Press release

Synairgen plc
('Synairgen' or the 'Company')

Patent Update

Southampton, UK – 9 September 2020: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces an update on its intellectual property (IP) for its wholly-owned inhaled interferon beta asset, SNG001.

Following the results of the interim analysis of Synairgen's exploratory Phase II clinical trial of inhaled SNG001 in Chronic Obstructive Pulmonary Disease (COPD) patients (announced 8 September 2020), Synairgen has submitted a patent application for the use of inhaled interferon beta to treat virus-induced exacerbations in COPD patients undergoing treatment with systemic corticosteroids (e.g. oral corticosteroids).

Prior to this in July, Synairgen also submitted a patent application for the use of inhaled interferon beta in COVID-19 patients.

The Company will update the market on the progress of these patent applications as appropriate.

Richard Marsden, CEO Synairgen, said: *"We are very pleased to have generated patentable findings for our wholly-owned inhaled interferon beta candidate, SNG001, in both COPD and COVID-19 patients. Whilst recognising that the COPD trial data provide a strong rationale for assessing SNG001 in COPD patients with severe viral lung infections, our immediate priority is to progress SNG001 as a therapeutic for COVID-19. Together with our advisors we are working to protect the value of this drug for shareholders and commercial partners over the longer term."*

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 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 lung viral defence in asthma, COPD, and COVID-19, uses its differentiating human biology BioBank platform and world-renowned international academic KOL network to discover and develop novel therapies for respiratory disease. Synairgen is quoted on AIM (LSE: SNG). For more information about Synairgen, please see www.synairgen.com

About COPD

COPD is a progressive lung disease, punctuated by periods of exacerbation characterised by acute worsening of symptoms which require treatment with oral corticosteroids and/or antibiotics, which have major implications for both the patient and the healthcare system. COPD exacerbations are the second most common cause of unplanned hospitalisation in England.

About SG015 - COPD Trial

In 2018 Synairgen commenced a two-part COPD trial (SG015) to assess initially, the safety and lung antiviral biomarker responses to SNG001 in the absence of viral infection. In the first part of the trial SNG001 was well tolerated in patients with moderate to severe COPD. A strong antiviral biomarker signal was also observed, which was comparable to the response previously observed in asthmatic patients. This paved the way for the second part of the trial, which was designed to dose 120 patients with confirmed, naturally-acquired respiratory virus infections.

The second part of the trial included biomarker outcome measures (expression of interferon-stimulated antiviral genes in cells from sputum and proteins in blood samples such as CXCL10) and a number of clinical outcome measures, including changes in the Breathlessness, Cough and Sputum Score (BCSS), and changes in peak expiratory flow rate (PEFR, a measure of lung function).

Patients were stratified at the time of randomisation into two groups according to whether they were already experiencing an exacerbation of their COPD symptoms requiring treatment with oral corticosteroids and/or antibiotics (exacerbating patients), or whether they just had a viral infection (non-exacerbating patients). Some 32% of patients were exacerbating patients. The aim of treatment was to accelerate recovery in exacerbating patients and prevent a deterioration in non-exacerbating patients.

Recruitment into the trial commenced in earnest in January 2019 and was progressing well until the emergence of SARS-CoV-2, which made it difficult to test for virus and dose patients without potentially exposing them and research staff to SARS-CoV-2. Hence in March 2020 the trial was paused, with 109 out of the targeted 120 patients recruited. MHRA approval was received to run an unplanned interim analysis on the grounds that data from 109 COPD patients with confirmed viral infection could generate useful safety, biomarker and potentially efficacy data to support ongoing trials of SNG001 in COVID-19 patients.

Synairgen reported positive data from the interim analysis of its exploratory Phase II clinical trial of inhaled SNG001 in COPD patients with a confirmed respiratory viral infection on 8 September 2020. A link to the announcement of the results of this interim analysis can be found here.

About SG016 - COVID-19 Trial

Synairgen's clinical trial in COVID-19 patients (SG016) is a double-blind, placebo-controlled trial. The 220-patient trial comprised 100 patients treated in hospital and 120 patients to be treated in the home setting. The patients participating in the hospital setting, which completed recruitment in May 2020, were recruited across a number of NHS trusts and the trial was adopted by the NIHR Respiratory Translational Research

Collaboration - comprised of leading centres in respiratory medicine in the UK whose internationally recognised experts are working together to accelerate development and discovery for COVID-19.

On the 20th July 2020 Synairgen announced positive topline data generated from the 101 hospitalized patients in the SG016 trial. The key findings were that the odds of developing severe disease were reduced by 79% in patients receiving SNG001 compared to placebo, that patients who received SNG001 were more than twice as likely to recover from COVID-19 as those on placebo, and that their breathlessness was markedly reduced. Further analysis of the full data set is being conducted, with a peer-reviewed publication expected in due course. A link to the announcement of the topline data can be found here.

COVID-19

COVID-19, caused by the SARS-CoV-2 virus, is a global threat and there is an urgent need to assess new treatments to prevent and effectively treat the severe lower respiratory tract illness that can occur with this disease. Older people and those with co-morbidities such as heart and lung complications or diabetes are at greatest risk of developing severe or fatal disease.

Interferon beta (IFN-beta) applicability to COVID-19

Interferon beta is a naturally- occurring protein, which orchestrates the body's antiviral responses. There is evidence that deficiency in IFN-beta production by the lung could explain the enhanced susceptibility in 'at-risk' patient groups to developing severe lower respiratory tract (lung) disease during respiratory viral infections. Furthermore, viruses, including coronaviruses such as SARS-CoV-2 and MERS-CoV, have evolved mechanisms which suppress endogenous IFN-beta production, thereby helping the virus evade the innate immune system. The addition of exogenous IFN-beta before or during viral infection of lung cells either prevents or greatly diminishes cell damage and viral replication, respectively. Synairgen's SNG001 is a formulation of IFN-beta-1a for direct delivery to the lungs via nebulisation. It is pH neutral, and is free of mannitol, arginine and human serum albumin, making it suitable for inhaled delivery direct to the site of action.

Previously, two Phase II clinical trials in asthmatic patients showed that inhaled SNG001 treatment activated antiviral pathways in the lung, along with improving lung function in patients with a respiratory viral infection.