Press release

Synairgen plc
('Synairgen' or the 'Company')

Synairgen announces that dosing has commenced with its inhaled interferon beta product in US Government-funded NIH ACTIV-2 trial in COVID-19 outpatients

Southampton, UK – 15 February 2021: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces that dosing has begun in the inhaled interferon beta formulation (SNG001) sub-study of the ACTIV-2 Phase II/III trial, evaluating patients with mild to moderate COVID-19 symptoms not yet requiring hospitalisation.

Richard Marsden, CEO of Synairgen, said: *"We are delighted that our inhaled interferon beta formulation has been entered into this US Government-funded Phase II/III study and that dosing has now commenced. With mutations of COVID-19 now emerging, and the concern that mutations may render the vaccines less effective, the need for broad spectrum treatment options remains very high. Our product is a potentially effective treatment as it is a virus agnostic and, we believe, strain agnostic antiviral, which is easy to use in the hospital or home setting. We look forward to tracking the progress of the ACTIV-2 trial alongside our other COVID-19 trials."*

As announced by Synairgen on 25 January 2021, ACTIV is a public-private partnership to develop a coordinated research strategy to speed up the development of the most promising COVID-19 treatments and vaccines. ACTIV-2 is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), one of the National Institutes of Health, and is led by the NIAID-funded AIDS Clinical Trials Group (ACTG).

If an investigational agent shows promise by demonstrating safety and reducing COVD-19 symptoms through 28 days following administration, the ACTIV-2 trial is designed to expand seamlessly from a Phase II to a Phase III study to gather additional critical data from a larger pool of volunteers without delay. Phase II sub-studies enrol up to 220 volunteers, while exact enrolment size of Phase III sub-studies will vary depending on mode of administration of the investigational agent. The adaptive nature of the ACTIV-2 trial allows for comparison of multiple interventions with a shared group of placebo recipients. In addition to safety and symptomatic efficacy signals, the sub-studies in ACTIV-2 assess whether an investigational agent can reduce the amount of SARS-CoV-2 virus detectable in the nasopharynx.

For more information on the ACTIV-2 study, please visit www.riseabovecovid.org, or visit ClinicalTrials.gov and search identifier NCT04518410.

Synairgen is also running an international 610 patient Phase III trial, which is progressing well, assessing the efficacy of inhaled interferon beta in hospitalised patients with COVID-19. The Company also recently completed recruitment of a 120 'at-risk' COVID-19 patients study evaluating SNG001 as a treatment for use in the home setting, results are expected on track in Q2 2021.

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 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 beta1a 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

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 and diabetes are at greatest risk of developing severe or fatal disease.

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 systemically for 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 especially SARS-CoV-2, have evolved multiple mechanisms for suppressing endogenous IFN-beta production in the lung thereby 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 to reduce the severity of infection and accelerate recovery. Recognising the importance of achieving high concentrations in the lung where SARS-CoV-2 exerts most of its tissue damaging effects, 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 et al., 12 November 2020, accessible here: https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30511-7/fulltext.