Precigen Strategically Prioritizes Portfolio to Focus on First Potential Gene Therapy Launch

Aug 06, 2024

– PRGN-2012 is on track for a rolling BLA submission under an accelerated approval pathway; patient enrollment initiated in the confirmatory clinical trial –

GERMANTOWN, Md., Aug. 6, 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 announced a strategic reprioritization of the Company's clinical portfolio and streamlining of resources, including a reduction of over 20% of its workforce, to focus on potential commercialization of the PRGN-2012 AdenoVerse® gene therapy for the treatment of recurrent respiratory papillomatosis (RRP).

These strategic changes substantially reduce required resources for non-priority programs and will enable the Company to focus on pre-commercialization efforts on PRGN-2012, including supporting submission of a rolling biologics license application (BLA) under an accelerated approval pathway anticipated in the second half of 2024, conducting the confirmatory clinical trial, and manufacturing of commercial product. Additionally, the Company will continue acceleration of commercial readiness efforts for a potential launch in 2025, led by the Company's new Chief Commercial Officer, Phil Tennant.

Strategic prioritization will also include:

- **PRGN-2009 AdenoVerse® Gene Therapy Clinical Trials:** The Company plans to continue PRGN-2009 Phase 2 trials under a 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. PRGN-2009 clinical trial enrollment at non-NCI clinical sites will be paused.
- **UltraCAR-T® Clinical Programs:** The Company has completed enrollment of the Phase 1b trial for PRGN-3006 in acute myeloid leukemia (AML), which received Fast Track designation from the US Food and Drug Administration (FDA), and is preparing for an end of Phase 1b meeting with the FDA to discuss next steps. The Company will pause all other UltraCAR-T clinical programs, including PRGN-3005 and PRGN-3007. The Company will minimize UltraCAR-T spend and focus on strategic partnerships to further advance UltraCAR-T programs.
- **Preclinical Programs:** The Company will pause all preclinical programs.
- **ActoBio:** The Company has initiated a shutdown of its Belgium-based ActoBio subsidiary operations, including planned elimination of all ActoBio personnel. In conjunction with this shutdown, ActoBio's portfolio of intellectual property will be made available for prospective transactions.

"We are on track toward our goal of submitting a rolling BLA for PRGN-2012 in the second half of this year and we are pleased to announce that the confirmatory clinical trial, an important step guided by the FDA to support an accelerated approval, has already been initiated and is actively enrolling patients," said Helen Sabzevari, PhD, President and CEO of Precigen. "These prioritization steps enhance our ability to rapidly prepare for potential commercialization of PRGN-2012, which if approved, we believe has the safety, efficacy, and route of administration profile to be the first and best-in-class therapy for RRP patients."

Please refer to the Company's 8-K filing for additional details.

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.

AdenoVerse®
Precigen's AdenoVerse 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 gene therapies 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.

About PRGN-2012 AdenoVerse® Gene Therapy
PRGN-2012 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 RRP. PRGN-2012 was the first to receive Breakthrough Therapy Designation and an accelerated approval pathway for RRP from the US Food and Drug Administration (FDA). PRGN-2012 received Orphan Drug Designation from the FDA and from the European Commission. Results from the Phase 1 portion of the Phase 1/2 study were published in the peer-reviewed journal, *Science Translational Medicine*, a leading publication from the American Association for the Advancement of Science (AAAS). Pivotal data was presented at the 2024 American Society of Clinical Oncology annual meeting.

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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, the Company's ability to successfully partner or sell its paused programs and activities in a timely manner, the timing and progress of clinical trials, and related milestones including BLA submission and potential launch of PRGN-2012, and the promise of the Company's portfolio of 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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