



# PRECIGEN

## Precigen Regains Exclusive Rights to Proven CAR-T Targets, CD19 and BCMA, to Enable Unencumbered Development and Commercialization of UltraCAR-T®

April 3, 2023

- *Precigen amends exclusive license agreement with Alauonos to bolster portfolio and broaden strategic opportunities –*
- *The Company also regains exclusive rights to IL-12 gene therapy, including application through the AdenoVerse™ platform*
  - *Agreement eliminates all future royalties to Alauonos –*
- *Precigen to host business and clinical update call on Tuesday, April 4, 2023 at 8:30 AM ET –*

GERMANTOWN, Md., April 3, 2023 /PRNewswire/ -- [Precigen, Inc.](https://www.precigen.com) (Nasdaq: PGEN), a biopharmaceutical company specializing in the development of innovative gene and cell therapies to improve the lives of patients, today announced the amendment of its exclusive license agreement with Alauonos Therapeutics, Inc. (Alauonos).



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ADVANCING MEDICINE WITH PRECISION™

With this amendment, Precigen has the unique ability to utilize the clinically validated UltraCAR-T platform for unencumbered development and commercialization of two proven CAR-T targets, CD19 and B-cell maturation antigen (BCMA). These targets enhance Precigen's UltraCAR-T library approach, which is designed to transform the personalized cell therapy landscape for cancer patients through the development and validation of a library of non-viral plasmids to target various hematological and solid tumor-associated antigens. Enabled by the design and manufacturing advantages of UltraCAR-T, coupled with the capabilities of the UltraPorator® system, Precigen is working to empower cancer centers to deliver personalized, autologous CAR-T treatment with overnight manufacturing for cancer patients. The addition of CD19 and BCMA targets positions Precigen as a front runner in the CAR-T space.

Precigen also regained exclusive rights to its interleukin (IL)-12 gene therapy, including application through the off-the-shelf AdenoVerse™ immunotherapy platform, paving the way for potential future treatments in oncology given the important role of IL-12 cytokines in targeting many types of tumors such as HPV-associated cancers. Precigen maintains the right to pursue non-neoantigen T-cell receptors (TCRs). As part of the amendment, all milestone payments and royalties between the parties have been eliminated.

"We are excited to regain exclusive rights and have full autonomy over UltraCAR-T development and commercialization with the potential to bring cost-effective UltraCAR-T therapies using two validated targets to cancer patients. We believe rapidly progressing CD19 and BCMA toward the clinic, on our own or through strategic partnerships, will bolster our current UltraCAR-T clinical program, which currently includes the MUC16 targeted PRGN-3005 UltraCAR-T in patients with advanced, recurrent platinum resistant ovarian, fallopian tube or primary peritoneal cancer, CD33 targeted PRGN-3006 UltraCAR-T in adult patients with relapsed or recurred acute myeloid leukemia (AML) or high-risk myelodysplastic syndrome (MDS) and ROR1 targeted PRGN-3007 UltraCAR-T in patients with advanced hematologic and solid tumor malignancies," said Helen Sabzevari, PhD, President and CEO of Precigen. "We are also pleased to regain the right to include IL-12 gene therapy for implementation through our AdenoVerse platform to address oncology indications, including HPV-associated cancers."

Further details on the terms of the transaction are available within Precigen's report on 8-K filed with the SEC.

The Company will host a conference call on Tuesday, April 4, 2023 at 8:30 AM ET to provide business and clinical updates related to recent announcements. The conference call may be accessed by dialing 1-888-317-6003 (Domestic US), 1-866-284-3684 (Canada) or 1-412-317-6061 (International) and providing the participant access code 0835947. Participants are asked to dial in 10-15 minutes in advance of the scheduled call time to facilitate timely connection to the call. Event details can be found on Precigen's website in the [Events & Presentations](#) section.

### **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](http://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® Library Approach**

Precigen's UltraCAR-T library approach is designed to transform the personalized cell therapy landscape for cancer patients. Precigen's goal is to develop and validate a library of non-viral plasmids to target tumor-associated antigens. Enabled by design and manufacturing advantages of UltraCAR-T, coupled with the capabilities of the UltraPorator® system, Precigen is working to empower cancer centers to deliver personalized, autologous UltraCAR-T treatment with overnight manufacturing to any cancer patient. Based on the patient's cancer indication and biomarker profile, one or more non-viral plasmids would be selected from the library to build a personalized UltraCAR-T treatment. After initial treatment, this approach has the potential to allow for redosing of UltraCAR-T targeting the same or new tumor-associated antigen(s) based on the treatment response and the changes in antigen expression of the patient's tumor. Precigen believes that the combination of the advanced UltraVector® DNA construction platform and the ease of overnight manufacturing gives this library approach a proprietary advantage over traditional T-cell therapies.

### **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.

### **Trademarks**

Precigen, UltraCAR-T, UltraPorator, 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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