ENA RESPIRATORY

Media Release

First-in-Class, Broad-Spectrum Nasal Spray to Prevent COVID-19 and Other Common Respiratory Illnesses Set to Begin Phase 2 Trials

-- ENA Respiratory engages PPD, Inc. for Phase 2 COVID-19 post-exposure prophylaxis study and hVIVO for influenza challenge study to assess the efficacy of fast-acting nasal spray designed to boost innate immunity

Sydney, Australia, 28 September 2021 – ENA Respiratory, a biotechnology company developing a first-in-class nasal spray for the prevention of COVID-19 and other respiratory viral infections, announced today that it has engaged research partners PPD, Inc. and hVIVO, a division of Open Orphan, to conduct its Phase 2 studies. The self-administered nasal spray, INNA-051, is being developed to stimulate the innate immunity in the nose, where most respiratory viral infections begin. This announcement follows encouraging preliminary results from the ongoing Phase 1 study which supports decision to progress INNA-051 development to Phase 2 studies.

In partnership with PPD, Inc., ENA Respiratory will conduct a Phase 2, randomised COVID-19 post-exposure antiviral prophylaxis study, to determine whether INNA-051 reduces the incidence and severity of symptomatic COVID-19 following close contact with COVID-19 positive individuals. The study will also evaluate whether the nasal spray reduces the magnitude and duration of SARS-CoV-2 nasal shedding, to understand potential broader public health benefits. The study will be conducted in several countries and will initially recruit adults ages 18 to 55 who have had recent exposure to someone with confirmed COVID-19. Recruitment is expected to begin in January 2022.

“We are pleased that Ena Respiratory has entrusted us with helping develop its Phase 2 studies for this important therapeutic,” said Elisha Talley-Roithner, senior vice president of development operations and portfolio management for PPD. “Our early, direct and ongoing experience managing COVID-19 trials enables us to continue providing customers with innovative solutions to support development of therapies and vaccines to address the global pandemic.”

Additionally, in partnership with hVIVO (part of Open Orphan plc), ENA Respiratory will begin an influenza challenge pre-exposure prophylaxis study in adults ages 18 to 55. The study will evaluate the safety and efficacy of INNA-051 in reducing the total viral load of treated participants versus placebo. The study will be conducted in the United Kingdom and is expected to begin in January 2022.

Cathal Friel, executive chairman of Open Orphan plc said, “We are pleased to partner with ENA Respiratory to carry out this Phase 2a trial, using hVIVO’s Influenza human challenge study model. As the world leading provider of human challenge trials, we have significant experience in successfully conducting these types of trials, and we look forward to working alongside the ENA Respiratory team to investigate the efficacy of this candidate.”

"In recent months, SARS-CoV-2 variants including the Delta variant have continued to spread around the world, at the same time other respiratory viruses like RSV have seen a resurgence in some countries. There continues to be an urgent need for treatments that will work alongside vaccines, especially for those at high risk of complications or those who do not mount an adequate immune response to vaccines, such as the elderly, patients with chronic respiratory diseases and the immunocompromised," said Christophe Demaison, Ph.D., co-founder and CEO of ENA Respiratory. "These Phase 2 studies will take us closer to understanding whether our nasal spray can prevent illness and reduce the risk of community spread of common respiratory viruses."

The Phase 1 study of INNA-051, designed to investigate safety and tolerability of single and multiple administrations of INNA-051 in healthy adults aged 18 -85, is expected to be completed in Q1 2022, with interim results available in late Q4 2021. It is being conducted at Scientia Clinical Research in Randwick, New South Wales, Australia.

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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 treatment and prevention of respiratory viral infections in at-risk populations. The company is based in Melbourne and Sydney, Australia.

INNA-051 is a potent innate immune agonist that targets the receptor TLR2/6. 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.[1,2] INNA-051 and close analogues have been shown in preclinical studies to be effective against to multiple respiratory viruses, including SARS-CoV-2[3], influenza (H1N1 and seasonal H3N2)[2&4] and rhinovirus[1].

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, durable immune response supporting weekly administration and compatibility with vaccine[5] and intranasal corticosteroids. [1]

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

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