Press release

Synairgen plc

('Synairgen' or the 'Company')

Update on expanded SG016 trial for patients with COVID-19: Synairgen initiates dosing of SNG001 in home setting to treat patients earlier in the illness

Southampton, UK – 26 May 2020: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces that it has launched an expansion of the SG016 trial of SNG001 (inhaled formulation of interferon-beta-1a) in COVID-19 patients to dose patients in the home setting. The expansion of the trial aims to dose patients earlier in the illness, within three days of symptoms developing.

This follows receipt of the necessary approvals to expand the ongoing SG016 trial from the original 100 patients, to include enrolling an additional 120 patients in the home environment, as announced by the Company on 30 April 2020.

Richard Marsden, CEO of Synairgen, commented: *"We are really pleased to be able to expand the SG016 trial to patients in the home environment which enables us to test the drug much earlier in the course of the illness. If successful, we would hope to protect the lungs and prevent the development of the severe lower respiratory tract illness which puts the healthcare system under such strain. We have also been pleased with the progress of the SG016 trial in the hospital environment, having dosed 98 of 100 patients, and look forward to announcing top line data in July."*

Professor Tom Wilkinson, Professor of Respiratory Medicine at the University of Southampton and Trial Chief Investigator, commented: *"Expansion of the SG016 placebo controlled trial where we will be treating patients at the first sign of COVID-19 symptoms is something of a first and reflects the ingenuity and expertise of Synairgen and our researchers here at the University of Southampton. This novel approach is designed to reduce infection risks for both patients and front-line workers. Critically, it also allows us to gather clinical evidence for SNG001 more quickly, a treatment we believe could play a crucial role in tackling the COVID-19 pandemic."*

Professor Nick Francis, Professor of General Practice at the University of Southampton, commented: *"This novel trial approach is essential for the ongoing health of those at higher risk because of increasing age or other risk factors. The approach could be rolled out across many areas of primary care involving the interaction with vulnerable patients, including the elderly, if it is successful. We are in desperate need of a treatment for COVID-19 that can be given to patients early in the course of the illness in order to prevent progression to severe symptoms."*

Expanded SG016 trial

The expanded trial includes patients who have had symptoms for less than 72 hours and are aged 50 or over with a high-risk comorbidity (such as cardiovascular disease, diabetes or a chronic lung condition), or aged 65 and over. Eligible patients are assessed via video call, and subsequently sent a swab by courier for self-swabbing. These swabs will be tested by Synairgen, and eligible patients with a positive sample will be sent a box containing all necessary equipment, aerosol delivery device, pulse oximeter, thermometer, other consumables and the study medication SNG001/placebo. The Southampton Clinical Trials Unit from the University of Southampton have joined forces with Synairgen to conduct the clinical trial, with additional support provided by the primary care delivery team at the NIHR Clinical Research Network Wessex (CRN Wessex).

Recruitment for the home setting of the trial will depend on the prevalence of the virus in the community and the degree to which the targeted 'at risk' patients become infected. The novel, virtual trial design, means it is readily scalable if necessary.

SG016 Trial Progress
Synairgen's Phase II trial in COVID-19 patients is a double-blind, placebo-controlled trial. The treatment of patients in the hospital setting of the SG016 pilot trial is progressing well, with 98 patients out of 100 now dosed. Top line data is now expected in July. Patients in the hospital setting have typically had symptoms for a longer period of time, and the objective is to accelerate recovery and prevent progression of the disease from being able to breathe spontaneously (with or without oxygen) to requiring ventilation.

Data from the hospital initiated (late) patient and home initiated (early) patient populations will be analysed separately as soon as possible, and then together as one population at the end. Top line data from the trial in the hospital setting is expected in July 2020.

This announcement contains inside information as contained 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 lung viral defence in 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.

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

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) potential 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 of these 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.

SNG001 could prove to have an important role to play in outbreaks such as the current COVID-19 pandemic, particularly in respect of the population at highest risk of being severely affected by this and similar viruses.

Two Phase II clinical trials in asthma showed that inhaled SNG001 treatment activated antiviral pathways in the lung along with improving lung function in patients with a respiratory viral infection. We have also shown that treatment with inhaled SNG001 reduced lung viral load and lung pathology in an *in vivo* swine flu driven model of viral pneumonia. At the time of the MERS-CoV outbreak in 2013, Synairgen collaborated with the National Institutes of Health (NIH) in the US to show that SNG001 could protect against MERS-CoV infection of lung cells *in vitro*.

COVID-19 Clinical Trial

Synairgen's Phase II trial in COVID-19 patients (SG016) is a double-blind, placebo-controlled trial. The Pilot phase of SG016 will now involve 100 patients initiated in hospital and 120 patients initiated in the home setting. Those patients participating in the hospital setting will take place across a number of NHS trusts and has been adopted by the NIHR Respiratory Translational Research Collaboration which is 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. A successful outcome from the pilot phase will inform onwards progression of SNG001 in COVID-19 patients.