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INNA-051 pre-exposure prophylaxis in a human influenza infection model

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INNA-051 is a Toll-like receptor 2/6 agonist delivered via intranasal (i.n.) spray being developed to prevent respiratory viral illness by induction of local innate immunity. A randomised, placebo-controlled study in 123 healthy adults evaluated the effect of INNA-051 compared to placebo on viral load and symptoms when given prior to i.n. influenza A challenge. Serum hemagglutinin inhibition (HAI) titers were measured at screening to exclude participants with titers >10. Participants were admitted to the quarantine unit and received i.n. 300µg INNA-051, 150 µg INNA-051, or placebo on Day -4 and Day -1, followed by administration of influenza A/Perth/16/2009 (H3N2) challenge virus on Day 0. Assessments were conducted through Day 8. Infection rates, viral load area under the curve (AUC) and peak viral loads were all unexpectedly lower than historical placebo data. Investigation identified 31 participants (26%) across all 3 groups had HAI titers >10 at quarantine admission indicating pre-existing immunity to the challenge virus. Post-hoc analyses of participants with HAI titers <10 at quarantine admission and PCR confirmed infection identified a statistically significant reduction in the duration of qRT-PCR detectable viral nucleic acid in the 300µg INNA-051 group relative to placebo. This group also demonstrated a significantly lower viral load on Days 6-8 relative to placebo and a trend towards a shorter duration of clinical symptoms. These results in a healthy adult viral challenge study confirm data observed in preclinical challenge models and suggest the potential for a clinical benefit in the setting of natural infection in adults at risk for more severe clinical outcomes.