

PRECIGEN

US FDA Approval of
PAPZIMEOS™

August 18, 2025



Forward-looking Statement

This presentation 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 and the Company’s other product candidates, the timing of clinical trials and their results, the Company’s ability to commence clinical studies or complete ongoing clinical studies, and the ability of PAPZIMEOS to treat RRP. 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.

Call Participants



Helen Sabzevari, PhD
President and CEO



Harry Thomasian Jr.
Chief Financial Officer



Phil Tennant
Chief Commercial Officer



Rutul Shah
Chief Operating Officer

Agenda



RRP Landscape



PAPZIMEOS Prescribing Information and Label Details



PAPZIMEOS Pivotal Clinical Data



Commercial Strategy and Launch Plans



Q&A



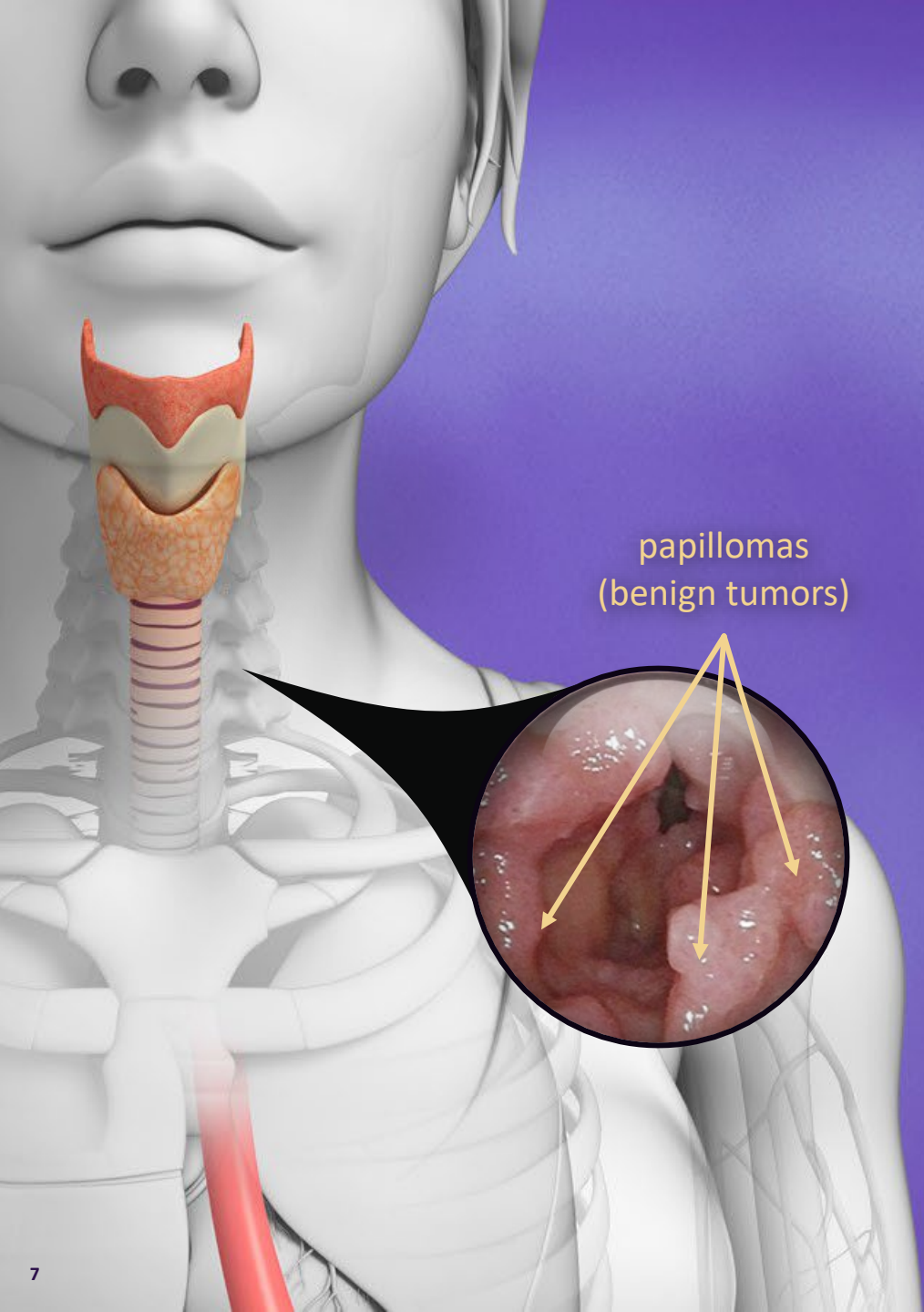
**First and Only FDA-Approved Therapy for the Treatment of
Adults with Recurrent Respiratory Papillomatosis (RRP)**

