



Press release

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

Synairgen Reports Positive Safety Data with SNG001 in COPD Patients

Southampton, UK – 22 June 2018: Synairgen (LSE: SNG), the respiratory drug discovery and development company, announces that interim safety data from the ongoing Phase II trial of its antiviral therapy SNG001 in patients suffering from chronic obstructive pulmonary disease (COPD) shows that SNG001 is being well tolerated.

Synairgen’s two-part 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. 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. The Drug Safety Monitoring Committee has reviewed the safety data from the first part and has approved progression to the second part of the trial.

Richard Marsden, Chief Executive of Synairgen, said: *“COPD is a very severe disease and it is reassuring to establish that SNG001 is well tolerated in these patients. We look forward to seeing the biomarker analysis, which is due in the near term to see whether SNG001 has switched on the antiviral defence mechanisms. Changes in biomarkers translated into clinical benefit in Phase II trials in asthma. Therefore, if we see similar biomarker changes in this study, it will greatly increase our confidence in the potential of SNG001 in COPD, where colds and flu can cause more severe symptoms than in asthma.”*

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.

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 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.¹

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.² The risk that a cold will cause an exacerbation of COPD is around 50%³ and could be even higher in certain at-risk patients⁴ (considerably higher than for asthmatic patients, where the risk that a cold will cause an exacerbation is less than 10%).

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 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. 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

References

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