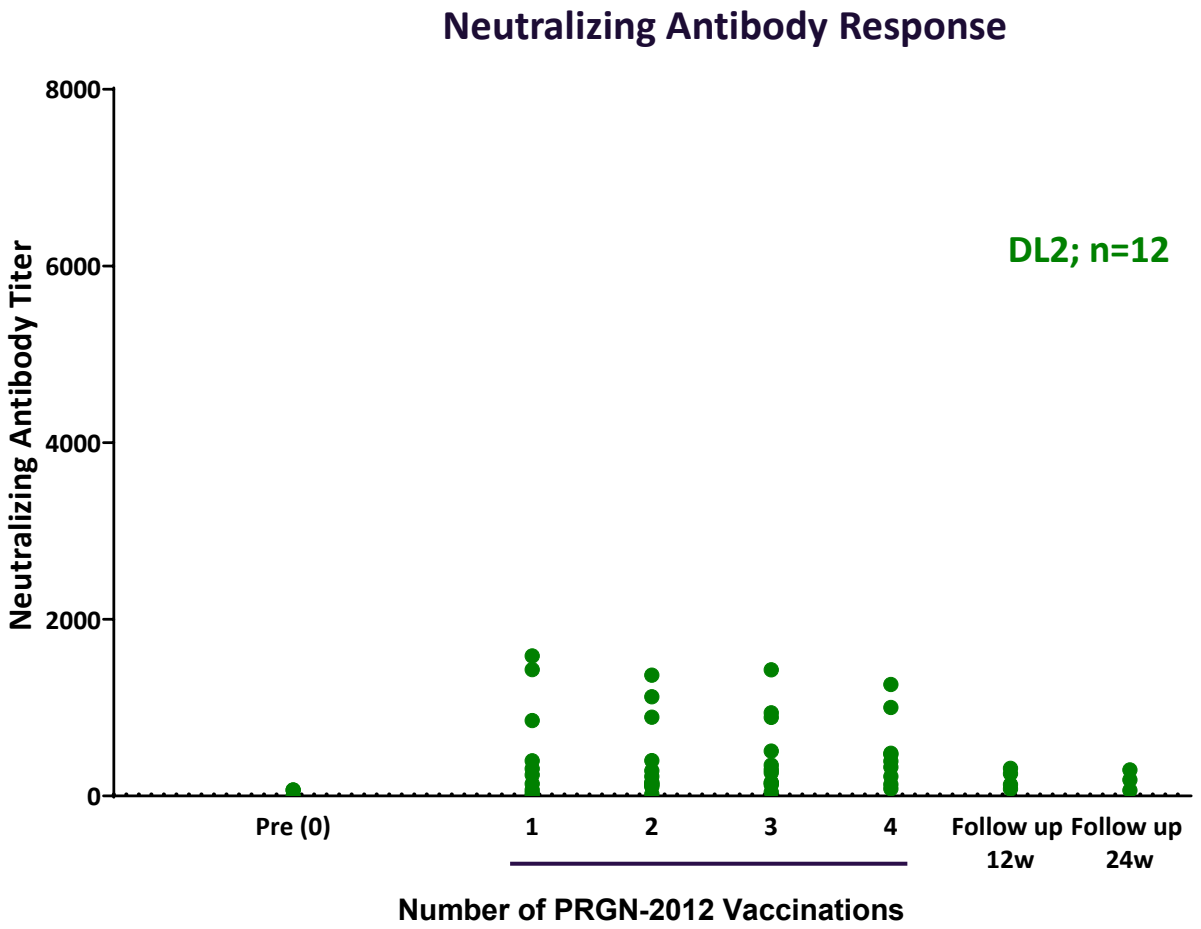


RRP patients had significant# improvement in VHI-10 score at 24 week follow up compared to baseline

p=0.0008; paired t-test

One subject did not have a VHI-10 score assessment at the 24 week follow-up interval

Repeat Administrations of PRGN-2012 did not Lead to Substantial Increase in Neutralizing Antibody Response



- Low-level increase in neutralizing Ab after first administration
- Validates ability to repeat administer AdenoVerse therapies