www.PAPZIMEOS.com

RRP Landscape



Recurrent Respiratory Papillomatosis (RRP), a Rare HPV-driven Disease



- RRP is a rare, debilitating disease of the respiratory tract caused by HPV 6 or HPV 11 infection
- RRP was previously managed mainly by surgical interventions; repeat surgeries are associated with significant morbidities
- Affects both adults and children
- RRP can cause severe voice disturbance, airway compromise, fatal pulmonary lesions, and invasive cancers
- RRP is potentially life-threatening especially if pulmonary or malignant transformation occurs

PAPZIMEOS has Potential to Become the Standard-of-care for Adults with RRP

Prevalence of RRP in US¹

Approximately

27,000

adult patients in US



PAPZIMEOS has the potential to define a new treatment paradigm for adults with RRP



PAPZIMEOS

Prescribing Information and Label Details



First FDA-approved Therapy for Adults with RRP



PAPZIMEOS received full approval

No requirement for the confirmatory clinical trial

**BROAD LABEL enables adults with RRP
to be eligible for PAPZIMEOS**

**Strong efficacy, durability of response,
and favorable safety profile**

PAPZIMEOS US Prescribing Information Overview



INDICATION

PAPZIMEOS is a non-replicating adenoviral vector-based immunotherapy indicated for the **treatment of adults with recurrent respiratory papillomatosis**

DOSAGE & ADMINISTRATION

PAPZIMEOS is for subcutaneous injection only

The recommended dose of PAPZIMEOS is 5×10^{11} particle units (PU) per injection administered by subcutaneous injection four (4) times over a 12-week interval

PAPZIMEOS US Prescribing Information Overview



Warnings and Precautions

Injection-site reactions: Injection-site reactions, have been observed. Monitor patients for local site reactions for at least 30 minutes after the initial treatment.

Thrombotic events: Thrombotic events may occur following administration of adenoviral vector-based therapies. Monitor patients for signs and symptoms of thrombotic events and treat events according to clinical practice.

Adverse Reactions

The most common adverse reactions were injection site reactions, fatigue, chills, pyrexia, myalgia, and nausea.

