



Press release

**Synairgen plc**  
(‘Synairgen’ or the ‘Company’)

**First patient dosed in Part 2 of Synairgen’s Phase II clinical trial in patients with COPD**

*~ Part 2 assesses the efficacy and safety of inhaled SNG001 in patients with COPD with a confirmed cold or flu virus*

**Southampton, UK** – 22 October 2018: Synairgen (LSE: SNG), the respiratory drug discovery and development company, announces that dosing has commenced in Part 2 of its Phase II clinical trial for its wholly-owned inhaled interferon-beta (IFN-beta) therapeutic candidate, SNG001, in patients with chronic obstructive pulmonary disease (COPD).

Part 1 of the trial successfully assessed the safety and antiviral biomarker activity of SNG001 in COPD patients when patients were free of viral infection. The aim of Part 2 is to study the efficacy and safety of inhaled SNG001 in up to 120 COPD patients with a confirmed respiratory viral infection.

IFN-beta is a naturally-occurring antiviral protein produced by lung cells on exposure to a respiratory virus. Lung cells from patients with COPD have been shown to have a poor antiviral response *in vitro*. Treating cells with SNG001 has been shown to orchestrate antiviral defence mechanisms which protect COPD lung cells against respiratory viruses in *in vitro* models. In addition, independent research published by *Nature Communications* suggests that the increased risk of pneumonia associated with the use of inhaled corticosteroids to treat exacerbations in COPD could be due to suppression of interferons and proposes that inhaled IFN-beta therapy could be protective.<sup>1</sup>

**Richard Marsden, Chief Executive Officer of Synairgen, said:** *“Cold and flu respiratory viruses cause approximately 50% of COPD exacerbations and are the second most common cause of unplanned hospital admission in England, presenting a significant health risk and economic burden.*

*“With no effective broad spectrum antiviral treatment on the market, we believe treating COPD patients with our wholly-owned product, SNG001, has the potential to enhance greatly the patient’s defences against viral infection, reduce exacerbations, increase quality of life and reduce hospitalisations. Commencement of Part 2 of this Phase II trial in advance of the winter virus season is clearly another key milestone for Synairgen.”*

This announcement contains inside information as defined in Article 7 of the Market Abuse Regulation No. 596/2014 (‘MAR’)

For more information on the trial please visit:

<https://clinicaltrials.gov/ct2/show/NCT03570359?term=SNG001&rank=2>

- Ends -

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## **Notes for Editors**

### **About 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 unplanned hospitalisation.<sup>2</sup> The risk that a cold will cause an exacerbation of COPD is around 50%<sup>3</sup> and could be even higher in certain at-risk patients<sup>4</sup> (considerably higher than for asthmatic patients, where the risk that a cold will cause an exacerbation is less than 10%).

### **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 running a two-part Phase II trial evaluating SNG001, the Company's wholly-owned inhaled interferon beta (IFN-beta) therapeutic candidate. 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 circa 17% of any future net partnering proceeds from all 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. Singanayagam A, et al. Corticosteroid suppression of antiviral immunity increases bacterial loads and mucus production in COPD exacerbations. *Nature Communications* 2018. Doi: 10.1038/s41467-018-04574-1
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3. Johnston NW, et al. Colds as predictors of the onset and severity of COPD exacerbations. *International Journal of COPD* 2017;12: 839-848
4. 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