Title: DNA Immunotherapy (INO-3107) Demonstrates a Durable Response for Treatment of HPV-6/11 Recurrent Respiratory Papillomatosis

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Introduction: Recurrent Respiratory Papillomatosis (RRP) is a debilitating chronic disease caused by Human Papillomavirus (HPV-6 and 11). INO-3107, DNA immunotherapy designed to generate HPV-6 and 11 antigen-specific T-cells, was evaluated in a 52-week Phase I/II study (NCT04398433) and retrospective observational trial for long-term safety and efficacy. Here we describe durability of response to treatment through Year 2.

Methods: Eligibility included HPV-6 and/or 11 confirmed patients, requiring ≥2 RRP surgical interventions in the year preceding dosing that participated in both Phase I/II and follow-up studies. Patients received four INO-3107 doses via intramuscular injection, after undergoing surgical debulking within 14 days of Dose 1. Primary endpoint was safety and tolerability. Secondary endpoint was efficacy as post-INO-3107 surgical intervention frequency.

Results: Patients receiving INO-3107 demonstrated a durable response to treatment. At Year 1 post-INO-3107, 81% of patients (26/32) experienced a reduction of at least on surgery (OCR, overall clinical response) compared to the year prior to treatment, which was maintained in 91% (21/23) of those not lost to follow-up at Year 2 (evaluable). Non-responder rate (NR, no surgery reduction) was seen in 19% (6/32) patients at Year 1, but by end of Year 2, only 2 of 5 evaluable patients had experienced no reduction in surgeries and were still classified as non-responders.

Conclusion: INO-3107 for recurrent respiratory papillomatosis demonstrates a durable response through post-treatment Year 2 with 91% of patients continuing to experience clinical effect. Two years post-INO-3107, no response to treatment was limited to only 2 patients. This supports INO-3107's ability to provide long-term immunologic and clinical effects.