

Ethris Announces Positive Initial Phase 1 Data Demonstrating Nasal Delivery of mRNA Lead Candidate ETH47

- ETH47 resulted in a dose-dependent increase in target protein expression in the nasal cavity
- Nasal administration of ETH47 was generally safe and well-tolerated, with no severe adverse events or drug-related adverse events of clinical relevance
- Full data readout expected in the third quarter of 2024
- Following the Phase 1 study, Ethris plans to advance ETH47 for patients with uncontrolled asthma

Munich, Germany, June 25, 2024 – Ethris GmbH, a leading biotechnology company pioneering nextgeneration RNA therapeutics and vaccines, announced today preliminary positive data from its Phase 1 dose escalation clinical trial evaluating the safety, tolerability, and target engagement of lead mRNA candidate ETH47 encoding interferon lambda (IFN λ), in healthy participants. IFN λ has a key role in viral immunity in the respiratory tract. The data indicates that ETH47, administered nasally, was generally safe and well-tolerated, with no severe adverse events or drug-related adverse events of clinical relevance across all dose levels. Initial results also show target engagement and suggest no systemic biodistribution of ETH47. A full data readout is planned for the third quarter of 2024.

"These preliminary results are highly encouraging as they provide the first clinical validation of our innovative SNIM®RNA platform and SNaP LNP technology, which allows localized administration directly at virus entry sites and supports the potential of ETH47 as a broadly protective antiviral candidate for respiratory diseases," **said Dr. Thomas Langenickel, Chief Medical Officer of Ethris.** "We look forward to sharing comprehensive Phase 1 data later this year as we continue evaluating ETH47 for the treatment of uncontrolled asthma. Furthermore, successful nasal delivery opens up mRNA therapeutics as a new potential modality to treat diseases of the respiratory tract"

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. Susceptibility to viral infections in asthma is associated with dysregulation of IFN λ in asthmatics. The promising safety and tolerability profile of ETH47 observed in the clinical trial, along with its potential to enhance mucosal immune defense and correct low IFN λ levels, could represent a significant advancement in the treatment landscape for uncontrolled asthma.

Professor Eric Bateman, MD, Key Opinion Leader and Member of the Board of the Global Initiative for Asthma (GINA) said, "Given the strong association between viral infections, particular with rhinovirus, and asthma exacerbations, Ethris' mRNA product candidate ETH47, with its unique mechanism of action has the potential to fill a significant gap in the asthma treatment paradigm."

The Phase 1 trial is a randomized, placebo-controlled, double-blind, single-ascending dose design to evaluate the safety and tolerability of ETH47 in healthy participants. ETH47, Ethris' lead candidate developed using the company's proprietary technologies was designed to address the unique challenges of delivering mRNA to the lungs, including physiological barriers, low transfection efficiency and delivery vehicle-induced inflammatory responses. This initial data assessment indicates proof of principle with ETH47 and supports its continued development toward human viral challenge studies, including a rhinovirus challenge study in mild asthmatics.



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 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 more information, visit www.ethris.com

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