Synairgen and Clinigen sign Managed Access Program agreement with SNG001 for treatment of hospitalised patients with COVID-19

Southampton and Burton-on-Trent, UK – 29 September, 2020: Synairgen plc (AIM: SNG, 'Synairgen'), the respiratory drug discovery and development company and Clinigen Group plc (AIM: CLIN, 'Clinigen'), the global pharmaceutical and services company, have signed an agreement to launch a Managed Access Program for Synairgen's inhaled formulation of interferon beta (IFN-beta), SNG001, in the UK and the EU for the treatment of hospitalised COVID-19 patients.

SNG001 is an inhaled formulation of IFN-beta for direct delivery to the lungs via nebulisation. Synairgen announced positive topline data generated from 101 patients hospitalised with COVID-19 in its phase II trial, SG016, on the 20 July 2020. The trial of SNG001 in hospitalised patients produced very encouraging findings; patients who received SNG001 were more than twice as likely to recover over the course of the treatment period compared to those receiving placebo. Synairgen is currently in discussions with regulatory agencies to progress this potential COVID-19 treatment.

Richard Marsden, Chief Executive Officer of Synairgen, commented: *"We are working tirelessly to progress SNG001 through the required clinical and regulatory channels to make this potentially critical treatment widely available to COVID-19 patients around the world. In the meantime, we are delighted to partner with Clinigen, whose extensive European experience and regulatory expertise will support access to treatment with SNG001 for hospitalised patients who most urgently need it."*

Shaun Chilton, Clinigen Chief Executive Officer, added: *"We are working with a number of companies who have products being tested against COVID-19 and are very pleased to be working with Synairgen to make this highly promising COVID-19 treatment available internationally. The early study results demonstrate that SNG001 may have a vital role in helping hospitalised patients recover more quickly from the disease."*

Healthcare professionals in the EU can obtain details about the SNG001 Managed Access Program by calling the customer service team at +44 (0) 1283 494 340 or emailing medicineaccess@clinigengroup.com.

Patients seeking information should contact their physician.

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

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Notes to Editors

About Synairgen
Synairgen is a respiratory drug discovery and development company founded by University of Southampton Professors 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 www.synairgen.com

About Clinigen Group
Clinigen Group plc (AIM: CLIN) is a global pharmaceutical and services company with a unique combination of businesses focused on providing ethical access to medicines. Its mission is to deliver the right medicine to the right patient at the right time through three areas of global medicine supply; clinical trial, unlicensed and licensed medicines. The Group has sites in North America, Europe, Africa and Asia Pacific.

Clinigen now has over 1,100 employees across five continents in 14 countries, with supply and distribution hubs and operational centres of excellence in key long-term growth regions. The Group works with 22 of the top 25 pharmaceutical companies; interacting with over 15,000 registered users across over 100 countries, shipping approximately 6.4 million units in the year.

For more information on Clinigen, please visit www.clinigengroup.com

The COVID-19 study
Synairgen's clinical trial in COVID-19 patients (SG016) is a double-blind, placebo-controlled trial. The 221 patient trial comprised 101 patients initiated in hospital and 120 patients to be initiated in the home setting. The patients participating in the hospital setting, which completed recruitment in May, were recruited across a number of NHS trusts and the trial was adopted by the NIHR Respiratory Translational Research Collaboration, which is comprised of leading centres in respiratory medicine in the UK, whose internationally recognised experts are working together to accelerate development and discovery for COVID-19.

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.

Interferon beta (IFN-beta) potential applicability to COVID-19

Interferon beta is a naturally occurring protein, which orchestrates the body's antiviral responses. There is 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 and MERS-CoV, have evolved mechanisms which suppress endogenous IFN-beta production, thereby helping the virus 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.

Two Phase II clinical trials in asthma showed that inhaled SNG001 treatment activated antiviral pathways in the lung, along with improving lung function in patients with a respiratory viral infection.