Clinical Assessment of Adjuvant Immunotherapy, INO-3107, in Adult Patients with Recurrent respiratory papillomatosis (RRP)

Objective(s): To evaluate the safety, immunogenicity, and efficacy of INO-3107, a DNA vaccine designed to elicit targeted T-cell responses against HPV-6 and HPV-11, in adult patients with recurrent respiratory papillomatosis (RRP; NCT04398433)

Methods: Eligible patients required ≥2 surgical interventions for RRP in the year preceding dosing (median 4 surgeries/preceding year). INO-3107 was administered by intramuscular (IM) injection via a device on Weeks 0, 3, 6, and 9. Patients underwent surgical debulking within 14 days of the first dose, and office laryngoscopy with staging at screening and Weeks 6, 11, 26, and 52. The primary endpoint was safety and tolerability assessed by treatment-emergent adverse events (TEAEs). Secondary endpoints included the frequency of surgical interventions post INO-3107 and cellular immune responses.

Results: Of the 32 adult RRP patients enrolled in the study 13 (41%) reported a treatment-related AE. The most frequent treatment-related AE's reported were Injection site pain (31%) and fatigue (9%). One TEAE (pain) was Grade 2 severity. All other TEAE reports were Grade 1. No treatment-related adverse events greater than grade 2 severity were reported. Modified Derkay-Pransky severity scores improved from baseline to Week 52. INO-3107 induced durable cellular responses and was able to generate T-cells against HPV-6 and HPV-11. Reduction of surgeries compared to baseline was demonstrated in 26 patients (81.3%).

Conclusion: INO-3107 is tolerable and immunogenic. The evidence demonstrates a clinical benefit as the majority of adult RRP patients who received therapy required fewer surgical procedures compared to baseline.