Precigen Highlights Pipeline Updates to be Presented at the 42nd Annual J.P. Morgan Healthcare Conference

Jan 08, 2024

– PRGN-2012 Phase 2 pivotal study data in RRP is anticipated in the second quarter of 2024; the Company plans to submit a BLA under an accelerated approval pathway in the second half of 2024; commercial readiness preparations are underway for a potential launch in 2025 –

– Company presentation scheduled for January 10 at 5:15 PM PST –

GERMANTOWN, Md., Jan. 8, 2024 /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 released highlights of pipeline updates to be presented at the 42nd Annual J.P. Morgan Healthcare Conference on January 10, 2024 at 5:15 PM PST in San Francisco, California.

AdenoVerse ™ Immunotherapies

"In the second quarter of this year, we anticipate presenting Phase 2 pivotal study data for our lead asset, PRGN-2012, in recurrent respiratory papillomatosis, RRP, and submitting the Company's first BLA under an accelerated approval pathway in the second half of this year. In anticipation of a potential launch in 2025, we are actively preparing for commercial readiness. This is an exciting time for Precigen as we prepare to transition from a clinical to commercial stage biotechnology company. I am incredibly proud of the Precigen team for achieving the first breakthrough therapy designation and accelerated approval pathway so rapidly for an RRP treatment and for the life-changing potential that PRGN-2012 has for RRP patients," said Helen Sabzevari, PhD, President and CEO of Precigen.

- **PRGN-2012 in RRP:** PRGN-2012 is an investigational off-the-shelf AdenoVerse immunotherapy designed to elicit immune responses directed against cells infected with human papillomavirus (HPV) 6 or HPV 11 for the treatment of RRP. The US Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation and Orphan Drug Designation for PRGN-2012 for the treatment of RRP.
  - PRGN-2012 is currently under investigation in a Phase 1/2 pivotal single-arm study in adult patients with RRP (clinical trial identifier: NCT04724980).
  - PRGN-2012 demonstrated strong efficacy and favorable safety profile in the Phase 1 portion of the study with 50% of patients (N=12) in durable and ongoing Complete Response more than two years after PRGN-2012 treatment.
  - A Phase 2 data presentation is anticipated in the second quarter of 2024.
  - A planned Biologics License Application (BLA) submission under an accelerated approval pathway is anticipated in the second half of 2024.
  - Commercial readiness preparations are underway for a potential launch in 2025.
- **PRGN-2009 in OPSCC and Cervical Cancer:** PRGN-2009 is an investigational off-the-shelf AdenoVerse immunotherapy designed to activate the immune system to recognize and target HPV-associated cancers.
  - The Phase 2 study of PRGN-2009 in combination with pembrolizumab in newly diagnosed patients with HPV-associated oropharyngeal squamous cell carcinoma (OPSCC) is currently enrolling patients (clinical trial identifier: NCT05996523).
  - The Phase 2 randomized, open-label study of PRGN-2009 in combination with pembrolizumab in patients with recurrent/metastatic cervical cancer is anticipated to initiate in the first quarter of 2024 (clinical trial identifier:

NCT06157151).

UltraCAR-T® Cell Therapies
"We continue to advance our UltraCAR-T clinical programs and remain enthusiastic about the data we are seeing in our Phase 1b expansion studies. Precigen's UltraCAR-T cell therapies are engineered to specifically address the limitations of conventional CAR-T therapies by improving *in vivo* CAR-T expansion and persistence, adding a safety/kill switch to reduce the risk of toxicity and malignancy, utilizing a non-viral design to reduce the risk of malignant transformation associated with lentivirus and retrovirus vectors, eliminating long turnaround times for manufacturing and reducing the high cost of treatment," adds Sabzevari. "We look forward to sharing new results for these assets during the planned presentations for our PRGN-3006 and PRGN-3007 UltraCAR-T programs in 2024. In addition to ongoing clinical trials, we are excited by the preclinical data for a new and differentiated CD19 targeted UltraCAR-T, which has best-in-class potential for this validated target capitalizing on the unique advantages of the UltraCAR-T platform over conventional CAR-T."

- **PRGN-3006 in AML/MDS:** PRGN-3006 is an investigational multigenic, autologous chimeric antigen receptor T cell (CAR-T) therapy engineered to simultaneously express a CAR specifically targeting CD33, membrane bound IL-15 (mbIL15), and a safety/kill switch. PRGN-3006 has been granted Orphan Drug Designation in patients with acute myeloid leukemia (AML) and Fast Track Designation in patients with relapsed/refractory (r/r) AML by the FDA.
    - PRGN-3006 is currently under evaluation in a Phase 1b clinical trial (clinical trial identifier: NCT03927261) for the treatment of patients with r/r AML or higher-risk myelodysplastic syndromes (MDS).
    - The first-in-human, Phase 1 dose escalation portion of the study with lymphodepletion was completed in r/r AML and higher-risk MDS patients.
    - Phase 1 dose escalation data showed that PRGN-3006 was well-tolerated with no dose-limiting toxicities (DLTs) and a 27% objective response rate (ORR) in heavily pre-treated r/r AML patients infused following lymphodepletion.
    - An interim Phase 1b dose expansion data presentation is anticipated in the second half of 2024.
- **PRGN-3005 in Ovarian Cancer:** PRGN-3005 is an investigational multigenic, autologous CAR-T cell therapy engineered to express a CAR specifically targeting the unshed portion of MUC16, mbIL15, and a safety/kill switch.
    - The Phase 1b dose expansion portion of the Phase 1/1b study is ongoing (clinical trial identifier: NCT03907527).
- **PRGN-3007 in Advanced ROR1+ Hematological and Solid Tumors:** PRGN-3007 is an investigational multigenic, autologous CAR-T cell therapy engineered to express a CAR targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1), mbIL15, a safety/kill switch, and a novel mechanism for the intrinsic blockade of PD-1 gene expression.
    - The Phase 1 dose escalation portion of the Phase 1/1b study is ongoing (clinical trial identifier: NCT05694364).
    - A preliminary Phase 1 dose escalation data presentation is anticipated by the end of 2024.
- **UltraCAR-T Targeting CD19:** Preclinical data for the Company's UltraCAR-T targeting CD19 (a validated target) have demonstrated significant potential and the Company is preparing to initiate a Phase 1 study to support a potential best-in-class CD19 CAR-T leveraging the unique advantages of the UltraCAR-T platform.

Precigen's 42nd Annual J.P. Morgan Healthcare Conference presentation will be available on the Company website in the Events & Presentations section following the presentation.

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 X @Precigen, LinkedIn or YouTube.

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, product candidate approval and commercialization 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 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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