

## For Media and Investors

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### Synairgen plc

('Synairgen' or the 'Company')

### Synairgen presents detailed analysis of Phase 3 SPRINTER trial evaluating SNG001 in hospitalised COVID-19 patients at ATS 2022

- *Post hoc* analyses conducted in patient populations at greater risk of progression to severe disease or death suggests that SNG001 may have an important clinical effect on top of standard of care
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**Southampton, UK** – 16 May 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 first presentation of the full data analysis from its Phase 3 SPRINTER trial evaluating the efficacy and safety of SNG001 in patients hospitalised with COVID-19.

SPRINTER (SG018; NCT04732949) was a global, randomised, placebo-controlled, double-blind clinical trial assessing the efficacy and safety of inhaled SNG001 for the treatment of adults hospitalised due to COVID-19 who required treatment with supplemental oxygen. The trial recruited a total of 623 patients who were randomised to receive SNG001 (n=309) or placebo (n=314) on top of standard of care (SOC).

The data from this pivotal trial will be presented today at the Clinical Trials Symposium of the American Thoracic Society 2022 (ATS 2022) International Conference, being held in San Francisco, California from 13-18 May 2022. A separate poster presentation is scheduled for 17 May 2022.

Synairgen announced in February 2022 that the Phase 3 SPRINTER trial did not meet the primary endpoints of discharge from hospital and recovery. There was, however, an encouraging signal in reduction in the relative risk (RRR) of progression to severe disease or death within 35 days (25.7%<sup>1</sup> reduction in the Intention-to-Treat population and 36.3% reduction in the Per Protocol population).<sup>2</sup>

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<sup>1</sup> This was reported as 27.1% in the topline analysis in February 2022 but changed between 35- and 90-day database lock.

<sup>2</sup> The main reason patients were excluded from the Per Protocol population was failure to receive two full doses in the first three days of treatment.

To assess the strength of this signal and identify specific patient populations that might benefit most from treatment, *post hoc* analyses were performed on groups of patients recognised to be at greater risk of developing severe disease in hospital. These analyses included patients  $\geq 65$  years old, those with co-morbidities associated with worse COVID-19 outcomes, and those who, at baseline, despite receiving low flow oxygen, had clinical signs of compromised respiratory function (defined as oxygen saturation of  $\leq 92\%$  or respiratory rate  $\geq 21$  breaths/min).

These analyses showed stronger treatment effects with SNG001 in these high-risk patient sub-groups, with the strongest effect observed in those who had clinical signs of compromised respiratory function. In these patients, who represented approximately one-third of the SPRINTER trial population, SNG001 significantly reduced the risk of progression to severe disease and death compared to placebo by 70% in the Per Protocol population (Odds Ratio (95% Confidence Interval) 0.23 (0.06, 0.98);  $p=0.046$ ).

SNG001 was well tolerated in the SPRINTER trial with a favourable safety profile consistent with previous studies:

- The proportion of patients with any treatment-emergent adverse events (TEAE) related to study treatment was 22.6% for SNG001 vs. 25.4% for placebo.
- The proportion of patients with any serious TEAE was 12.6% for SNG001 vs. 18.2% for placebo.
- The proportion of patients with a serious respiratory<sup>3</sup> TEAE was 4.7% for SNG001 vs. 9.9% for placebo.

**Phillip Monk, Ph.D., Chief Scientific Officer of Synairgen, said:** “The *post hoc* analyses presented at the ATS conference today suggest that SNG001 may be having a beneficial effect with respect to prevention of severe disease or death. These results provide a strong clinical rationale to continue to investigate SNG001 in a trial evaluating progression and/or mortality in hospitalised patients with COVID-19 and more widely in patients with severe viral lung infections.”

**Tom Wilkinson, Chief Investigator of the SPRINTER trial and Professor of Respiratory Medicine, University of Southampton, said:** “The improvement in standard of care for COVID-19 means that most patients are currently discharged fairly rapidly from hospital; however, this further analysis shows that some patients struggle in their battle with the virus and show signs of respiratory compromise, with faster breathing rates and lower oxygen saturations, despite being on oxygen. For these higher-risk patients, there remains an urgent need for new treatment options, and this analysis suggests that SNG001 could be a potentially efficacious treatment option for them.”

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<sup>3</sup> Respiratory, thoracic and mediastinal system organ class

The full analysis of the Phase 3 SPRINTER trial data will be submitted for publication in a peer-reviewed journal. A company recording of the ATS presentation will be available on the Synairgen website by 12:00 Pacific Daylight Time/20:00 British Summer Time today, and for ATS members, the symposium recording will be available on the ATS website.

SNG001 is not approved for use anywhere in the world.

For further information on the ATS International Conference visit: <https://conference.thoracic.org/>

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 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 (SOC) 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, currently being investigated as a potential host-directed antiviral treatment for patients hospitalised with COVID-19. SNG001 has broad potential applicability for patients hospitalised with respiratory symptoms due to viral infections such as influenza, Respiratory Syncytial Virus (RSV) and para-influenza.

The SARS-CoV-2 virus has 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 including SARS-CoV-2 and Alpha, Beta, Gamma, Delta and Omicron variants.

## **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](http://www.synairgen.com).