



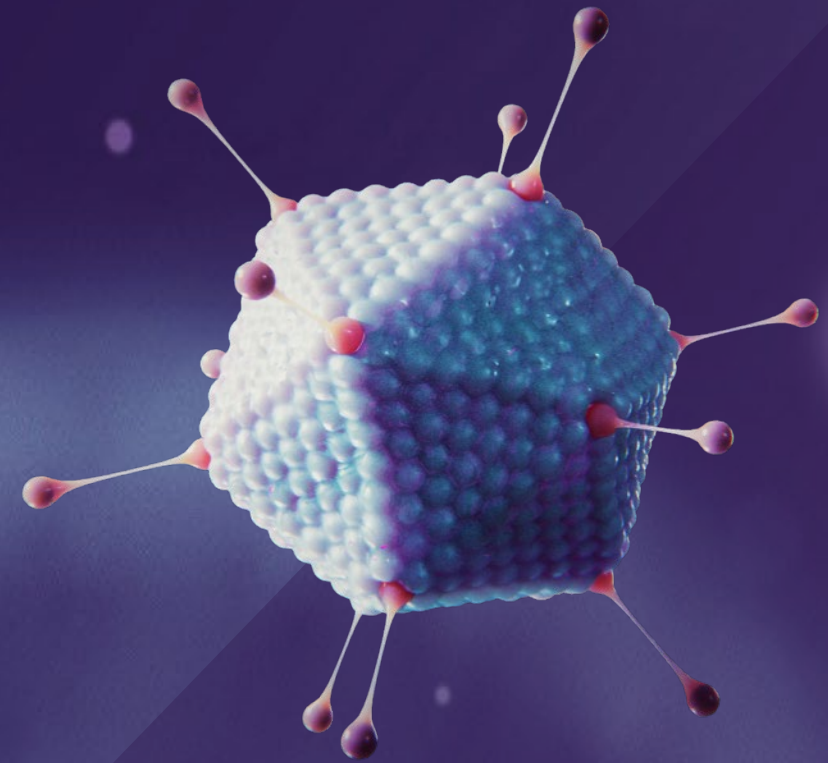
# PRECIGEN

ADVANCING MEDICINE WITH PRECISION™

## 42<sup>nd</sup> Annual J.P. Morgan Healthcare Conference

Helen Sabzevari, PhD  
President and CEO

January 10, 2024



Nasdaq: PGEN

# Forward-looking Statements

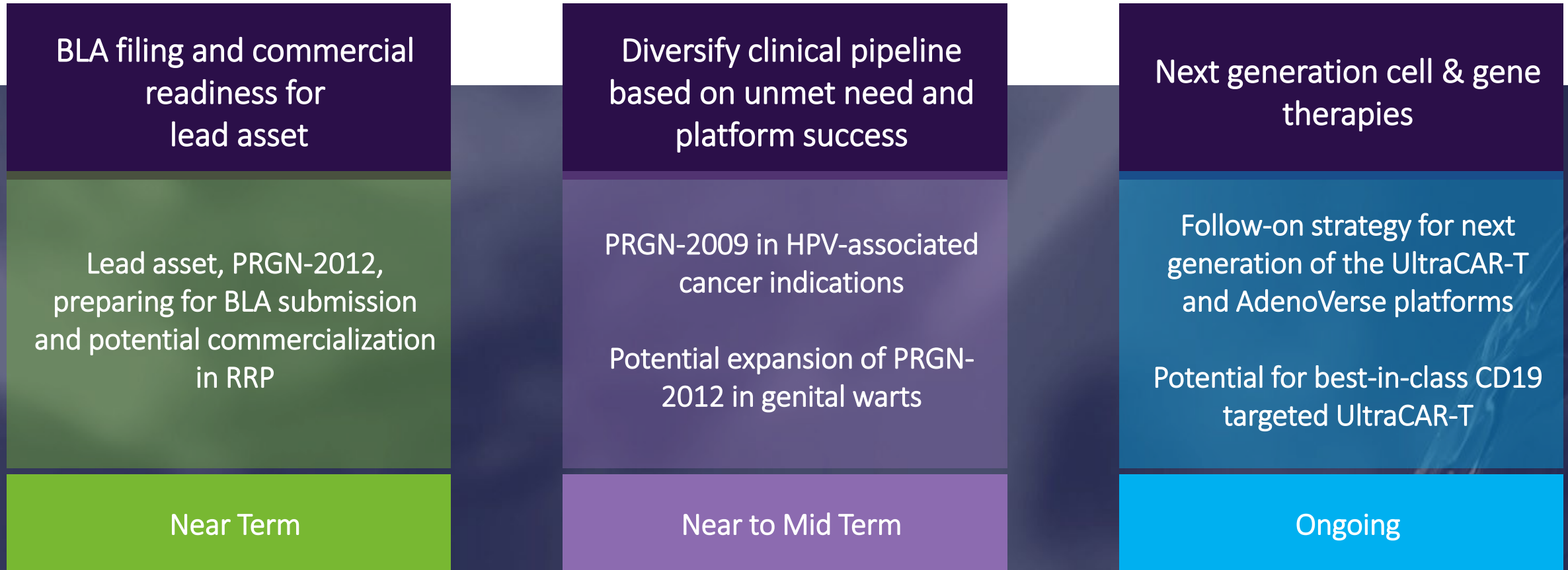
Some of the statements made in this presentation are forward-looking statements. These forward-looking statements are based upon the Company's current expectations and projections about future events and generally relate to plans, objectives, and expectations for the development of the Company's business, including the timing and progress of preclinical studies, clinical trials, discovery programs, product candidate approval and commercialization, and related milestones, the promise of the Company's portfolio of therapies, and in particular its CAR-T and AdenoVerse 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 the Company's clinical trials, product candidate approvals or plans for commercial launch of might be impacted by economic conditions, the COVID-19 pandemic or other factors, and actual future results may be materially different from the plans, objectives and expectations expressed in this presentation. The Company 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 the Company'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.

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.

All of the pharmaceutical products described in this presentation are investigational new drugs, which are currently undergoing pre-clinical and/or human clinical trial testing. As a result, none of them have had their safety or efficacy established or are approved by the U.S. Food and Drug Administration or any other regulatory agency.

All information in this presentation is as of the date of its cover page, and Precigen undertakes no duty to update this information unless required by law.

