



PRECIGEN

# 39<sup>th</sup> Annual J.P. Morgan Healthcare Conference

Helen Sabzevari, PhD  
President & CEO

13 January 2021

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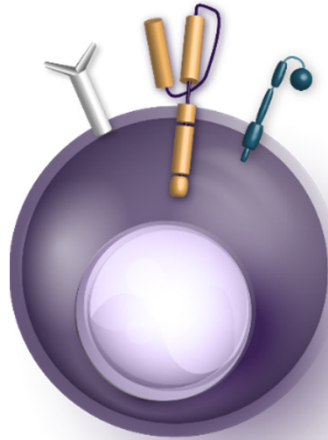
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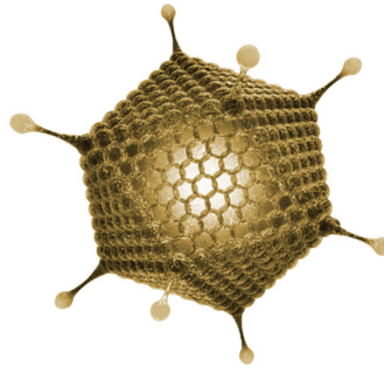
# Precigen: Deploying Novel Approaches to Address Unmet Healthcare Needs

**UltraCAR-T®**



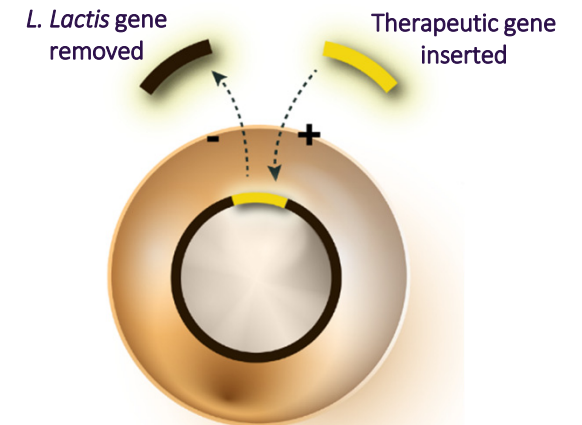
- Non-viral multi-gene delivery
- Non-exhausted, stem-like T cell phenotype
- Higher antigen-specific expansion
- Enhanced *in vivo* persistence
- Ability to deplete with kill switch
- Overnight manufacturing process

**AdenoVerse™  
Immunotherapy**






- Large payload capacity
- Low seroprevalence in humans
- Ability for repeat administration
- Durable antigen-specific immune response
- Highly productive manufacturing process


**ActoBiotics™**




- Food-grade bacteria, *L. lactis*
- Long history of safe use in humans
- Easy genetic manipulation
- Cost-effective and scalable manufacturing
- Convenient oral or topical delivery
- Local expression of genes at disease site

# Precigen Clinical Pipeline

| Immunology | PRODUCT   | PLATFORM                     | INDICATION        | DISCOVERY   | PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 |
|------------|-----------|------------------------------|-------------------|---|-------------|---------|---------|---------|
|            | PRGN-3005 | UltraCAR-T                   | Ovarian Cancer    |  |             |         |         |         |
|            | PRGN-3006 | UltraCAR-T                   | AML, MDS          |  |             |         |         |         |
|            | PRGN-2009 | OTS AdenoVerse Immunotherapy | HPV+ Solid Tumors |  |             |         |         |         |

| Autoimmune | PRODUCT | PLATFORM    | INDICATION      | DISCOVERY   | PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 |
|------------|---------|-------------|-----------------|---|-------------|---------|---------|---------|
|            | AG019   | ActoBiotics | Type 1 Diabetes |  |             |         |         |         |

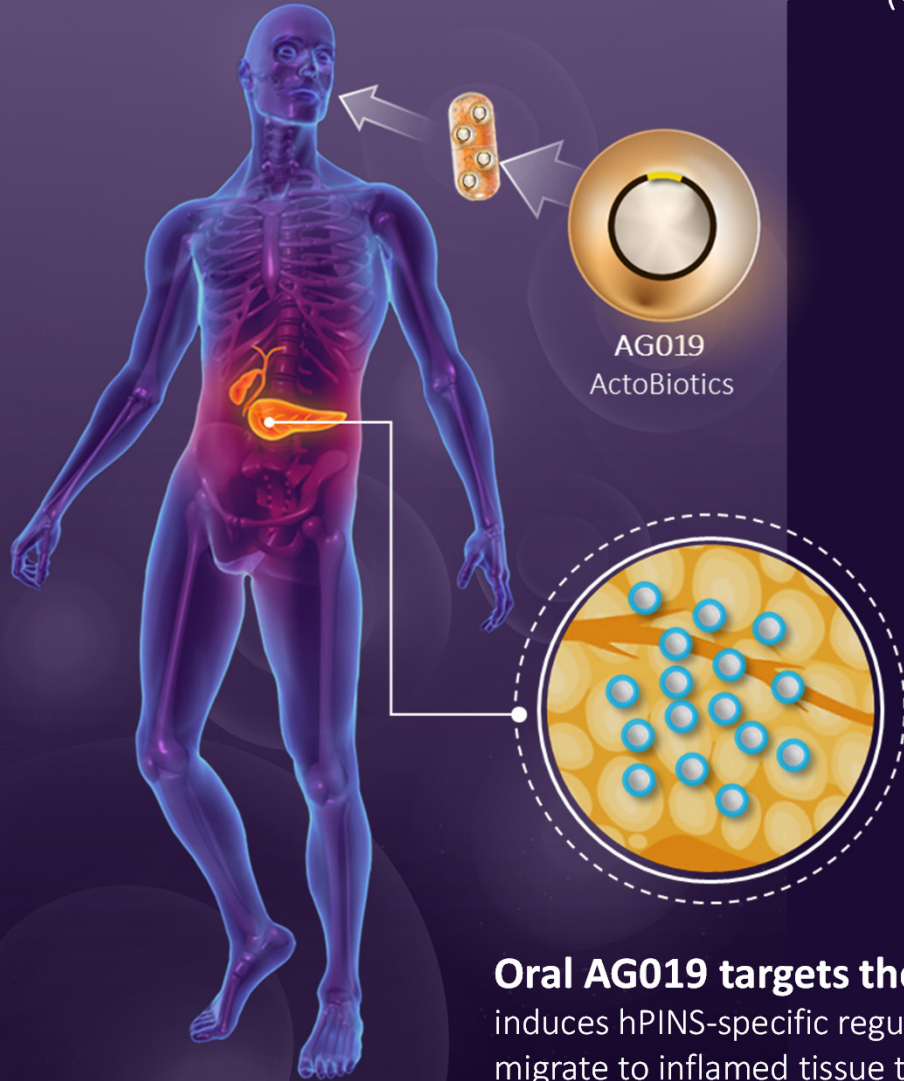
| Infectious | PRODUCT   | PLATFORM                     | INDICATION                           | DISCOVERY   | PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 |
|------------|-----------|------------------------------|--------------------------------------|---|-------------|---------|---------|---------|
|            | PRGN-2012 | OTS AdenoVerse Immunotherapy | Recurrent Respiratory Papillomatosis |  |             |         |         |         |

| Emerging | PRODUCT   | PLATFORM              | INDICATION    | DISCOVERY   | PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 |
|----------|-----------|-----------------------|---------------|---|-------------|---------|---------|---------|
|          | INXN-4001 | Non-viral UltraVector | Heart Failure |  |             |         |         |         |

