ENA Respiratory Partners with University of Maryland and Leading Respiratory Disease Expert to Conduct Phase 2 Study of INNA-051 Antiviral Host Defence Enhancer

- Phase 2 to evaluate safety, tolerability and efficacy of INNA-051 in the prevention of illness due to viral respiratory infections
- Study to be led by global health physician scientist, Dr. Justin Ortiz, Professor of Medicine at the University of Maryland School of Medicine

Melbourne, Australia, 9 April 2025 – ENA Respiratory, a clinical-stage pharmaceutical company developing antiviral host defence enhancers to minimize the impact of viral respiratory infections, announces today that it has secured the University of Maryland's renowned global health institution, CVDGH, as clinical partner to conduct a Phase 2 proof of concept study of INNA-051. Dr. Justin Ortiz, Professor of Medicine at the University of Maryland School of Medicine's Center for Vaccine and Global Development (CVD) and a global health physician scientist with expertise in respiratory virus protection and control will be Principal Investigator.

INNA-051 is being developed as a convenient, once-a-week nasal dry powder product to reduce the impact of viral respiratory infections and prevent severe complications in at-risk populations, including the elderly, those with an underlying medical condition and individuals with occupational risk such first responders, military or essential services personnel.

The study will be a randomized, double-blind, placebo-controlled, multicenter, study of INNA-051 in generally healthy adult participants who are at increased risk to viral respiratory infections during the North American 2025/26 fall/winter season. Top line data is anticipated in Q3 2026.

"Partnering with CVD and having Professor Justin Ortiz as one of the Principal Investigators for this Phase 2 trial is a significant step for ENA Respiratory," **said Christophe Demaison, PhD CEO of ENA Respiratory**. "The esteemed team at the University of Maryland School of Medicine, led by Professor Justin Ortiz alongside colleagues Professor Kirsten Lyke and Dr. Meagan Deming, brings extensive experience and a proven track record in conducting similar trials. We now look forward to working together to deliver the next step in the development of what we believe could be a significant new approach to reducing the enormous burden of respiratory viral diseases."

Dr. Justin Ortiz, Principal Investigator, said: "Viral respiratory infections are a major global public health problem and there is a clear need for new approaches to tackle the complications that lead to significant morbidity and mortality. We are excited to be partnering with ENA Respiratory on this important study to test their new approach for boosting the body's natural host defence pathways."

-ENDS-

Note: Dr. Ortiz previously served as a paid scientific advisor for ENA Respiratory, but he no longer maintains any financial relationship beyond funding for research.

About ENA Respiratory

ENA Respiratory is a clinical-stage pharmaceutical company tackling respiratory viral infections through the development of host defence enhancers which locally prime and boost the body's natural first line of defence against invading pathogens. Being virus-agnostic, ENA's approach offers a solution to protect against common and emerging respiratory viruses for which vaccines or direct-acting antivirals have limitations or do not exist.

The company's lead product, INNA-051, is being developed as a convenient, once-a-week nasal dry powder product to reduce the impact of viral respiratory infections and prevent severe complications in at-risk populations, including the elderly, those with an underlying medical condition (including chronic lung conditions, diabetes, kidney disease, and cardiovascular disease) and individuals with occupational risk (e.g. first responders, military or essential services personnel).

INNA-051 is a potent agonist of toll-like receptor 2/6 (TLR2/6) which plays a key role in recognising pathogens and potentiating innate immune responses. With a safety profile supporting seasonal prophylaxis use, it has demonstrated accelerated virus clearance and stimulation of antiviral host defences, including IFN Type I & III responses, in a Phase IIa proof-of-principle study using a human influenza-challenge model.

Headquartered in Melbourne, Australia, the company has raised US$33 million (AU$46 million) in financing from Brandon Capital, The Minderoo Foundation, Flu Lab and Uniseed. It is partnered with the US COPD Foundation to support patient-centered clinical development of INNA-051 in COPD and has been awarded a US$13.1 million contract from the U.S. Department of Defense. It is an alumni member of BLUE KNIGHT™, a joint initiative between Johnson & Johnson Innovation and BARDA designed to accelerate novel potential solutions for future pandemics.

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