Title: DNA Immunotherapy (INO-3107) Results in a 72% Overall Response Rate for Treatment of Recurrent Respiratory Papillomatosis Caused by HPV-6 & 11

Authors: Mau T, Amin M, Belafsky P, Best S, Friedman A, Klein AM, Lott D, Pransky S, Saba NF, Sumner M, Skolnik J

Background: Recurrent Respiratory Papillomatosis (RRP) is a chronic disease caused by Human Papillomavirus (HPV) characterized by recurrent benign but aggressive airway growths. INO-3107, DNA immunotherapy in development for adult RRP, was evaluated for safety, immunogenicity, and efficacy in a Phase I/II study (NCT04398433). Efficacy is described as a complete response (CR) with no surgeries during 12-month follow-up or partial response (PR) with at least 50% surgery reduction (PR) compared to the preceding year. Overall response rate (ORR) was defined as either complete or partial response.

Methods: Eligible HPV-6 and/or 11 confirmed patients that required ≥2 RRP 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 and were not required to undergo additional surgeries during the administration phase. Office laryngoscopy was conducted at screening and Weeks 6, 11, 26, and 52. The primary endpoint was safety and tolerability. Secondary endpoints included efficacy as frequency of surgical interventions post-INO-3107 and cellular immune responses.

Results: There were no major treatment-emergent adverse events (TEAEs), 31% (10/32) experienced transient injection site pain and 9% (3/32) experienced transient fatigue. ORR for INO-3107 was 72% (23/32), with 9 (28%) requiring no surgeries (CR) and 14 (44%) experiencing a partial response (PR).

Conclusion: Treatment of recurrent respiratory papillomatosis with INO-3107 was safe and effective. The majority (72%) of patients experienced either no surgeries or at least a 50% surgery reduction in the year post-treatment. Nine patients (28%) experienced a complete response.

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