PRGN-2012 Treatment Induces Robust HPV 6/11-specific T-cell Response

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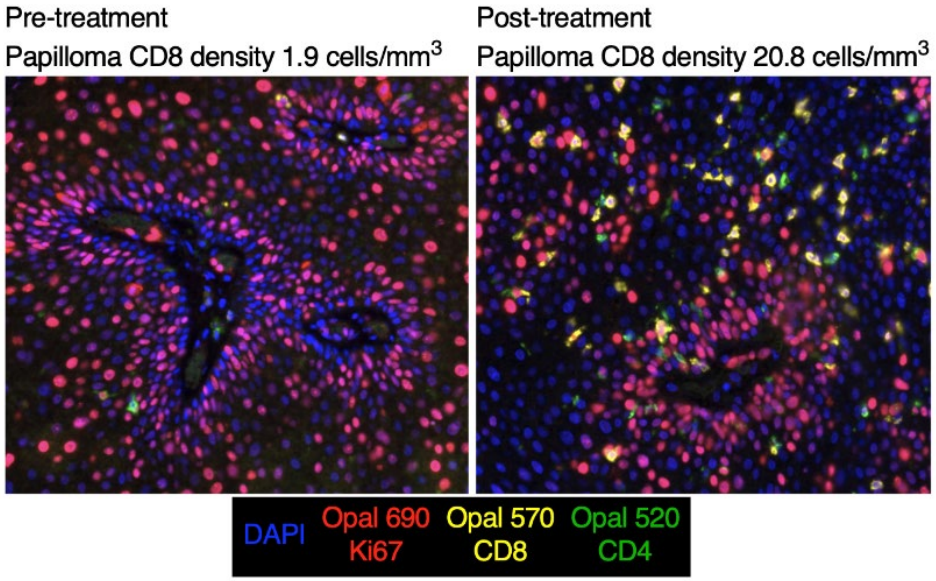
T-cell Infiltration in Papillomas Following PRGN-2012 Treatment



- RRP patients have been shown to lack significant HPV-specific T-cells
- PRGN-2012 treatment resulted in infiltration T-cells into papillomas

PRGN-2012 Phase 1 Study: Case study, Subject # 5, *COMPLETE RESPONSE*

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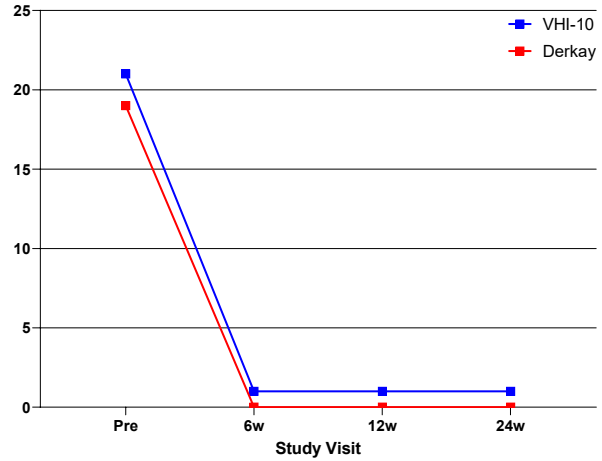
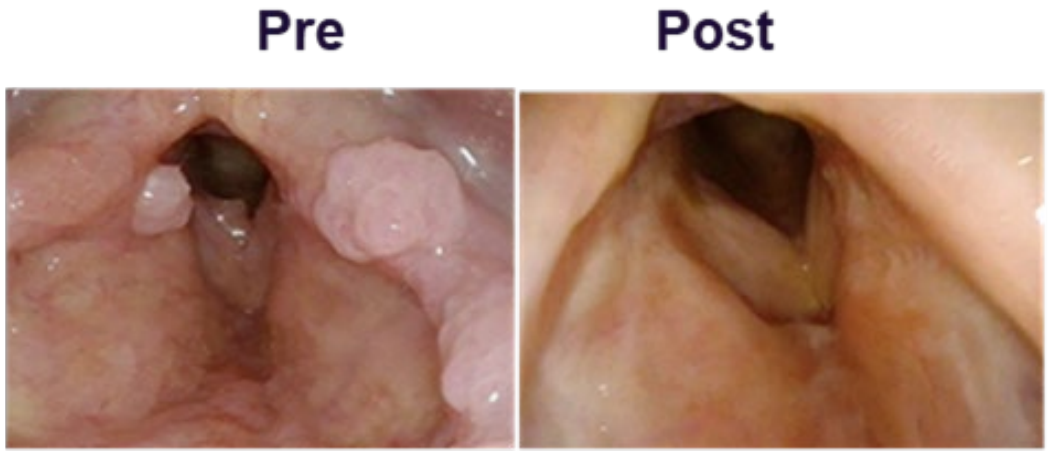
- 40 year old male
- Required debulking every ~6 weeks prior to treatment to control papilloma growth

