Precigen to Present Plans for Realizing Commercial Vision for PRGN-2012 at the 43rd Annual J.P. Morgan Healthcare Conference

Jan 13, 2025

– PRGN-2012 has potential to be first FDA-approved therapeutic for treatment of RRP, a rare and devastating chronic disease –

– Company completed BLA submission for PRGN-2012 for treatment of adults with RRP –

– Commercial readiness activities underway in anticipation of potential launch of PRGN-2012; Company started 2025 with approximately $100 million cash on-hand with cash runway well into 2026, beyond the anticipated launch in the second half of 2025 –*

– According to recently updated internal analysis derived from review of claims data, the market opportunity for PRGN-2012 in RRP is estimated to be approximately 27,000 adult patients in the US –

– Immense market potential for AdenoVerse platform in other HPV6/11-driven indications, such as genital warts, which has significant unmet need with annual global incidence of more than 4 million and prevalence of more than 25 million, and HPV16/18-driven indications, such as cervical cancer and head and neck cancers –

– Company presentation on Thursday, January 16, 2025 at 9:00 AM PT in San Francisco –

GERMANTOWN, Md., Jan. 13, 2025 /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 highlights for the upcoming company presentation at the 43rd Annual J.P. Morgan Healthcare Conference on Thursday, January 16, 2025 at 9:00 AM PT/12:00 PM ET. Participants may view details for Precigen's company presentation at Precigen's website in the Events & Presentations section at investors.precigen.com/events-presentations.

"Our recent BLA submission for PRGN-2012 in RRP puts our commercial readiness activities in high gear and we are well underway to ensure full readiness in anticipation of a potential launch in the second half of this year. We have made tremendous progress in the past six months on payer and prescriber analysis, clarifying the market opportunity, building out our commercial and distribution infrastructure, and other activities to ensure we fully coordinate the payor, provider, and patient journeys for launch," said Phil Tennant, Chief Commercial Officer of Precigen. "Our updated analysis of the market using claims data and electronic health records underscores the significant potential for PRGN-2012 in RRP with approximately 27,000 adult patients now identified in the US and we expect more than 125,000 patients ex-US. We are confident that we will be ready to commercialize in the US as soon as we receive approval so that patients can gain access to this game-changing treatment."

"With 100% manufacturing success rate demonstrated to date, we anticipate our in-house commercial drug substance cGMP manufacturing facility will be ready to meet the projected demand to support potential commercial launch in the second half of this year," said Rutul Shah, Chief Operating Officer of Precigen.

"We continue to de-risk our PRGN-2012 asset and now that we have submitted the BLA in RRP, we are a step closer to completing our transition to a commercial-stage company. As we start 2025, we are laser focused on working with the FDA and advancing commercial readiness efforts in anticipation of a potential launch in the second half of this year. In addition, we are preparing for submissions to other health authorities in our prioritized global markets. Beyond RRP, we see immense potential for the AdenoVerse platform in other HPV6/11-driven indications, such as genital warts, and HPV16/18-driven indications, such as cervical cancer and head and neck cancers," said Helen Sabzevari, PhD, President and CEO of Precigen. "As communicated previously, we plan to pursue strategic partnerships to advance our UltraCAR-T programs, which deliver autologous, antigen-specific CAR-T cells overnight to a patient at the patient's medical center. In conjunction, we are preparing for an end of Phase 1b meeting with the FDA for PRGN-3006 to share results for this highly promising program, including new clinical biomarker data that may further enable patient

stratification and positively impact efficacy."

Realizing Precigen's Commercial Vision for PRGN-2012 AdenoVerse® Gene Therapy in RRP

- PRGN-2012 (INN: zopapogene imadenovec†) is an investigational off-the-shelf AdenoVerse gene therapy designed to elicit immune responses directed against cells infected with human papillomavirus (HPV) 6 or HPV 11 for the treatment of recurrent respiratory papillomatosis (RRP), a rare and devastating chronic disease for which the current standard-of-care is repeated surgeries. If approved, PRGN-2012 has the potential to be the first US Food and Drug Administration (FDA)-approved therapeutic for the treatment of RRP.
- PRGN-2012 received Breakthrough Therapy Designation from the FDA. PRGN-2012 also received Orphan Drug Designation from the FDA and Orphan Drug Designation from the European Commission.
- In December 2024, the Company announced that it had completed the submission of a biologics license application (BLA) with a request for priority review for PRGN-2012 for the treatment of adults with RRP to the FDA. The submission is in the initial 60 day review period, during which time the FDA will decide whether to accept the BLA for further review and set the Prescription Drug User Fee Act (PDUFA) action date. The BLA included a request for priority review, which, if granted, would reduce the review timeline from the standard 10-month to a priority 6-month review from the date the submission is accepted by the FDA.
- The BLA, under an accelerated approval pathway, is supported by data from the Phase 1/2 pivotal study in which more than 50% of patients achieved Complete Response and more than 85% of patients had a decrease in surgical interventions in the year after PRGN-2012 treatment compared to the year prior to treatment. PRGN-2012 was well-tolerated with no dose-limiting toxicities and no treatment-related adverse events greater than Grade 2.
- The confirmatory clinical trial of PRGN-2012 was initiated and is enrolling patients in accordance with the guidance from the FDA to initiate the study prior to submission of the BLA.
- The Company continues to rapidly advance its commercial and manufacturing readiness campaign in anticipation of a potential 2025 launch.

Maximizing the Potential of PRGN-2009 AdenoVerse® Gene Therapy in HPV-associated Cancers

- PRGN-2009 Phase 2 clinical trials under a cost-effective cooperative research and development agreement (CRADA) with the National Cancer Institute (NCI) in recurrent/metastatic cervical cancer and in newly diagnosed HPV-associated oropharyngeal cancer are ongoing.
- Enrollment was paused in the cervical cancer Phase 2 clinical trial at non-NCI sites as part of strategic reprioritization activities in 2024.

Maximizing the Value of the UltraCAR-T® Platform through Strategic Partnerships

- Enrollment was completed for the Phase 1b trial for PRGN-3006, which received Fast Track designation from the FDA for the treatment of relapsed or refractory (r/r) acute myeloid leukemia (AML).
- Based on the results of correlative studies of the patient samples from the Phase 1/1b study, the Company has identified clinical biomarkers that correlate to objective responses after PRGN-3006 treatment in r/r AML patients. This advancement may further enable patient stratification and positively impact efficacy.
- The Company is preparing for an end of Phase 1b meeting with the FDA to discuss results and next steps.
- The Company plans to focus on strategic partnership opportunities to advance this promising UltraCAR-T program in AML.

*Cash on-hand is preliminary and unaudited and reflects preliminary financial information as of December 31, 2024. In preparing this information, the Company's actual financial position as of December 31, 2024 has not yet been finalized by management or reviewed or audited by the Company's independent registered public accounting firm. This information is also not a comprehensive statement of financial position or results of operations as of or for the year-ended December 31, 2024. Subsequent information or events may lead to material differences between the foregoing preliminary financial information and those reported in the Company's subsequent SEC filings. Accordingly, investors should not place undue reliance on this preliminary financial information.

†zopapogene imadenovec is the international nonproprietary name (INN) for the investigational therapeutic known as PRGN-2012. Zopapogene imadenovec has not been approved by any health authority in any country for any indication.

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 LinkedIn or YouTube.

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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, regulatory approvals, commercial launches 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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