



Precigen Announces First Patient Dosed in Phase 1 Study of PRGN-3005 UltraCAR-T™ in Patients with Advanced, Recurrent Platinum Resistant Ovarian, Fallopian Tube or Primary Peritoneal Cancer

August 5, 2019

- Milestone represents the first patient dosed with UltraCAR-T targeting solid tumors

- First-in-class investigational therapy using autologous CAR-T cells targeting advanced, recurrent platinum resistant ovarian, fallopian tube or primary peritoneal cancer

GERMANTOWN, Md., Aug. 5, 2019 /PRNewswire/ -- [Precigen, Inc.](#), a wholly-owned subsidiary of Intrexon Corporation (NASDAQ: XON) and a biopharmaceutical company specializing in the development of innovative gene and cellular therapies to improve the lives of patients, today announced that the first patient has been dosed with Precigen's PRGN-3005, a first-in-class investigational therapy using Precigen's UltraCAR-T™ therapeutic platform. PRGN-3005 UltraCAR-T is an autologous chimeric antigen receptor T (CAR-T) cell therapy manufactured using non-viral gene delivery and is under investigation for the treatment of patients with advanced, recurrent platinum resistant ovarian, fallopian tube or primary peritoneal cancer (clinical trial identifier: [NCT03907527](#)).

PRGN-3005 utilizes Precigen's transformative UltraCAR-T therapeutic platform, which eliminates *ex vivo* expansion and reduces manufacturing time to allow for rapid next day administration of UltraCAR-T cells following non-viral gene transfer. PRGN-3005 UltraCAR-T is a multigenic CAR-T cell investigational therapy utilizing Precigen's advanced non-viral gene delivery system to co-express a chimeric antigen receptor, membrane-bound interleukin-15 (mIL15), and a kill switch for better precision and control.

"This is an important milestone in our efforts to develop a new treatment option for patients with ovarian cancer," said Helen Sabzevari, PhD, President of Precigen. "With the first ovarian cancer patient dosed with Precigen's PRGN-3005 UltraCAR-T investigational therapy, we remain steadfast in our goal of delivering critical new therapies to solid tumor patients with high unmet need."

Conducted in collaboration with the University of Washington and Fred Hutchinson Cancer Research Center, the PRGN-3005 UltraCAR-T clinical study is an open-label, first-in-human Phase 1 dose escalation study to evaluate the safety and maximal tolerated dose of PRGN-3005 UltraCAR-T delivered by intraperitoneal infusion (IP) or intravenous infusion (IV). 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.

"Many women with ovarian, fallopian tube and primary peritoneal cancer have historically poor outcomes," 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. "Dosing the first patient with the PRGN-3005 UltraCAR-T represents a potentially significant development for the use of CAR-T cell therapies in solid tumors."

About Ovarian Cancer

Worldwide, nearly 300,000 women are diagnosed with ovarian cancer every year¹ with approximately 22,000 of them in the US². Since early ovarian cancer is often without obvious symptoms, the disease is frequently diagnosed at an advanced stage where cancer has spread to distant parts of the body, such as the liver or lungs^{2,3}. Five-year survival rates depend on stage and type of ovarian cancer with rates decreasing for advanced stage cancers that have spread to distant parts of the body³.

Precigen : Advancing Medicine with Precision™

Precigen is a dedicated discovery and clinical stage biopharmaceutical company advancing the next generation of gene and cellular therapies using precision technology to target the most urgent and intractable diseases in immuno-oncology, autoimmune disorders, and infectious diseases. Precigen also follows the science opportunistically in pursuit of promising programs in emerging therapeutics. 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. Precigen was founded as a wholly-owned subsidiary of [Intrexon Corporation](#) (NASDAQ: XON) and leverages a diverse portfolio of technology platforms to advance human health. For more information about Precigen, visit www.precigen.com or follow us on Twitter [@Precigen](#) and [LinkedIn](#).

Precigen's UltraCAR-T™ Therapeutic Platform

Precigen's UltraCAR-T platform has the potential to disrupt the CAR-T treatment landscape by increasing patient access through shortening manufacturing time, decreasing manufacturing-related costs, and improving outcomes using advanced approaches for precise tumor targeting and control of the immune system. The platform brings several key advancements: 1) Non-viral gene transfer using multigenic vectors for expression of multiple effector genes leads to better precision and control of tumor targeting and eliminates the need for virus; 2) Sustained persistence and desired phenotype of infused UltraCAR-T helps address T-cell exhaustion, a common issue with current CAR-T therapies; 3) T-cell control by incorporation of kill switch technology to potentially improve the safety profile; and 4) Rapid manufacturing of UltraCAR-T cells using our proprietary non-viral gene transfer process, which eliminates the need for *ex vivo* propagation, thus dramatically reducing wait times for patients from weeks to one day after gene transfer.

Safe Harbor Statement

Some of the statements made in this press release are forward-looking statements. These forward-looking statements are based upon our current

expectations and projections about future events and generally relate to plans, objectives and expectations for the development of our business, including the timing and progress of preclinical and clinical trials and discovery programs. 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 and actual future results may be materially different from the plans, objectives and expectations expressed in this press release.

¹World Health Organization, International Agency for Research on Cancer, Global Cancer Observatory. Cancer Today, Estimated number of new cases in 2018. Accessed July 2019 via [WHO IARC GCO website](#).

²American Cancer Society Ovarian Cancer Special Section. Accessed July 2019 via [ACS website](#). ³American Cancer Society. Survival Rates for Ovarian Cancer. Accessed July 2019 via [ACS website](#).

Precigen Media Contact:

Donelle M. Gregory
press@precigen.com

SOURCE Precigen, Inc.