	Pre-treatment	Post-treatment
Number of RRP surgeries	8	0
Time to recurrence	48.3 days	No recurrence (18m+)

Complete Response with No Need for Surgeries for >1 Year Following PRGN-2012 Treatment



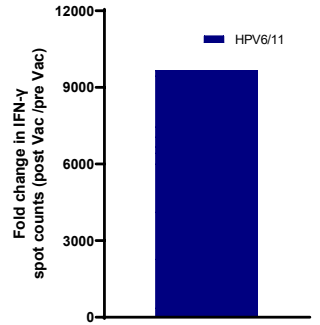
- Extent of papilloma growth, as measured by Derkay score, decreased to zero following completion of treatment
- Subjects vocal function was returned to normal levels following treatment, as indicated by the VHI-10



Pre: Baseline before treatment initiation
Post: 24-week post PRGN-2012 treatment completion

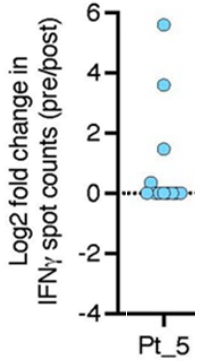
Significant Increase in HPV-specific Immune Response in Blood and Papilloma Tissue after PRGN-2012 Treatment

Peripheral Blood



PBMCs were stimulated with HPV-specific peptide pools in IFN-γ ELISpot assay and sum of fold change for each peptide pool was plotted.

Papilloma Tissue



T-cells infiltrating papillomas were cultured and pulsed with individual pools of different HPV epitopes; each dot represents response against a specific peptide pool in ELISpot assay.

PRGN-2012 Phase 1 Study: Case study, Subject # 5

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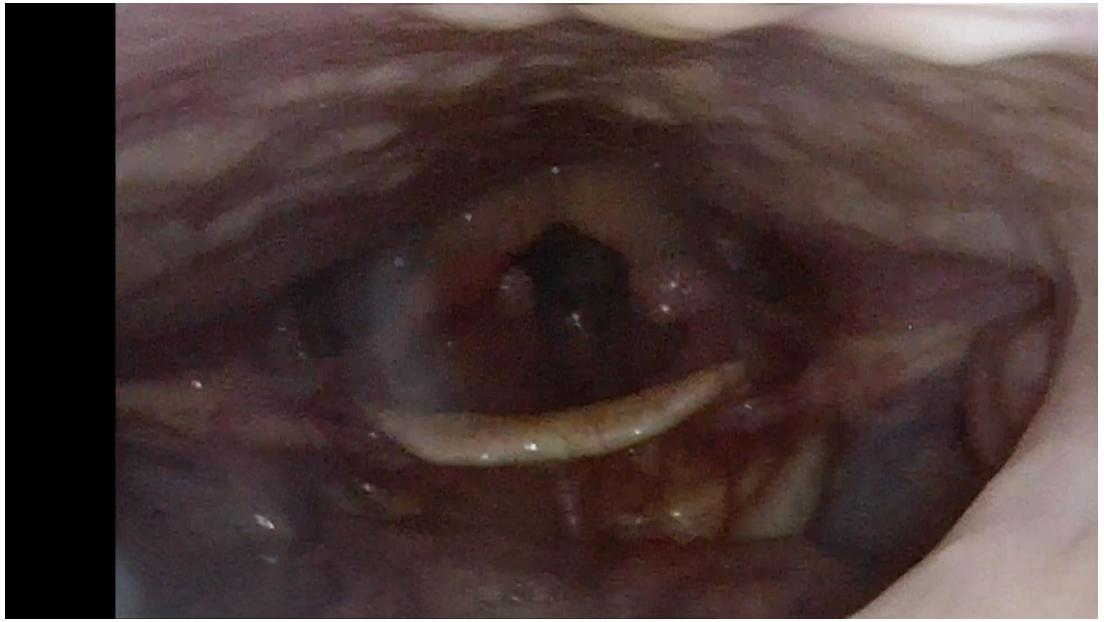
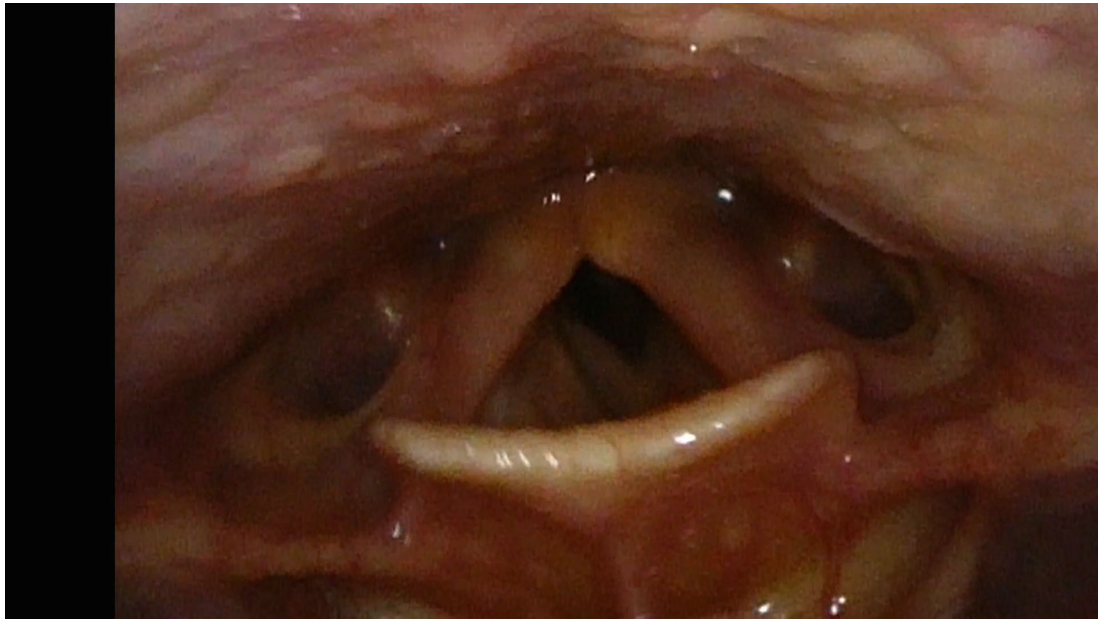
Pre-treatment
8 surgeries in Prior 12-months



