Precigen Announces First Patient Dosed in Phase I/II Study of First-in-Class PRGN-2009 AdenoVerse™ Immunotherapy to Treat HPV-associated Cancers

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- First-in-class investigational, off-the-shelf immunotherapy utilizing AdenoVerse™ platform designed to activate the immune system to recognize and target HPV-positive solid tumors -

- HPV-associated cancers represent a significant global health burden -

GERMANTOWN, Md., Aug. 17, 2020 /PRNewswire/ -- Precigen, Inc. (Nasdaq: PGEN), 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-2009, a first-in-class, off-the-shelf (OTS) investigational immunotherapy utilizing the AdenoVerse ™ platform designed to activate the immune system to recognize and target HPV^{+} solid tumors (clinical trial identifier: NCT04432597). HPV-associated cancers represent a significant health burden in indications such as head and neck, cervical, vaginal and anal cancer.

The Phase I portion of the study will use 3+3 dose escalation to evaluate the safety of PRGN-2009 administered as a monotherapy and to determine the recommended Phase II dose (R2PD) followed by an evaluation of the safety of the combination of PRGN-2009 at the R2PD and bintrafusp alfa (M7824), an investigational bifunctional fusion protein, in patients with recurrent or metastatic HPV-associated cancers. The Phase II portion of the study will evaluate PRGN-2009 as a monotherapy or in combination with bintrafusp alfa as a neoadjuvant or induction therapy in patients with newly-diagnosed stage II/III HPV16-positive oropharyngeal cancer.

PRGN-2009 leverages Precigen's proprietary UltraVector® and AdenoVerse platforms to optimize HPV antigen design. Such design is differentiated from other therapies due to the gorilla adenovector's large payload capacity and potential for repeat administration due to very low to no seroprevalence in the human population.

PRGN-2009 is under development through a Cooperative Research and Development Agreement, or CRADA, with the laboratory of Dr. Jeffrey Schlom, Chief of the Laboratory of Tumor Immunology and Biology (LTIB), Center for Cancer Research (CCR), National Cancer Institute (NCI). This CRADA has allowed Precigen to rapidly and cost-effectively advance PRGN-2009. The Phase I/II clinical trial of PRGN-2009 is being conducted at the NIH Clinical Center and will be led by Dr. Julius Strauss, Co-Director of the LTIB's Clinical Trials Group, and Dr. James Gulley, Chief of the Genitourinary Malignancies Branch, CCR, NCI. For patients interested in enrolling in this clinical study, please call NCI's toll-free number 1-800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615), email NCIMO_Referrals@mail.nih.gov, and/or visit the website: https://trials.cancer.gov.

"We appreciate working in collaboration with such renowned partners at the NCI to achieve this important milestone in our efforts to develop a new off-the-shelf immunotherapy treatment option for patients with HPV-associated cancers," said Helen Sabzevari, PhD, President and CEO of Precigen. "We are excited to investigate Precigen's proprietary gorilla adenovector platform for the first time in a clinical setting and achieve this milestone during the COVID-19 global pandemic."

About HPV-associated Cancers

HPV infects the squamous cells that line the inner surfaces of certain organs and, consequently, most HPV-related cancers are a type of cancer called squamous cell carcinoma. Some cervical cancers come from HPV infection of gland cells in the cervix and are referred to as adenocarcinomas.[1] HPV-related cancers include cervical, oropharyngeal, anal, penile, vaginal, and vulvar.[1] Nearly 44,000 HPV-associated cancers occur in the United States each year. Of these, approximately 25,000 occur in women and 19,000 occur in men.[2] HPV is considered responsible for more than 90% of

anal and cervical cancers, about 70% of vaginal and vulvar cancers, and more than 60% of penile cancers.[2] Recent studies indicate that about 70% of cancers of the oropharynx also may be related to HPV.[2]

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 unique therapies toward clinical proof-of-concept and commercialization.

For more information about Precigen, visit www.precigen.com or follow us on Twitter @Precigen and LinkedIn.

References

[1] HPV and Cancer, National Institutes of Health. Accessed in July 2020

[2] HPV-Associated Cancer Statistics, Centers for Disease Control and Prevention. Accessed in July 2020

Trademarks

Safe Harbor Statement

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 and clinical trials and discovery programs, the promise of the Company's portfolio of therapies, the Company's refocus to a healthcare-oriented business, and its continuing evaluation of options for the Company's non-healthcare businesses. 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 trial 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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