Title: DNA immunotherapy, INO-3107, generates targeted immunologic response and results in surgery reduction for 81% of adults with recurrent respiratory papillomatosis

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Background: Recurrent Respiratory Papillomatosis (RRP) is a debilitating disease caused by HPV-6 and 11. INO-3107, DNA immunotherapy designed to generate T-cells against HPV-6 and 11, was evaluated in a 52-week Phase 1/2 study (NCT04398433).

Methods: Thirty-two adults with HPV-6 and/or 11 confirmed RRP requiring ≥2 surgical interventions in the year preceding dosing received 4 INO-3107 doses via intramuscular injection. Patients underwent surgical debulking within 14 days of Dose 1. Primary endpoints were safety and tolerability. Secondary efficacy endpoint was surgical frequency. Immunologic response was evaluated in periphery and localized tissue.

Results: INO-3107 was safe and well-tolerated. 41% (13/32) reported treatment-related adverse events; most common being transient injection site pain (31%) and fatigue (9%). Peripheral T-cell activity against HPV-6 and 11 was confirmed and clonal expansion was detected through Week 52. Excised papilloma revealed T-cell infiltration inclusive of activation and cytotoxicity. 81% (26/32) demonstrated surgery reduction (overall clinical response) and 72% (23/32) experienced either no surgery (9/32) or surgery reduction of at least 50% versus prior year (14/32).

Conclusion: INO-3107 was well-tolerated in adults with recurrent respiratory papillomatosis, inducing a durable cellular response against HPV-6/11, supporting the proposed mechanism of action. Most patients (81%) required fewer surgical procedures following treatment.