Precigen's strategy is designed to generate value over time based on continued success for the AdenoVerse and UltraCAR-T platforms

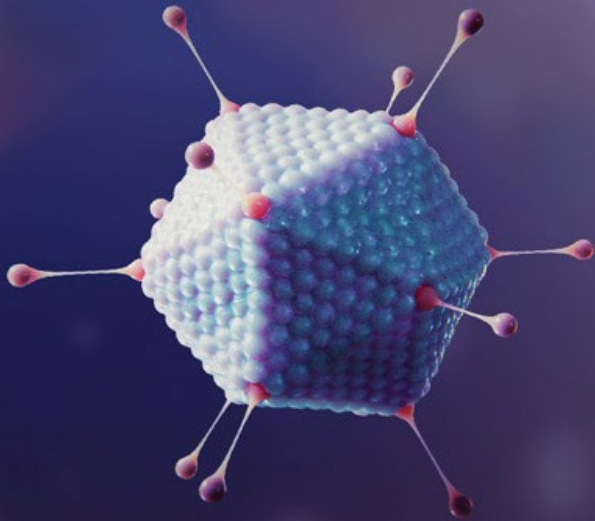


# Precigen is deploying novel gene & cell therapeutic approaches to address high unmet healthcare needs

## AdenoVerse™ Immunotherapy

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

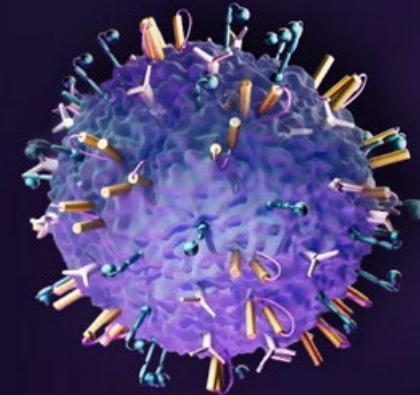
- Large payload capacity
- Low seroprevalence in humans
- Ability for repeat administration
- Durable antigen-specific immune response
- Highly productive manufacturing process



## UltraCAR-T®

Novel cell therapy platform to engineer the immune system *ex vivo* (from OUTSIDE the body) rapidly with overnight manufacturing

- 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 at the hospital



**Training the immune system to fight disease through *in vivo* and *ex vivo* activation**

# Precigen pipeline

Product	Target	Indication	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 1B	PHASE 2	PHASE 3
<b>ADENOVERSE IMMUNOTHERAPY</b>								
PRGN-2012	HPV 6/11	RRP	Breakthrough Therapy Designation, Orphan Drug Designation					
PRGN-2009 (+pembrolizumab)	HPV 16/18	OPSCC/Head & Neck Cancer						
PRGN-2009 (+pembrolizumab)	HPV 16/18	R/M Cervical Cancer	Phase 2 IND cleared					
<b>ULTRACAR-T</b>								
PRGN-3005	Unshed MUC16	Ovarian Cancer						
PRGN-3006	CD33	R/R AML, MDS	Fast Track Designation, Orphan Drug Designation					
PRGN-3007	ROR1	ROR1 <sup>+</sup> Hematological & Solid Tumors						
PRGN-3008	CD19	B-cell Malignancies						

**ACRONYMS:** RRP=recurrent respiratory papillomatosis; OPSCC=oropharyngeal squamous cell carcinoma; R/M=recurrent/metastatic; R/R=relapsed or refractory; AML=acute myeloid leukemia; MDS=myelodysplastic syndrome; ROR=receptor tyrosine kinase-like orphan receptor; HPV=human papillomavirus; MUC=mucin



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# PRGN-2012 for Recurrent Respiratory Papillomatosis



Recurrent respiratory papillomatosis (RRP) is a rare HPV-driven disease with no FDA-approved therapeutic

papillomas  
(benign tumors)

Severe RRP

- 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



There has **never been an FDA-approved therapeutic option for the RRP patient community**, and we are incredibly hopeful that this will change in the near future. Our community faces **ongoing risks from hospitalizations and repeat surgeries**, coupled with daily quality-of-life challenges, such as obstructed breathing, difficulties swallowing, and impaired speech, and our community bears a **tremendous financial burden from the significant lifetime costs** to patients and their families affiliated with this disease.

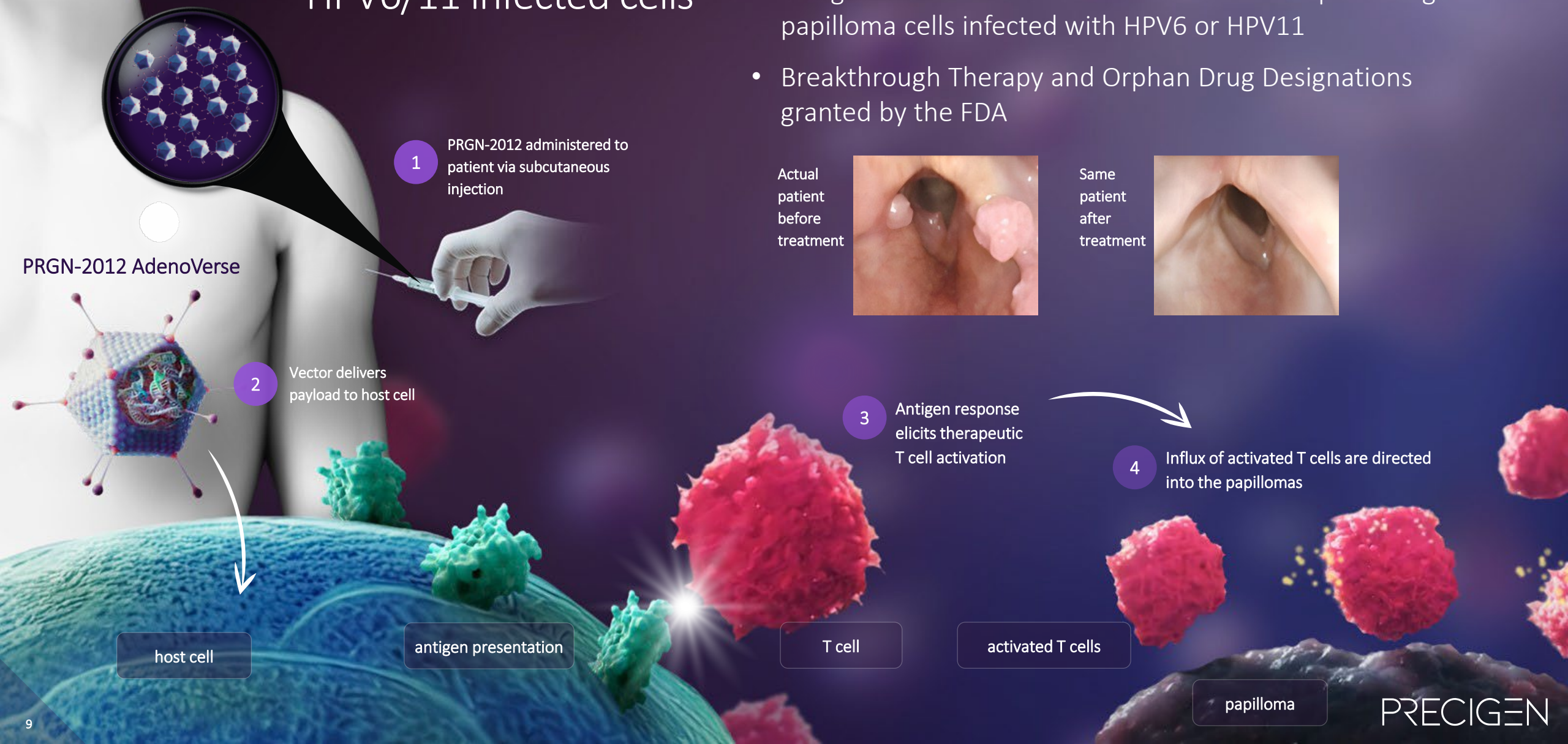
Kim McClellan  
President  
Recurrent Respiratory  
Papillomatosis Foundation



