ENA Respiratory Announces FDA IND Clearance for its Prophylactic Intranasal INNA-051 - a First-in-Class Antiviral Innate Immunomodulator

Melbourne, Australia, 29 April 2024 – ENA Respiratory, a clinical-stage pharmaceutical company developing innate immune modulators for the prevention of complications associated with respiratory viral infections in at-risk populations, announces today that the U.S. Food and Drug Administration ('FDA') has issued a 'safe to proceed' notice for its investigational new drug ('IND') application for a Phase 1b study of its novel dry powder formulation of INNA-051.

A virus-agnostic intranasal antiviral host defence immunomodulator, INNA-051 is a potent first-in-class agonist of toll-like receptor 2/6 (TLR2/6) which plays a key role in recognizing pathogens and triggering the innate immune response. Having demonstrated accelerated viral clearance and local stimulation of antiviral host defences in a Phase IIa proof-of-principle study using a liquid formulation in an influenza-challenge model, ENA Respiratory has developed an improved dry powder formulation to take into further clinical development.

ENA Respiratory's CEO, Christophe Demaison, PhD said: "We are pleased that the FDA has cleared our IND for our dry powder formulation of INNA-051, which is expected to provide extended shelf life at room temperature. FDA clearance is a significant milestone for the company as it supports late-stage clinical development of INNA-051."

In parallel with the IND application, ENA has submitted ethics approval for a Phase 1b study in Australia. This study is expected to be initiated in mid-2024 with the aim to assess the safety, tolerability, pharmacodynamics, and pharmacokinetics of the dry powder formulation of INNA-051 in older adults.

ENA Respiratory's Medicine Development Leader Ruth Tal-Singer, PhD said: "The study is an essential step in supporting our planned international seasonal prophylaxis Phase 2b study in older adults at risk of severe complications from viral respiratory diseases due to conditions including diabetes, cardiovascular or lung diseases. By targeting the innate immune system at the primary site of most viral respiratory infections, INNA-051 has the potential to address an unmet need in this most vulnerable population as a complementary virus-agnostic approach to available vaccines and direct-acting antivirals, which are often virus-specific".

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About ENA Respiratory

ENA Respiratory is a clinical-stage pharmaceutical company tackling serious respiratory viral infections through the development of host defence immune modulators which locally prime and boost the body's innate immune response – the natural first line of defence. Being virus-agnostic, immune modulators are complementary to often virus-specific vaccines and existing direct-acting antivirals.

The company's lead product, INNA-051, is a potent agonist of toll-like receptor 2/6 (TLR2/6) which plays a key role in recognising pathogens and triggering the innate immune response.

With a safe profile supporting prophylaxis use, it has demonstrated accelerated viral clearance and stimulation of antiviral host defences, including IFN Type I & III responses, in a Phase IIa proof-of-principle study using an influenza-challenge model. INNA-051 is being developed as a convenient, once-a-week nasal dry powder product to prevent complications associated with respiratory viral infections 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).

Headquartered in Melbourne, Australia, the company has raised US$26M (AU$44million) in equity financing from Brandon Capital, The Minderoo Foundation and Uniseed. It is partnered with the COPD Foundation to support the clinical development of INNA-051 in COPD and has been awarded a US$8.18million contract from the U.S. Department of Defence. It is a member BLUE KNIGHT™, a joint initiative between Johnson & Johnson Innovation and BARDA designed to accelerate next-gen potential solutions for future pandemics.

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