Synairgen meets a development milestone with the commencement of dosing in hospitalised COVID-19 patients in its international Phase III trial of inhaled interferon beta

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tranScrip is delighted with the initiation of dosing in Synairgen's international Phase III trial (SG018) of inhaled interferon beta in hospitalised COVID-19 patients. tranScrip has provided a range of specialist support services to Synairgen for over 10 years and has been involved in the COVID-19 programme since the beginning.

The trial is anticipated to be completed by early summer and, subject to positive results, authorisation of the drug to be used in patients in the UK and other countries would be expected to follow shortly afterwards.

Richard Marsden, CEO of Synairgen, commented: *"We need treatments as well as vaccines to fight highly pathogenic viruses such as SARS-CoV-2. Development of treatments like ours will remain necessary in cases where vaccines are not effective, for those who do not get vaccinated, and in case the virus mutates to the point where vaccines become less effective. We believe this trial presents an opportunity for a significant UK scientific breakthrough and, if given the right support, our drug could rapidly assist with the global crisis."*

Dr Marcin Mankowski, Deputy Managing Partner of tranScrip, commented: *"Synairgen has been a long-standing client of tranScrip and we are delighted to see that the COVID-19 programme which our team has been actively involved in has progressed to the pivotal stage. Our experienced medical, PV and regulatory teams will continue to support Synairgen during this critical stage of development of the product and hope to bring this much needed medicine to the patients in need as soon as possible."*

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Notes for Editors

About tranScrip

tranScrip is an innovative UK based provider of specialist professional services, supporting the drug development and lifecycle management activities of pharmaceutical and biotechnology companies. The Business deploys multi-disciplinary project teams to deliver both strategic leadership and operational support to clients covering strategic development, medical, regulatory, drug safety and commercial services across a multitude of therapy areas.

tranScrip's approach benefits clients by maximising opportunities, reducing risk and creating value which continues to result in high quality, long-term relationships, with contracts often lasting many years. Synairgen is one of a number of tranScrip's clients with COVID 19 programmes.

The COVID-19 trial

Synairgen's clinical trial in COVID-19 patients (SG018) is a randomised placebo-controlled trial being conducted in approximately 20 countries enrolling a total of 610 COVID-19 patients who require supplemental oxygen. After reporting the results for the primary and key secondary endpoints of the trial, enrolled patients will continue to be assessed for long-COVID-19 symptoms.

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) 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 either prevents or greatly diminishes cell damage and viral replication, respectively. 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.

Reference:

Synairgen plc Press Release
BBC News