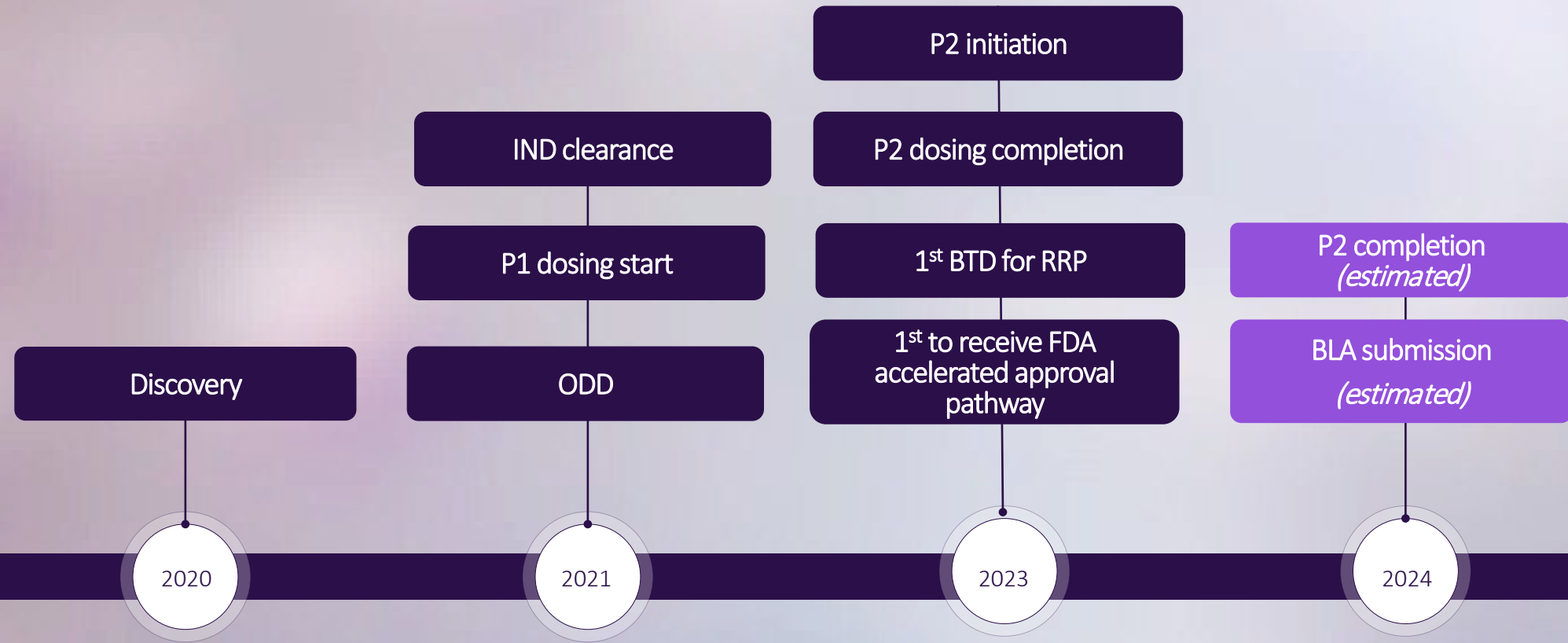


# PRGN-2012 targets HPV6/11 infected cells

- 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 and Orphan Drug Designations granted by the FDA



# Precigen spearheaded the innovation of a new therapeutic option for RRP patients and is leading clinical and regulatory development in RRP



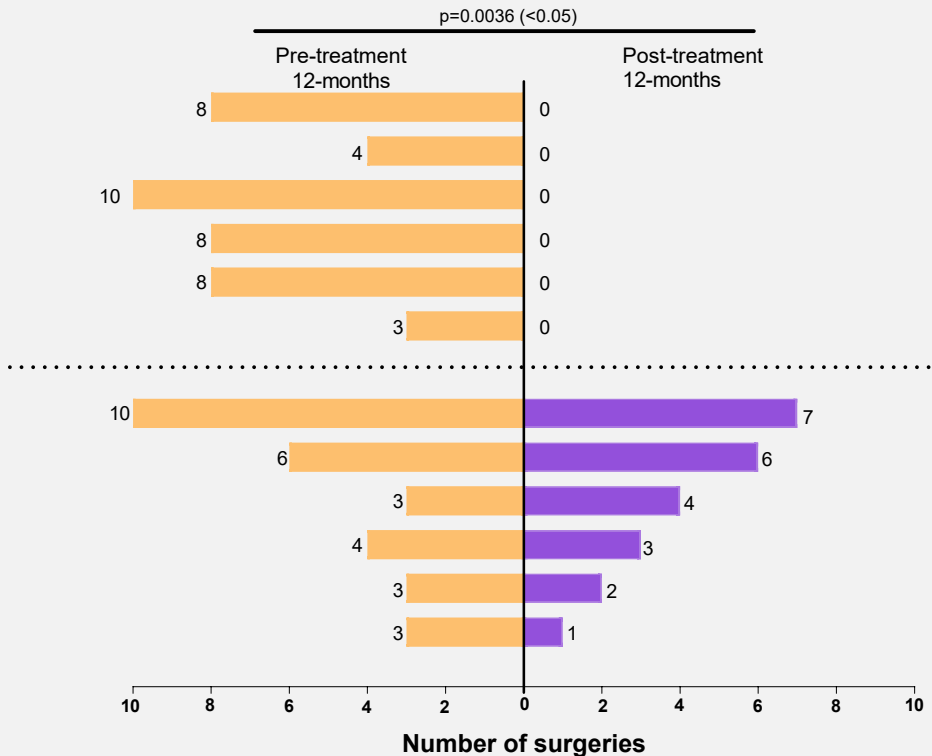
**ACRONYMS:** IND=investigational new drug application; ODD=orphan drug designation; BTD=Breakthrough Therapy Designation; FDA=Food and Drug Administration; P1=Phase 1; P2=Phase 2; RRP=recurrent respiratory papillomatosis; BLA=biologics license application