Post-treatment
Complete Response; No surgeries needed



Pre-treatment: Baseline before treatment initiation
Post-treatment: 24-week post PRGN-2012 treatment completion

PRGN-2012 Phase 1 Study: Case study, Subject # 10, *COMPLETE RESPONSE*

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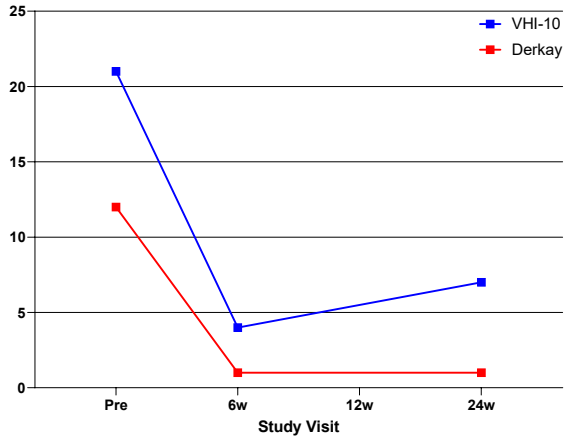
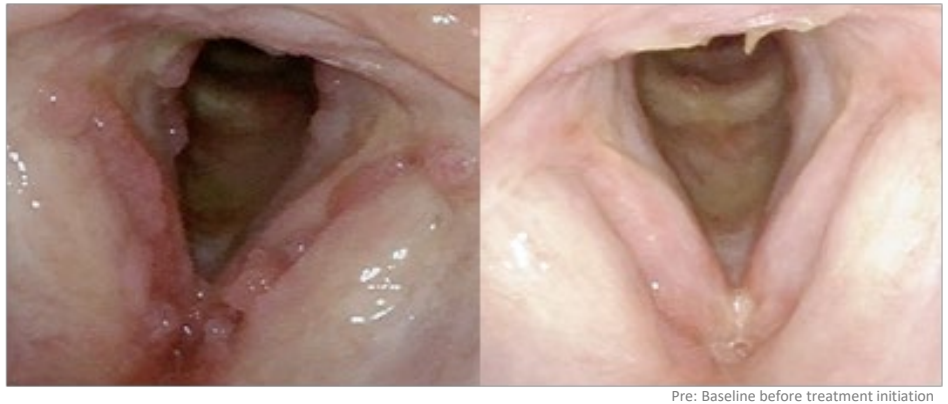
- 73 year old female
- Required debulking every ~ 5 weeks prior to treatment to control papilloma growth

	Pre-treatment	Post-treatment
Number of RRP surgeries	10	0
Time to recurrence	40.4 days	No recurrence (15m+)