No REMS

No Boxed Warnings

No Contraindications

Full prescribing information is available at www.PAPZIMEOS.com

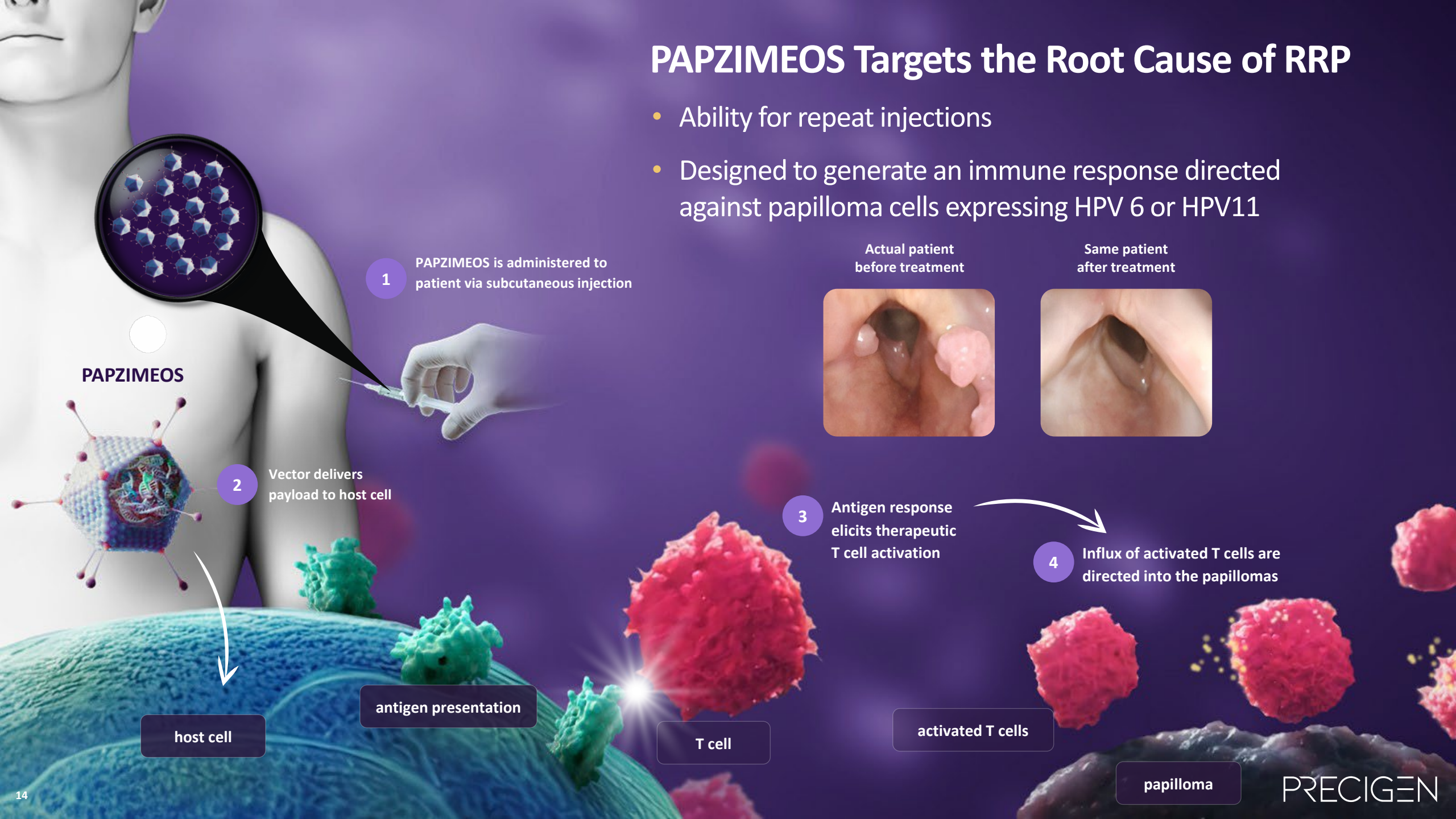
PAPZIMEOS

Pivotal Clinical Data



PAPZIMEOS Targets the Root Cause of RRP

- Ability for repeat injections
- Designed to generate an immune response directed against papilloma cells expressing HPV 6 or HPV11