# PRGN-2012 clinical data has demonstrated strong efficacy, safety and durability of response

*50% of patients with durable, ongoing complete response at  $\geq 2$  years*

*83% of patients with reduction in need for RRP surgeries*

## Phase 1 Results: RRP Surgeries Pre- vs. Post-Treatment



- Favorable safety profile (No DLTs, No TRAEs greater than Grade 2)
- Strong response with significant reduction in surgeries
  - **50% of patients in durable complete response (CR)**
  - **83% of patients with reduction in need for RRP surgeries**

- Eligibility
  - Adult patients with 3 or more RRP surgeries in prior year
- Dosing
  - Four subcutaneous PRGN-2012 administrations
- Enrollment Status
  - Phase 1: N=12\*; dosing and 1 year follow up complete
  - Phase 2: N=23; dosing complete; follow up ongoing
- **Phase 2 data anticipated in Q2 2024**
- **BLA submission under accelerated approval pathway planned for 2H 2024**

\* Patients treated at recommended Phase 2 dose

# PRGN-2012 is on track for potential commercial launch in 2025

## Preparing for BLA submission

- Phase 2 study to be completed in Q2 2024
- BLA submission for the treatment of RRP planned for 2H 2024
- Potential commercial launch planned in 2025

## Significant potential market opportunity

- ~15-20K US RRP patients



- >125K ex-US RRP patients



- Concentrated prescriber base (laryngologists)



## Preparing for successful 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



# Assessing the key characteristics of a potential RRP product; Selected feedback from KOLs and laryngologists

## Reducing Surgical Burden is the #1 Unmet Need

*"All we can do today is surgery, it's like mowing the lawn with RRP. We get rid of it then it comes back and we have to mow the lawn again. All of my patients would be interested in a new therapeutic treatment option."*

KOL

## Durability of Response

*"It is nice to see that durability of response is now out to 24 months for all patients that had a complete response in the Phase 1 study."*

Laryngologist

## Preferred Route of Administration

*"It's four subcutaneous doses, I imagine that patients would prefer a SQ injection."*

Laryngologist

## Reassuring Safety

*"Anything that can reduce the number of surgeries is very positive, and it is well tolerated. It is very appealing."*

Laryngologist



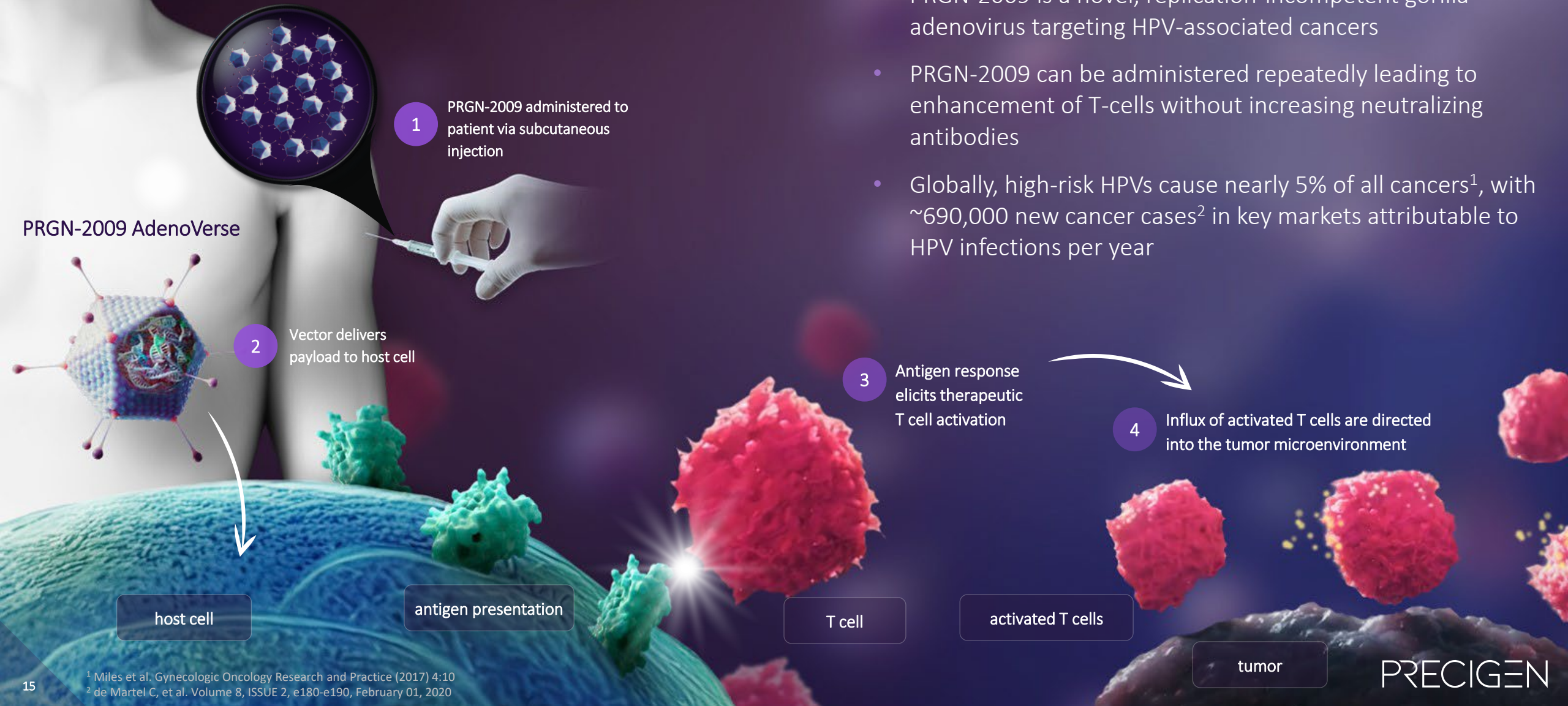
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## PRGN-2009 for HPV-associated Cancers

