Precigen's UltraPorator™ Receives FDA Clearance for Manufacturing UltraCAR-T® Cells in Clinical Trials

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- Technology transfer of UltraPorator to clinical sites dosing UltraCAR-T successfully completed -

- UltraPorator poised to transform manufacturing and accessibility of CAR-T therapies for cancer patients -

GERMANTOWN, Md., Oct. 15, 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 US Food and Drug Administration (FDA) clearance and successful technology transfer for its UltraPorator ™ system, an exclusive device and proprietary software solution for the scale-up of rapid and cost-effective manufacturing of UltraCAR-T® therapies. The FDA cleared UltraPorator as a manufacturing device for clinical trials of Precigen's investigational UltraCAR-T therapies in compliance with current good manufacturing practices (cGMP). In addition, the Precigen team has successfully completed technology transfer of the UltraPorator system for the manufacturing of UltraCAR-T in the ongoing clinical trials for PRGN-3005 in ovarian cancer at the University of Washington/Fred Hutchinson Cancer Research Center and for PRGN-3006 in acute myeloid leukemia (AML) at the Moffitt Cancer Center.

"UltraPorator is a game-changer for rapid manufacturing of UltraCAR-T therapy for our PRGN-3005 clinical trial," 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. "With the tech transfer process complete, we are now ready to use UltraPorator to rapidly deliver personalized UltraCAR-T therapy to patients."

The UltraPorator device is a high-throughput, semi-closed electroporation system for reprograming T-cells using Precigen's *Sleeping Beauty* non-viral gene transfer technology. The UltraPorator system includes proprietary hardware and software solutions and potentially represents major advancements over current electroporation devices by significantly reducing the processing time and contamination risk. UltraPorator is intended to be a viable scale-up and commercialization solution for decentralized UltraCAR-T manufacturing. The UltraPorator device was designed to enable rapid manufacturing for a range of gene and cell therapies beyond UltraCAR-T and is available as a stand-alone device for strategic partnerships.

"UltraPorator is poised to transform the manufacturing and accessibility of CAR-T therapies for cancer patients," said Dr. Helen Sabzevari, President and CEO of Precigen. "For patients with cancer, delays associated with current CAR-T treatments can have significant negative impacts on health outcomes and survival. Precigen's exclusive UltraPorator device improves the scalability of the UltraCAR-T rapid manufacturing process and supports overnight delivery of personalized UltraCAR-T to patients."

The UltraCAR-T platform is differentiated from the current generation of CAR-T therapies that rely on a long and complex manufacturing process that includes the use of viral vectors and several weeks of CAR-T cell expansion in centralized facilities before treatment is administered to patients. UltraCAR-T is comprised of genetically modified autologous T-cells that simultaneously express an antigen-specific CAR, membrane bound IL-15 and a kill switch. The inclusion of the gene encoding membrane bound IL-15 slows the aging of UltraCAR-T cells, which results in superior expansion of cells *in vivo*, eliminating the need for multiple weeks of expansion in culture. The kill switch, which allows for rapid destruction of UltraCAR-T cells in the event of any significant adverse events, has the potential to improve the safety profile of UltraCAR-T therapies.

Current methods for gene transfer rely on electroporation devices requiring labor intensive and manual handling of samples which may increase contamination risk and require multiple batches and extensive hours to manufacture a single dose. In contrast, UltraPorator is capable of handling the electroporation of billions of T-cells in minutes and further streamlines the UltraCAR-T overnight manufacturing process. "UltraPorator represents a pivotal advance in the field of personalized gene and cell therapy, allowing us to bring the drug manufacturing process as close as possible to patients in a commercially viable and expedient way," Dr. Sabzevari concluded.

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.

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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	**Media Contact:**
Vice President, Investor Relations	Erich Sandoval
Tel: +1 (301) 556-9850	Lazar-FINN Partners
investors@precigen.com	erich.sandoval@finnpartners.com

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