RNS REACH
Press release

Synairgen plc

('Synairgen' or the 'Company')

National expansion of Synairgen's home-based COVID-19 trial of inhaled SNG001

Southampton, UK – 18 June 2020: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces the expansion of the placebo-controlled home setting clinical trial of SNG001 (inhaled formulation of interferon-beta-1a) in patients with COVID-19. The trial has been expanded beyond the Southampton area to include patients across the majority of the UK.

Patients in almost any part of the UK who have tested positive for coronavirus, and meet the additional eligibility criteria, can now participate in the home setting arm of Synairgen's COVID-19 trial. Daily video calls with a doctor or nurse will be conducted to supervise dosing with the study medication and for the assessment of trial endpoints. All trial supplies, including a pulse oximeter, thermometer, nebuliser and the trial drug, will be delivered directly to the patient, minimising the chance of spreading the virus.

Visits to the trial website for SNG001 have shown that the majority of eligible patients who have completed the online assessment have lived too far from Synairgen's virus testing laboratory in Southampton for entry into the trial. Synairgen has therefore amended the trial protocol to allow patients from elsewhere in the UK into the trial, provided they have a positive test result from another laboratory e.g. from an NHS testing facility. NHS COVID-19 testing facilities have seen a significant increase in capacity and turnaround times since the Test and Trace service was launched in May, making it now possible to get a test result within the timeframe required for entry into the home setting arm of Synairgen's COVID-19 trial.

The design of this home-based trial will not only test the effectiveness of SNG001 on patients identified earlier in the disease progression, but it will also generate valuable experience in the design and practical delivery of a model of remote care for at risk patients in this and future outbreaks.

Richard Marsden, CEO of Synairgen, commented: *"We are really pleased to expand patient access to this first-of-its-kind trial. Not only does the home setting trial design allow us to test the drug much earlier in the illness, possibly preventing the worsening of symptoms, but it also reduces the infection risk for both patients and front-line workers due to its virtual format. We also believe this novel trial design presents a practical way to utilise SNG001 in a real-world primary care setting.*

"The reduced incidence of COVID-19 demonstrates good progress in the battle to bring this disease under control, but a second wave of infection still presents a significant risk to public health. Synairgen's trial design, and its expansion nationally, lends itself to recruit additional patients more easily, particularly in the event of a second wave of this disease. In the meantime, we are on track to report the results of the 100 patients who have been successfully treated in the hospital setting in July."

Professor Nick Francis, Professor of General Practice at the University of Southampton, commented: *"This trial is unique in that we are targeting individuals with risk factors for severe illness, very early on in the course of their infection. By setting up a 'virtual network' of study doctors and nurses we are able to recruit, consent, and provide daily monitoring to patients in their own homes, just about anywhere in the UK. We have developed robust and efficient systems for screening, consenting, delivery of drug and trial materials, daily monitoring, and safety reporting. We are very excited about being able to evaluate this promising drug in such a unique*

setting. Early treatment may be the key to preventing serious complications, hospitalisations, and death, and we look forward to robustly addressing this important question."

The home setting arm of Synairgen's SG016 trial aims to recruit 120 patients who are either aged 65 or over, or are aged 50 and over with a high-risk comorbidity (such as cardiovascular disease, diabetes or a chronic lung condition). Patients must have had symptoms for less than four days (previously three days). This increase in the "recruitment window" will allow more time for local virus testing and the shipment of the trial drug and supplies to the homes of patients.

Recruitment for the home setting of the SG016 trial will depend on the prevalence of the virus in the community and the degree to which the targeted 'at risk' patients become infected.

More details about the trial of SNG001 in at-risk patients in the home setting, can be found at www.covidtrialathome.com

For further enquiries, please contact:

Synairgen plc
Richard Marsden, Chief Executive Officer
John Ward, Finance Director
Tel: + 44 (0) 23 8051 2800

finnCap
Geoff Nash, Kate Bannatyne, Charlie Beeson (Corporate Finance)
Alice Lane, Manasa Patil (ECM)
Tel: + 44 (0) 20 7220 0500

Consilium Strategic Communications (Financial Media and Investor Relations)
Mary-Jane Elliott, Sue Stuart, Olivia Manser
synairgen@consilium-comms.com
Tel: +44 (0) 20 3709 5700

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

The COVID-19 study
Synairgen's clinical trial in COVID-19 patients (SG016) is a double-blind, placebo-controlled trial. The 220 patient trial comprises 100 patients initiated in hospital and 120 patients initiated in the home setting. The patients participating in the hospital setting , which completed recruitment in May, have been recruited across a number of NHS trusts and the trial 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 will inform onwards progression of SNG001 in COVID-19 patients. Results from the hospital setting are expected in July 2020.

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.

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*.