Ethris Presents Positive Topline Phase 1 Data with mRNA Lead Candidate ETH47 for Uncontrolled Asthma

- Nasal administration of ETH47 continued to demonstrate localized dose-dependent interferon lambda protein expression and target engagement
- ETH47 was generally safe and well-tolerated at all dose levels with no serious or severe adverse events or observable systemic bioavailability
- Ethris plans to initiate a Phase 2a clinical trial in Q2 2025 to evaluate the ability of ETH47 to reduce symptoms after a rhinovirus infection in asthma patients

Munich, Germany, January 30, 2025 – Ethris GmbH, a leading biotechnology company pioneering next-generation RNA therapeutics and vaccines, today announced promising topline data from the completed Phase 1 clinical trial of its lead mRNA therapeutic candidate, ETH47, in healthy volunteers. Designed to address the upstream trigger of asthma exacerbations, ETH47 encodes interferon lambda (IFNλ), a protein essential for viral immunity in the respiratory tract. These topline results provide the first clinical validation of Ethris' pioneering targeted RNA therapeutic approach and its ability to induce a downstream cascade of antiviral interferon-stimulated genes locally following nasal administration. Thomas Langenickel, MD, Chief Medical Officer at Ethris, presented the results on January 30th, 2025, at the mRNA-Based Therapeutics Summit Europe in Frankfurt, Germany.

"These positive Phase 1 results reinforce the promise of ETH47 as a potentially safe and transformative treatment option for asthma patients, while also validating our SNIM® and SNaP® proprietary technology platforms as a viable delivery option for mRNA therapeutics to the respiratory tract," said Dr. Thomas Langenickel, Chief Medical Officer at Ethris. "This significant milestone demonstrates the ability of our technology to deliver precisely designed mRNA candidates to the respiratory tract, facilitating production of the encoded protein and engagement with the intended target. With this strong foundation, we look forward to advancing ETH47 into Phase 2 trials in 2025 and remain committed to exploring its potential to transform care for patients with asthma and broader respiratory conditions."

The Phase 1 study assessed the safety, tolerability, and target engagement of ETH47 after nasal administration in 40 healthy participants.

Key Results from the Phase 1 Study:

- Safety and tolerability: ETH47 was generally safe and well tolerated across all dose levels, with no serious or severe adverse events and no adverse events leading to discontinuation reported in the healthy participants. The study also demonstrated no systemic bioavailability of the mRNA, the produced protein IFNλ, or the proprietary lipidoid compound, minimizing the risk of off-target effects.

- Dose-dependent target engagement: ETH47 exhibited a clear dose-dependent production of IFNλ in the nasal lining fluid exceeding predicted therapeutic levels. ETH47 administration also activated the mRNA expression of antiviral interferon-stimulated genes (ISGs) in nasal brush samples. These findings confirm ETH47's pharmacodynamic activity and support its proposed mechanism of action.

Based on the encouraging Phase 1 results, Ethris filed a Clinical Trial Application (CTA) for a Phase 2a rhinovirus challenge study in asthma patients, planned to begin in Q2 2025. This upcoming trial will focus on evaluating the ability of ETH47 to reduce lower respiratory symptoms in asthma patients following rhinovirus infection.

About ETH47
ETH47 is Ethris' first-in-class mRNA-based product candidate encoding interferon lambda (IFNλ) that was developed using the company's Stabilized Non-Immunogenic mRNA (SNIM®RNA) platform, and uniquely designed to be administered locally to the respiratory tract through inhalation or nasal spray using Ethris' proprietary Stabilized NanoParticle (SNaP®) LNP platform. ETH47 is meant to induce a mucosal innate immune defense response at virus entry sites as well as inhibit viral replication. ETH47's versatile, virus- and mutation-independent mode of action has the potential to broadly address seasonal and emerging respiratory virus infections, including virus-driven exacerbation of chronic respiratory diseases such as asthma.

About Uncontrolled Asthma
Uncontrolled asthma is a significant burden for patients, including 4.4 million moderate to severe asthma patients in the US alone. Approximately 80% of acute asthma attacks (exacerbations) are associated with virus infections. Asthma exacerbations cause excessive inflammation and mucus hyperproduction. They remain a significant burden for patients, leading to increased healthcare costs and decreased quality of life. ETH47's innovative mechanism of action aims to prevent those exacerbations at their source, potentially improving outcomes for millions of patients worldwide.

About Ethris
Ethris, a clinical-stage biotechnology company, has paved a new path from genes to therapeutic proteins, using its proprietary RNA and lipidoid nanoparticle technology platforms 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 optimized formulation and nebulization 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 more information, visit www.ethris.com

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