# ActoBiotics® Platform

# AG019 ActoBiotics

A First-in-Class Oral Investigational Therapy in Type 1 Diabetes



AG019  
ActoBiotics

## Oral AG019 targets the GALT

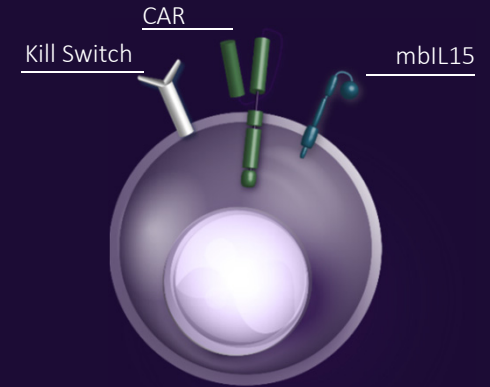
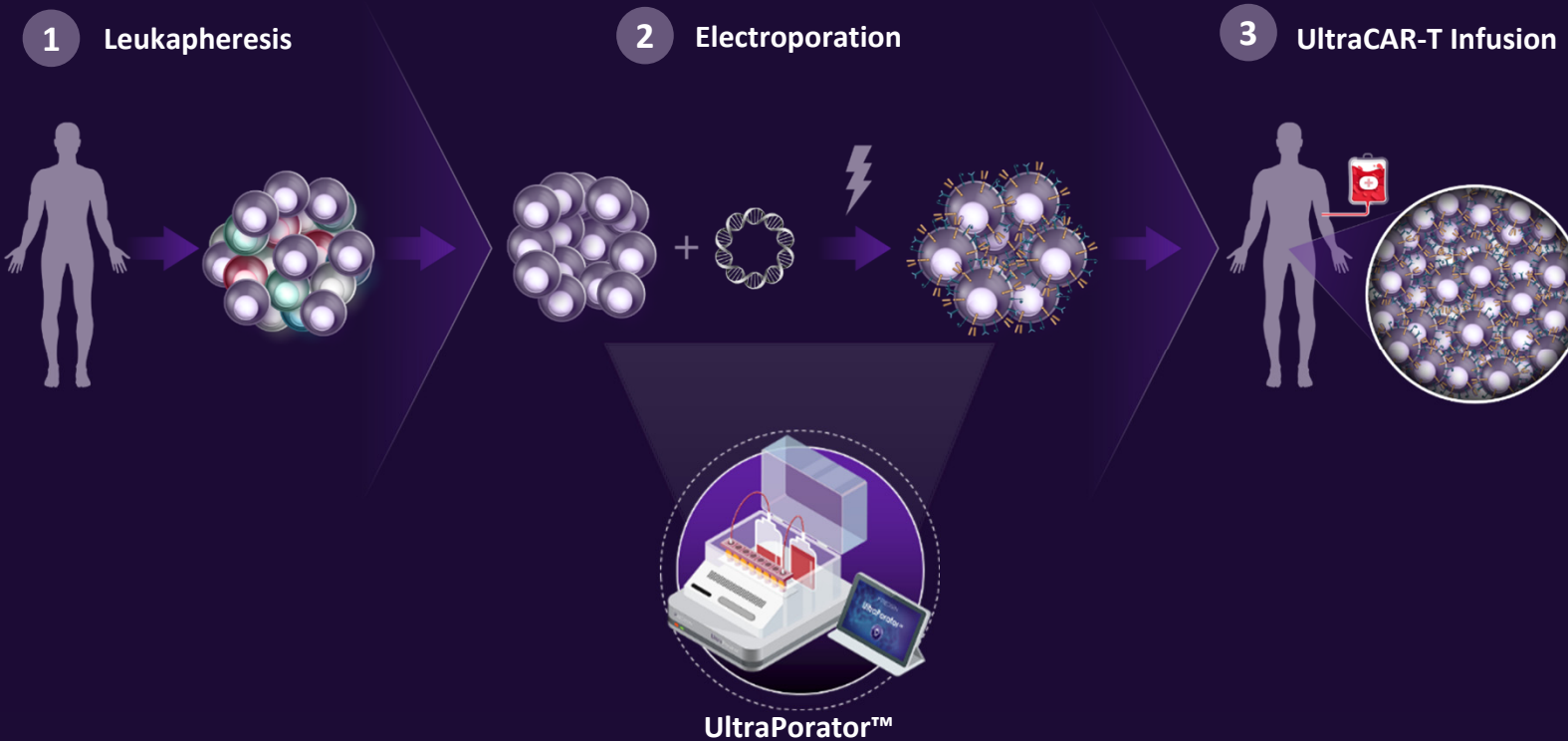
induces hPINS-specific regulatory T cells which migrate to inflamed tissue to block tissue destruction

- Positive interim data reported from Phase 1b (monotherapy) and Phase 2a (combination) arms<sup>1</sup>:
  - AG019 monotherapy as well as the combination of AG019 and teplizumab were well-tolerated and safe
  - 58% (7/12) and 70% (7/10) adults showed insulin C-peptide stabilization at 6-months in monotherapy and combination arms respectively
  - Increase in preproinsulin (PPI)- specific Type 1 regulatory (Tr1) cells in both monotherapy and combination arms
  - Significant decrease in PPI-specific CD8<sup>+</sup> T cells in both monotherapy and combination arms

# UltraCAR-T<sup>®</sup> Platform

# UltraCAR-T: Overnight, Decentralized Manufacturing Process Promises a Potentially More Effective Way to Treat Patients

## UltraCAR-T® Platform is Engineered to Address Major Challenges of Current CAR-T Cell Approaches



### UltraCAR-T Advantages

- Non-viral multi-gene delivery
- Uniform, multigenic cell product
- Stem-like T cell memory phenotype
- Higher antigen-specific expansion
- Enhanced *in vivo* persistence
- Ability to deplete with kill switch
- Overnight manufacturing process

UltraCAR-T Platform is Designed to Bring Benefits of Off-the-Shelf Allogeneic Therapy to Autologous CAR-T Treatment

# Precigen's Potential through Differentiated Platforms

## UltraCAR-T®

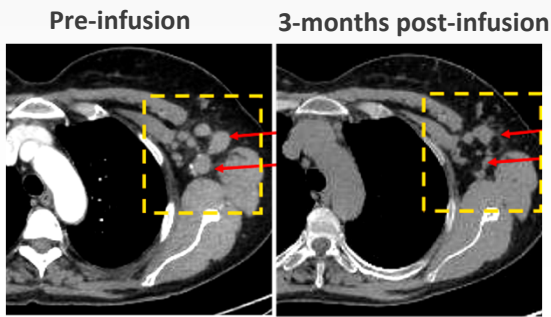
### PRGN-3005 UltraCAR-T

#### PRGN-3005 UltraCAR-T in Ovarian Cancer

- Positive initial data reported from Phase 1 IP arm:
  - PRGN-3005 treatment was safe and well-tolerated with no dose-limiting toxicities (DLTs) to date
  - 100% manufacturing success to date
  - Encouraging expansion and persistence (N=6)
  - 50% (3 of 6) of patients treated the two lowest doses showed reduction in total target tumor burden

