ENA RESPIRATORY

Media Release

Nasal Spray Significantly Accelerates Respiratory Virus Clearance in Phase 2a Clinical Study

-- Post hoc analyses found a statistically significant reduction in the duration of flu infection and a dose-related trend toward a reduction in symptom duration.

-- These results support the further clinical development of INNA-051 to mitigate the impact of natural infection by respiratory viruses such as SARS-CoV-2 and its variants: influenza, RSV, and the common cold, in individuals at risk of more severe illness.

Melbourne, Australia, 14 February 2023 – ENA Respiratory, a clinical-stage pharmaceutical company, announced that INNA-051, a first-in-class, broad-spectrum, innate immunomodulator in development for the prophylaxis of respiratory viral infections, was found to significantly impact the course of viral infection in a Phase 2a flu challenge study.

The study included 123 adults (ages 19 to 53) randomized to receive two doses of INNA-051 (low and high dose) or placebo, then challenged with a substantial dose of H3N2 influenza A virus. The viral inoculum was expected to result in a large majority of participants being infected. Interpretation of the study was complicated by lower than anticipated rates of infection in the placebo arm and an unexpectedly large proportion of participants having pre-existing immunity to the challenge strain across all groups (assessed using the hemagglutination inhibition assay). Post hoc analyses excluding those with pre-existing immunity showed that INNA-051-treated participants with PCR laboratory-confirmed infection had a statistically significant shorter duration of infection. This effect was greater with the higher dose. Although not statistically significant, a dose-related reduction in the duration of symptoms was also observed.

Notably, the study confirmed the safety profile of INNA-051. Compared with the placebo group, participants receiving INNA-051 showed no increase in the incidence, magnitude, or duration of any flu symptom, nor enhanced local or systemic signs or symptoms associated with the viral challenge. The most common adverse events associated with the study medication were mild, short-lived and similar to those observed during the initial Phase 1 study.

“This study further supports the concept that boosting the local innate immune response to common respiratory viruses has potential clinical benefit. In this study, INNA-051 was found to be safe and to significantly impact the course of infection. We are eager to investigate INNA-051’s clinical benefit in the context of natural viral respiratory tract infections in individuals at increased risk of more severe illness,” said Christophe Demaison PhD, Managing Director and CEO of ENA Respiratory.

Earlier research in humans and animals has shown that INNA-051 activates the innate immune system in the nose, a common site of infection. These Phase 2a study results mirror those seen in animal respiratory infection models, and are consistent with the INNA-051 mechanism of action.

INNA-051 accelerates virus clearance and reduces virus spread to other parts of the body. It is anticipated that INNA-051 prophylaxis will reduce illness severity and healthcare utilization in individuals exposed to respiratory viral infections, especially in those at high risk of complications.

"Many people around the world have now been impacted by a 'tripledemic' of flu, RSV and SARS-Cov-2 viruses that have been circulating together in recent months. The surge in illness and hospitalization demonstrates the urgent need for a broad-spectrum treatment to boost immunity against common respiratory illnesses, and these data suggest INNA-051 is a promising option," said Scott White MD, Chief Medical Officer, ENA Respiratory.

ENDS

Notes to Editors

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

- Glenn Silver, Finn Partners, +1 973 818 8198, glenn.silver@finnpartners.com

About ENA Respiratory and INNA-051

ENA Respiratory aims 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. 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. 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. 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.