Precigen Announces Clearance of IND to Initiate Phase I/II Study for First-in-Class PRGN-2009 AdenoVerse™ Immunotherapy to Treat HPV-positive (HPV+) Solid Tumors

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- First off-the-shelf AdenoVerse™ immunotherapy to enter the clinic -
- Immunotherapy designed to activate the immune system to recognize and target HPV+ solid tumors -

GERMANTOWN, Md., April 20, 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 that the US Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application to initiate a Phase I/II trial for 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. HPV^+ 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 follow 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 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 the bifunctional fusion protein in patients with newly-diagnosed stage II/III HPV16-positive oropharyngeal cancer.

PRGN-2009 leverages Precigen's UltraVector® and AdenoVerse platforms to optimize HPV antigen design in combination with its gorilla adenovector with a large payload capacity and the ability for repeat administration due to very low to non-existent seroprevalence in the human population.

PRGN-2009 is under development through a Cooperative Research and Development Agreement, or CRADA, within 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 to the clinic. The Phase I/II clinical trial of PRGN-2009 will be 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.

"Globally, high-risk HPVs cause nearly 5% of all cancers, with about 570,000 women and 60,000 men diagnosed with HPV-related cancers each year," said Helen Sabzevari, PhD, President and CEO of Precigen. "We are incredibly proud of our continued relationship with NCI and the tremendous progress in bringing forward this novel asset class in such a short period of time. Advancements are critically needed to better target HPV^+ tumors across multiple patient groups, and we have been encouraged by the promising preclinical data for PRGN-2009 in potentially targeting this patient population."

About HPV^+ 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 April 2020

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