Press release

Synairgen plc

('Synairgen' or the 'Company')

Data from SG016 Phase II Clinical Trial published in Lancet Respiratory Medicine

- ***Data published in the peer-reviewed journal shows positive results for SNG001 in hospitalised COVID-19 patients***

Southampton, UK – 13 November 2020: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces the publication of data from the Company's SG016 trial in *The Lancet Respiratory Medicine* journal. The SG016 trial randomised 101 hospitalised COVID-19 patients to either SNG001, Synairgen's inhaled formulation of interferon beta-1a, or placebo. Positive topline results from the trial were originally announced on 20 July 2020, with more detailed results of primary endpoint analyses disclosed in the Company's 2020 Interim Results on 29 September 2020.

The double-blind, randomised, placebo-controlled trial assessed the efficacy and safety of inhaled SNG001 as a therapy for patients hospitalised with COVID-19. Patients were randomised (1:1) to receive SNG001 or placebo by inhalation via a mouthpiece once daily for 14 days. The primary endpoint was the change in clinical condition using the WHO Ordinal Scale for Clinical Improvement (OSCI) during the dosing period in the intention-to-treat population (ITT).

SNG001 was shown to be well tolerated and patients who received the drug had greater odds of improvement and recovered more rapidly. Patients receiving SNG001 had greater odds of improvement across the OSCI scale (OR 2·32; 95% CI: 1·07, 5·04; p=0·033) and were more likely to recover to "no limitation of activity" during treatment (HR 2·19; 95% CI: 1·03, 4·69; p=0·043). There were three deaths in the placebo group and none in the SNG001 group.

The full title of the publication is: *"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"*, and can be accessed here.

Professor Tom Wilkinson, Professor of Respiratory Medicine at the University of Southampton and Lead Author, said: "*The results confirm our belief that interferon beta, a widely known drug approved for use in its injectable form for other indications, may have the potential as an inhaled drug to restore the lung's immune response and accelerate recovery from COVID-19. This pH neutral, inhaled interferon beta-1a formulation (SNG001) provides high, local concentrations of the immune protein which boosts lung defences rather than targeting specific viral mechanisms. This might carry additional advantages of treating COVID-19 when it occurs alongside infection by another respiratory virus such as influenza or Respiratory Syncytial Virus that may well be encountered in the winter months."*

For further enquiries, please contact:

Synairgen plc
Richard Marsden, Chief Executive Officer
John Ward, Finance Director
Tel: + 44 (0) 23 8051 2800

finnCap
Geoff Nash, Kate Bannatyne, Charlie Beeson (Corporate Finance)
Alice Lane, Sunila de Silva (ECM)
Tel: + 44 (0) 20 7220 0500

Numis Securities Limited (Joint Broker)
James Black, Freddie Barnfield

Tel: +44 (0) 20 7260 1000

Consilium Strategic Communications (Financial Media and Investor Relations)
Mary-Jane Elliott, Sue Stuart, Olivia Manser
synairgen@consilium-comms.com
Tel: +44 (0) 20 3709 5700

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 comorbidity) 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.