**Press release**

# Synairgen plc

**('Synairgen' or the 'Company')**

## Synairgen announces commencement of dosing in its international Phase III study of inhaled interferon beta in hospitalised COVID-19 patients

Southampton, UK – 13 January 2021: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces that the first patient has been dosed in the UK as part of its global Phase III trial (SG018) evaluating Synairgen's inhaled formulation of interferon beta-1a (SNG001), for the treatment of hospitalised COVID-19 patients.

As previously announced, Synairgen has appointed Parexel Biotech, a division of the leading global clinical research organisation, Parexel, to help conduct the Phase III trial and several UK sites have now been initiated, with further sites in the US and the EU expected to follow. The trial is deemed an Urgent Public Health study by the UK's National Institute for Health Research (NIHR). In the US, SNG001 has been granted Fast Track status from the US Food and Drug Administration (FDA). The Company is seeking further equivalent prioritisations and support from governments in participating countries.

Synairgen's SG018 trial is a randomised placebo-controlled study being conducted in approximately 20 countries enrolling a total of 610 COVID-19 patients who require supplemental oxygen. After reporting the results for the primary and key secondary endpoints of the study, enrolled patients will continue to be assessed for long-COVID-19 symptoms.

**Richard Marsden, CEO of Synairgen, commented:** *"We need treatments as well as vaccines to fight highly pathogenic viruses such as SARS-CoV-2. Development of treatments like ours will remain necessary in cases where vaccines are not effective, for those who do not get vaccinated, and in case the virus mutates to the point where vaccines become less effective. We believe this trial presents an opportunity for a significant UK scientific breakthrough and, if given the right support, our drug could rapidly assist with the global crisis."*

Synairgen is also running an ongoing Phase II trial of inhaled interferon beta in non-hospitalised 'at risk' patients, (SG016), that is progressing rapidly. For more information and to take part, visit www.covidtrialathome.com.

This announcement contains inside information as contained in Article 7 of the Market Abuse Regulation No. 596/2014 ('MAR').

**-ENDS-**

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## Notes for Editors

### About Synairgen

Synairgen is a clinical-stage respiratory drug discovery and development company founded by University of Southampton Professors Sir Stephen Holgate, Donna Davies and Ratko Djukanovic. Synairgen is currently fully focused on progressing its inhaled interferon beta broad spectrum antiviral drug as an effective treatment for people suffering with COVID-19 infection.

Synairgen's differentiating human biology BioBank platform and world-renowned international academic KOL network has broader applicability for lung viral defence in other respiratory disorders including asthma and COPD. Synairgen is quoted on AIM (LSE: SNG). For more information about Synairgen, please see www.synairgen.com

### SNG001 (inhaled Interferon beta) applicability to COVID-19

Interferon beta ('IFN-beta') is a naturally-occurring protein, which orchestrates the body's antiviral responses. It is used widely in the treatment of multiple sclerosis and is a safe and well tolerated drug. 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, potentially reducing the severity of infection and accelerating recovery. 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.

In July 2020, Synairgen announced the results of its Phase II double-blind, placebo-controlled study of 101 randomised COVID-19 hospitalised patients, which showed that SNG001 given for 14 days was associated with greater odds of improvement versus placebo on the WHO Ordinal Scale for Clinical Improvement and more rapid recovery to the point where patients were no longer limited in their activity, with a greater proportion of patients recovering during the 28-day study period.

The results were published in 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.