#### PRGN-3005: Encouraging Expansion, Persistence and Clinical Activity in Patients Treated at Two Lowest Doses in IP Arm of Phase 1 Study

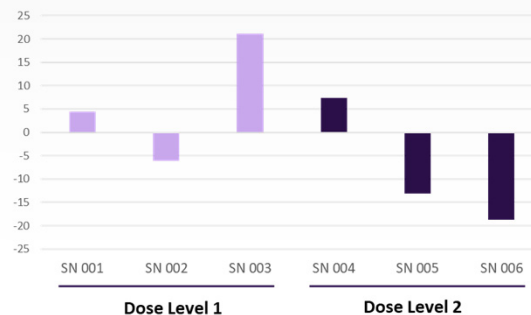
##### Complete Response in Axillary Lymph Node Target Lesion (Case Study: Dose Level 1)



7.5 x 10<sup>6</sup> total PRGN-3005 UltraCAR-T cells administered via IP infusion

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#### Percent Change in Total Target Tumor Burden



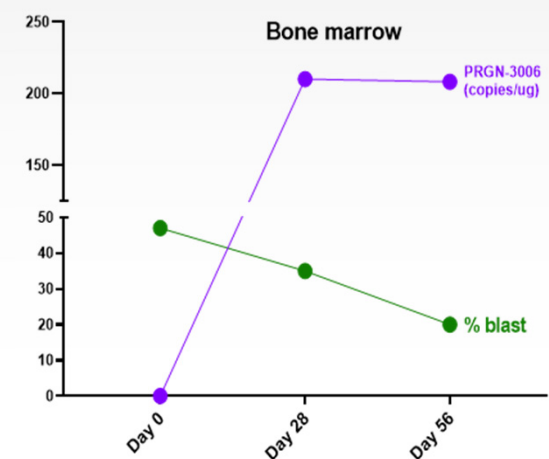
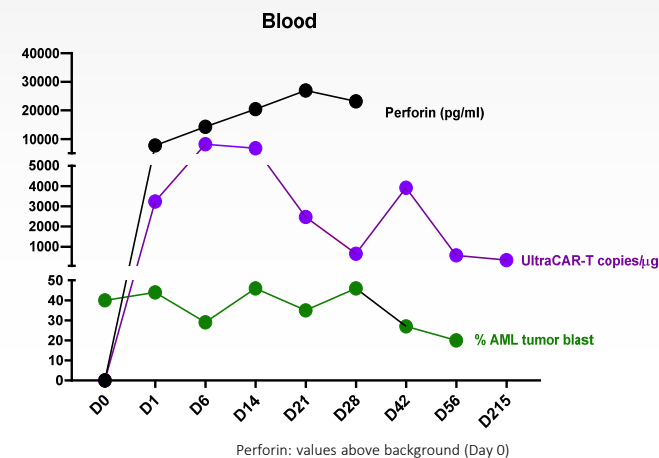
Target Tumor Burden Regression in 50% (3 out of 6) Patients

### PRGN-3006 UltraCAR-T

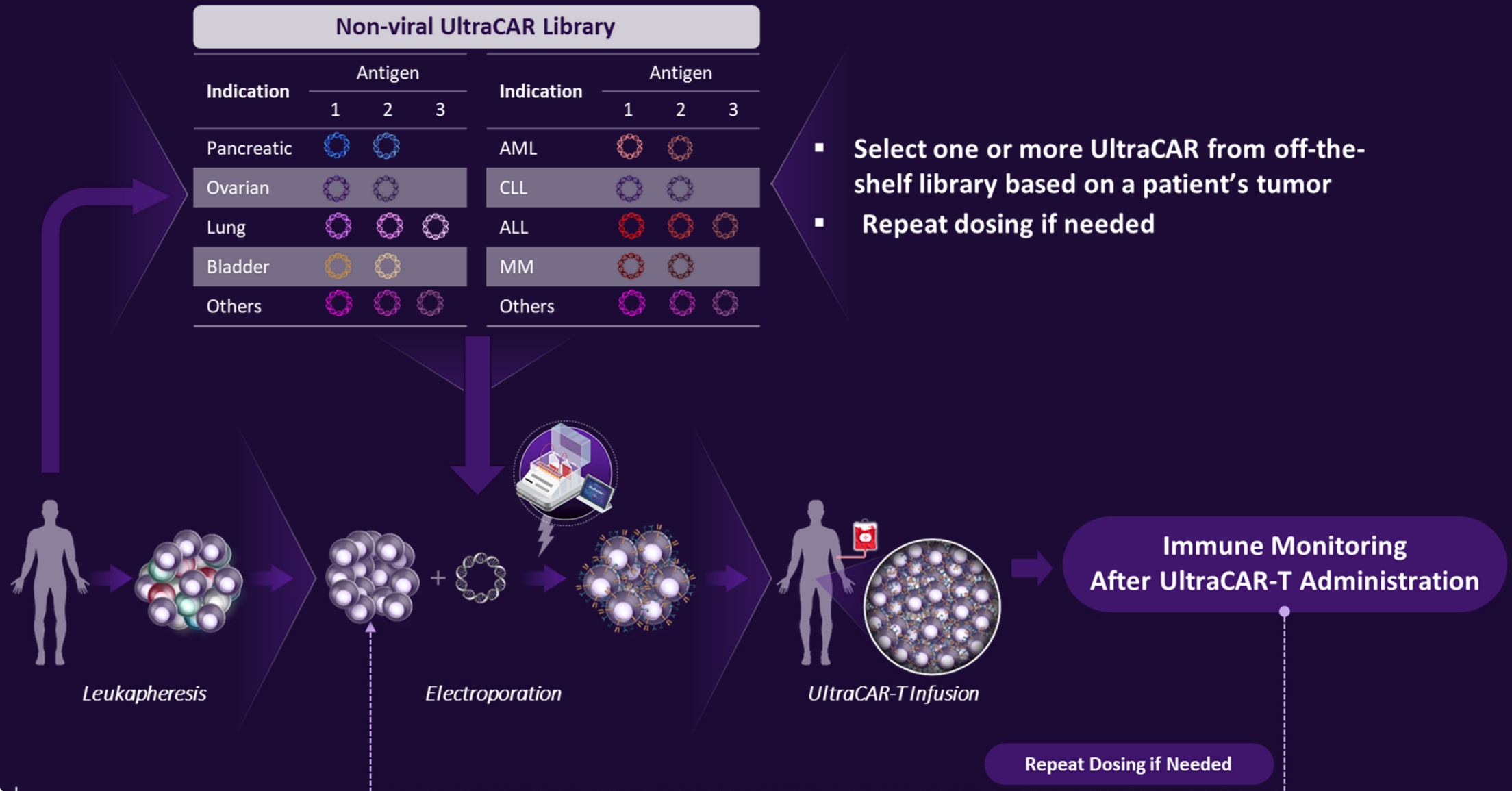
#### PRGN-3006 UltraCAR-T in AML, MDS

- Positive initial data reported from Phase 1:
  - PRGN-3006 treatment was safe and well-tolerated with no DLTs to date
  - 100% manufacturing success to date
  - Encouraging expansion and long-term persistence in blood and bone marrow with or without lymphodepletion (N=9)
  - Preliminary signs of clinical activity as evidenced by reduction in AML tumor blast levels