Pivotal Study Met Primary Efficacy Endpoint

51% Complete Response Rate

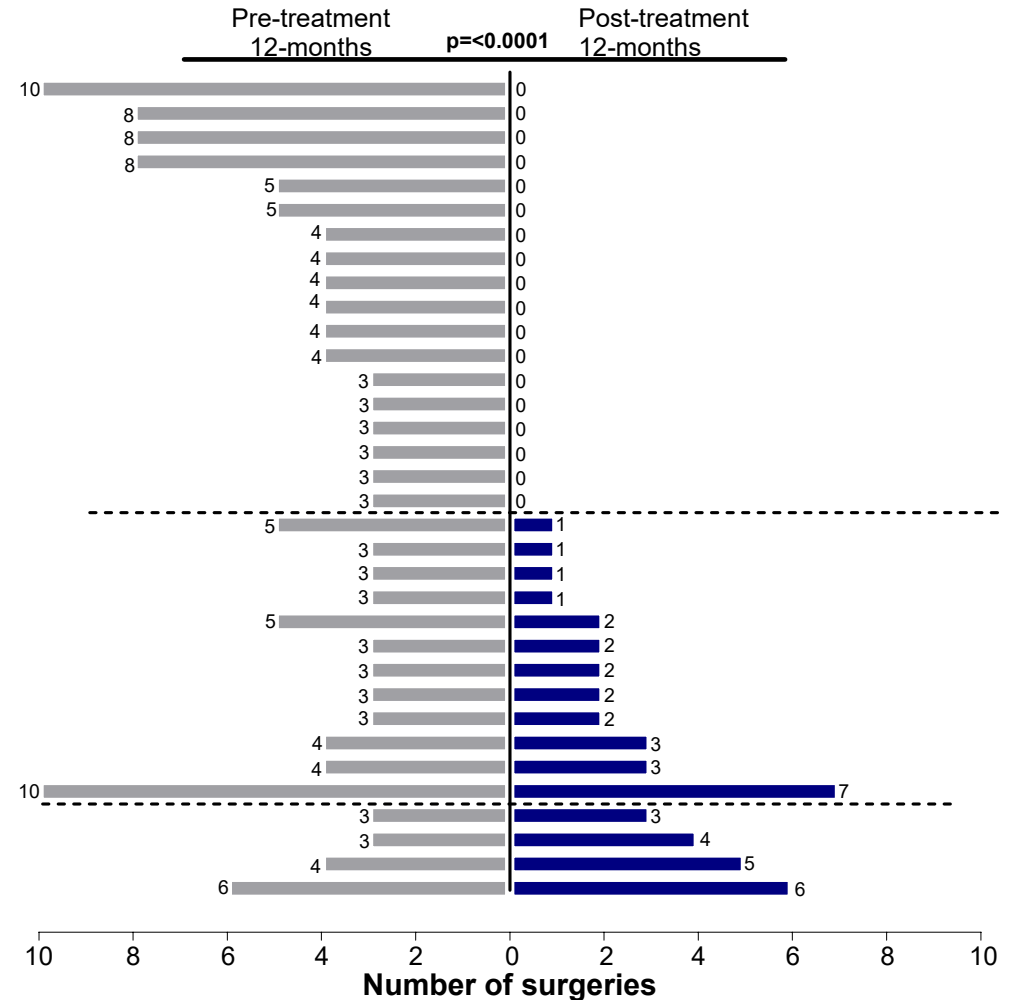
(95% CI [34-69%])

Durable Complete Responses

15 out of 18 Complete Responders evaluated at 2 years demonstrated continued Complete Response

PAPZIMEOS induced HPV 6/11-specific T cell responses in RRP study patients with a significantly greater expansion of peripheral HPV-specific T cells in responders compared with non-responders

PAPZIMEOS was well-tolerated with no dose-limiting toxicities and no treatment-related adverse events greater than Grade 2



Complete Response: No need for surgery for 12 months after PAPZIMEOS treatment completion

Note: One subject was excluded as they did not complete 12 months of follow-up

Sources: PAPZIMEOS Prescribing Information; Norberg SM et al., 2024 ASCO Annual Meeting

Commercial Strategy and Launch Plans


Papzimeos™
 zopapogene imadenovec-drba



PAPZIMEOS: the First and Only FDA-approved Therapy for Adults with RRP

Poised to become the standard of care for patients with this chronic, debilitating condition

Broad Label

Adults with RRP

Durable Complete Responses

CRs ongoing and beyond 2 years in many patients¹

Concentrated Patient Population

IDNs and Community hospitals account for >90% of identified patient potential



PRECIGEN

Targeted Launch Strategy with a Highly Experienced Field Team

Team Structure

18 dedicated sales territories will cover >90% of ENT patient potential

Dedicated MSLs, Payer Team and Sales Leadership deployed since April

Field reimbursement support active

Launch Readiness

IDN and HCP targeting complete: over 90% of account, patient and procedural potential covered by launch footprint

PIE presentations with population health decision makers

National and Regional thought leader base built

Commercial distribution channels, patient hub services and support (*PapzimeosSUPPORT.com*)

Immediate Focus

93 IDNs and community hospitals account for 80% of initial target potential

Total target universe of ~500 accounts

Payer formulary and IDN Pharmacy & Therapeutics (P&T) process support

Key Indicators of Launch Success

**KOL asset
advocacy**

**Prescription
dynamics at HCP
and Institutional
level**

**Formulary status
/ covered lives
with favorable
access**

**Patient Hub
dynamics**

Comprehensive PAPZIMEOS Support Program for HCPs and Patients

Support for HCPs

Order Support

Help coordinating ordering and delivery of PAPZIMEOS via specialty pharmacy services

