ENA RESPIRATORY

Media Release

ENA Respiratory Expands Leadership Team and Extends U.S. Department of Defense Funding to Enable Phase II Program of INNA-051 in Community-Acquired Viral Respiratory Infections

-- New $3.8 million DOD contract extension will fund non-clinical safety studies to support a three-month seasonal prophylaxis Phase 2b study in at-risk populations, comprising elderly individuals with comorbidities, including chronic lung diseases and diabetes.

-- ENA Respiratory names new clinical leaders and consultants to accelerate and optimize its research and development program.

Sydney, Australia, 29 August 2023 – Clinical-stage pharmaceutical company ENA Respiratory has been awarded an additional $3.8 million contract from the U.S. Department of Defence (DOD) to support ongoing research and development of INNA-051, a first-in-class, intranasal, innate immune modulator for the prevention of complications associated with respiratory viral infections in at-risk populations. The company also announced new clinical leadership and consultants as it plans for a seasonal prophylaxis Phase 2b study.

The new funding adds to the $4.38 million initial DOD funding the company announced in January 2023, which has been used to implement INNA-051 manufacturing on a larger scale. The funds also supported the development of a dry powder formulation that is expected to provide long-term stability of at least 24 months at room temperature. The new funding will support the non-clinical toxicology and safety studies needed to enable a seasonal prophylaxis Phase 2b study to demonstrate the safety, tolerability, and efficacy of intranasal INNA-051 in preventing respiratory illness in people aged 65 or older.

“Early studies validated the safety of INNA-051 and provided proof of pharmacology by accelerating virus clearance and boosting host defense responses against common respiratory viruses,” said Christophe Demaison, Ph.D., co-founder and CEO of ENA Respiratory. “We are grateful for the U.S. DOD support and look forward to continuing to study INNA-051 in preventing respiratory illnesses, especially in those at greatest risk of exposure, complications, or hospitalization.”

The contract was awarded by the DOD’s Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), Joint Project Manager for Chemical, Biological, Radiological, and Nuclear Medical in collaboration with the Defense Innovation Unit (DIU).

ENA Respiratory Names Expanded Clinical Leadership

The company also announced new leadership and consultants to accelerate and optimize its research and development program.

Ruth Tal-Singer, Ph.D., joins as Medicine Development Leader to oversee all clinical development efforts. Previously, Dr. Tal-Singer was a Consultant and Board Member for ENA Respiratory. She is an internationally recognized scientist with extensive experience in molecular biology, immunology, and application of digital technology and in vivo disease models in clinical development. Most recently, she served as President and CEO of the COPD Foundation, where she launched the Foundation's digital health, medical devices, and therapeutics development accelerator network, COPD360Net®, and championed its partnership with ENA Respiratory. Her efforts to ensure the patient voice is central to lung disease therapeutics development continue in her volunteer role as Chief Scientific Officer of the Global Allergy and Airways Patient Platform (GAAPP). Earlier in her career, she served in senior leadership roles at GSK R&D.

Courtney Crim, M.D., joins as Clinical Consultant and acting Chief Medical Officer. He also serves as Clinical Associate Professor of Medicine in the Division of Pulmonary and Critical Care Medicine at the University of North Carolina in Chapel Hill. Previously, he was Group Director in Clinical Development in Respiratory Clinical Sciences at GSK, designing Phase 2-4 clinical trials. He has also served on the FDA Pulmonary and Allergy Drug Advisory Committee and presented drug approval submissions to U.S., European, and other regulatory agencies.

Bruce Miller, Ph.D., joins as a Clinical Consultant with more than 30 years of experience developing therapies for COPD and other inflammatory-driven diseases. He has previously served in senior scientific roles at GSK, Johnson & Johnson, Rhone-Poulenc Rorer, and Sterling Winthrop Pharmaceuticals. Active in the industry, he previously served as co-chair of the COPD Foundation's COPD Biomarker Qualification Consortium's Fibrinogen Working Group, which was instrumental in gaining regulatory qualification for a biomarker as a drug development tool in COPD trials.

"Our accomplished team brings decades of experience leading clinical research programs for respiratory diseases and successfully submitting new therapies for regulatory approvals in the U.S., Europe, and other regions," said Dr. Demaison. "With these additions to our team, we are well-positioned to continue the clinical development of INNA-051 in the context of natural respiratory tract infections in individuals with increased risk of severe illness or exposure."

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Notes to Editors

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About ENA Respiratory

ENA Respiratory is aiming to transform the prevention of complications associated with 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.

In 2022, ENA Respiratory partnered with the US-based COPD Foundation to accelerate the clinical development of INNA-051 in COPD through its access to patients, a global network of accredited centres, scientific expertise, and patient investigators. That year, the company was also the first in the Asia Pacific region to be selected to join BLUE KNIGHT™, a joint initiative between Johnson & Johnson Innovation and U.S. BARDA. In 2023, the company was additionally awarded a USD $4.38 million contract from the U.S. Department of Defense to support ongoing development of INNA-051.

About INNA-051

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, Human Rhinovirus, RSV, and influenza, initially infect and replicate in nasal mucosa epithelial cells.

By targeting protective host defense mechanisms that are virus agnostic and through its simple route of administration, INNA-051 has the potential to address a major unmet need in at-risk populations. It also has the potential to be rapidly deployed and complement vaccine and direct-acting antiviral efforts in the battle against current and future respiratory virus outbreaks, including COVID-19.

In a Phase IIa influenza-challenge study, INNA-051 was found to accelerate virus clearance and boost host responses against influenza virus, including interferon responses. The human data confirmed pre-clinical data in human airway epithelial cells as well as rhinovirus, influenza, and COVID-19 animal infection models. INNA-051 is well-tolerated in humans at single and repeat doses.

Key features of INNA-051 intranasal administration include minimal systemic bioavailability, durable immune response (supporting weekly administration), and compatibility with available vaccines and corticosteroids. Importantly, INNA-051 activity is not significantly affected by senescence (inflammaging), and its safety profile supports prophylaxis use.

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