Press release

Synairgen plc

('Synairgen' or the 'Company')

COVID-19 Clinical Programme Update

- ***SNG001 given Fast Track designation and IND cleared by the US FDA***
- ***Phase III trial design adapted which will expedite results***
- ***Phase III trial to commence dosing in UK imminently***

Southampton, UK – 18 December 2020: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces updates to the Company's Phase III trial design evaluating SNG001 as a treatment for patients with COVID-19 and positive progress on the regulatory path.

Update to Phase III trial (SG018) protocol in COVID-19 patients
Following discussions with the regulatory agencies, the trial has been amended as follows:

- Removal of the lower dose arm, thereby reducing the number of patients required to complete the placebo-controlled trial from 900 patients to 610 patients
- Addition of a second primary endpoint. The primary endpoints are now 'time to hospital discharge' and 'time to recovery'. The primary assessment of efficacy will be supported by the key secondary endpoint of 'progression to severe disease or death' and other secondary endpoints. Both primary endpoints have at least 90% power to detect a statistically significant effect of SNG001 compared to placebo
- Addition of assessments for Long COVID-19 symptoms on day 60 and day 90

Initiation of the first SG018 sites has commenced in the UK, with dosing expected to commence imminently. The SG018 trial was deemed an Urgent Public Health study and recognised as a National Priority by the National Institute for Health Research (NIHR) in October 2020.

Investigational New Drug clearance and Expedited Regulatory Pathway granted from the FDA
Synairgen's Investigational New Drug (IND) application to the FDA to evaluate SNG001 as a treatment for patients with COVID-19, has been cleared, enabling Synairgen to initiate its SG018 trial in the US. Furthermore, the FDA has awarded SNG001 Fast Track status, enhancing the ability of Synairgen to interact with the FDA and shortening review timelines.

Update on the SG016 home trial in COVID-19 patients
This trial targets patients with a positive SARS-CoV-2 test result who are aged over 65 and those over the age of 50 with 'high risk' medical conditions. It is a trial designed to make it easy and safe for trial participants and researchers to conduct the research; all supplies for the trial are delivered directly to the patient's door by courier, and all trial visits and assessments are conducted virtually by video call. After a slow start in the summer, recruitment and dosing are now progressing well with a noticeable increase in the last two months. Those interested in participating in the trial can visit www.covidtrialathome.com.

Richard Marsden, CEO of Synairgen, said: *"With this adaptation we should be able to reduce the time taken to complete the trial, which, together with an expedited review from the FDA, could allow us to get this therapy approved for patient use in COVID-19 more rapidly. With trial sites now being set up, we anticipate dosing the first patients imminently. SNG001[1] is one of the few potential treatments to have shown efficacy against severe viral lung infections such as COVID-19, and multiple approaches will be needed to minimise the impact of this deadly virus.*

"There remains a great need to develop breakthrough treatments for patients who become ill with COVID-19, despite the recent successes from the vaccine developers. This is especially important if vaccine uptake is poor for any reason, or if any mutations in the SARS-CoV-2 virus render the vaccines less effective."

References

1. *The Lancet Respiratory Medicine*: *"Safety and efficacy of inhaled nebulised interferon beta-1a (SNG001) for treatment of SARS-CoV-2 infection: a randomised, double-blind, placebo-controlled, phase 2 trial". Monk, P D PhD, et al., 12 November 2020, accessible here*.

Information within this announcement is deemed by the Company to constitute inside information under the Market Abuse Regulation (EU) No. 596/2014

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Notes for Editors

About Synairgen

Synairgen is a respiratory drug discovery and development company founded by University of Southampton Professors Sir Stephen Holgate, Donna Davies and Ratko Djukanovic. The business, focused primarily on lung viral defence in asthma, COPD, and COVID-19, 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 https://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.

Synairgen is currently recruiting into a trial of SNG001 in COVID-19 patients (over the age of 65, or those over 50 with a pre-existing medical condition) in the home setting. For more information about the trial please visit www.covidtrialathome.com.

Interferon beta applicability to COVID-19

Interferon beta ('IFN-beta') is a naturally-occurring protein, which orchestrates the body's antiviral responses. There is growing 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, have evolved mechanisms which suppress endogenous IFN-beta production, helping the virus to evade the innate immune system. The addition of exogenous IFN-beta before or during viral infection of lung cells *in vitro* either prevents or greatly reduces viral replication. 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. Phase I and II trial data have shown that SNG001 activates lung antiviral defences as measured in sputum cells, and that SNG001 has been well tolerated in approximately 280 asthma/COPD/COVID-19 patients to-date.