Ethris Initiates First-in-Human Dosing in Phase 1 Study of ETH47 a First-In-Class mRNA for Respiratory Viral Infections

- Phase 1 clinical trial will enroll 88 healthy volunteers in the United Kingdom
- ETH47 is a first-in-class, broadly protective antiviral candidate developed using Ethris' proprietary platform technologies for the treatment and prophylaxis of viral asthma exacerbations

Munich, Germany, December 18, 2023 – Ethris GmbH, a leading biotechnology company pioneering next-generation RNA therapeutics and vaccines, today announced the dosing of the first healthy participant in its first-in-human study of lead candidate ETH47, which was developed using Ethris' Stabilized Non-Immunogenic mRNA (SNIM®RNA) platform and encodes for type III interferon (IFN) that plays a vital role in early antiviral response. ETH47 was also designed to be administered locally to the lung through inhalation or nasal spray using the company's proprietary Stabilized NanoParticle (SNaP) LNP platform. The Phase 1 study will primarily evaluate ETH47's safety and tolerability in healthy participants. The program, although initially focused on virus-induced asthma, has the potential to be applied for pandemic preparedness against influenza and SARS-CoV-2 due to its broad applicability.

"Our strategy with ETH47 was to develop a therapeutic that would induce mucosal innate immune responses at viral entry sites with a virus- and mutation-independent mode of action," **said Dr. Thomas Langenickel, Chief Medical Officer of Ethris**. "Entering the clinic with our first program is a major milestone for Ethris and a testament to the capability of our best-in-class platform technology. Following promising preclinical results, we will evaluate ETH47 as a therapeutic and as a prophylactic medicine for prevention of severe disease following respiratory viral infections in patients with chronic respiratory disease such as asthma. We look forward to sharing the progress of our ETH47 clinical study in due course."

The Phase 1 clinical trial is a randomized, placebo-controlled, double-blind, single-ascending dose design to evaluate the safety and tolerability of ETH47. Other objectives of the study include determining its pharmacokinetics and its target engagement. The study will be conducted at a single trial site in the UK and will enroll 88 healthy participants between the ages of 18 to 55. The study will contain 3 parts based on the type of delivery of ETH47, which includes nasal, inhaled and a nasal/inhaled combination. The trial is partially funded by the Bavarian BayTherapie2020 Grant program by the Bavarian Ministry of Economics. A full data readout is expected in the second quarter of 2024.

About viral asthma exacerbations

Viral asthma exacerbations, characterized by acute respiratory attacks necessitates emergency treatment, hospitalization or systemic corticosteroids and represents a significant global health burden. These exacerbations manifest as a respiratory airway inflammation to environmental triggers, with respiratory virus infections as the most common cause. Interferons (IFNs)—especially type I (IFN-a/b) and type III (IFN-ls) play a major role in mediating early antiviral responses. Current treatment options include either quick-relief or long-acting medications to reduce airway swelling.

About Ethris' Technology Platforms

To harness the therapeutic potential of mRNAs, Ethris utilizes its two integrated proprietary technology platforms, the Stabilized Non-Immunogenic mRNA (SNIM® RNA) and the Stabilized Nanoparticle (SNaP) LNP delivery platform.

The SNIM® RNA technology is an mRNA therapy platform that incorporates chemical modifications into its structural elements, which enables the repetitive administration of SNIM® RNAs, resulting in a sustained production of therapeutically active proteins within the human body. The SNIM®RNA can replace or augment missing or non-functional disease-causing proteins, introduce new proteins to modulate the course of the disease or its symptons and be used to develop vaccines.

The SNaP LNP is a nucleic acid delivery system that protects the cargo RNA during transport to the target cells and offers precise exposure control by locally retaining lipidoid nanoparticles (LNP), mitigating concerns related to biodistribution and side effects. With 300x potency and twice the cargo capacity of conventional methods, the SNaP LNP platform enables multi-route, multi-payload, and multi-cell type applications. Its lipidoid formulation supports long-term storage at room temperature through advanced lyophilization and rapid rehydration processes, ensuring efficient delivery of high-quality LNP aerosols into the respiratory tract for the full therapeutic potential of the RNA therapy.

About Ethris

Ethris has paved a new path from genes to therapeutic proteins, using its proprietary RNA and lipidoid nanoparticle technology platform to discover, design and develop innovative therapies. With more than a decade as an mRNA pioneer, Ethris is a global leader in delivering stabilized mRNAs directly to the respiratory system via optimised formulation and nebulisation technologies. The company is rapidly advancing its mRNA pipeline of immuno-modulation, protein replacement therapies, and differentiated vaccines, with the ultimate goal of improving patients' lives.

For Ethris, please contact:
Dr. Philipp Schreppel
+49 89 244 153 042
schreppel@ethris.com

Media Relations for Ethris:
Madelin Hawtin
LifeSci Communications
mhawtin@lifescicomms.com