PRESS RELEASE
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Enterprise Therapeutics achieves primary efficacy outcome in Phase 2 clinical trial for cystic fibrosis with novel inhaled ENaC blocker ETD001

- *First investigational inhaled ENaC blocker to deliver clinically relevant and statistically significant change in lung function compared to placebo*
- *Inhaled therapeutic designed to treat the 10% of people with cystic fibrosis with the highest unmet medical need*
- *ETD001 overall safe and well tolerated*

Brighton, UK, 12 May 2026: Enterprise Therapeutics Ltd (Enterprise), a biopharmaceutical company dedicated to the discovery and development of novel therapies to improve the lives of people with respiratory diseases, today announced that its Phase 2 trial for ETD001, the Company's lead candidate for treatment of cystic fibrosis (CF), achieved its primary efficacy outcome. The trial aimed to investigate the efficacy, safety, tolerability and pharmacokinetics of inhaled ETD001 in the 10% of people with CF (pwCF) with the highest unmet medical need, who do not benefit from treatment with CFTR modulators. Data from the trial demonstrate improvement in lung function over a 28 day period compared to placebo.

ETD001 is an investigational inhaled epithelial sodium channel (ENaC) blocker, designed to increase lung function by improving mucus clearance and reducing airway obstruction. The data from the trial demonstrate a difference of 3.4% points (p value = 0.0053) in percent predicted forced expiratory volume in 1 second (ppFEV1) in pwCF when dosed with ETD001, compared to placebo. Exploratory analysis showed that participants had a three times higher likelihood of improving ppFEV1, and therefore improving lung function, when receiving ETD001 compared to placebo. The results also show that ETD001 is overall well-tolerated in pwCF, with adverse events consistent with those expected in this trial population of pwCF receiving inhaled medicines.

The trial was split into two parts and performed at sites located in UK, Germany, France and Italy in pwCF who are either ineligible for, or are not receiving, CFTR modulators. Part A assessed the safety and tolerability of repeat inhaled doses of ETD001 over 7 days, through monitoring adverse events. Part B used a double-blind, placebo-controlled, cross-over design to examine the effect of repeat BID (twice daily) dosing of ETD001 (4.5 mg) over 28 days on absolute change in ppFEV1. Participants were randomised to receive either placebo or ETD001 for 28 days in a two group, two sequence cross-over design, with a 28-day washout period. The results from this clinical trial (NCT06478706) will be presented at the European Cystic Fibrosis Society conference in Lisbon in June (www.ecfs.eu/lisbon2026).

Enterprise is planning to advance to longer duration Phase 2b dose ranging trials in pwCF, and to evaluate the efficacy of ETD001 on top of CFTR modulators. Due to the overwhelming evidence that individuals with non-CF bronchiectasis also suffer from high mucus burden and mucus plugging, Enterprise plans to additionally initiate a clinical trial in this patient population.

Dr Renu Gupta, CMO, Enterprise Therapeutics, said: "*We are delighted to report positive results from this Phase 2 trial of ETD001. These data demonstrate that this novel, inhaled ENaC blocker is well tolerated in pwCF, and has shown improvement in lung function over a 28 day period compared to placebo. We are encouraged by the potential of ETD001 to be a novel therapeutic option for improving the lives of all pwCF, particularly those currently without effective therapies, and we are grateful to everyone who took part in this trial.*"

Dr Martin Gosling, CSO, Enterprise Therapeutics, commented: "*The data from this trial represents a critical milestone as it is the first time an ENaC blocker has demonstrated efficacy in pwCF. We are excited by the potential that these data offer for enhancing treatment options for all pwCF, and to expand into other muco-obstructive lung diseases including bronchiectasis. To observe lung function improvement within 28 days of treatment with ETD001 is a significant milestone and we are now looking forward to progressing into longer duration clinical trials, where we expect to see further clinical benefit.*"

Dr John Ford, CEO, Enterprise Therapeutics, added: *"I would like to thank everyone involved in developing the ETD001 programme to this stage, it's really heartening to see the results from this Phase 2 trial. We are now looking forward to developing this candidate further, and being one step closer to improving outcomes for people living with respiratory disease."*

Cystic fibrosis is estimated to affect over 100,000 people worldwide, and leads to reduced life expectancy. Failed mucociliary clearance and mucus congestion in the lungs leads to cycles of infection and inflammation and an ongoing decline in lung function.

For more information about Enterprise Therapeutics, visit www.enterprisetherapeutics.com

ENDS

Dr Renu Gupta, CMO, Enterprise Therapeutics

Dr Martin Gosling, CSO, Enterprise Therapeutics

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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, bronchiectasis 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's lead asset, ETD001, is a novel inhaled blocker of the epithelial sodium channel (ENaC) with first in class potential. Enterprise has also nominated a drug development candidate that reduces mucus

production by overcoming goblet cell metaplasia, 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.

About ETD001
ETD001 is a novel investigational product for the treatment of cystic fibrosis (CF) with broader applicability in other muco-obstructive diseases as bronchiectasis and COPD. It has been designed to be a long-acting, potent and selective epithelial sodium channel (ENaC) blocker. By inhibiting ENaC in the airway epithelium, ETD001 is intended to improve airway hydration and mucociliary clearance, helping to reduce mucus obstruction in the lungs.

ETD001 has been granted ‘rare paediatric disease designation’ (RPD) in the US by the Food and Drug Administration (FDA) for the treatment of pwCF.