Complete Response with No Need for Surgeries for >1 Year Following PRGN-2012 Treatment



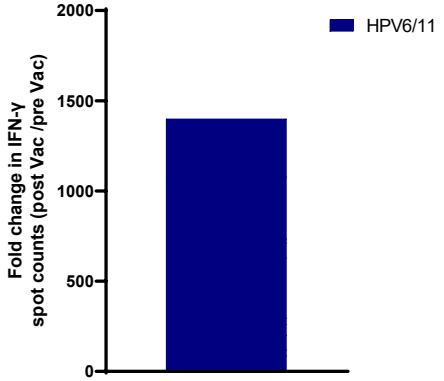
- Extent of papilloma growth, as measured by Derkay score, decreased following completion of treatment
- Subjects vocal function was returned to normal levels following treatment, as indicated by the VHI-10



Pre: Baseline before treatment initiation
Post: 24-week post PRGN-2012 treatment completion

Significant Increase in HPV-specific Immune Response in Peripheral Blood Tissue after PRGN-2012 Treatment

Peripheral Blood



PBMCs were stimulated with HPV-specific peptide pools in IFN-γ ELISpot assay and sum of fold change for each peptide pool was plotted.

*No papilloma tissue was available for biopsy/analysis

PRGN-2012 Phase 1 Study: Case study, Subject # 11, *COMPLETE RESPONSE*

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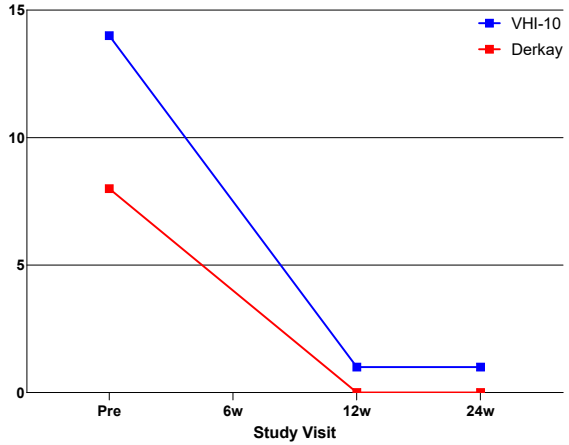
- 48 year old female
- Required debulking every ~6 weeks prior to treatment to control papilloma growth

	Pre-treatment	Post-treatment
Number of RRP surgeries	8	0
Time to recurrence	50.4 days	No recurrence (15m+)

Complete Response with No Need for Surgeries for >1 Year Following PRGN-2012 Treatment



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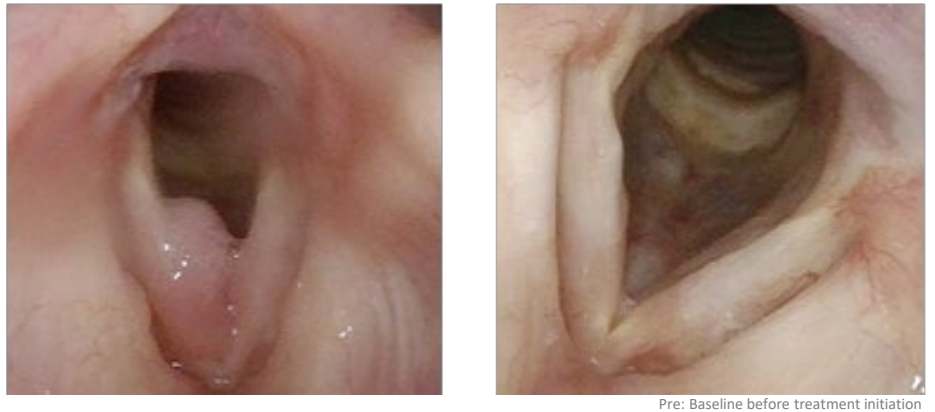
Pre **Post**



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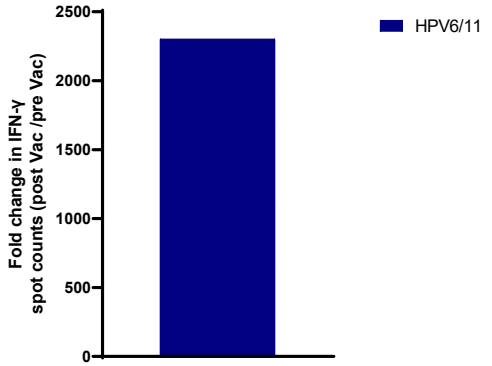

PBMCs were stimulated with HPV-specific peptide pools in IFN-γ ELISpot assay and sum of fold change for each peptide pool was plotted.