# PRGN-2009: Attractive opportunity for AdenoVerse in targeting HPV 16/18-associated cancers

- PRGN-2009 is a novel, replication-incompetent gorilla adenovirus targeting HPV-associated cancers
- PRGN-2009 can be administered repeatedly leading to enhancement of T-cells without increasing neutralizing antibodies
- Globally, high-risk HPVs cause nearly 5% of all cancers<sup>1</sup>, with ~690,000 new cancer cases<sup>2</sup> in key markets attributable to HPV infections per year



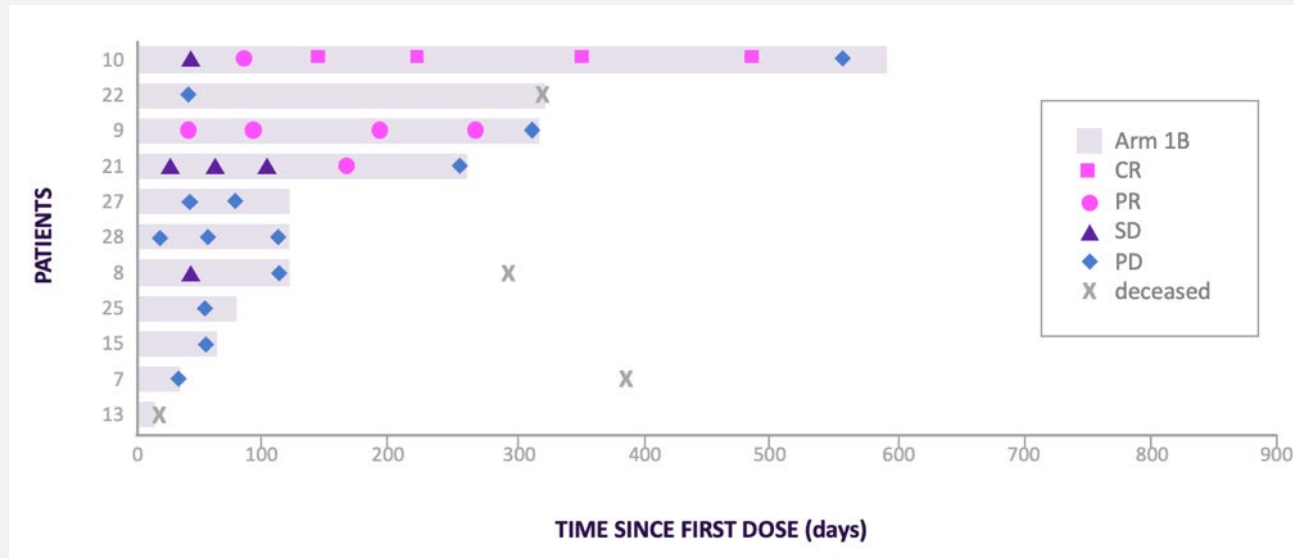
# Potential of AdenoVerse platform from rare disease to oncology indications

## *PRGN-2009: Promising preliminary safety and efficacy data in HPV-associated cancers*

### Phase 1 Study in R/M HPV-associated Cancers

PRGN-2009 as Monotherapy (Arm 1A) and in Combination with Checkpoint Inhibitor (bintrafusp alfa) (Arm 1B)

#### Clinical Responses (PRGN-2009 Combination Arm)



- Favorable safety profile with no DLTs
- **30% ORR (1 CR, 2 PR) including checkpoint blockade resistant patients<sup>3</sup>**
- PRGN-2009 induced robust HPV-specific T cell responses

### PRGN-2009 Phase 2 Studies

#### Phase 2 study in newly diagnosed OPSCC

- Phase 2 study of PRGN-2009 + pembrolizumab is currently enrolling patients

#### Phase 2 study in r/m cervical cancer

- HPV infection responsible for 90% of cervical cancers cases<sup>1</sup>
- Response rates for checkpoint inhibitors in low teens in 2L cervical cancer represents attractive opportunity<sup>2</sup>
- Phase 2 randomized, open-label study of PRGN-2009 + pembrolizumab in r/m cervical cancer
  - Prior pembrolizumab treated patients eligible for study
  - IND cleared by FDA in 2023
  - Study initiation anticipated in Q1 2024





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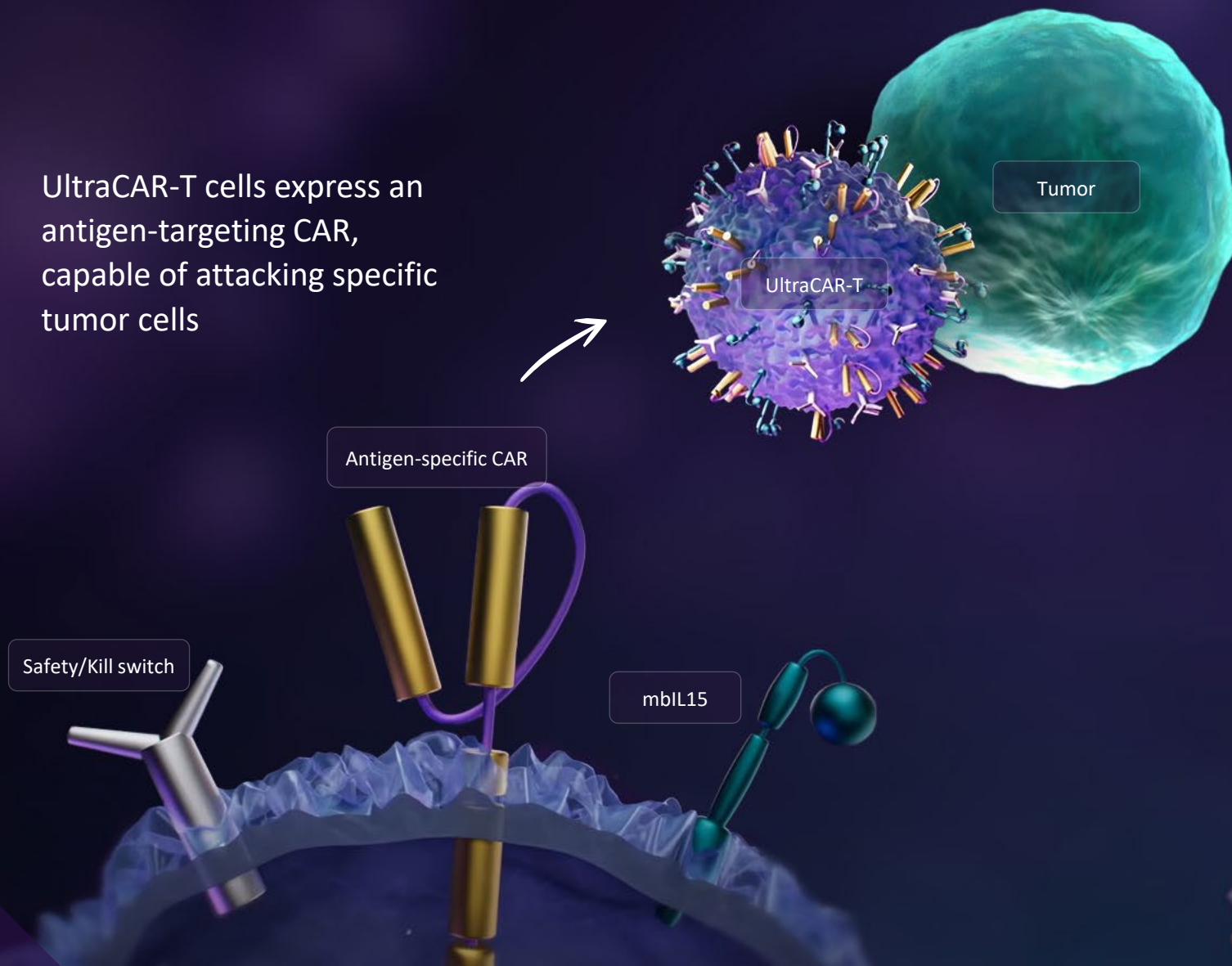
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## UltraCAR-T Platform

