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## Synairgen doses first patients with COVID-19 drug



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UK biotech Synairgen has started dosing patients in its phase 2 trial of SNG001, an inhaled formulation of interferon beta-1a that aims to treat coronavirus infections.

The drug is already widely used in an injectable form for multiple sclerosis, and Synairgen has already tested its inhaled version in clinical trials involving more than 200 asthma patients with a cold or flu infection, showing improvements in lung function.

The Southampton-based company says the first patient with COVID-19 has now been given SNG001 at the University Hospital Southampton NHS Foundation Trust, with another six trial sites due to start dosing additional subjects in the next few days.

Last week, Synairgen raised £14 million (around \$17 million) in an oversubscribed funding round to pay for the SNG001 trial, shortly after getting a green light for the study from the UK Medicines and Healthcare products Regulatory Agency (MHRA) and Health Research Authority (HRA).

Interferon beta orchestrates the body's response to a viral infection, and there is some evidence to suggest that people who get dangerously sick after being infected with SARS-CoV-2 – the virus that causes COVID-19 – have lower than usual levels of interferon beta in the lungs.

Synairgen also says viruses – including coronaviruses such as SARS-CoV-2 and MERS-CoV – have evolved mechanisms which suppress the production of interferon beta in the body, helping them evade the immune system.

If its hypothesis is correct, giving SNG001 via a nebuliser into the lungs could reduce viral replication and cell damage, hastening patients' recovery from the infection. That's backed up by animal data showing reduced lung viral load and lung pathology in a swine flu model of viral pneumonia.

The trial is being led by Professor Tom Wilkinson, a consultant in respiratory medicine at University Hospital Southampton and professor of respiratory medicine at the University of Southampton.

Investigators aim to enroll 100 patients in the pilot phase, expected to last about two months, and expand the study population if initial results are encouraging. The hope is that the drug could be made swiftly available, for example under emergency use measures, if SNG001 proves to be effective.

There is of course still a long way to go before that point however, and questions remain about how quickly production could be scaled up to meet demand as confirmed cases of COVID-19 hit almost 800,000 worldwide, including more than 22,100 in the UK.

"A successful outcome from this trial in COVID-19 patients would be a very important step towards a major breakthrough in the fight against this coronavirus pandemic," said Richard Marsden, Synairgen's chief executive.

The company is also close to completing a 120-patient phase 2 trial of SNG001 in chronic obstructive pulmonary disease (COPD) patients with viral infections, with 109 patients enrolled, but further recruitment has been put on hold during the pandemic to minimise the chance of vulnerable patients being exposed to COVID-19.

The start of the trial was welcomed by BioIndustry Association CEO Steve Bates, who said: "The UK life science ecosystem is stepping up across the piece on coronavirus."

He went on: "This shows the speed at which our ecosystem can move; linking SMEs, the established UK clinical trials infrastructure of the NHS and

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an enabling regulator in the UK's MHRA."

"The sector is also working flat out on innovative emergent ventilator capacity, novel vaccine scale-up capacity, new ways to support NHS patients at home with digital products and investigating antibody technology for therapeutic use."

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