ENA Respiratory Announces Publication Supporting the Potential of its Novel Intranasal Therapy INNA-051 to Reduce the Impact of Viral Respiratory Infections in Older Adults

- Clinical studies demonstrated that INNA-051's natural defence boosting mechanism is effective in older adults
- Administration of INNA-051 to older adults (65 years old) in a Phase 1 study was well-tolerated and increased important antiviral host-defence pathways
- Pre-clinical data demonstrated reduced influenza virus dissemination to the lungs of aged mice, consistent with results from studies in younger animals
- Data published in ERJ Open Research, a leading open access journal in respiratory medicine

Melbourne, Australia, 2 April 2025 – ENA Respiratory, a clinical-stage pharmaceutical company developing antiviral host defence enhancers to minimize the impact of viral respiratory infections, announces today the early view publication of results of a Phase I extension study in older adults (66-80) of its liquid formulation of INNA-051, a novel TLR2/6 agonist, in ERJ Open Research, a leading research journal of the European Respiratory Society[1].

In a placebo-controlled dose-escalation Phase 1 study, a cohort of healthy older volunteers (66 – 80 years) received repeated intranasal doses of INNA-051. Biomarker analysis showed that INNA-051 triggered host defence pathways within eight hours of each dose. INNA-051 was also well-tolerated.

The publication also includes supportive preclinical data. Dosing of INNA-051 in aged mice challenged with H3N2 seasonal influenza virus was shown to stimulate natural nasopharyngeal host defences and resulted in reduced viral dissemination to the lungs.

Ruth Tal-Singer PhD, Medicine Development Leader (Consultant) at ENA Respiratory said: "These newly published results form part of a growing body of data supporting the potential of INNA-051 as a new virus-agnostic approach to protecting people from significant morbidity and mortality resulting from respiratory viral infections. Increased age is a major risk factor for such infections and these data demonstrate that INNA-051 is well-tolerated in an older population and stimulates natural host defence pathways in the nose aiming to provide rapid clearance of respiratory viruses which may prevent severe disease."

ENA will soon report the full results of a recently completed Phase 1b study of a more stable dry powder formulation in adults aged 18-80 years. Headline results demonstrate that INNA-051 was well-tolerated in all age groups and led to local activation of host defence pathways. This study provides further evidence for INNA-051 development in a broad age range.

ENA is planning to initiate a Q4 2025 Phase II community infection study in the US to assess the potential efficacy of INNA-051 to reduce the incidence, severity and duration of

symptomatic infections caused by common respiratory viruses, including coronaviruses, seasonal influenza, rhinoviruses, respiratory syncytial virus and human metapneumovirus.

1. ERJ Open Research 2025 01044-2024; DOI: https://doi.org/10.1183/23120541.01044-2024

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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.

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

Follow us on LinkedIn.

For further information please contact:

Media – Australia

Kirrily Davis, E: kdavis@bcpvc.com M: +61 (0)401 220228

Media – International

Charles Consultants

Sue Charles, E: sue.charles@charles-consultants.com M: +44 (0)7968 726585

Chris Gardner, E: Chris@CGComms.onmicrosoft.com M: +44 (0)7956 031077