*No papilloma tissue was available for biopsy/analysis

PRGN-2012: Summary

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- Repeated administrations of PRGN-2012 were well-tolerated with no treatment related DLTs or SAEs; All Treatment-related AEs were ≤ Grade 2
- Phase 1 efficacy data shows strong response in RRP patients with 50% of patients in Complete Response following PRGN-2012 treatment at Dose Level 2; All Complete Responders remain surgery-free post-treatment as of data cutoff (minimum 12-months follow up)
- 83% of patients treated at Dose Level 2 had reduced surgeries post PRGN-2012 treatment
- PRGN-2012 treatment shows significant improvement in Derkay scores and voice quality in RRP patients
- PRGN-2012 treatment resulted in robust HPV-specific T-cell response in blood and papillomas
- Neutralizing antibody data support repeated administrations of gorilla adenovirus based AdenoVerse therapies
- Phase 2 study is enrolling patients with a total of 32 patients (N=12 in Phase 1/expansion cohort; N=20 in Phase 2) enrolled at Dose Level 2 to-date

PRGN-2012 Potential

The Product Profile for PRGN-2012 is Considered to Have Paradigm Changing Potential, Driven by the Clear Reduction in Need for Surgery

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Mechanism of Action is Seen as Very Promising

- Physicians described the PRGN-2012 MOA as ***promising***, and KOLs were particularly impressed that PRGN-2012 generates a ***T-cell response that specifically targets HPV-6 and HPV-11 viral sub-types***
  - *"It's basically like getting a vaccine because you are stimulating the immune system to target the pathogen." – Otolaryngologist*

Reduced Need for Surgery is Paradigm Changing

- Physicians were ***overwhelmingly positive regarding the product profile***, and considered this to be ***a potential game-changer in the treatment paradigm for RRP***
  - *"This looks like a great drug. Anything that can reduce the number of surgeries is very positive, and it is well tolerated. It is very appealing." – Otolaryngologist*

Reassuring Safety

- Physicians viewed ***PRGN-2012's safety profile favorably***, and no specific concerns were voiced, they also felt that PRGN-2012 ***would have a positive impact on patients QoL***

Reasonable Administration for Disease Burden

- 4 doses in 12 weeks was **perceived as fair, and subcutaneous injection** is seen as attractive and acceptable to patients
  - *It's four subcutaneous doses, it's not like it's a local delivery in the vocal chord." – Otolaryngologist*

Recurrent Respiratory Papillomatosis (RRP): Need for Safe and Effective Treatment

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RRP DISEASE PREVALENCE

Active Cases in US[1]

~10,000 Adult Cases

~6,000 Juvenile Cases

Active Cases Ex-US[2,5]

Up to 60,000 Adult Cases

ESTIMATED MARKET OPPORTUNITY

>$1B

Peak annual market opportunity in US[4]

~$2B

Peak annual market opportunity including ex-US[5]

US ECONOMIC BURDEN ON RRP PATIENTS

~$100,000 + INDIRECT COSTS = $MILLIONS

ANNUAL DIRECT COSTS[3] | E.G., LOSS OF INCOME/WORK | IMPLIED LIFETIME COSTS

NEXT STEPS

- Continued market research with clinicians, patients, caregivers and payers to further define value proposition across these stakeholders
- Further define burden Outside US via in-depth market research

[1]Derkay, C. S., Task force on recurrent respiratory papillomas: a preliminary report. Archives of Otolaryngology–Head & Neck Surgery (1995).121(12), 1386-1391; About RRP – RRPF NIH Publication No. 10-4307 (2017)
[2]Donne, A. J., et al., Prevalence and management of recurrent respiratory papillomatosis (RRP) in the UK: cross-sectional study. (2016). DOI: 10.1111/coa.12683
[3]Derkay, C. S., et al., Update on Recurrent Respiratory Papillomatosis. (2019). DOI: 10.1016/j.otc.2019.03.011
[4]Commissioned internal Precigen research; RRPF; OrphaNet; NORD; CDC; ScienceDirect; Wangu, Z., et al., (2016); Evaluate Pharma; GlobalData; FDA; CapitalIQ; OECD; WorldBank; FiercePharma; Gordon et al. (2018)
[5]Commissioned internal Precigen research on ex-US case numbers and discounted US penetration and pricing numbers


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Q&A

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