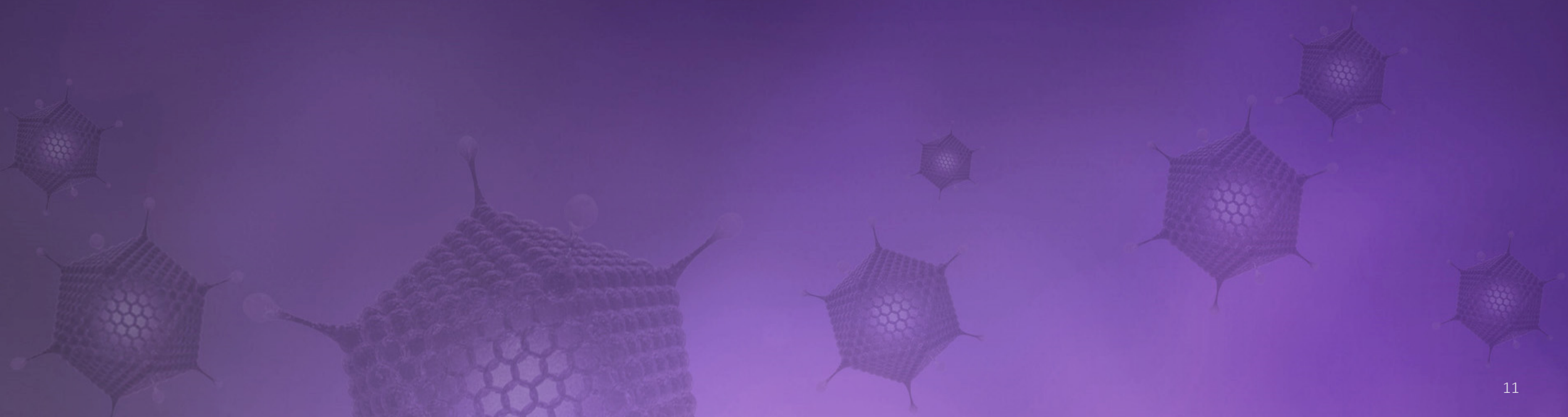
#### PRGN-3006 Case Study: Dose Level 2 Without Lymphodepletion



# UltraCAR-T Library Approach: Precigen's Vision is to Transform the Personalized Cell Therapy Landscape for Cancer Patients

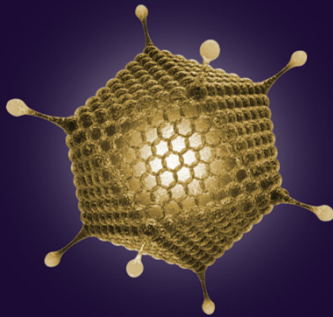


# AdenoVerse™ Immunotherapy Platform



# AdenoVerse™: Industry-leading Adenovector Technology

**Precigen's Gorilla Adenovectors Show Superior Characteristics Over Ad5 and other Rare Human and Non-human Primate Adenoviruses**



## AdenoVerse Advantages

- Large genetic payload capacity
- Off-the-shelf availability
- Ability for repeat administration
- Durable antigen-specific immune response
- Non-replicating adenoviruses
- Highly productive manufacturing process

## Limitations of Competing Approaches

### Vaccines

- Limited antigen coverage
- DNA vaccines may have relatively poor immunogenicity
- Pre-existing immunity to human Ad5 may limit efficacy<sup>1</sup>

### TCR-T Cells

- Applicable in only a small subset of patients due to HLA polymorphism
- Target only a single antigen epitope
- Long and expensive manufacturing process
- Potential for the mispairing of endogenous and exogenous TCR chains

A Library of Adenoviral Vectors with Diverse and Unique Biological Properties is Differentiated from Competition

# PRGN-2009: An Attractive Opportunity in HPV-associated Cancers

## HPV-associated Cancers: Market Opportunity

- HPV infections account for 5% of all cancers globally<sup>1</sup>
- Globally 690,000 new cancer cases attributable to HPV infections per year<sup>2</sup>



### Cervical Cancer

Addressable New Cases Per Year:  
**570,000**



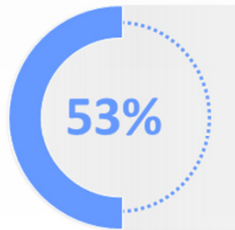
### Anal Cancer

Addressable New Cases Per Year:  
**29,000**



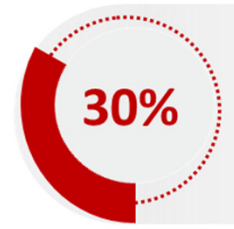
### Vaginal Cancer

Addressable Patient Population:  
**14,000**



### Penile Cancer

Addressable New Cases Per Year:  
**18,000**



### Oropharyngeal Cancer

Addressable New Cases Per Year:  
**42,000**



### Vulvar Cancer

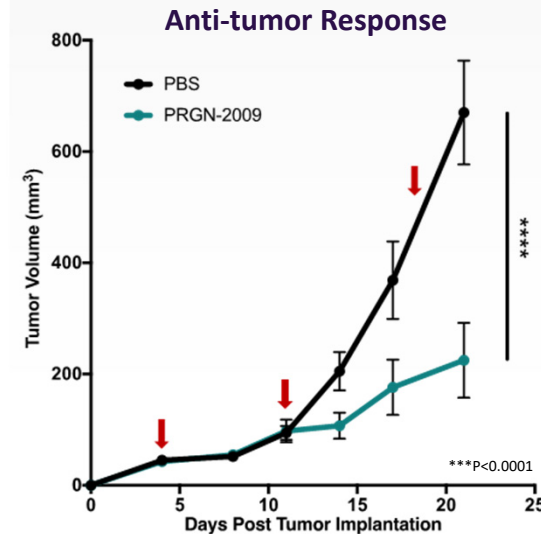
Addressable New Cases Per Year:  
**11,000**

\*% of new cases that are HPV attributable<sup>2</sup>

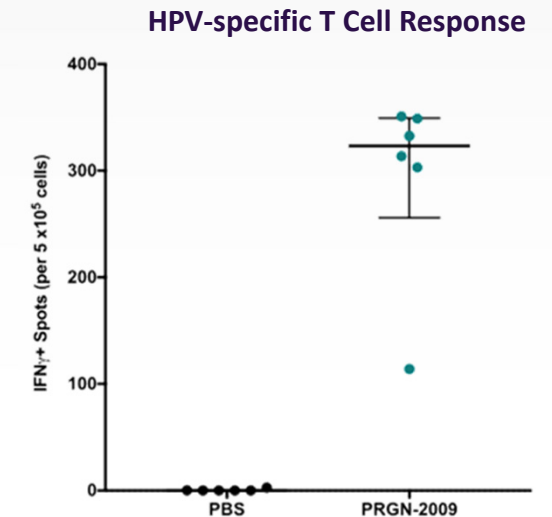
## PRGN-2009 Multi-epitope Antigen Design targets HPV16/18

- Gorilla adenoviral vector, with ability for repeat injections, designed to activate immune system to recognize and target HPV<sup>+</sup> solid tumors
- Novel multi-epitope antigen design differentiates from competition

