ESMO 2025 Abstract Details:

- Conference date/location: Oct 17-21, 2025, Berlin, Germany
- Submission deadline: May 13th
- Presenter: Non-industry (Dr. Saba has volunteered)
- One table allowed
- Title cannot include claim or results
- Character limit: 2000 (title, body, table)

Title: DNA Immunotherapy (INO-3107) in HPV-6 & 11 Recurrent Respiratory Papillomatosis – Long-Term Efficacy

Authors: Saba NF, Amin MR, Belafsky PC, Best SR, Friedman AD, Klein AM, Lott DG, Mau T, Paniello RC, Pransky SM, Welsh C, Slog S, Skolnik JM

Background: Recurrent Respiratory Papillomatosis (RRP) is a debilitating airway disease caused by Human Papillomavirus (HPV 6 and 11) and characterized by recurrent benign tumor growths with potential for malignant transformation. INO-3107, a DNA immunotherapy designed to generate E6/E7 antigen-specific HPV6/11 T cells, was evaluated in a 52-week Phase I/II study (NCT04398433) and follow up observational study up to 156 weeks.

Methods: Eligibility included HPV 6 and/or 11 confirmed disease, requiring ≥2 RRP surgical interventions in the year prior to enrollment. Patients underwent surgical debulking within 14 days before Dose 1 and then received 4 INO-3107 doses via intramuscular injection followed by electroporation. Primary and secondary endpoints were safety and efficacy (post-INO-3107 surgery frequency and cellular immune responses), respectively. 28 of 32 patients enrolled in the 52-week Phase I/II study consented to the observational follow up study.

Results: INO-3107 demonstrated systemic emergent T cells generation against HPV 6 and/or 11 E6/E7, clonal expansion, and infiltration of infected airway papillomas inclusive of activation and cytotoxicity in Year 1 (Y1). A 78% reduction in mean annual surgeries was seen at Year 2 (Y2) compared to 1 year pre-treatment period (0.9, n=28 vs 4.1, n=32). This confirmed a persistent clinical benefit with improved disease control that exceeded the observed reduction in Y1 surgeries (59%; 1.7 vs 4.1, n=32). Of the follow up patients, 89% (25/28) experienced a reduction of ≥1 surgery at Y2 and 11% (3/28) were non-responders. No additional treatment-related SAEs were reported during follow-up.

Parameter (compared to 52-week pre-treatment period)	Year 1	Year 2
Overall Clinical Response: % Patients with ≥1 surgery reduction	82% (23/28)	89% (25/28)
No Response: % Patients with no surgery reduction	18% (5/28)	11% (3/28)
% Mean change in surgeries	59% [4.1 vs 1.7]	78% [4.1 vs 0.9]

Conclusion: INO-3107 demonstrates a continued clinical benefit in patients with recurrent respiratory papillomatosis with a persistent decline in number of surgeries through Year 2 post-therapy. These data support an on-going immunological effect resulting in improved disease control and surgery reduction.