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Precigen Showcases Rapid Commercialization Momentum and Growing Market Adoption of First-and-Only FDA-Approved Therapy for RRP at the 44th Annual J.P. Morgan Healthcare Conference

Jan 12, 2026

- *Precigen transitioned to a commercial stage company with the US approval of PAPZIMEOS in August 2025, the first-and-only FDA-approved treatment for adults with RRP*
- *PAPZIMEOS commercialization is well underway and PAPZIMEOS is being prescribed nationwide, with patients actively receiving treatment*
- *PAPZIMEOS patient hub enrollment has surpassed 200 registered patients, doubling since November, and reflecting significant demand at both major medical centers and community practices*
- *Patient access continues to expand, with private health plan coverage now at approximately 170 million US lives, including the majority of leading insurers. PAPZIMEOS is also covered under Medicare and Medicaid*
- *The European Medicines Agency has validated the Marketing Authorization Application for PAPZIMEOS for the treatment of adults with RRP*
- *The Company continues to expect current capital resources to fund operations through cash flow break-even*

GERMANTOWN, Md., Jan. 12, 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 provided an update on the rapid commercialization momentum and growing market adoption of PAPZIMEOS™ (zopapogene imadenovec-drba), the first-and-only US Food and Drug Administration (FDA)-approved therapy for recurrent respiratory papillomatosis (RRP). [Precigen's company presentation](#) at the 44th Annual J.P. Morgan Healthcare Conference will be on January 15, 2026 at 7:30 AM PT.



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ADVANCING MEDICINE WITH PRECISION

"Commercialization of PAPZIMEOS is proceeding as planned following FDA approval, with rapid and broad adoption supported by compelling safety, efficacy, and long-term durability data, expanding payer access, and strong engagement across major medical centers and community practices nationwide," said Helen Sabzevari, PhD, President and CEO of Precigen. "We are seeing tremendous enthusiasm from physicians across the country who are eager to bring this therapy to their patients. Importantly, we are moving rapidly to make PAPZIMEOS available globally, highlighted by the European Medicines Agency validation of the Marketing Authorization Application. As the first-and-only FDA-approved therapy for adults with RRP, PAPZIMEOS is redefining the treatment paradigm, and the momentum we are seeing underscores its impact and value as we advance toward anticipated cash-flow break-even and global expansion."

"Our commercial launch continues to build strong momentum, with patient hub enrollment doubling since November, expanding commercial health plan coverage alongside Medicare and Medicaid, and near-complete field engagement across target centers," said Phil Tennant, Chief Commercial Officer of Precigen. "Manufacturing and supply chain capabilities are fully in place to meet current demand and anticipated growth, and patients are now receiving PAPZIMEOS nationwide. Importantly, PAPZIMEOS remains the only FDA-approved therapy for adults with RRP, providing an exclusive window to execute our commercial strategy. Based on these dynamics, we expect adoption to continue accelerating as PAPZIMEOS becomes established as the preferred first-line treatment and new standard of care."

PAPZIMEOS: Establishing a New Standard of Care for the Treatment of Adults with RRP

- **PAPZIMEOS full approval with broad label:** In August 2025, the FDA [granted full approval of PAPZIMEOS](#) with a broad

label and no requirement for a confirmatory trial for the treatment of adults with RRP.

- **PAPZIMEOS prescribing, treatment, and distribution:** PAPZIMEOS is being prescribed nationwide, with patients actively receiving treatment. PAPZIMEOS is currently shipping to prescribers across the US, supported by established cold-chain logistics and coordinated solutions to address site-level needs.
- **Rapid commercialization:** Rapid commercial launch execution is underway with over 96% of target centers engaged since full deployment of the sales team in September. To date, more than 200 patients have been registered in the PAPZIMEOS patient hub, doubling since November. In addition to these registered patients, a significant number of patients have been identified outside of the PAPZIMEOS hub through the Company's field engagement efforts.
- **Positive payer coverage:** Private health plan coverage is progressing rapidly with approximately 170 million lives covered to date, including the majority of leading insurers. PAPZIMEOS is also covered under Medicare and Medicaid.
- **Compelling long-term clinical and real-world evidence published:** At AAO-HNSF 2025 and SITC 2025, the Company reported [long-term durable complete responses with PAPZIMEOS](#), and at ISPOR Europe 2025, the Company published data demonstrating the [substantial healthcare resource utilization](#) and [patient-reported quality-of-life burden of RRP](#), underscoring the disease's significant clinical, economic, and human impact.
- **EMA validation complete:** Following a submission in November 2025, the European Medicines Agency has validated the Marketing Authorization Application for PAPZIMEOS for the treatment of adults with RRP.

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. Full prescribing information can be found at www.precigen.com/papzimeos-prescribing-information.pdf.

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, 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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