Press release

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

Synairgen confirms commencement of dosing in trial of SNG001 in COVID-19

Southampton, UK – 31 March 2020: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces that it has now commenced dosing patients in its trial of SNG001 (inhaled formulation of interferon-beta-1a) in COVID-19 patients. This announcement follows the one made by the Company on 18 March 2020.

The first patient has been dosed at the initial trial site (University Hospital Southampton NHS Foundation Trust). Synairgen has initiated a further six trial sites which are expected to start dosing in the coming days.

Richard Marsden, CEO of Synairgen, commented: “We are delighted to get this trial underway with the dosing of the first patient. The team has worked tirelessly and intensively with the relevant authorities and collaborators to get to this stage, and we now look forward to recruiting more patients and completing the trial as soon as possible. A successful outcome from this trial in COVID-19 patients would be a very important step towards a major breakthrough in the fight against this coronavirus pandemic.”

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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.

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) will be a double-blind, placebo-controlled trial. Initially, the pilot phase of the study will involve 100 COVID-19 patients, 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.