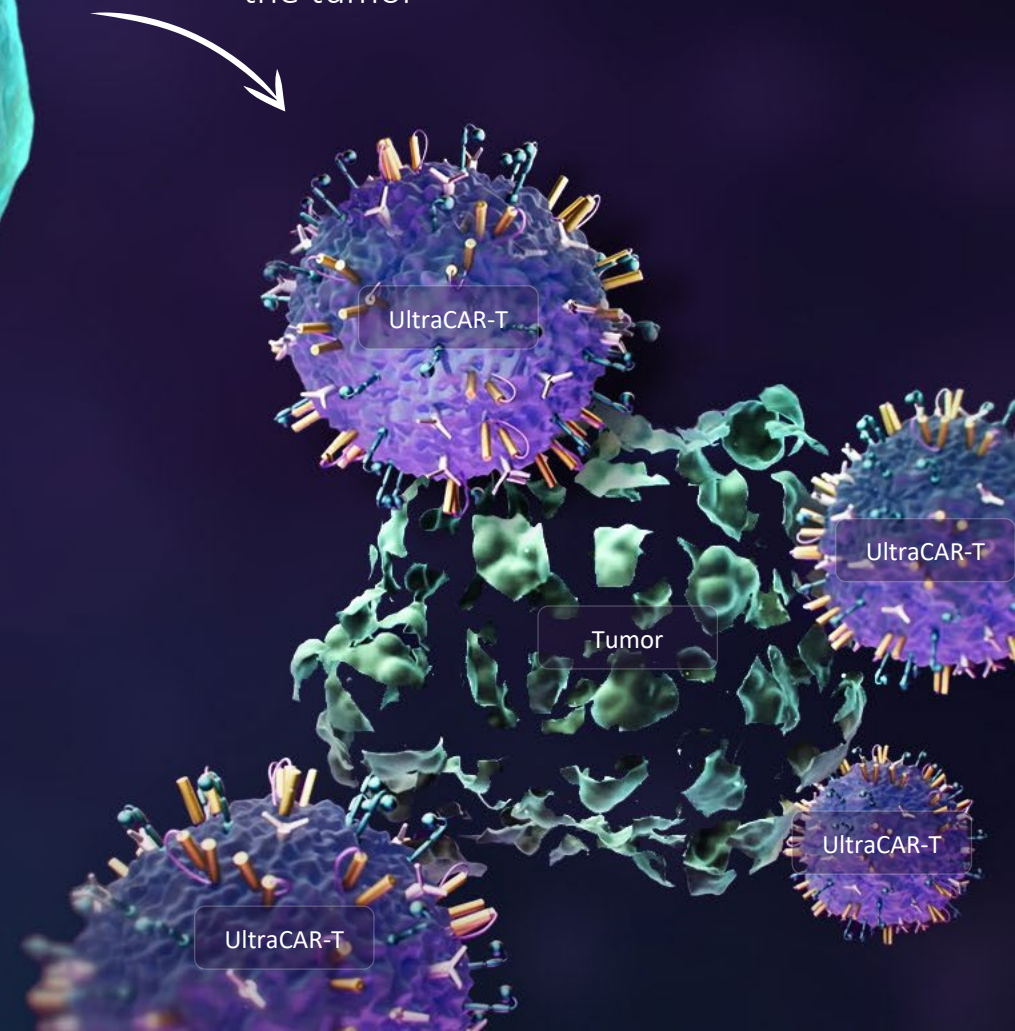
# UltraCAR-T

## Design and mechanism of action

UltraCAR-T cells express an antigen-targeting CAR, capable of attacking specific tumor cells



After infusion, UltraCAR-T cells kill cancer cells when they recognize the tumor-associated antigen expressed by the tumor



# Precigen's UltraCAR-T is the leading platform addressing safety and manufacturing shortcomings of conventional CAR-T therapies at a lower cost

UltraCAR-T			Conventional CAR-T
	✓	Non-viral design	✗
	✓	Safety/kill switch	✗
	✓	<i>In vivo</i> persistence/durability	✗
	✓	Overnight manufacturing	✗
	✓	Same day quality control release	✗
	✓	Reduced manufacturing costs	✗
			

