

Synairgen announces positive results from trial of SNG001 in hospitalised COVID-19 patients

- ***Patients who received SNG001 had a 79% lower risk of developing severe disease compared to placebo***
- ***Patients who received SNG001 were more than twice as likely to recover from COVID-19 as those on placebo***
- ***A briefing for journalists will be held via webinar at 12:30 BST today***

Southampton, UK – 20 July 2020: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company which originated from research at the University of Southampton, is pleased to announce positive results from its clinical trial of SNG001, its wholly-owned inhaled formulation of interferon beta, in hospitalised COVID-19 patients.

Richard Marsden, CEO of Synairgen, said: *"We are all delighted with the trial results announced today, which showed that SNG001 greatly reduced the number of hospitalised COVID-19 patients who progressed from 'requiring oxygen' to 'requiring ventilation'. It also showed that patients who received SNG001 were at least twice as likely to recover to the point where their everyday activities were not compromised through having been infected by SARS-CoV-2. In addition, SNG001 has significantly reduced breathlessness, one of the main symptoms of severe COVID-19. This assessment of SNG001 in COVID-19 patients could signal a major breakthrough in the treatment of hospitalised COVID-19 patients. Our efforts are now focused on working with the regulators and other key groups to progress this potential COVID-19 treatment as rapidly as possible."*

The double-blind placebo-controlled trial recruited 101 patients from 9 specialist hospital sites in the UK during the period 30 March to 27 May 2020. Patient groups were evenly matched in terms of average age (56.5 years for placebo and 57.8 years for SNG001), comorbidities and average duration of COVID-19 symptoms prior to enrolment (9.8 days for placebo and 9.6 days for SNG001).

Key findings:

The odds of developing severe disease (e.g. requiring ventilation or resulting in death) during the treatment period (day 1 to day 16) were significantly reduced by 79% for patients receiving SNG001 compared to patients who received placebo (OR 0.21 [95% CI 0.04-0.97]; p=0.046).

Patients who received SNG001 were more than twice as likely to recover (defined as 'no limitation of activities' or 'no clinical or virological evidence of infection') over the course of the treatment period compared to those receiving placebo (HR 2.19 [95% CI 1.03-4.69]; p=0.043).

Over the treatment period, the measure of breathlessness was markedly reduced in patients who received SNG001 compared to those receiving placebo (p=0.007).

Three subjects (6%) died after being randomised to placebo. There were no deaths among subjects treated with SNG001.

In the patients with more severe disease at time of admission (i.e. requiring treatment with supplemental oxygen), SNG001 treatment increased the likelihood of hospital discharge during the study, although the difference was not statistically significant (HR 1.72 [95% CI 0.91-3.25]; p=0.096). Median time to discharge was 6 days for patients treated with SNG001 and 9 days for those receiving placebo. Furthermore, patients receiving SNG001 appeared to be more than twice as likely to have recovered by the end of the treatment period (HR 2.60 [95% CI 0.95-7.07]; p=0.062), although this strong trend did not reach statistical significance. However by day 28, patients receiving SNG001 treatment had statistically significantly better odds of recovery (OR 3.86 [95% CI 1.27-11.75]; p=0.017).

Interestingly, the efficacy analyses indicate there is no evidence of an association between the SNG001 positive treatment effects and prior duration of COVID-19 symptoms.

Further analysis will be conducted over the coming weeks and reported in due course.

Professor Tom Wilkinson, Professor of Respiratory Medicine at the University of Southampton and Trial Chief Investigator, commented: *"We are delighted with the positive data produced from this trial, which is the result of a momentous coordinated effort from Synairgen, the University of Southampton, University Hospital Southampton NHS Foundation Trust and the highly expert research teams across the NIHR network and regulatory bodies in the UK. The results confirm our belief that interferon beta, a widely known drug that, by injection, has been approved for use in a number of other indications, has huge potential as an inhaled drug to be able to restore the lung's immune response, enhancing protection, accelerating recovery and countering the impact of SARS-CoV-2 virus."*

Professor Stephen Holgate CBE, Medical Research Council Clinical Professor of Immunopharmacology at the University of Southampton and Co-Founder of Synairgen, said: *"Recognising that SARS-CoV-2 is known to have evolved to evade the initial antiviral response of the lung, our inhaled treatment of giving high local concentrations of interferon beta, a naturally occurring antiviral protein, restores the lung's ability to neutralise the virus, or any mutation of the virus or co-infection with another respiratory virus such as influenza or RSV, as could be encountered in the winter if there is a resurgence of COVID-19."*

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No. 596/2014 ('MAR').

Media briefing at 12:30 BST today

A briefing for journalists, hosted by Richard Marsden, Professor Tom Wilkinson and Professor Stephen Holgate, will be held at 12:30 BST today. A link to the webinar can be found here

<https://www.lsegissuerservices.com/spark/Synairgen/events/97cda0b9-0529-4be1-b1ca-471cc8dc1e94> and a conference call (for live Q&A) can be accessed via the following dial-in details:

UK Participant Local Dial-In Number: 020 3107 0289

US Participant International US-Toll Dial-In Number: (918) 922-6506

Conference ID: 6328984

If you have any difficulties accessing the webinar or call, please contact synairgen@consilium-comms.com.

The slides of the presentation will also be made available on Synairgen's website at <https://www.synairgen.com/investors/presentations/>. A recording of the call will be made available on Synairgen's website www.synairgen.com for up to 30 days.

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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

The COVID-19 study

Synairgen's clinical trial in COVID-19 patients (SG016) is a double-blind, placebo-controlled trial. The 220 patient trial comprised 100 patients initiated in hospital and 120 patients to be 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.

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 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.

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.