

Kither Biotech Initiates Dosing of Patients in Phase 1b / 2a Study of KIT2014 in COPD

- *KIT2014 is a novel inhaled peptide therapy being developed for respiratory diseases including chronic obstructive pulmonary disease (COPD), non-CF bronchiectasis (NCFB), idiopathic pulmonary fibrosis (IPF) and cystic fibrosis (CF)*
- *The first patients have now been dosed in Kither's randomised, double-blind, placebo-controlled, dose-ranging Phase 1b / 2a trial in adults with moderate to severe COPD*
- *The Australia-based multicentre study will evaluate the safety, tolerability and pharmacokinetics of KIT2014, plus early signs of efficacy*
- *KIT2014's unique and proprietary mode of action, involving balanced dual PDE3/4 inhibition, acts to improve respiratory symptoms by enhancing bronchodilation and reducing lung inflammation*

Turin, Italy – 29 September 2026 – Kither Biotech Pty Ltd and Kither Biotech Srl, a clinical-stage biopharmaceutical group of companies developing innovative therapies for respiratory diseases, today announced that it has dosed the first patients in its Phase 1b / 2a clinical study of KIT2014 in adults with moderate to severe COPD.

Administered by inhalation, KIT2014 is a novel, proprietary cell-permeable peptide, consisting of 42 amino acids, which acts to enhance bronchodilation and reduce lung inflammation through balanced dual inhibition of the enzymes phosphodiesterase 3 and 4 (PDE3/4). This dual inhibition increases local concentrations of the key signalling molecule cAMP (cyclic adenosine monophosphate).

Dr. Dimitrios Goundis, CEO of Kither Biotech, said: "The dosing of patients in Kither's Phase 1b / 2a study of our novel inhaled peptide KIT2014 in COPD, comes less than three months after we announced the successful completion of the Phase 1 study in healthy participants. This study will investigate the safety, tolerability and pharmacokinetics of KIT2014, as well as early signs of efficacy, in patients with moderate to severe COPD."

Anita van der Meer, Director of Kither Biotech Pty Ltd, added: "More effective treatments for COPD, which is the third largest cause of morbidity and mortality globally, are desperately needed. We believe KIT2014's balanced and multimodal mechanism and its consequent bronchodilation and anti-inflammatory effects make it particularly well suited to this debilitating lung disease, and we look forward to the results of this Phase 1b / 2a clinical trial."

The Phase 1b / 2a study is a randomised, double-blind, placebo-controlled, dose-ranging trial to investigate the safety, tolerability, pharmacokinetics and early efficacy of inhaled KIT2014, taking place at multiple sites in Australia.

The primary focus is the safety and tolerability of inhaled KIT2014. Secondary endpoints include lung function (peak FEV1 over four hours, AUC over 12 hours, and trough FEV1) to assess bronchodilation and pharmacokinetic data. The study will also explore changes in inflammatory cells and protein biomarkers in induced sputum, to investigate changes in lung inflammation. Initial results are expected by Q1 2027.

The start of the Phase 1b / 2a study comes after the successful conclusion of Kither's double-blind, randomised, placebo-controlled Phase 1 study in 56 healthy participants, which showed inhaled KIT2014 was safe and well tolerated in daily doses ranging from 0.1 mg to 2 mg, in up to 7 days of treatment. It also showed blood plasma levels of KIT2014 were below the limit of detection at all dose levels, both in the single ascending dose (SAD) and multiple ascending dose (MAD) parts of the study, indicating that direct administration to the lungs results in very low systemic exposure.

For more information, visit [clinicaltrials.gov NCT07668518](https://clinicaltrials.gov/NCT07668518).

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Notes for editors

About Kither Biotech

Kither Biotech is a clinical-stage biopharmaceutical company focused on developing innovative therapies for respiratory diseases. The company's lead program, KIT2014, represents a novel approach to treating respiratory conditions by targeting multiple respiratory disease pathways, simultaneously. Kither Biotech has successfully raised over \$30 million to date from leading life sciences investors including Claris Ventures, 2Invest, 3B Future Health, CDP Venture Capital, Italian Angels for Growth, Club degli Investitori, Ersel and ACE Venture. For more information, please visit www.kitherbiotech.com and follow us on LinkedIn.

About KIT2014

KIT2014 is a proprietary first-in-class inhaled peptide therapy that targets multiple pathways critical to respiratory disease pathophysiology. By equally inhibiting both phosphodiesterase 3 and 4 (PDE3/4) and enhancing cyclic adenosine monophosphate (cAMP) levels in airway cells, KIT2014 improves airway flow via relaxation of airway smooth muscle and bronchodilation, reduces epithelial and neutrophil-driven inflammation, and increases CFTR gating to improve

chloride ion transport and airway mucus hydration and clearance. Through PDE3/4 inhibition, the therapy can also help prevent inflammation-induced fibrosis, reducing the amount of scar tissue in the lungs. Inhaled delivery allows direct targeting of the lungs while minimising systemic exposure, potentially offering an improved safety profile compared to similar therapies with greater systemic exposure and side effects.

About KIT2014's target indications

KIT2014 has the potential to address significant unmet needs across respiratory diseases including **COPD**, **NCFB**, **IPF** and **CF**.

Chronic obstructive pulmonary disease (COPD) affects more than 400 million people globally and continues to be the third largest cause of death worldwide. It is an irreversible airflow-limiting disease primarily caused by smoking and environmental exposures, characterised by chronic respiratory symptoms, and progressive decline in lung function. The underlying pathology is driven by inflammation leading to small airway remodelling, and parenchymal destruction.

Non-CF bronchiectasis (NCFB) impacts approximately 500,000 people in the US and a similar number in Europe, with limited treatment options available. It is a chronic airway disease characterised by permanent dilation of the bronchi, leading to cough, sputum production, and recurrent infective exacerbations. The disease creates a vicious cycle of mucus accumulation, infection and neutrophilic inflammation.

Idiopathic pulmonary fibrosis (IPF), which affects approximately three million people worldwide, is a chronic and debilitating lung disease characterised by scarring (fibrosis) of the tissue surrounding lung alveoli, the small air sacs at the ends of the lungs' bronchioles. IPF is a progressive disease which causes a dry, persistent cough, fatigue and increasing breathlessness. It can also lead to pulmonary hypertension and heart failure. Prognosis is poor, with around half of patients dying within three years of diagnosis. Most currently available treatments aim to address symptoms, to ease breathing, but do not target the underlying pathology.

Cystic fibrosis (CF) affects approximately 130,000 people worldwide and, despite advances in CFTR modulators, many patients continue to experience persistent inflammation and recurrent infections. It is a life-limiting genetic disease caused by mutations in the CFTR gene, leading to defective chloride ion transport in multiple organ systems. In the lungs, this results in thick, sticky mucus buildup promoting chronic bacterial infections, persistent inflammation and decline in lung function.