## PRGN-2009 treatment induces strong HPV-specific immune response and anti-tumor response in a syngeneic mouse model of HPV<sup>+</sup> cancer



↓ PRGN-2009 administration

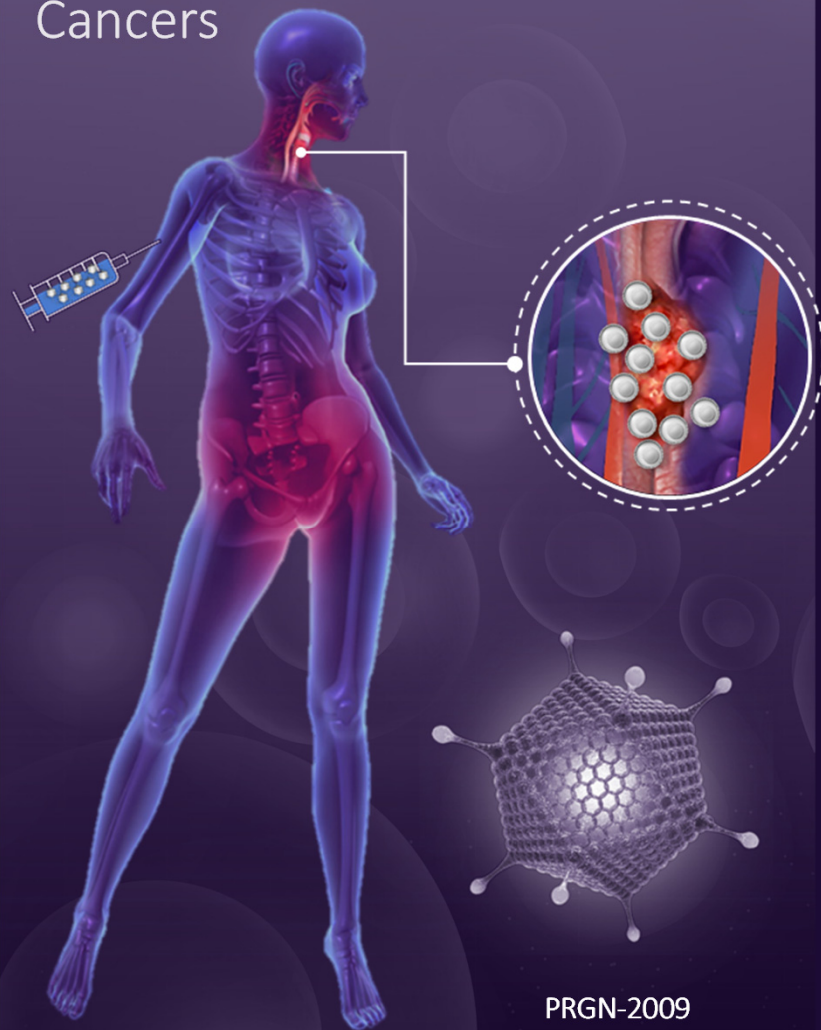


<sup>1</sup>Miles et al. Gynecologic Oncology Research and Practice (2017) 4:10

<sup>2</sup>de Martel C, et al. Volume 8, ISSUE 2, e180-e190, February 01, 2020

# PRGN-2009

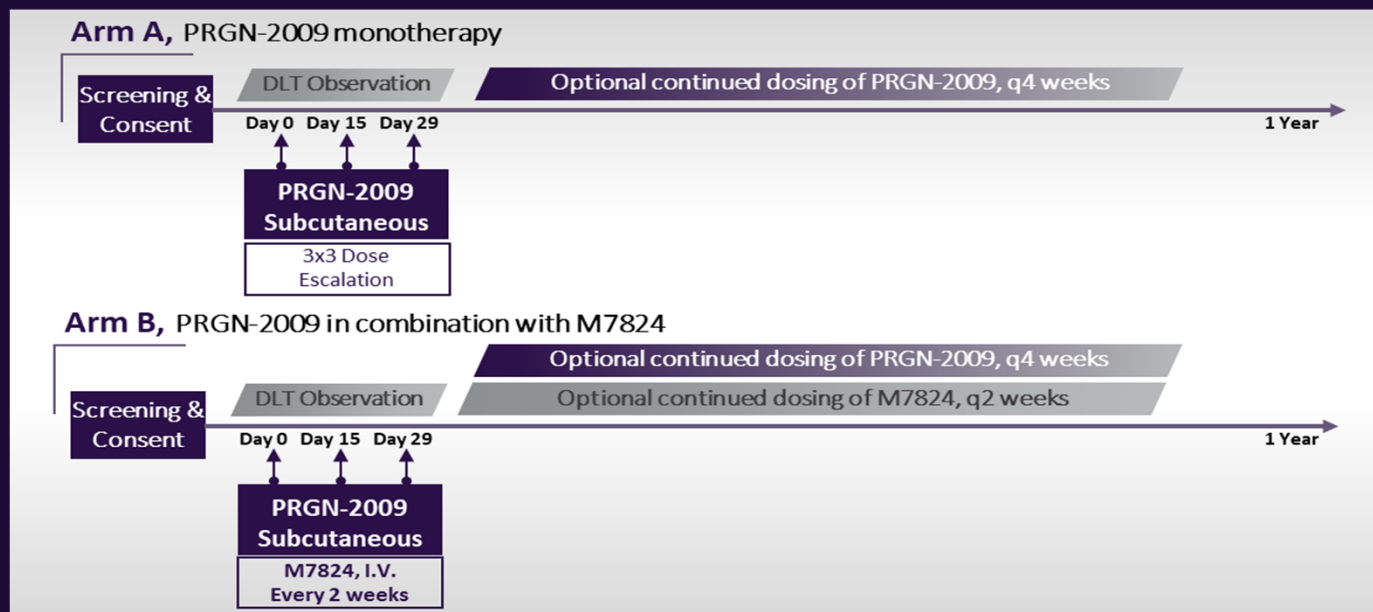
A First-in-Class Investigational Therapy for HPV-associated Cancers



PRGN-2009

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- Phase 1 portion of Phase 1/2 trial is ongoing in collaboration with NCI through a CRADA
  - Phase 1 study is evaluating safety and response of PRGN-2009 alone and in combination with M7824 (bintrafusp alfa) in patients with HPV-associated cancers
  - Clinicaltrials.gov identifier: NCT04432597; Principal Investigator: Charalampos Floudas, M.D.
- Enrollment in Phase 1 monotherapy arm (Arm A) completed**
  - All 6 patients enrolled in monotherapy arm received multiple PRGN-2009 administrations to date
  - Repeated administration of PRGN-2009 treatment was safe and well-tolerated with no DLTs reported to date
- Enrollment in Phase 1 combination arm (Arm B) initiated**
- Phase 1 trial schema**