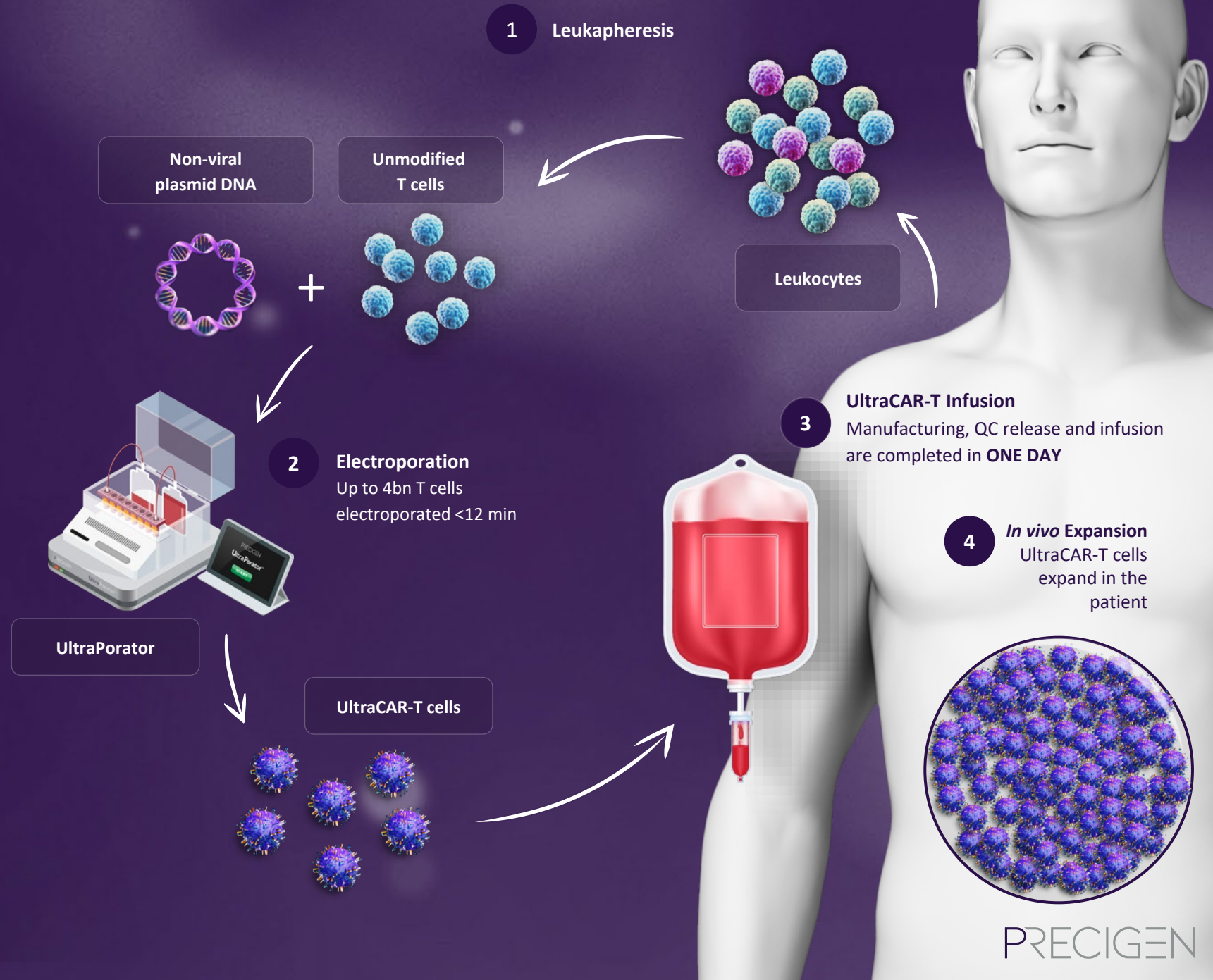
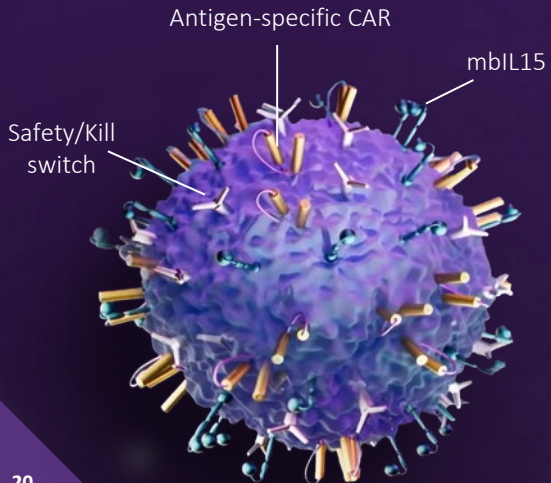
The information presented in this table is based on our internal assessment of the state of general development of such technologies



# UltraCAR-T Platform

Overnight, decentralized manufacturing process and next-day infusion significantly reduces wait time for autologous CAR-T treatment

- Proprietary UltraPorator® Automated System
  - Rapid, high efficiency gene transfer protocol
- Non-viral multi-gene delivery
- Overnight manufacturing
- Same day QC testing & release
- Uniform, multigenic cell product
- No *ex vivo* T cell activation or expansion





# UltraCAR-T pipeline

Product	Target	Indication	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 1B	PHASE 2	PHASE 3
ULTRACAR-T								
PRGN-3005	Unshed MUC16	Ovarian Cancer						
PRGN-3006	CD33	R/R AML, MDS	Fast Track Designation, Orphan Drug Designation					
PRGN-3007	ROR1	ROR1 <sup>+</sup> Hematological & Solid Tumors						
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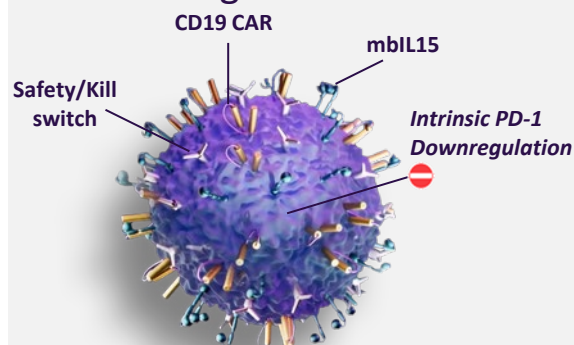
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## Preclinical CD19 UltraCAR-T

