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Precigen Announces Dosing of First Patients with UltraCAR-T® Cells Manufactured Using Proprietary UltraPorator™ System in Ongoing PRGN-3005 and PRGN-3006 Phase 1 Clinical Trials

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- First patients dosed with UltraPorator manufactured PRGN-3005 UltraCAR-T cells at University of Washington/Fred Hutchinson Cancer Research Center and PRGN-3006 UltraCAR-T cells at Moffitt Cancer Center

- UltraPorator system is an exclusive device and proprietary software solution for the scale-up of rapid and cost-effective, decentralized manufacturing of UltraCAR-T therapies

GERMANTOWN, Md., Nov. 16, 2020 /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 implementation of its UltraPorator™ system, a device exclusive to Precigen for the scale-up of rapid and cost-effective decentralized manufacturing of UltraCAR-T® therapies. Precigen and its clinical partners have now successfully dosed the first patients with UltraCAR-T cells manufactured using the UltraPorator system. The patients were dosed with PRGN-3005 UltraCAR-T cells in the intraperitoneal (IP) arm of the ongoing Phase 1 study for advanced ovarian cancer patients conducted in collaboration with the University of Washington/Fred Hutchinson Cancer Research Center and with PRGN-3006 UltraCAR-T cells in the ongoing Phase 1/1b study for patients with relapsed or refractory acute myeloid leukemia (AML) and higher risk myelodysplastic syndrome (MDS) conducted in collaboration with the Moffitt Cancer Center. UltraCAR-T eliminates *ex vivo* expansion, which reduces manufacturing time to allow for rapid next day administration of UltraCAR-T cells following non-viral gene transfer.



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"Dosing the first patients with UltraCAR-T cells manufactured using our proprietary UltraPorator system in both of our UltraCAR-T trials represents a major advance in our ability to transform how personalized cancer therapies are manufactured and administered within a medical center's own labs. This milestone positions UltraPorator as the essential go-to platform for cell therapy manufacturing," said Helen Sabzevari, PhD, President and CEO of Precigen. "Our long-term goal is to streamline the process of oncology drug manufacturing so that healthcare professionals can treat their patients as quickly as possible in a commercially viable and expedient way."

UltraPorator is a high-throughput, semi-closed electroporation system for reprogramming T-cells using Precigen's next generation *Sleeping Beauty* non-viral gene transfer technology. UltraPorator reduces manufacturing risk and allows the medical center to generate UltraCAR-T cells within its own facilities. UltraPorator is capable of handling the electroporation of billions of T-cells in minutes, and further streamlines the UltraCAR-T overnight manufacturing process, allowing for rapid manufacturing of UltraCAR-T cells in higher doses and quantities, which is critical as the Company moves to expansion phases for its clinical studies.

"Current methods for non-viral gene transfer require labor intensive, manual handling of samples, which may increase contamination risk, requires multiple batches and involves extensive hours to manufacture a single dose," said Mary L. (Nora) Disis, MD, faculty member at the University of Washington and Fred Hutchinson Cancer Research Center and one of the lead investigators for the PRGN-3005 study. "The UltraPorator system is a critical piece of the puzzle for personalized manufacturing by significantly reducing processing times, further streamlining UltraCAR-T manufacturing and allowing us to deliver personalized treatment to patients faster than ever."

"Time is critical when selecting and administering treatment to relapsed or refractory AML patients," said David A. Sallman, MD, lead investigator for the PRGN-3006 study at the Moffitt Cancer Center. "The ability to conveniently manufacture PRGN-3006 UltraCAR-T cells using the UltraPorator device overnight and administer treatment the next day can be a game-changer for these patients."

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 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 unique therapies toward clinical proof-of-concept and commercialization. For more information about Precigen, visit www.precigen.com or follow us on [LinkedIn](#).

About PRGN-3005 UltraCAR-T

PRGN-3005 UltraCAR-T is a multigenic autologous CAR-T cell treatment utilizing Precigen's *Sleeping Beauty* system to simultaneously express a CAR specifically targeting the unshed portion of MUC16, which is highly expressed on ovarian tumors with limited normal tissue expression; membrane bound IL-15 for enhanced *in vivo* expansion and persistence; and a kill switch to conditionally eliminate CAR-T cells for an improved safety profile. PRGN-3005 is being evaluated in collaboration with the University of Washington and Fred Hutchinson Cancer Research Center in an investigator-initiated open-label, dose escalation Phase 1 study to evaluate the safety and maximal tolerated dose of PRGN-3005 delivered by intraperitoneal infusion (IP) or intravenous infusion (IV) (clinical trial identifier: [NCT03907527](#)). The study population includes patients with advanced stage (III/IV) recurrent ovarian, fallopian tube, and primary peritoneal cancer who are platinum-resistant and have progressed after receiving standard-of-care therapies or are not eligible to receive available therapies with known clinical benefit.

About PRGN-3006 UltraCAR-T

PRGN-3006 UltraCAR-T is a multigenic autologous CAR-T cell treatment utilizing Precigen's *Sleeping Beauty* system to simultaneously express a CAR specifically targeting CD33, which is over expressed on acute myeloid leukemia blasts with lesser expression on normal hematopoietic stem cell populations and minimal non-hematopoietic expression; membrane bound IL-15 for enhanced *in vivo* expansion and persistence; and a kill switch to conditionally eliminate CAR-T cells for improved safety profile. PRGN-3006 is being evaluated in collaboration with the Moffitt Cancer Center in a nonrandomized, investigator-initiated Phase 1/1b dose escalation study to evaluate the safety and maximal tolerated dose of PRGN-3006 UltraCAR-T (clinical trial identifier: [NCT03927261](#)). The study population includes patients with relapsed or refractory acute myeloid leukemia or higher risk myelodysplastic syndrome.

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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 therapies, and the Company's refocus to a healthcare-oriented business. 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.

For more information, contact:

Investor Contact:

Steven Harasym
Vice President, Investor Relations
Tel: +1 (301) 556-9850
investors@precigen.com

Corporate Contact:

Glenn Silver
Lazar-FINN Partners
glenn.silver@finnpartners.com

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