Precigen Receives Orphan Drug Exclusivity for PAPZIMEOS (zopapogene imadenovec-drba) in the United States

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- *FDA grants orphan drug exclusivity for PAPZIMEOS for the treatment of adults with recurrent respiratory papillomatosis*
- *Seven-year period of PAPZIMEOS market exclusivity is effective through August 14, 2032*
- *PAPZIMEOS, the first and only FDA-approved therapy for adults with recurrent respiratory papillomatosis, is commercially available in the US*

GERMANTOWN, Md., May 27, 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 US Food and Drug Administration (FDA) has granted orphan drug exclusivity for PAPZIMEOS™ (zopapogene imadenovec-drba) for the treatment of adults with recurrent respiratory papillomatosis (RRP). PAPZIMEOS was granted full approval by the FDA in August 2025, becoming the first and only approved treatment for adults with RRP, a rare, chronic and debilitating disease. PAPZIMEOS is commercially available in the US and is being prescribed nationwide across both major medical centers and community practices, with patients spanning a range of disease severities actively receiving treatment.

Orphan drug exclusivity is granted to certain drugs and biologics approved for rare diseases or conditions that affect fewer than 200,000 people in the United States. The orphan drug exclusivity granted by the FDA for PAPZIMEOS for the treatment of adults with RRP is effective through August 14, 2032, providing seven years of market exclusivity in the US from the PAPZIMEOS approval date.

"We appreciate the FDA's recognition of seven years of orphan drug exclusivity for PAPZIMEOS, which is a testament to the groundbreaking pivotal study data and the transformative potential of PAPZIMEOS in addressing the root cause of this rare disease," said Helen Sabzevari, PhD, President and CEO of Precigen. "This regulatory exclusivity, together with Precigen's patent portfolio covering PAPZIMEOS and its therapeutic use, enhances the product's value by strengthening market protection and long-term revenue potential, which in turn supports continued innovation for rare diseases."

About RRP
RRP is a rare, debilitating, and potentially life-threatening disease of the upper and lower respiratory tract caused by chronic HPV 6 or HPV 11 infection. RRP can lead to severe voice disturbance, compromised airways, and recurrent post-obstructive pneumonia. Although rare, RRP has the potential for transformation to malignant cancer and can be fatal. Management of RRP has primarily consisted of repeated surgeries, which do not address the underlying cause of the disease and can be associated with significant morbidity as well as significant patient and health system burden. As the number of lifetime surgeries increases, the risk for irreversible iatrogenic laryngeal injury increases with each surgery, and patients may undergo hundreds of these surgeries over their lifetimes. RRP can impact patients' work and social lives, financial stability, and mental health. Patients with RRP can experience substantial impacts to daily living with decreased quality of life and high health care utilization. Based on an internal analysis of claims data and electronic health records, there are approximately 27,000 adult RRP patients in the US.

About PAPZIMEOS ™ (zopapogene imadenovec-drba), for subcutaneous injection only
PAPZIMEOS is the first and only FDA-approved therapy for the treatment of adults with RRP and the first and only approved therapy to address the root cause of RRP. PAPZIMEOS is a non-replicating adenoviral vector-based immunotherapy designed to express a fusion antigen comprising selected regions of human papillomavirus (HPV) types 6 and 11 proteins. PAPZIMEOS is designed to generate an immune response directed against HPV 6 and HPV 11 proteins in patients with RRP. Discovered and designed in Precigen's labs using Precigen's proprietary AdenoVerse therapeutic platform, PAPZIMEOS represents a new therapeutic paradigm for RRP.

Indication and Important Safety Information

What is PAPZIMEOS?
PAPZIMEOS is a type of immunotherapy used to treat a condition called recurrent respiratory papillomatosis (RRP) in adults.

What is the most important information I should know about PAPZIMEOS?
Some people may have a reaction to the shot. Signs and symptoms may include redness, pain, swelling, itching, or warmth where the shot was given. After your first treatment, your healthcare provider will watch you for at least 30 minutes to make sure you're feeling okay.

Please contact your doctor immediately if you develop an infection, the reaction to your shot worsens, or you experience any of the below symptoms, which may indicate a systemic allergic reaction:

- Difficulty breathing
- Widespread rash
- Facial swelling

Thrombotic events (blood clots that block your blood vessels) may occur after your PAPZIMEOS shot. Please notify your doctor immediately if you have the following symptoms:

- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Severe or persistent headaches
- Blurred vision

What should I know before taking PAPZIMEOS?
Before taking PAPZIMEOS, tell your healthcare provider about all of your medical conditions, including:

- If you are pregnant or plan to become pregnant because it is not known if PAPZIMEOS will harm the unborn baby.
- If you are breastfeeding or plan to breastfeed. It is unknown if PAPZIMEOS is present in breast milk, or how it affects the breastfeeding child or milk production. Talk to your healthcare provider about the best way to feed your baby during treatment with PAPZIMEOS.

What are the most common side effects of PAPZIMEOS?
The most common side effects include:

- Pain, redness, or swelling where the shot was given
- Feeling tired
- Chills
- Fever
- Muscle aches
- Nausea (feeling sick)
- Headache
- Increased heart rate
- Diarrhea
- Vomiting
- Sweating a lot

These are not all of the possible side effects of PAPZIMEOS. Call your healthcare provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Precigen, Inc. at 1-855-PGE-NRRP (1-855-743-6777).

Please see full Prescribing Information**.**

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, 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 including the revenue that the Company expects to realize from such efforts, 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 including the Company's ability to reach cash flow break-even, 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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