

### Synairgen plc

('Synairgen' or the 'Company')

# Results from SPRINTER Phase 3 trial published in the European Respiratory Journal Open Research

**Southampton, UK** – 23 December 2022: Synairgen plc (LSE: SNG), the respiratory company developing SNG001, an investigational formulation for inhalation containing the broad-spectrum antiviral protein interferon beta, today announces the online publication of data from its Phase 3 SPRINTER trial in the peer reviewed *European Respiratory Journal Open Research (ERJOR)*.

Topline results from this global, double-blind, placebo-controlled trial were first shared in February 2022, with the data analysis presented at the American Thoracic Society International Conference in San Francisco in May 2022.

While the SPRINTER trial did not meet the primary endpoints of discharge from the hospital and recovery, there was an encouraging signal in reduction in the relative risk (RRR) of progression to severe disease or death within 35 days (25.7% reduction in the Intention-to-Treat population and 36.0% reduction in the Per Protocol population). SNG001 was well tolerated as has been seen in previous clinical trials.

The full title of the online publication is: "Nebulised interferon beta-1a (SNG001) in hospitalised COVID-19: SPRINTER Phase III Study" and can be accessed <u>here</u>.

**Phillip Monk, CSO of Synairgen and Lead Author, said**: "The results from the SG016<sup>1</sup> Phase 2 and the SPRINTER trial of SNG001 in hospitalised patients, and the ACTIV-2 trial in the home setting suggest that SNG001 may be preventing progression to severe disease. With these data we remain confident in the potential of SNG001 as a broad-spectrum antiviral for high-risk patient populations infected with respiratory viruses including influenza and RSV and are focused on its continued clinical development."

SNG001 is not approved for use anywhere in the world.

<sup>&</sup>lt;sup>1</sup> Protocol No. SG016; <u>NCT04385095</u>

## synairgen

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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 severe viral lung infections, including COVID-19, as potentially the first host-targeted, broad-spectrum antiviral treatment delivered directly into the lungs. SNG001 has been granted Fast Track status from the US Food and Drug Administration (FDA). 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.

### About SPRINTER (SG018) trial

The SPRINTER trial (SG018; NCT04732949) was a global Phase 3, randomised, placebo-controlled, double-blind, clinical trial assessing the efficacy and safety of inhaled SNG001 on top of standard of care for the treatment of adults



hospitalised due to COVID-19 requiring treatment with supplemental oxygen by mask or nasal prongs. Patients requiring high-flow nasal oxygen therapy, non-invasive ventilation, or endotracheal intubation (invasive ventilation) at randomisation were excluded. COVID-19 was confirmed using a validated molecular test for the presence of the SARS-CoV-2 virus.

### About SNG001

SNG001 is a pH-neutral formulation of interferon-beta (IFN-beta) for inhalation that is delivered directly into the lungs using a mesh nebuliser, which the Company is developing as a potential host-directed antiviral treatment for patients hospitalised with severe viral lung infections, including COVID-19. SNG001 has broad potential applicability for patients hospitalised with respiratory symptoms due to viral infections such as SARS-CoV-2, influenza, respiratory syncytial virus (RSV), adenovirus, para-influenza and rhinoviruses.

Viruses have been shown to suppress the production of IFN-beta, a naturally occurring protein that orchestrates the body's antiviral defences, with the aim of evading host immune responses. By administering IFN-beta into the lungs, the aim is to correct this deficiency, potentially switching back on the lungs' antiviral pathways to clear the virus. SNG001 has been shown to demonstrate potent in vitro antiviral activity against a broad range of viruses at concentrations that are achievable following inhaled delivery of SNG001 including RSV, rhinovirus, various influenza strains including H5N1, MERS-CoV and SARS-CoV-2 including Alpha, Beta, Gamma, Delta and Omicron variants of concern.