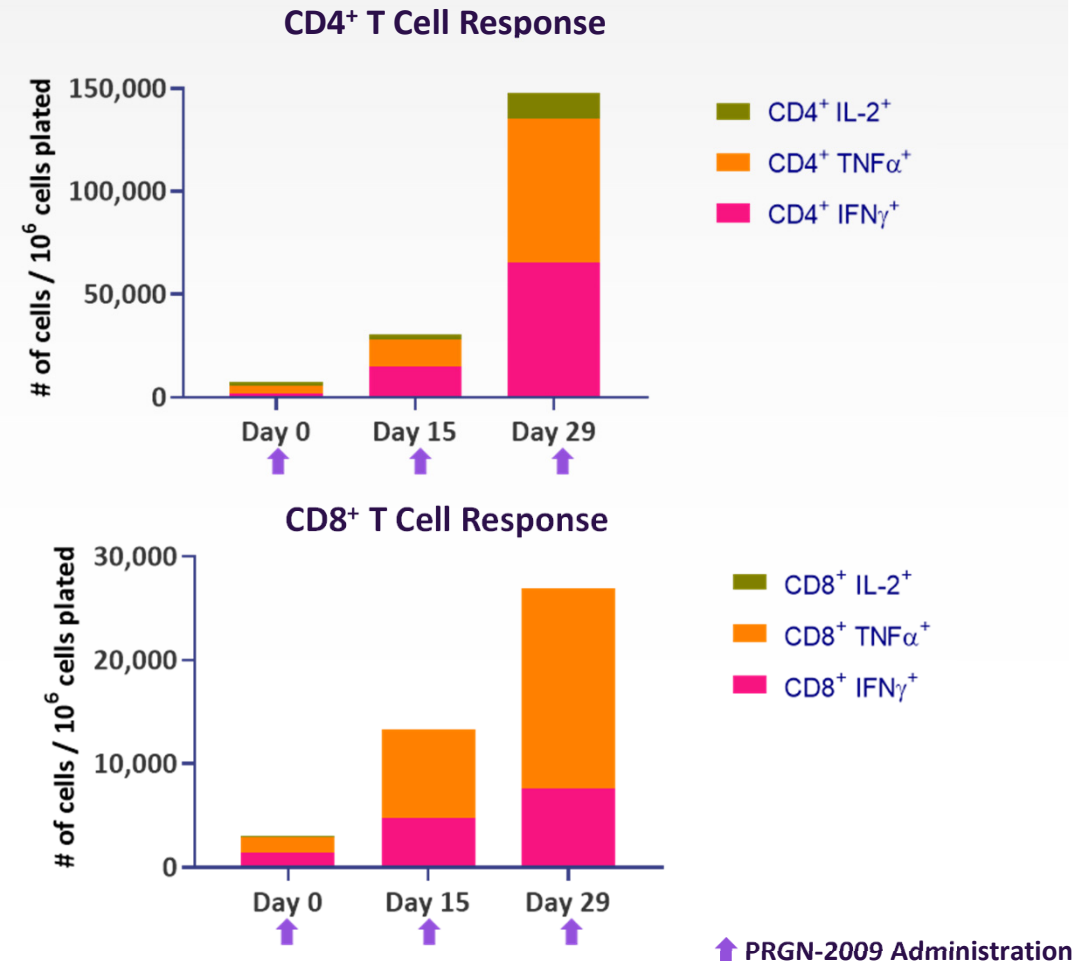


# Preliminary Phase 1 Data Demonstrate Increase in HPV-specific T Cell Response in Patients Upon Repeated Dosing of PRGN-2009

## PRGN-2009 Induced Immune Response in Patients

- All patients (N=6) enrolled in Phase 1 monotherapy arm (Arm A) have received multiple PRGN-2009 administrations to date
- Preliminary correlative analysis of peripheral blood mononuclear cells (PBMC) from patients treated at Dose Level 1 demonstrated:
  - 100% (3 out of 3) patients treated at Dose Level 1 showed increase in HPV16 and/or HPV18 specific T cells post PRGN-2009 administration
  - **Increase in magnitude and breadth of immune response with repeat administration of PRGN-2009**

## Subject 3 Enrolled at Dose Level 1



Data shown represents HPV16 specific T cell response in 1 of 3 patients treated at Dose Level 1  
Source: National Cancer Institute

# Recurrent Respiratory Papillomatosis (RRP)

## Recurrent Respiratory Papillomatosis

- RRP is caused by HPV6 or HPV11 infection
- A rare disease in which benign tumors called papillomas grow in the respiratory tract
- Symptoms include hoarse voice, difficulty sleeping and swallowing, chronic coughing, or breathing problems
- Affects both children and adults

## Current Treatment Paradigm

- There is currently no cure for RRP
- Repeated surgical excision or debulking is the only current treatment and these procedures are needed multiple times a year
- Some patients require tracheotomy and need trach tube indefinitely to keep breathing passage open

**Therapeutic Vaccine Designed to Target HPV6 and HPV11 is Highly Desirable for Treatment of RRP Patients**

## Disease Snapshot



### High Unmet Need

No current treatment for pulmonary RRP



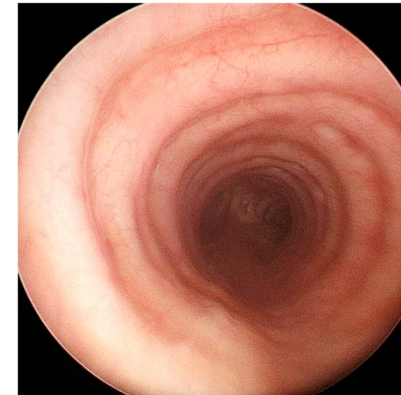
**20K Active Cases in US<sup>6</sup>**

### 4 per 100K

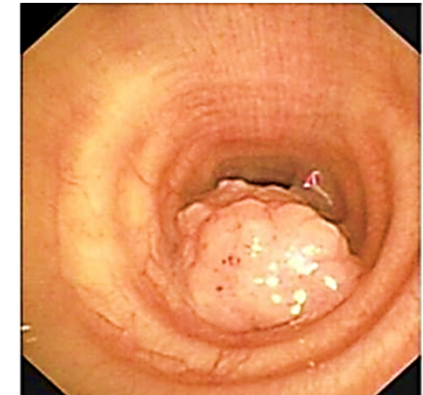
Incidence of RRP in children<sup>1-4</sup>

### 2-3 per 100K

Incidence of RRP in adults<sup>5</sup>



**Normal trachea**



**RRP Patient trachea<sup>7</sup>**

<sup>1</sup>Derkay and Wiatrak 2008, National Organization for Rare Disorders 2019

