Precigen Receives FDA Clearance of IND to Initiate Phase 2 Study of PRGN-2009 Off-the-Shelf AdenoVerse Immunotherapy in Combination with Pembrolizumab to Treat Patients with Recurrent or Metastatic Cervical Cancer

May 31, 2023

– HPV is responsible for more than 90 percent of cervical cancer cases globally with approximately 300,000 women living with cervical cancer in the US –

– Current response rates to second line treatments in recurrent or metastatic cervical cancer are very low and associated with a high rate of toxicity –

– PRGN-2009 is designed to generate de novo T-cell immune response against HPV 16/18-positive solid tumors cells and is differentiated from other platforms due to the ability of gorilla adenovectors to enable repeat administrations –

– PRGN-2009 Phase 1 data to be presented at the 2023 ASCO annual meeting on June 3 (Abstract # 2628); PRGN-2009 in combination with a checkpoint inhibitor demonstrated a favorable safety profile and resulted in a 30% ORR in patients with heavily pre-treated HPV-associated cancers, including those who have previously failed checkpoint inhibitors –

– Phase 2 study of PRGN-2009 is in combination with pembrolizumab in the second line setting in patients with recurrent or metastatic cervical cancer previously treated with pembrolizumab for recurrent or metastatic disease –

– CMC path in place to support delivery of product for Phase 2 study as well as future framework to support potential pivotal trials –

GERMANTOWN, Md., May 31, 2023 /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 2 study of the first-in-class PRGN-2009 Off-the-Shelf (OTS) AdenoVerse ™ immunotherapy in combination with pembrolizumab in patients with recurrent or metastatic cervical cancer. The Phase 2 randomized, open-label, two-arm, multicenter study will evaluate the efficacy and safety of PRGN-2009 in combination with pembrolizumab versus pembrolizumab monotherapy in patients with recurrent or metastatic cervical cancer who are pembrolizumab resistant. The study will enroll approximately 46 patients who previously have been treated with pembrolizumab for recurrent or metastatic disease.

In the Phase 1 study, PRGN-2009 was evaluated as a monotherapy (N=6) and in combination with a checkpoint inhibitor (N=11) in patients with recurrent or metastatic human papillomavirus (HPV)-associated cancers. Interim Phase 1 data showed a favorable safety profile of repeated PRGN-2009 administrations in both the monotherapy and the combination arms with no dose limiting toxicities (DLTs). Interim Phase 1 data showed encouraging clinical activity with objective responses when combined with a checkpoint inhibitor in heavily pre-treated recurrent/metastatic cancer patients who had previously failed checkpoint inhibitor treatment. Full Phase 1 data will be presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting on June 3, 2023 from 8:00 to 11:00 AM CT (Abstract # 2628).

"Cervical cancer is a devastating disease for which there remains a significant unmet need for new and improved treatment options in the recurrent or metastatic setting," said Helen Sabzevari, PhD, President and CEO of Precigen. "We are encouraged by the 30% ORR in the Phase 1 study which demonstrated a favorable safety profile with no dose-limiting toxicities, strong antigen-specific immune response and lack of significant neutralizing antibody response upon repeat administrations in combination with a checkpoint inhibitor. Based on these Phase 1 safety and efficacy data, the FDA has allowed us to treat patients as early as the second line in the recurrent or metastatic setting in this Phase 2 cervical cancer study. Additionally, we are pleased that in collaboration with FDA, we have agreed upon a CMC path to support the delivery of product for the Phase 2 study as well as a future framework to support potential pivotal trials."

Patients in the Phase 2 study will be randomized 1:1 to the combination of PRGN-2009 and pembrolizumab (cohort 1) or pembrolizumab monotherapy (cohort 2). Patients randomized to the PRGN-2009 plus pembrolizumab cohort will receive PRGN-2009 via subcutaneous (SC) injection (5×10^{11} PU every 3 weeks for three administrations followed by administration each 6 weeks thereafter). Patients in the PRGN-2009 plus pembrolizumab cohort and pembrolizumab monotherapy cohort will receive pembrolizumab via intravenous (IV) infusion (400 mg every 6 weeks). Patients randomized to the pembrolizumab monotherapy cohort will be offered the option to crossover to the PRGN-2009 plus pembrolizumab cohort if certain conditions are met.

The primary objective of the Phase 2 study is to assess the objective response rate (ORR) per RECIST v1.1 following treatment with PRGN-2009 in combination with pembrolizumab or pembrolizumab monotherapy. Secondary objectives include the evaluation of safety and tolerability, progression-free survival (PFS), overall survival (OS), best overall responses (BOR), Disease Control Rate (DCR), time to response and duration of response.

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 therapies toward clinical proof-of-concept and commercialization. For more information about Precigen, visit www.precigen.com or follow us on Twitter @Precigen, LinkedIn or YouTube.

About Cervical Cancer[1,2]

The human papillomavirus is responsible for more than 90 percent of cervical cancer cases. In 2023, there will be an estimated 13,960 new cervical cancer cases in the United States. In 2018, there were an estimated 293,394 women living with cervical cancer in the United States. Cancer stage at diagnosis determines treatment options and influences survival. The majority of cervical cancer cases are diagnosed at the local stage when the cancer has spread to other parts of the body. About 16% of cervical cancers cases are distant, when the cancer has metastasized. The 5-year survival rate for cases at the local stage is about 91% and cases at the distant stage are roughly 17%.

AdenoVerse ™ Immunotherapy

Precigen's AdenoVerse immunotherapy platform utilizes a library of proprietary adenovectors for the efficient gene delivery of therapeutic effectors, immunomodulators, and vaccine antigens designed to modulate the immune system. Precigen's gorilla adenovectors, part of the AdenoVerse library, have potentially superior performance characteristics as compared to current competition. AdenoVerse immunotherapies have been shown to generate high-level and durable antigen-specific T-cell immune responses as well as an ability to boost these responses via repeat administration. Superior performance characteristics and high yield manufacturing of AdenoVerse vectors leveraging UltraVector® technology allows Precigen to engineer cutting-edge investigational gene therapies to treat complex diseases.

AdenoVerse ™ Immunotherapy Clinical Program

Precigen's AdenoVerse immunotherapy platform is currently under clinical investigation in a Phase 1/2 study of PRGN-2009 AdenoVerse immunotherapy alone or in combination with anti-PDL1/TGF-Beta Trap (bintrafusp alfa) in patients with HPV-associated cancers (NCT04432597) and a Phase 2 study of PRGN-2012 AdenoVerse immunotherapy in patients with recurrent respiratory papillomatosis (RRP) (NCT04724980). PRGN-2012 has been granted Orphan Drug Designation in patients with RRP by the FDA.

Trademarks

Precigen, AdenoVerse, UltraVector and Advancing Medicine with Precision are trademarks of Precigen and/or its affiliates. Other names may be trademarks of their respective owners.

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 and AdenoVerse therapies. 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.

References

[1] Cancer Stat Facts: Cervical Cancer, National Cancer Institute, Surveillance, Epidemiology, and End Results Program.

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

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