



Press release

Synairgen plc

(‘Synairgen’ or the ‘Company’)

Phase II Clinical Trial Commences Dosing in Patients with COPD

Southampton, UK – 7 February 2018: Synairgen (LSE: SNG), the respiratory drug discovery and development company, today announces that the first patients have been dosed in the Company’s Phase II trial of inhaled SNG001 in patients with chronic obstructive pulmonary disease (COPD).

COPD is a progressive lung disease punctuated by periods of exacerbation involving acute worsening of symptoms, which have major implications for both the patient and the healthcare system. COPD exacerbations are the second most common cause of hospitalisation¹. The risk that a cold will cause an exacerbation of COPD is around 50%² and could be even higher in certain at-risk patients³ (considerably higher than for asthmatic patients, where the risk that a cold will cause an exacerbation is less than 10%).

SNG001, which is wholly-owned by Synairgen, is an inhaled interferon beta (IFN-beta) therapeutic candidate, which has been shown to ‘orchestrate’ antiviral defence mechanisms to protect COPD lung cells against a range of common viruses in *in vitro* models.

Synairgen’s two-part Phase II trial, called SG015, has been designed to assess the effects of SNG001 in COPD patients.

The first part of the SG015 trial involves dosing 10 COPD patients who have no evidence of viral infection to examine levels of antiviral biomarkers in response to SNG001. The aim is to assess whether administering SNG001 boosts antiviral defence mechanisms in the lung in the absence of a respiratory virus. The first part of the trial is scheduled to complete in March 2018.

The second part of the SG015 trial is designed to measure various efficacy endpoints and biomarker levels in patients with a respiratory virus. In this part, 80 patients will be randomised to receive either inhaled SNG001 or placebo. This part of the trial will bridge the end of the 2017/2018 winter/spring virus season and the 2018 virus season which starts in the autumn.

Richard Marsden, Chief Executive Officer of Synairgen, said: *“We are excited to begin the clinical evaluation of SNG001 in COPD, where exacerbations are a significant health risk and economic burden. We have already shown in in vitro models that SNG001 protects the lung cells of COPD patients when infected with viruses that cause exacerbations such as flu and the common cold. However, up until now, our ability to identify those patients who may benefit from an inhaled anti-viral therapy made the design of a prospective study challenging. This has now changed with the development of a point- of-care diagnostic tool which enables rapid confirmation of the existence of a respiratory viral infection in COPD patients. This enables us to treat only those patients who are infected with a virus, significantly reducing the number of subjects required to show the potential effect of SNG001.”*

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Notes for Editors

About Synairgen

Synairgen is a respiratory medicine discovery and development company founded by University of Southampton Professors Stephen Holgate, Donna Davies and Ratko Djukanovic. Core to Synairgen's business strategy is to create value around promising respiratory assets and conduct licensing transactions. The Company has a proven business model as demonstrated by its relationship with Pharmaxis. Synairgen helped validate Pharmaxis's oral LOXL2 inhibitor programme which is in clinical development to reduce fibrosis in indications including liver fibrosis (NASH) and idiopathic pulmonary fibrosis (IPF). Synairgen has advanced its lead therapeutic candidate SNG001 into a Phase II trial in COPD. The Company uses its differentiating BioBank platform and world-renowned international academic KOL network to discover and develop novel therapies for respiratory disease. Leveraging its scientific and clinical facilities at Southampton General Hospital, Synairgen uses in vitro and ex vivo models of respiratory disease to progress programmes into clinical development. The BioBank of human samples is used in these models to increase confidence in the likelihood of successful drug development. Synairgen is quoted on AIM (LSE: SNG). For more information about Synairgen, please see www.synairgen.com.

About COPD

Chronic Obstructive Pulmonary Disease (COPD) is a lung condition characterised by airflow limitation that is not fully reversible. This airflow limitation is normally progressive and is associated with an abnormal inflammatory response of the lung to pathogenic stimulus. The majority of COPD is associated with long-term cigarette smoking.

Symptoms of COPD include cough, excessive sputum production and shortness of breath. Exacerbations of COPD are defined as the worsening of COPD symptoms beyond normal day-to-day variations and are associated with irreversible loss of lung function and, therefore, accelerated disease progression.

Exacerbations severely impact on the patient's quality of life (patients typically take a number of weeks to recover) and are a major healthcare burden. Exacerbations are currently treated with oral corticosteroids and antibiotics. Systemic administration of corticosteroids is associated with unwanted side effects and there is a drive to reduce antibiotic usage.

Respiratory viral infections, such as the common cold and flu, are a major driver of exacerbations in patients with lung disease when infections spread from the upper respiratory tract to the lungs to worsen pre-existing lung inflammation. Furthermore, particularly in COPD, there is growing evidence that viral infections increase susceptibility to follow on bacterial infections. Therefore, there is strong rationale to develop anti-viral treatments to prevent or treat exacerbations of COPD.

References

1. Department of Health. An Outcomes Strategy for Chronic Obstructive Pulmonary Disease (COPD) and Asthma in England. Published July 2011.
2. Johnston NW, et al. Colds as predictors of the onset and severity of COPD exacerbations *International Journal of COPD* 2017;12: 839-848
3. Wilkinson TMA, et al. A prospective, observational cohort study of the seasonal dynamics of airway pathogens in the aetiology of exacerbations in COPD *Thorax* 2017;0:1-9. Doi:10.1136/thoraxjnl-2016-209023