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Zopapogene imadenovec-drba, a novel adenovector-based immunotherapy, induces complete and durable responses in recurrent respiratory papillomatosis

Introduction

Recurrent respiratory papillomatosis (RRP) is a rare, neoplastic disorder caused by chronic human papillomavirus (HPV) type 6 or 11 infection. Repeat surgical debulking has historically been the most common treatment for RRP symptom management. Zopapogene imadenovec-drba (zopa), a novel adenoviral vector-based immunotherapy, is the first and only FDA-approved treatment for adults with RRP. Zopa is now recommended as the first-line treatment for adults with RRP in an RRP Foundation position statement authored by 16 key opinion leaders (Best et al, Laryngoscope 2026).

Methods

The pivotal trial (NCT04724980) evaluated zopa in patients with RRP requiring ≥ 3 clinically indicated interventions 12 months (m) prior to treatment. 12m follow-up data was reported and demonstrated that 4 subcutaneous injections of zopa (5×10^{11} particle units per injection; n=35) were well-tolerated, with no serious adverse events, no grade >2 treatment-related adverse events, and no early treatment discontinuations. The most common adverse events were injection-site reaction, fatigue, chills, fever, and myalgia.

Robust efficacy was observed following zopa treatment with 51% (34 to 69; 95% CI) of patients achieving a complete response (CR), defined as no requirement for interventions in the 12m following treatment. Here we present data up to 51m of follow-up.

Results

As of December 15, 2025, with a median duration of follow-up of 36m (range: 30-51m), 83% (15/18) of patients who achieved a CR at 12m remain in CR with no recurrence of papilloma requiring surgical or medical intervention. Out of the 15 patients remaining in CR, 3 patients have reached 4 years of follow-up.

No new safety events were observed during long-term follow-up.

Conclusions

Zopa treatment demonstrated significant clinical benefit with the vast majority of CR patients experiencing ongoing durable complete responses for up to 4 years with excellent long-term safety. Updated follow-up results for all patients achieving CR will be available at the time of presentation.

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Biography

Marco Avila, MD is Executive Director of Medical Affairs at Precigen Inc., where he supports the clinical development and medical strategy for innovative gene and cell therapies in immunology, oncology, and infectious diseases. He has extensive experience in global medical affairs and collaborates closely with healthcare professionals and scientific communities to advance novel therapies for patients with significant unmet medical needs. Dr. Avila is actively involved in the dissemination of clinical research and has presented on emerging adenovector-based immunotherapies for recurrent respiratory papillomatosis and other innovative therapeutic approaches.