



**RNS REACH**  
**Press release**

## **Synairgen plc**

(‘Synairgen’ or the ‘Company’)

### **Phase II Clinical Trial Update in Patients with COPD**

*~ Clinical trial data to date shows impact of viruses on COPD patients*

**Southampton, UK** – 24 July 2019: Synairgen (LSE: SNG), the respiratory drug discovery and development company, today announces an update on the Company’s wholly-owned inhaled interferon beta (IFN-beta) programme, currently in a Phase II clinical trial, which is aimed at countering the adverse effects of common cold and influenza viruses in patients with chronic obstructive pulmonary disease (COPD).

The trial is progressing well in 15 centres around the UK and is scheduled to complete in the winter 2019-2020 virus season.

**Prof. Tom Wilkinson, Chief Investigator for the trial, said:** *“COPD exacerbations caused by cold and influenza viruses represent a significant health risk, particularly in the winter virus season<sup>1</sup>. Patients with COPD exacerbations are the second most likely group of patients to be hospitalised in England for unplanned events<sup>2</sup>.*

*“With no effective broad-spectrum antiviral treatment on the market, Synairgen’s inhaled IFN-beta may provide a novel approach for COPD patients, with the potential to greatly improve the patient’s defences against viral infection, reduce exacerbations, increase quality of life and reduce hospitalisations.”*

An analysis of all the patients dosed to date, as a single group regardless of treatment (the study will not be unblinded until the end of the trial), shows that cold and flu infections are having a considerable impact on symptoms in COPD patients, as assessed using the validated Breathlessness, Cough and Sputum Score (BCSS)<sup>3</sup>. A mean decrease in BCSS score > 1 represents substantial symptomatic improvement<sup>4</sup>. As we are seeing an increase in mean BCSS score >2, we have the potential to demonstrate a significant treatment effect. These changes contrast with the most recent asthma trial, where colds had less impact on patients.

The Company is also pleased to report that the rapid point-of-care test, being used to confirm that a patient has a viral infection, is ensuring that only the correct patients are being enrolled. The test ensures that only those patients for whom IFN-beta therapy may be effective are being dosed, thereby increasing the chance of the drug showing a beneficial effect. To date, approximately 35% of patients presenting with symptoms have tested positive for a viral infection. Viruses detected include rhinovirus, influenza, RSV, parainfluenza and coronavirus infections.

**Richard Marsden, CEO of Synairgen, said:** *“Aided by the rapid point-of-care test, the trial is successfully capturing marked changes in COPD symptoms in patients with confirmed*

*common cold and influenza virus infections. We have previously shown that inhaled IFN-beta boosts the lungs' antiviral defences in COPD patients and the magnitude of the symptom changes being observed so far in the current trial puts us in a good position to determine the potential benefit of inhaled IFN-beta in this patient population."*

- Ends -

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**About Synairgen**

Synairgen is a respiratory drug discovery and development company founded by University of Southampton Professors Stephen Holgate, Donna Davies and Ratko Djukanovic. The business, focused primarily on asthma and COPD, uses its differentiating human biology 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, the Company uses *in vitro* and *ex vivo* models to progress opportunities 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 currently conducting a two-part Phase II trial evaluating SNG001, the Company's inhaled interferon beta (IFN-beta) product. The Phase II trial, called SG015, has been designed to assess the safety of SNG001 in COPD patients and its clinical benefit in these patients when they have a cold or flu infection, a major driver of COPD exacerbations.

Core to Synairgen's business strategy is the realisation of value via licensing transactions. In August 2015 the Company entered into a collaboration with Pharmaxis to develop an oral LOXL2 inhibitor to reduce fibrosis in patients with idiopathic pulmonary fibrosis (IPF). In December 2017, the collaboration agreement was amended as Pharmaxis took on full responsibility for the programme, with Synairgen receiving a £5 million upfront payment and a share of at least 17% (net of allowable expenses) of any receipts from any onward licensing by Pharmaxis of the LOXL2 inhibitors in fibrotic indications.

Synairgen is quoted on AIM (LSE: SNG). For more information about Synairgen, please see [www.synairgen.com](http://www.synairgen.com)

## References

1. 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
2. Department of Health. An Outcomes Strategy for Chronic Obstructive Pulmonary Disease (COPD) and Asthma in England. Published July 2011
3. N. K. Leidy, J. K. Schmier, M. K. C. Jones, J. Lloyd, K. Rocchiccioli. Breathlessness, Cough and Sputum Scale. *Respiratory Medicine* 2003; Vol. 97 \$59-\$70
4. Nancy Kline Leidy, Stephen I. Rennard, Jordana Schmier, M. Kathryn C. Jones, Mitch Goldman, The Breathlessness, Cough, and Sputum Scale, The Development of Empirically Based Guidelines for Interpretation. 2003; *Chest*; 124:2182–2191