<sup>2</sup>Armstrong, Derkay et al. 1999

<sup>3</sup>Hermann, Pontes et al. 2012

<sup>4</sup>Seedat 2020

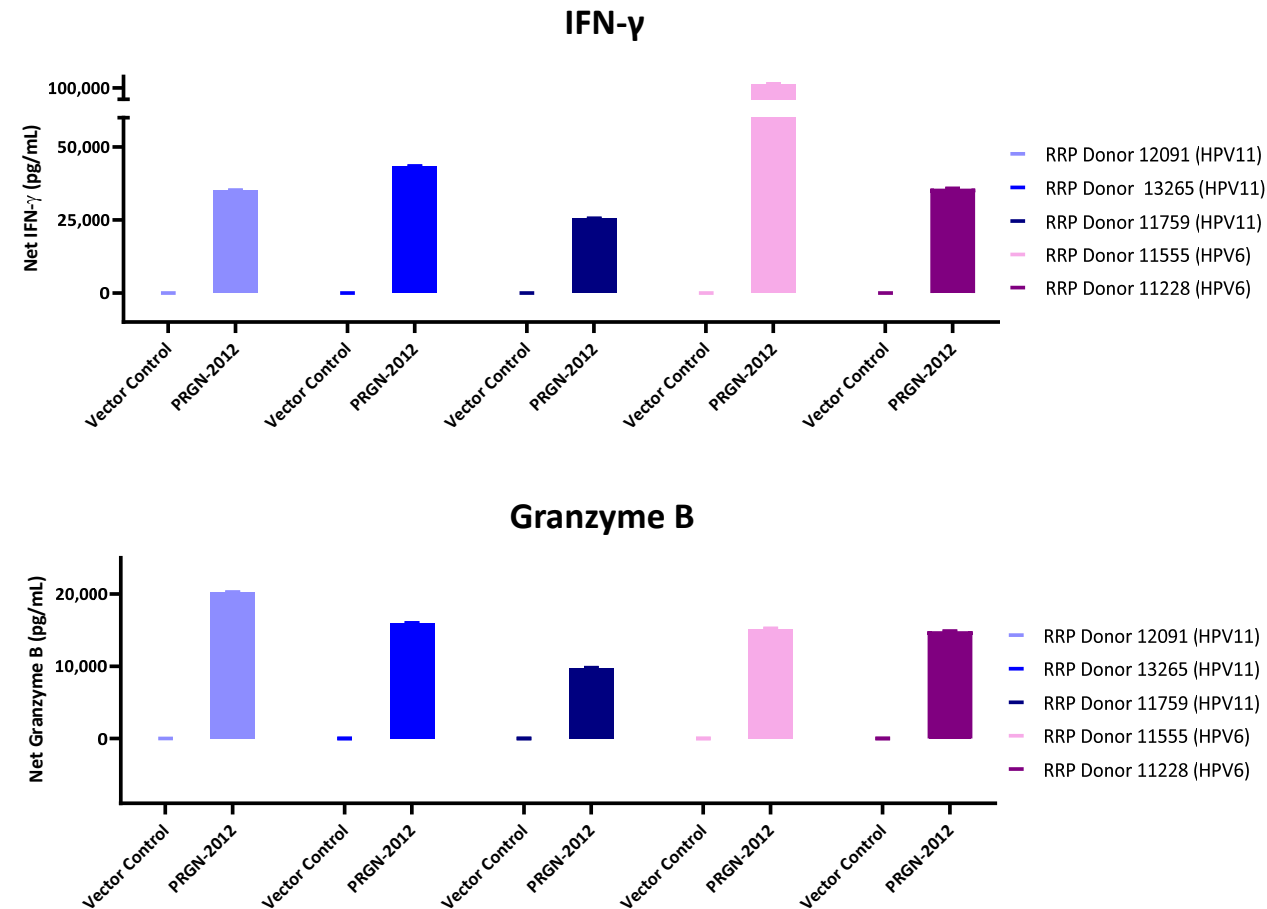
<sup>5</sup>National Organization for Rare Disorders 2019

<sup>6</sup>RRP Foundation: <http://www.rrpf.org/whatisRRP.html>

<sup>7</sup>Rodriguez-Garcia A et al., Front. Immunol., 2020

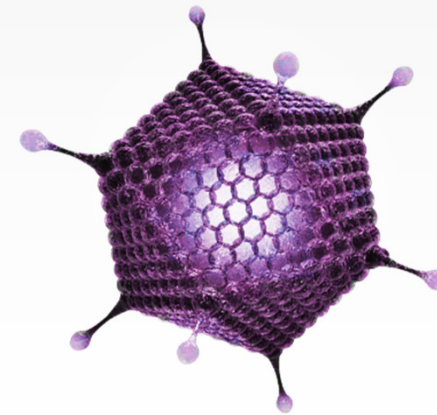
# PRGN-2012: AdenoVerse Immunotherapy Targeting HPV6 and HPV11 for Recurrent Respiratory Papillomatosis (RRP)

## PRGN-2012 Induces Robust HPV6 and HPV11 Specific T-cell Response in RRP Patient Samples *In Vitro*



## PRGN-2012 targets HPV6 and HPV11

- 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
- RRP is caused by HPV6 or HPV11 infection
- >90% of genital warts are related to HPV6 and HPV11



