



# PRECIGEN

## Precigen to Present Latest Clinical Advancements for PRGN-3005 UltraCAR-T® and PRGN-2009 Off-the-Shelf AdenoVerse™ Immunotherapy at the 2023 ASCO Annual Meeting

Apr 26, 2023

GERMANTOWN, Md., April 26, 2023 /PRNewswire/ -- [Precigen, Inc.](#) (Nasdaq: PGEN), a biopharmaceutical company specializing in the development of innovative gene and cell therapies to improve the lives of patients, today announced clinical data from the Phase 1 dose escalation study of PRGN-3005 UltraCAR-T in patients with advanced, recurrent platinum resistant ovarian cancer, and the Phase I study of PRGN-2009 AdenoVerse immunotherapy alone or in combination with an anti-PDL1/TGF-Beta trap checkpoint inhibitor in patients with HPV-associated cancers will be presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting taking place from June 2-6, 2023 at McCormick Place in Chicago, Illinois.



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ADVANCING MEDICINE WITH PRECISION

Abstract Title	Abstract #	Presentation Details
Phase I evaluation of PRGN-2009 alone and in combination with bintrafusp alfa in patients (pts) with recurrent/metastatic (R/M) HPV-associated cancers (HPV-C)	2628	Session Title: Developmental Therapeutics— Immunotherapy  Session Date and Time: June 3, 2023 8:00 AM-11:00 AM CT
Phase 1/1b study of PRGN-3005 autologous UltraCAR-T cells manufactured overnight for infusion next day to advanced stage platinum resistant ovarian cancer patients	5590	Session Title: Gynecologic Cancer  Session Date and Time: June 5, 2023 1:15 PM-4:15 PM CT

Event details are available on Precigen's website in the Events & Presentations section at [investors.precigen.com/events-presentations](https://investors.precigen.com/events-presentations).

### Precigen: Advancing Medicine with Precision™

Precigen (Nasdaq: PGEN) is a dedicated discovery and clinical stage biopharmaceutical company advancing the next generation of gene and cell therapies using precision technology to target the most urgent and intractable diseases in our core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases. Our technologies enable us to find innovative solutions for affordable biotherapeutics in a controlled manner. Precigen operates as an innovation engine progressing a preclinical and clinical pipeline of well-differentiated therapies toward clinical proof-of-concept and commercialization. For more information about Precigen, visit [www.precigen.com](https://www.precigen.com) or follow us on Twitter [@Precigen](#), [LinkedIn](#) or [YouTube](#).

### UltraCAR-T®

UltraCAR-T is a multigenic autologous CAR-T platform that utilizes Precigen's advanced non-viral Sleeping Beauty system to simultaneously express an antigen-specific CAR to specifically target tumor cells, mblL15 for enhanced in vivo expansion and persistence, and a kill switch to conditionally eliminate CAR-T cells for a potentially improved safety profile. Precigen has advanced the UltraCAR-T platform to address the inhibitory tumor microenvironment by incorporating a novel mechanism for intrinsic checkpoint blockade without the need for complex and expensive gene editing techniques. UltraCAR-T investigational therapies are manufactured via Precigen's overnight manufacturing process using the proprietary

UltraPorator® electroporation system at the medical center and administered to patients only one day following gene transfer. The overnight UltraCAR-T manufacturing process does not use viral vectors and does not require ex vivo activation and expansion of T cells, potentially addressing major limitations of current T cell therapies.

#### **UltraCAR-T® Clinical Program**

The UltraCAR-T platform has shifted the autologous CAR-T manufacturing paradigm using an advanced non-viral multigene delivery system and an overnight, decentralized manufacturing process for administration of autologous CAR-T cells one day after gene transfer to reduce vein-to-vein time for autologous CAR-T treatment. Precigen's UltraCAR-T platform is currently under clinical investigation for hematological and solid tumors, including a Phase 1/1b study of PRGN-3005 UltraCAR-T in patients with advanced, recurrent platinum resistant ovarian, fallopian tube or primary peritoneal cancer ([NCT03907527](#)), a Phase 1/1b study of PRGN-3006 UltraCAR-T in patients with relapsed or refractory acute myeloid leukemia (AML) or higher risk myelodysplastic syndrome (MDS) ([NCT03927261](#)) and a Phase 1/1b study of PRGN-3007 UltraCAR-T incorporating PD-1 checkpoint inhibition in patients with ROR1-positive (ROR1<sup>+</sup>) hematologic chronic lymphocytic leukemia (CLL), mantle cell lymphoma (MCL), acute lymphoblastic leukemia (ALL), diffuse large B-cell lymphoma (DLBCL) and solid tumor triple negative breast cancer (TNBC) malignancies ([NCT05694364](#)). PRGN-3006 UltraCAR-T has been granted [Orphan Drug Designation](#) and [Fast Track Designation](#) in patients with AML by the US Food and Drug Administration (FDA).

#### **UltraPorator®**

The UltraPorator system is an exclusive device and proprietary software solution for the scale-up of rapid and cost-effective manufacturing of UltraCAR-T therapies and potentially represents a major advancement over current electroporation devices by significantly reducing the processing time and contamination risk. The UltraPorator device is a high-throughput, semi-closed electroporation system for modifying T cells using Precigen's proprietary non-viral gene transfer technology. UltraPorator is being utilized for clinical manufacturing of Precigen's investigational UltraCAR-T therapies in compliance with current good manufacturing practices.

#### **AdenoVerse™ Immunotherapy**

Precigen's AdenoVerse immunotherapy platform utilizes a library of proprietary adenovectors for the efficient gene delivery of therapeutic effectors, immunomodulators, and vaccine antigens designed to modulate the immune system. Precigen's gorilla adenovectors, part of the AdenoVerse library, have potentially superior performance characteristics as compared to current competition. AdenoVerse immunotherapies have been shown to generate high-level and durable antigen-specific neutralizing antibodies and effector T cell immune responses as well as an ability to boost these antibody and T cell responses via repeat administration. Superior performance characteristics and high yield manufacturing of AdenoVerse vectors combined with UltraVector® technology allows Precigen to engineer cutting-edge investigational gene therapies to treat complex diseases.

#### **AdenoVerse™ Immunotherapy Clinical Program**

Precigen's AdenoVerse Immunotherapy platform is currently under clinical investigation in a Phase 1/2 study of PRGN-2009 AdenoVerse immunotherapy alone or in combination with anti-PDL1/TGF-Beta Trap (M7824) in patients with HPV-associated cancers ([NCT04432597](#)) and a Phase 2 study of PRGN-2012 AdenoVerse immunotherapy in patients with recurrent respiratory papillomatosis ([NCT04724980](#)). PRGN-2012 has been granted [Orphan Drug Designation](#) in patients with RRP by the FDA.

#### **Trademarks**

Precigen, UltraCAR-T, UltraPorator, UltraVector, AdenoVerse, and Advancing Medicine with Precision are trademarks of Precigen and/or its affiliates. Other names may be trademarks of their respective owners.

#### **Cautionary Statement Regarding Forward-Looking Statements**

Some of the statements made in this press release 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 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 might be impacted by the COVID-19 pandemic, and actual future results may be materially different from the plans, objectives and expectations expressed in this press release. 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.

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