

Press release

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

Synairgen to start trial of SNG001 in COVID-19 imminently

Southampton, UK – 18 March 2020: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces that it has received expedited approvals from the Medicines and Healthcare products Regulatory Agency (MHRA) and Health Research Authority (HRA) to conduct a trial of SNG001 (inhaled formulation of interferon-beta-1a) in COVID-19 patients to potentially assist with the global outbreak of the virus.

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 epidemic, particularly in respect of the population at highest risk of being severely affected by this and similar viruses.

SNG001 was identified in the WHO’s Landscape analysis of therapeutics as at 17 February 2020 as the only Phase 2/Phase 3/Observational therapy delivered by the inhaled route (https://www.who.int/blueprint/priority-diseases/key-action/Table_of_therapeutics_Appendix_17022020.pdf?ua=1).

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. The trial is expected to commence imminently.

Synairgen's other current activities with COVID-19

Since the outbreak of COVID-19, Synairgen has been approached by, and is in discussion with, a number of other medical, scientific, and Governmental bodies (both in the UK, US and internationally) seeking to investigate novel therapeutics in this area.

Update on SNG001 Phase II trial in COPD

Synairgen is now close to completing a Phase II study in chronic obstructive pulmonary disease (COPD) patients with confirmed respiratory viral infections and pre-existing significant impairment of lung function. With 109 out of a target 120 participants already dosed, this trial has been paused to minimise the chance of vulnerable patients being exposed to further infection risk and to minimise distraction for respiratory staff in the UK hospitals and GP sites conducting the trial, who will be at the forefront in dealing with patients suffering from COVID-19. We are currently exploring ways to adapt the trial to enable patients in the pre-treatment pool to be dosed if they become infected with SARS-CoV-2.

Early data from this double-blind, placebo-controlled trial have demonstrated that the antiviral responses in the lung (assessed using sputum biomarkers) are similar to those observed in the asthma trial, where we saw clinical benefit in lung function.

Richard Marsden, CEO of Synairgen, commented: *"We have worked intensively with the relevant authorities and collaborators to enable SNG001 to be assessed in COVID-19 patients. SNG001 has been well tolerated in clinical trials in over 200 respiratory patients to date and has accelerated lung function recovery in two Phase II asthma trials in patients with a cold or flu infection. A successful outcome from this trial in COVID-19 patients would be a major breakthrough in the fight against this coronavirus pandemic."*

Professor Tom Wilkinson, Professor of Respiratory Medicine at the University of Southampton and Trial Chief Investigator, commented: *"We are facing an unprecedented health challenge with COVID-19 which desperately requires the rapid development of new therapeutic strategies. There are a limited number of candidate new treatments available and so it is vital we can rapidly generate high quality evidence on the role of these in COVID-19 patients. The UK research delivery and regulatory teams have worked incredibly effectively to enable this world leading trial to achieve approvals so rapidly which has enabled our motivated and highly expert team of researchers to get this vital study running straight away."*

Professor Stephen Holgate, Medical Research Council (MRC) Professor of Immunopharmacology, commented: *"The reduced innate immune response that exists in the lung of those at most risk of serious COVID-19 disease such as older people and those with pre-existing lung disease makes such patients ideal candidates to receive inhaled SNG001 to replace their interferon deficiency. This is especially so because SARS-CoV-2, along with MERS-CoV and SARS-CoV, is equipped to evade this first line of viral defence. In the absence of a suitable vaccine, increasing the host's own immunity to enhance protection and virus elimination would seem a logical therapeutic approach."*

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 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