Insurance Navigation

Support during the process of determining a patient's insurance benefits for PAPZIMEOS and eligibility for affordability programs

Support for Patients

Treatment Education

Support through the treatment process, including education about PAPZIMEOS and help locating and coordinating treatment

Understanding Coverage

Help understanding the insurance process and what information their health plan may need

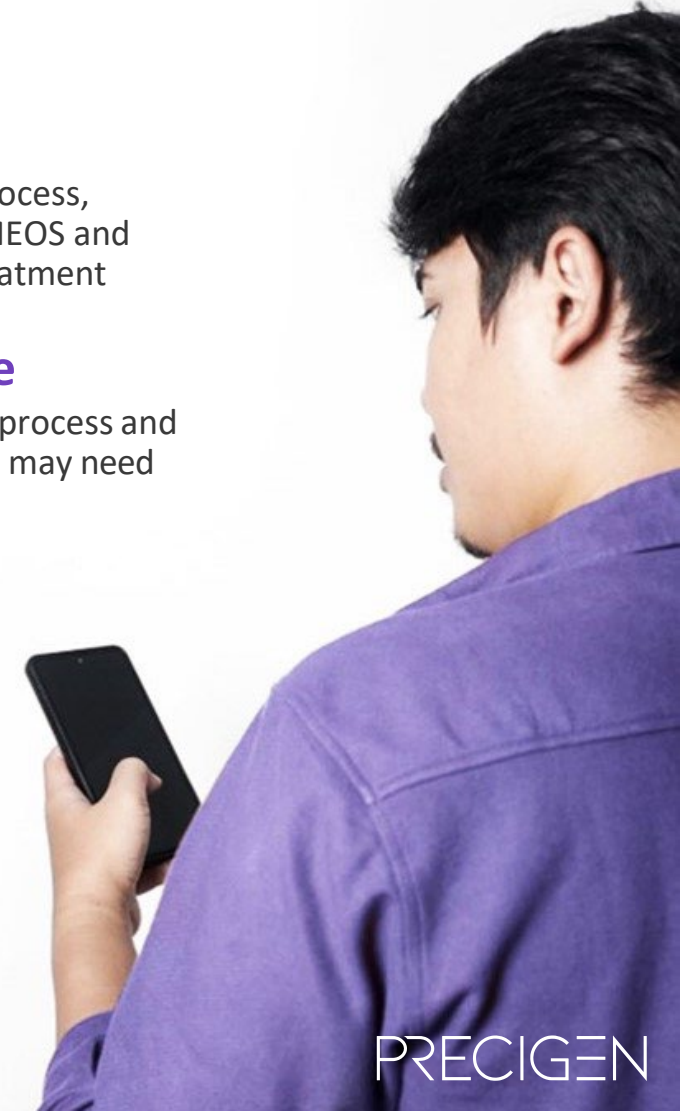
Financial Assistance

Information about available resources that may help to reduce or eliminate their out-of-pocket costs

Papzimeos SUPPORT can help support your patients and care team at any site of care throughout the access process.

**Download the enrollment form at
www.PapzimeosSUPPORT.com.**

For questions or support, call (866) 827-8180, Monday to Friday, 8 am to 8 pm ET.



PAPZIMEOS Offers a Significant Value Proposition



First and Only FDA-approved RRP Treatment



Transformative Clinical Benefit



Chronic, Debilitating Rare Disease



Committed to Serving RRP Community



Our goal is to ensure every eligible RRP patient has access to PAPZIMEOS

Q&A


Papzimeos™
zopapogene imadenovec-drba



“This long-awaited FDA approval represents a momentous milestone for the RRP community. For the first time, adult patients with RRP have access to an FDA-approved therapy that offers the potential to reduce—or even eliminate—endless repeated surgeries. This breakthrough brings long-overdue hope to patients and families who have endured so much.”

Kim McClellan
President, RRP Foundation



PRECIGEN