ENA RESPIRATORY

Media Release

First Participants Dosed in Phase 2a Study of Pan-Antiviral Nasal Spray

-- ENA Respiratory begins influenza challenge study for fast-acting nasal spray INNA-051, designed to boost innate immunity in patients at high risk of severe complications from respiratory infections

Sydney, Australia, 15th March 2022 – ENA Respiratory, a clinical-stage pharmaceutical company developing INNA-051, a first-in-class broad-spectrum antiviral innate immunomodulator for pre- and post-exposure prophylaxis of respiratory viral infections in populations at risk of complications, has dosed its first participants in a Phase 2a flu-challenge study.

The Phase 2a trial is a single centre, prospective, randomised, double-blind, placebo-controlled study exploring two dose levels of INNA-051 administered as an intranasal spray to healthy adults to evaluate the safety, tolerability, and antiviral efficacy of INNA-051 against H3N2 influenza virus infection. The study will enroll up to 123 participants. Efficacy is being assessed as the reduction of total viral load by RT-qPCR and total symptoms score in treated versus placebo participants.

This human influenza challenge pre-exposure prophylaxis study supports the development of INNA-051 for pan-antiviral use in those at high-risk of complications from SARS-CoV-2, rhinovirus, RSV, influenza, and other common respiratory viruses. It is being conducted in the United Kingdom, with results expected by the end of the year.

“Patients at high-risk of complications from a respiratory viral infection, such as the elderly and those with pre-existing lung, cardiovascular, liver and kidney chronic diseases, urgently need therapies that help the body respond faster and reduce the risk of hospitalization or complications. This study will take us another step closer to determining whether INNA-051 can provide a fast-acting, easy-to-use therapy to address this unmet need,” said Christophe Demaison, Ph.D., co-founder and CEO of ENA Respiratory.

A Phase 2 COVID-19 post-exposure antiviral prophylaxis study to determine whether INNA-051 reduces the incidence and severity of symptomatic COVID-19 is also expected to begin shortly. The study also will evaluate whether the nasal spray reduces the magnitude and duration of SARS-CoV-2 nasal shedding, to understand potential broader public health benefits. INNA-051 was found to be well-tolerated in a Phase 1 study, and complete Phase 1 results are expected soon.

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Notes to Editors

If you would like to arrange an interview, please contact:

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About ENA Respiratory and INNA-051

ENA Respiratory is aiming to transform the prevention of respiratory viral infections in populations at-risk of complications. The company is based in Melbourne and Sydney, Australia and it has secured a Series A investment from Brandon Capital Partners' managed funds, the Minderoo Foundation, and Uniseed.

INNA-051 is a potent innate immune TLR2/6 agonist. It is being developed for intranasal delivery to target the primary entry site of viral respiratory infections as most respiratory viruses, including SARS-CoV-2 and influenza, initially infect and replicate in nasal mucosa epithelial cells. Fast-acting and inducing a durable biologic response supporting weekly administration, INNA-051 works by recruiting innate immune cells and priming epithelial cells of the nasal mucosa to respond more quickly to infections, rapidly eliminating viruses and other pathogens before they spread throughout the body. INNA-051 and close analogues have been shown in preclinical studies to be effective against multiple respiratory viruses, including SARS-CoV-2, influenza (H1N1 and seasonal H3N2), and rhinovirus.

Key features of INNA-051 intranasal administration include limited minimal or no systemic bioavailability, minimal or no systemic pro-inflammatory cytokine release, no direct type I interferon upregulation which is known to be associated with fever in humans, durable immune response supporting weekly administration, and compatibility with vaccine and intranasal corticosteroids.

For more information, please visit https://enarespiratory.com