

Press Release

Synairgen plc (‘Synairgen’ or the ‘Company’)

Synairgen completes recruitment in its international Phase 3 SPRINTER study of SNG001 in hospitalised COVID-19 patients

- **Target of 610 patients from 17 countries achieved**
- **Synairgen remains on track for top line results early in 2022**

Southampton, UK – 11 November 2021: Synairgen plc (LSE: SNG), the respiratory company developing SNG001, a formulation for inhalation containing the broad-spectrum anti-viral protein interferon beta (IFN-beta) for the treatment of severe viral lung infections, today announces that it has achieved its recruitment target of 610 randomised patients for its global Phase 3 SPRINTER trial (SG018) evaluating SNG001 for the treatment of hospitalised COVID-19 patients.

Synairgen’s SG018 Phase 3 trial is a randomised, double-blind, placebo-controlled study being conducted in 17 countries. Once the final patients have completed the initial 35-day trial period, quality assurance and statistical analysis will be completed. Accordingly, as communicated previously, top line data from the trial is expected in early 2022 and, conditional upon a successful Phase 3 readout, the Company is preparing for the filing of an Emergency Use Authorisation (EUA) in the US for patients requiring hospitalisation due to COVID-19.

Richard Marsden, CEO of Synairgen, said: *“Even with extensive vaccine programmes, in the US alone, thousands of patients a day are still being hospitalised due to serious COVID-19 symptoms. Doctors have highlighted the urgent need for more treatment options for these patients. We believe that SNG001, our investigational inhaled formulation of interferon beta, a naturally-occurring, broad-spectrum antiviral protein, could offer a compelling new treatment option. With the trial having achieved its randomisation target we look forward to announcing top line data early in 2022.”*

Tom Wilkinson, Professor of Respiratory Medicine, University of Southampton, and SPRINTER Trial Chief Investigator, said: *“Over the past year, based on a growing body of clinical data, we have become even more confident that inhaled interferon beta may have an important role in helping hospitalised patients recover from COVID-19. Today’s milestone brings us one step closer to evaluating the potential of SNG001 as an innovative, new therapy for hospitalised COVID-19 patients, something that is urgently needed.”*

Monica Kraft, Professor, Medicine Chair, Department of Medicine, University of Arizona, and SPRINTER Trial Investigator, said: *“Reaching full recruitment across a global trial, with all the complexities that COVID-19 has brought, is a huge achievement. Finding effective COVID-19 therapies still remains a pressing unmet need and I’m therefore grateful to all the participants who have been involved in this important trial. I look forward to the readout of results in the near future.”*

The recent graduation last month of SNG001 into Phase 3 of the US National Institutes of Health-sponsored ACTIV-2 trial also supports its potential in the non-hospital setting. SG018 has been granted Fast Track status from the US Food and Drug Administration (FDA) and was classified as an Urgent Public Health study by the UK’s National Institute for Health Research (NIHR).

Synairgen will continue to work on the SPRINTER study with Parexel Biotech, a division of the leading global clinical research organisation, Parexel. Day 35 data will be reported in the first instance followed by the long COVID results which will be collected until Day 90.

IFN-beta is a naturally-occurring protein which orchestrates the body’s antiviral responses. It is a well-tolerated drug and there is growing evidence that deficiency in IFN-beta production in the lungs could

put vulnerable patient groups at risk of developing severe lower respiratory tract disease during respiratory viral infections.

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

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Notes for Editors

About Synairgen

Synairgen is a UK-based respiratory company focused on drug discovery, development and commercialisation. The Company's primary focus is developing SNG001 (inhaled interferon beta) for the treatment of COVID-19 as potentially the first host-targeted broad-spectrum antiviral treatment delivered directly into the lungs. Granted Fast Track status from the US Food and Drug Administration (FDA) and deemed an Urgent Public Health study by the UK's National Institute for Health Research (NIHR), Synairgen's Phase III clinical programme is currently evaluating nebulised SNG001 in patients across 17 countries. In a Phase II trial in hospitalised COVID-19 patients, SNG001 demonstrated a greater than twofold chance of recovery to 'no limitation of activities' versus placebo.¹

Founded by University of Southampton Professors Sir Stephen Holgate, Donna Davies and Ratko Djukanovic in 2003, Synairgen is quoted on AIM (LSE: SNG). For more information about Synairgen, please see www.synairgen.com.

¹[https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(20\)30511-7/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30511-7/fulltext)