**PRGN-2012**

### PRGN-2012 design Advantages

Innovative antigen design

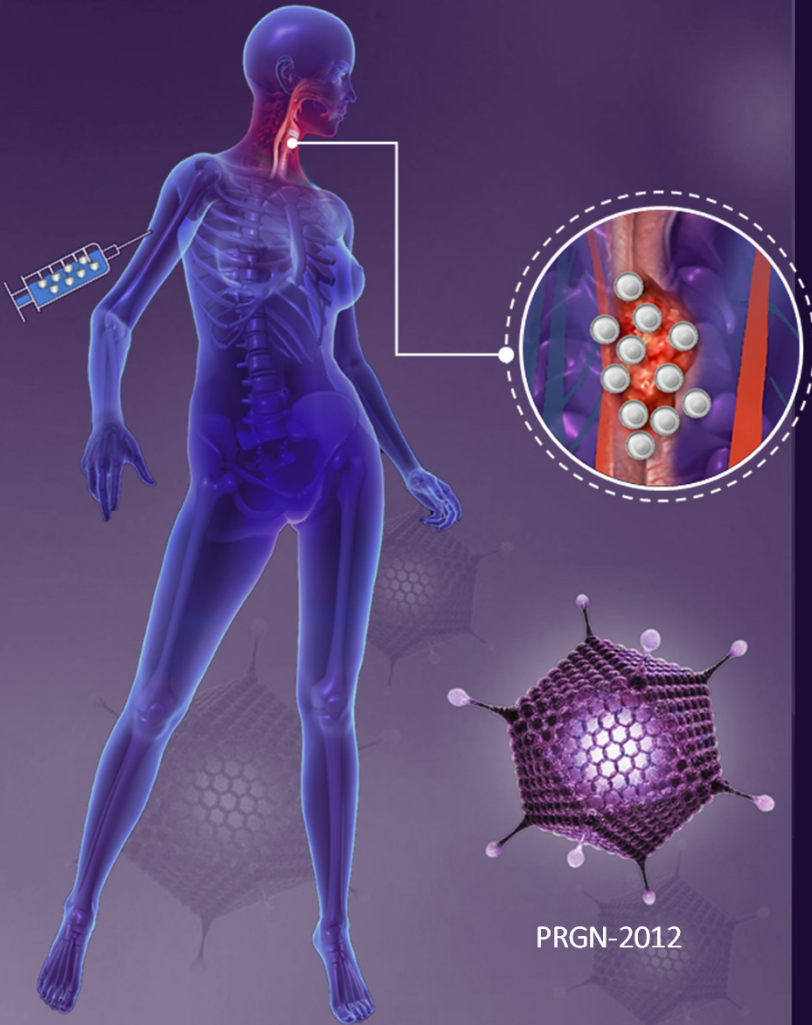
Robust antigen-specific immune response

Off-the-shelf availability

Ability to repeat administer

# PRGN-2012

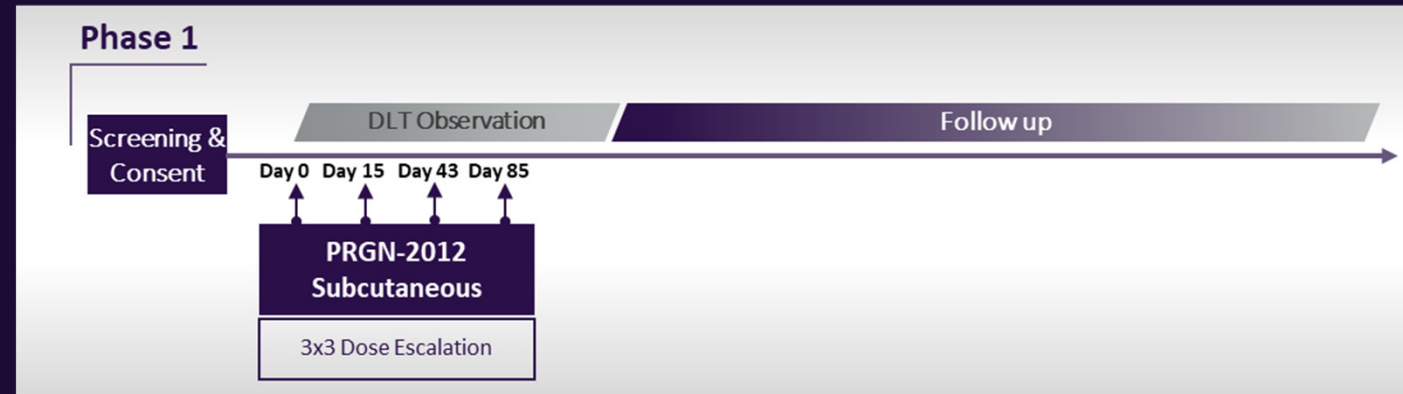
A First-in-Class Investigational Therapy for RRP



PRGN-2012

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- **IND application to initiate Phase 1 trial in was approved by the FDA**
- First AdenoVerse Immunotherapy to enter clinic for infectious disease indication
- Phase 1 study will evaluate safety and maximum tolerated dose of PRGN-2012
  - Patients with histologically confirmed diagnosis of laryngeal RRP



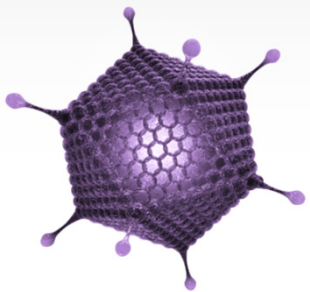
- **Clinical development in collaboration with NCI through a CRADA**

# PRGN-2013: Opportunity in Chronic Hepatitis B Virus (HBV) Infection

## Chronic Hepatitis B Virus Infection

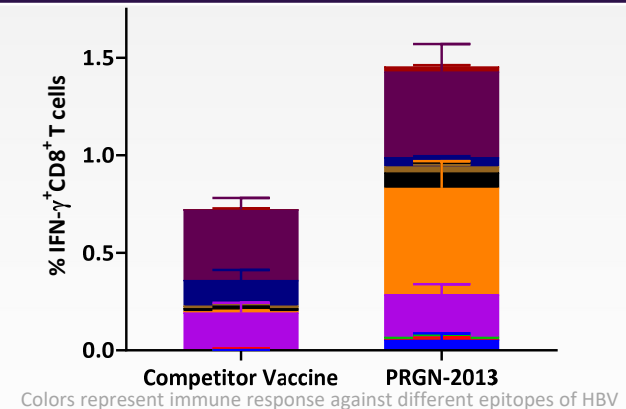
- Liver infection caused by HBV may lead to chronic infection and hepatocellular carcinoma (HCC)<sup>2</sup>
- Chronic HBV infection can cause serious health problems, including liver damage, cirrhosis, liver cancer, and death<sup>1</sup>
- No cure for chronic HBV infection
- Global prevalence of 257M<sup>3</sup>
- US prevalence of 850K<sup>1</sup>

## PRGN-2013 Targets HBV

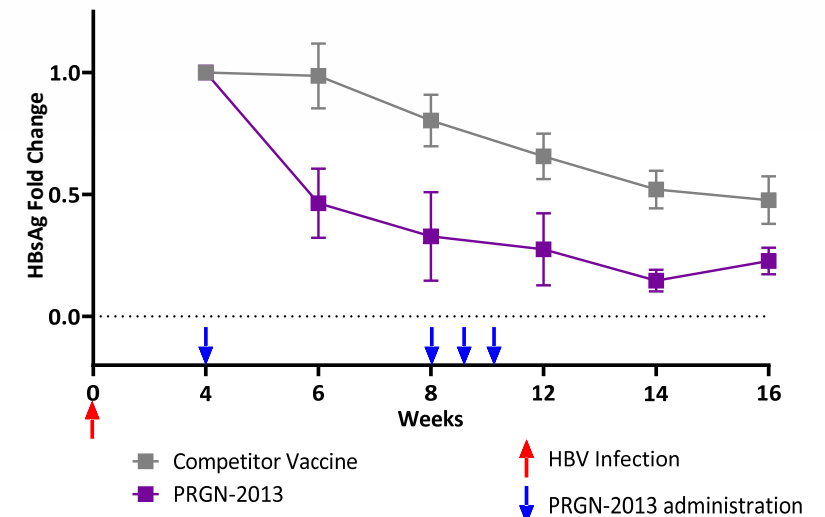


- Gorilla adenoviral vector, with ability for repeat injections, designed to elicit specific immune response against HBV
- Novel antigen design is differentiated from the competition

## PRGN-2013 Induces Superior Cytotoxic T-cell Response against more HBV epitopes in Mice and differentiates from Competition



## PRGN-2013 Administration Decreases Plasma Levels of HBsAg, the Key Marker of Chronic HBV Infection, in Mice










# Summary

# Precigen in 2020: Achieved All Anticipated Clinical Milestones

- ✓ Initial data released from the intraperitoneal (IP) arm of PRGN-3005 UltraCAR-T Phase 1 trial in Ovarian Cancer
- ✓ Initial data released from PRGN-3006 UltraCAR-T Phase 1 trial in AML and MDS
- ✓ Interim data released from Phase 2 trial of AG013 ActoBiotics in Oral Mucositis
- ✓ Interim data released from Phase 1b/2a trial of AG019 ActoBiotics in Type 1 Diabetes
- ✓ Phase 1 study of INXN-4001 completed in Heart Failure patients with LVAD
- ✓ Initiated Phase 1 trial of PRGN-2009 off-the-shelf AdenoVerse immunotherapy in HPV<sup>+</sup> cancers

# Precigen in 2021: Multiple Upcoming Milestones

-  Complete dose escalation phase and initiate expansion phase of PRGN-3005 UltraCAR-T IP arm in Ovarian Cancer. Initiate the IV arm of PRGN-3005 Phase 1 trial. Present corresponding interim data.
-  Present interim data from PRGN-3006 UltraCAR-T Phase 1 trial in AML and MDS and initiate dose expansion phase
-  Submit IND application for a new UltraCAR-T candidate
-  Present interim data from the Phase 1 trial of PRGN-2009 in HPV-associated cancers
-  Initiate dosing patients in Phase 1 trial of PRGN-2012 in Recurrent Respiratory Papillomatosis
-  Initiate IND-enabling studies for PRGN-2013 in chronic HBV infection
-  Present data from AG019 Phase 1b/2a trial in Type 1 Diabetes



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