



Press release

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

## **Synairgen Reports Positive Biomarker Data with SNG001 in COPD Patients**

~ SNG001 shown to increase lung antiviral biomarkers

**Southampton, UK** – 28 June 2018: Synairgen (LSE: SNG), the respiratory drug discovery and development company, announces positive biomarker data from the ongoing Phase II trial of its antiviral therapy SNG001 in patients suffering from 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 hospitalisation.<sup>1</sup> The risk that a cold will cause an exacerbation of COPD is approximately 50%<sup>2</sup> and could be even higher in certain at-risk patients<sup>3</sup> (considerably higher than for asthmatic patients, where the risk that a cold will cause an exacerbation is less than 10%). There is also evidence that COPD patients have impaired anti-viral immunity<sup>4</sup>.

Synairgen’s two-part Phase II trial, called SG015, has been designed to assess the safety of Synairgen’s wholly-owned programme, 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. The first part of SG015 involved dosing 10 patients who have COPD but no evidence of viral infection with the aim of assessing: (i) safety; and (ii) whether administering SNG001 boosts antiviral defence mechanisms in the lung in the absence of a respiratory virus, by means of biomarker analysis. On 22 June 2018 Synairgen announced that safety data had been analysed and SNG001 was well tolerated.

The antiviral biomarker analysis has now been completed and reveals that COPD patients inhaling SNG001 had significantly increased markers of antiviral activity. Sputum samples were taken before, during and after treatment. Gene expression was measured in cells extracted from sputum. The antiviral genes Mx1 and OAS1 were significantly higher at visits during the treatment phase ( $p < 0.0001$ ; gene expression was increased approximately 10-fold 5-fold respectively). These genes code for proteins that are known to interfere with viral replication. Other interferon stimulated genes which also have antiviral activity (CXCL10 (IP-10), GBP1 and IFIT2) were also upregulated.

**Professor Stephen Holgate CBE, leading international lung disease specialist and founder of Synairgen, commented:** *“Respiratory virus infections, such as the common cold and flu, cause a significant proportion of COPD exacerbations when these viruses spread from the nose to the lung, causing inflammation and lung damage. The aim of treatment with inhaled SNG001 is to boost deficient anti-viral defences in the lung to prevent the spread of virus infections from the upper respiratory tract. These biomarker data support the proposed mechanism of action, showing that anti-viral activity was boosted by SNG001. Similar changes in biomarkers (Mx1 and OAS1) translated into improvements in lung function and reduced symptoms in Phase II trials in asthma. As SNG001 has been found to be well tolerated in COPD and the impact of colds is more frequent and greater in COPD patients than in asthma, these*

*results greatly increase our confidence in the potential for SNG001 to provide clinical benefit in the second part of this trial, where we will look at the effects of treatment in patients with a confirmed respiratory virus infection.”*

The second part of SG015, scheduled to cover the 2018/19 winter cold virus season, is designed to measure various efficacy endpoints and biomarker levels in patients with a respiratory virus. This part of the trial aims to enrol 80 patients with confirmed respiratory viruses, who will be randomised to receive either inhaled SNG001 or placebo.

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

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**Notes for Editors**

**About SNG001**

SNG001 is an inhaled interferon beta (IFN-beta) therapeutic candidate, which has been shown to 'orchestrate' antiviral defence mechanisms to protect COPD lung cells against cold and flu 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>5</sup>

**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 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

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