Precigen Receives FDA Platform Technology Designation for AdenoVerse Platform

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- *Designation has the potential to accelerate development of current and future therapies built on Precigen's AdenoVerse platform*

GERMANTOWN, Md., Sept. 21, 2026 /PRNewswire/ -- Precigen, Inc. (Nasdaq: PGEN), a commercial-stage biopharmaceutical company specializing in the advancement of innovative precision medicines to improve the lives of patients, today announced that the United States Food and Drug Administration (FDA) granted platform technology designation to the AdenoVerse® immunotherapeutic platform, which is used in the company's first commercial product, PAPZIMEOS®. The designation reflects the adaptability and potential of the platform to address a broad range of indications, including HPV-positive malignancies such as head and neck, cervical, anal, vulvar and vaginal cancers, as well as other diseases that may be targeted by future AdenoVerse-based product candidates.

FDA platform technology designation creates a pathway to leverage data generated for the development of PAPZIMEOS to potentially accelerate development of future AdenoVerse programs by utilizing existing manufacturing and preclinical knowledge to support future marketing applications and reduce duplication of development work. Platform technology designation provides opportunities for early FDA engagement, the ability to receive timely advice by having additional engagement with the FDA during development, and consideration of prior FDA manufacturing inspections for future applications.

To qualify for the platform technology designation, a platform must already be used in an FDA-approved product and the available evidence must demonstrate that it is well characterized, reproducible and has the potential to be adaptable across multiple products without compromising quality, manufacturing or safety. In granting this designation, the FDA determined that the AdenoVerse platform can be applied consistently across multiple products and is reasonably likely to generate meaningful efficiencies to the development or manufacturing process, and to the regulatory review process.

"This designation has the potential to accelerate the development of Precigen's broader AdenoVerse portfolio by allowing us to build on the technology established through PAPZIMEOS, which was approved by the FDA in August 2025. We expect the near-term impact will be especially meaningful for PRGN-2009 across multiple HPV-associated cancers, including cervical cancer and oropharyngeal squamous cell carcinoma. Importantly, the potential extends beyond PRGN-2009 to future AdenoVerse candidates such as those targeting additional cancers and other diseases," said Helen Sabzevari, PhD, President and CEO of Precigen. "We thank the FDA for recognizing the potential of the AdenoVerse platform. This designation will enable us to leverage prior data and engage with the FDA earlier and more frequently, creating opportunities to reduce duplicative work and bring greater speed, efficiency and predictability to the development of future AdenoVerse therapies."

AdenoVerse® Clinical Portfolio

Precigen's AdenoVerse portfolio includes a Phase 2 study of PRGN-2009 in combination with pembrolizumab in newly diagnosed patients with HPV-associated oropharyngeal squamous cell carcinoma (NCT05996523) and a Phase 2 study of PRGN-2009 in combination with pembrolizumab in patients with recurrent or metastatic cervical cancer (NCT06157151). The portfolio also includes PAPZIMEOS® (zopapogene imadenovec-drba; formerly PRGN-2012), which is the first FDA-approved therapy for the treatment of adults with recurrent respiratory papillomatosis (RRP). An open-label study evaluating the efficacy of redosing PAPZIMEOS in adults with RRP is currently enrolling (NCT06538480).

Precigen: Advancing Medicine with Precision®

Precigen (Nasdaq: PGEN) is a commercial-stage biopharmaceutical company specializing in the advancement of innovative precision medicines to address difficult-to-treat diseases with high unmet patient need. Precigen is dedicated to advancing scientific breakthroughs from proof-of-concept through commercialization. With a strong commitment to innovation, Precigen is developing a robust pipeline of differentiated therapies across its core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases. 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

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the US Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what the Company expects. Examples of forward-looking statements include, among others, potential development efficiencies the platform technology designation may provide to accelerate the development of the Company's AdenoVerse clinical portfolio, potential benefits of the platform technology designation, information relating to the Company's business and business plans, the success of efforts to commercialize PAPZIMEOS® (zopapogene imadenovec-drba) for the treatment of recurrent respiratory papillomatosis (RRP) in adults, the Company's ability to successfully obtain foreign regulatory approvals for PAPZIMEOS, expectations about the safety and efficacy of PAPZIMEOS, the ability of PAPZIMEOS to treat RRP, the Company's future financial and operational results, and the Company's ability to commence clinical studies or complete ongoing clinical studies for the Company's clinical and pre-clinical stage candidates. 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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