Title: DNA Immunotherapy (INO-3107) Durability and Long-Term Clinical Effect in Treatment of Recurrent Respiratory Papillomatosis Caused by HPV 6 & 11

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Background: Recurrent Respiratory Papillomatosis (RRP) is a chronic disease caused by Human Papillomavirus (HPV-6 and 11). INO-3107, a 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 observational study with up to 3 years of follow-up.

Methods: Eligibility included HPV-6 and/or 11 confirmed disease, requiring ≥2 RRP surgical interventions in the year preceding enrollment in both Phase I/II and follow-up studies. Patients received four INO-3107 doses via intramuscular injection followed by electroporation, undergoing surgical debulking within 14 days prior to Dose 1. Primary endpoint was safety and tolerability. Secondary endpoints included efficacy defined as post-INO-3107 surgical intervention frequency and cellular immune responses.

Results: Planned data to be presented will include results from a recently completed observational study of up to 3 years of patient follow-up, safety, durability and long-term clinical efficacy of INO-3107. Data not yet publicly disclosed evaluated the number of surgical interventions for patients up to 3 years post-treatment. We compared end of Phase I/II Year 1 data to Year 2 and end of study follow-up for average annual surgeries and by clinical response (complete response (CR), defined as no surgeries, partial response (PR) at least a 50% reduction, overall clinical response (OCR) reduction of at least 1 surgery).

Conclusion: Long-term effects of INO-3107, for recurrent respiratory papillomatosis, were evaluated up to 3 years post-treatment, resulting in the longest efficacy assessment to date for a potential new therapeutic option in this disease.