# CD19 UltraCAR-T has potential to be best-in-class CAR-T targeting CD19

Significant opportunity in CD19 CAR-T space

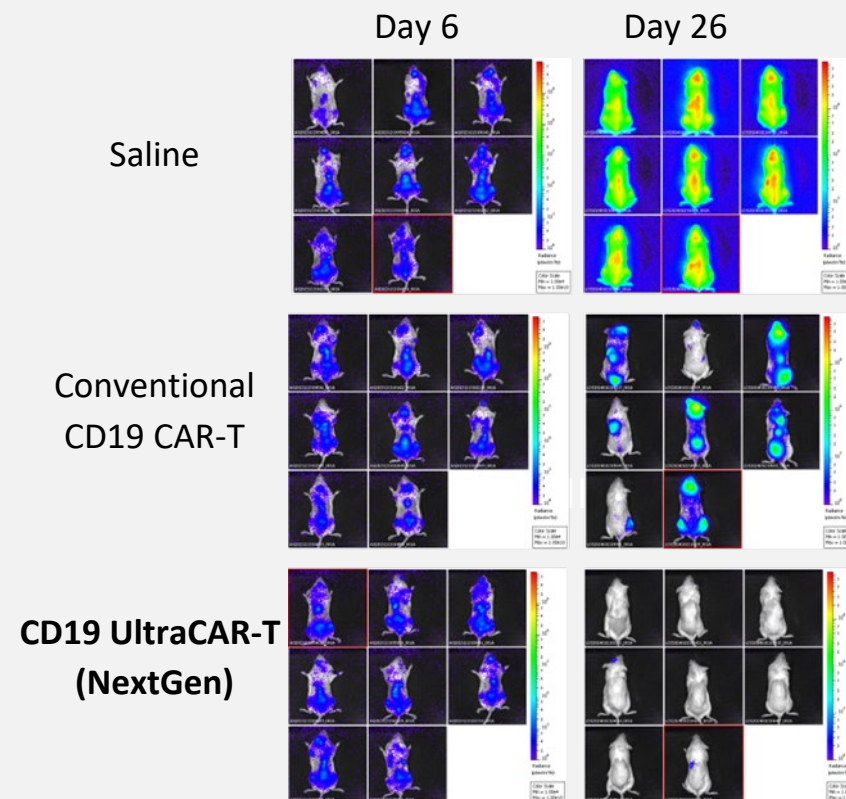
- **Next generation UltraCAR-T is engineered to address the limitations of conventional CD19 CAR-T therapies**
  - Poor CAR-T expansion and persistence
  - Potential for high toxicity and lack of safety switch
  - Risk of malignant transformation associated with lenti and retroviral vectors
  - Long turnaround times
  - High cost of manufacturing and treatment



**NextGen CD19 UltraCAR-T** with intrinsic PD-1 blockade showed significant improvement compared to conventional CD19 CAR-T in preclinical testing

In addition, CD19 UltraCAR-T has potential to be first and best-in-class CAR-T targeting **autoimmune diseases**

CD19 UltraCAR-T showed superior performance compared to conventional CAR-T in preclinical testing



- **NALM-6 tumor model in NSG MHC I/II knock out mice**
- **Single IV infusion of  $5 \times 10^6$  CAR-T cells per mouse**

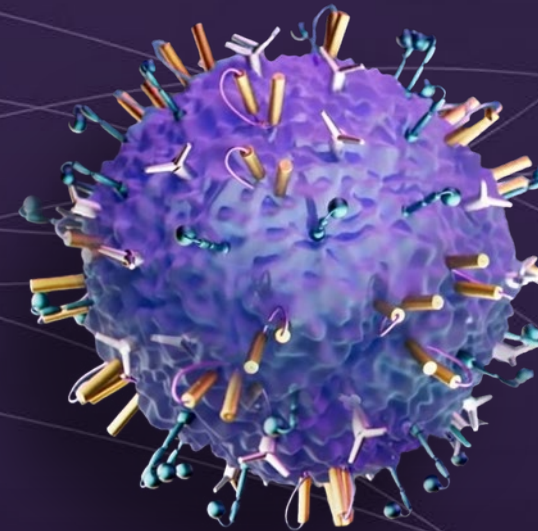
**ACRONYMS:** IV=intravenous; MHC=major histocompatibility complex; NSG=NOD scid gamma

# UltraCAR-T

## Library Approach

Precigen's Vision is to transform the personalized cell therapy landscape for cancer patients

- Select one or more UltraCAR vectors from the off-the-shelf library based on a patient's tumor
- Repeat dosing if needed



UltraVector® 



PANCREATIC



AML



OVARIAN



CLL



LUNG



ALL
























BLADDER



MM

Non-viral  
UltraCAR-T  
Library

Indication	Antigen			Indication	Antigen		
	1	2	3		1	2	3
Pancreatic				AML			
Ovarian				CLL			
Lung				ALL			
Bladder				MM			
Others				Others			

**ACRONYMS:** AML=acute myeloid leukemia; CLL=chronic lymphocytic leukemia; MCL=mantle cell lymphoma; ALL=acute lymphoblastic leukemia; DLBCL=diffuse large B-cell lymphoma; MM=multiple myeloma

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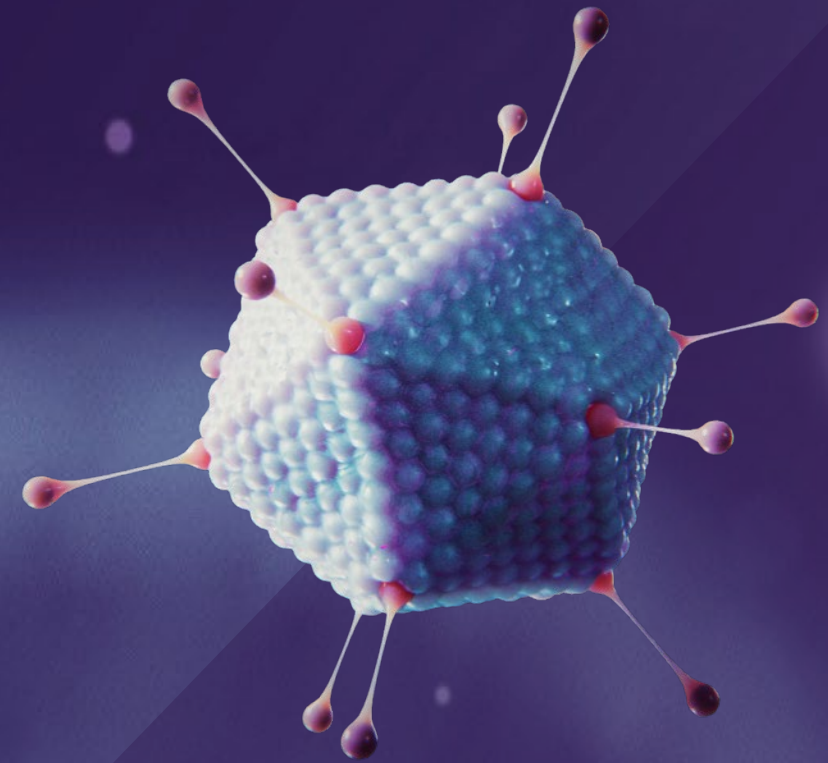




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## Thank You



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