



Enterprise Therapeutics Doses First Person with Cystic Fibrosis in Phase 2 Trial for Novel Therapy ETD001

- *Trial aims to deliver clinical proof-of-concept and assess the safety profile of novel long acting ENaC inhibitor ETD001*
- *ETD001, a CFTR mutation agnostic approach to CF, is focussed on providing a novel treatment for members of the CF community that do not benefit from currently available mutation-targeted therapies*

Brighton, UK, 23 July 2024: Enterprise Therapeutics Ltd (Enterprise), a biopharmaceutical company dedicated to the discovery and development of novel therapies to improve the lives of those suffering from respiratory disease, today announced dosing of the first person with cystic fibrosis (pwCF) in its Phase 2a trial of ETD001.

ETD001, a low molecular weight compound with first-in-class potential, targets the epithelial sodium channel (ENaC) in the airway epithelium to increase the hydration and clearance of mucus. The Phase 2a trial aims to deliver clinical proof-of-concept and to assess the safety profile of ETD001 in the 10% of pwCF with the highest unmet medical need. The study will be performed at sites located in UK, Germany, France and Italy and will assess lung function (FEV1) in pwCF who are either ineligible for or are not receiving CFTR modulators.

CF is estimated to affect over 100,000 people worldwide, with an average life expectancy of only 50 years. Failed mucociliary clearance and mucus congestion in the lungs of pwCF leads to cycles of infection and inflammation and an ongoing decline in lung function. Increasing fluid volume in the lung by inhibiting ENaC with ETD001 will hydrate mucus, improve clearance, reduce mucus congestion, and is expected to drive substantial improvements in lung function. ETD001 has previously demonstrated a strong safety profile in healthy participants in a Phase 1 trial and has been shown to be long-acting in pre-clinical studies.

Dr John Ford, CEO, Enterprise Therapeutics, said: *"The dosing of the first person with CF in our Phase 2a trial of ETD001 represents an incredible milestone, testament to Enterprise's dedication to advancing a novel approach to treating pwCF with the highest unmet medical need. ETD001 has already demonstrated an excellent safety profile in healthy participants, as well as a pharmacokinetic (PK) profile consistent with a long lung residency. We look forward to progressing ETD001 through Phase 2 trials and beyond."*

Paul Russell, Head of Development, Enterprise Therapeutics, commented: *"By targeting the underlying mechanisms of mucus congestion in the lungs through ENaC inhibition, ETD001 has the potential to be a transformative respiratory therapeutic. This is not only for the ~10% of pwCF who are not genetically suited to, or do not benefit from CFTR modulators, but also those suffering from other muco-obstructive lung diseases such as COPD and asthma. The commencement of our Phase 2a trial brings us an exciting step closer to realising that potential."*

Dr Renu Gupta, CMO, Enterprise Therapeutics, said: *“We are grateful to the pwCF participating in our Phase 2 study of ETD001, and to the clinical investigators for achieving this major milestone. We are hopeful that our steadfast commitment to advancing this innovative ENaC targeting molecule, along with our partnerships with the CF community, will lead to a treatment that will vastly improve the lives of people living with CF.”*

ENDS



**Dr John Ford,
CEO, Enterprise
Therapeutics**



**Paul Russell,
Head of Development,
Enterprise Therapeutics**



**Dr Renu Gupta, CMO,
Enterprise Therapeutics**

For high-resolution images please contact Zyme Communications.

Media contact:

Katie Odgaard
Zyme Communications
Tel: +44 (0)7787 502 947
Email: katie.odgaard@zymecommunications

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About Enterprise Therapeutics www.enterprisetherapeutics.com

Enterprise Therapeutics is discovering and developing new therapies that target the underlying mechanisms of mucus congestion in the lungs, one of the main causes of difficulty in breathing and increased risk of infection in respiratory diseases such as cystic fibrosis and COPD. Reducing mucus congestion will reduce the frequency of lung infections and improve patient quality of life.

The Company's approach is to increase the hydration and clearance of mucus. Enterprise has also identified novel targets and compounds that reduce mucus production, an approach that complements mucus hydration therapies.

The Enterprise Therapeutics management team has significant expertise in drug discovery, drug development, respiratory biology and ion channel pharmacology.