

Positive results trial for new asthma treatment

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Scientists from the University of Southampton and Synairgen, a respiratory drug development company spun out from the University, can announce positive data from its Phase II clinical trial, into the effectiveness of the drug SNG001 (inhaled interferon beta) for asthma patients.

This pioneering trial investigated the potential for SNG001 to protect [asthmatics](#) from [respiratory virus](#) infections, principally the common cold, that can spread to the lung, which are a major cause of worsening [asthma](#) symptoms.

There are 5.4 million asthmatics in the UK (Asthma UK) and 25.7 million in the USA (Centers for Disease Control and Prevention) and it is estimated that viral infection is associated with up to eight out of ten asthma-related emergency department visits.

The study, which took place at 20 sites, investigated SNG001 in 134 adult [asthma patients](#), representing 'mild-moderate' through to 'severe' asthmatics, who caught a cold. Patients with 'difficult to treat' asthma - approximately half of the patients in the trial - benefitted significantly from SNG001 treatment. This category of patient is estimated to represent between 10% and 20% of all adult asthma sufferers.

Results showed that SNG001 prevented asthma symptoms from getting worse during the first week of infection and treatment. There was a 65% reduction in the number of patients experiencing moderate exacerbations

during the treatment period and patients who were treated with the placebo had greater loss in lung function, as measured by morning peak expiratory flow rate (a measure of lung function).

Professor Stephen Holgate CBE, leading international asthma specialist at the University of Southampton and founder of Synairgen, says: "This is a really promising breakthrough for the future treatment of asthma and one of the most exciting developments that I have seen in years. This is the first clinical study which appears to demonstrate that, by boosting the antiviral defences of the lungs of asthmatics rather than trying to inhibit rapidly evolving viruses, we can limit the adverse effects of viral infection significantly to prevent worsening of asthma symptoms in a high risk group of patients.

"This trial is an important milestone in the development of our SNG001 programme from its origins in research supported by the MRC, Asthma UK, the British Lung Foundation, the National Institute of Health Research and the University of Southampton, to today's exciting results in this 'real world' asthma study. Not only have we established the potential of SNG001 as a novel treatment for viral [exacerbations](#) in difficult to treat asthma but also a crucial link between viral infection, [asthma symptoms](#) and severity of disease.

"These impressive findings across different endpoints, together with the accumulating body of evidence we have generated for other respiratory viruses such as influenza (Swine and Bird flu) and respiratory syncytial virus (RSV), strongly suggest that SNG001 has the potential to be used as a powerful broad spectrum antiviral respiratory drug in lung diseases such as COPD and pandemic flu."

Professor Ratko Djukanovic, a clinical respiratory specialist at the University of Southampton and University Hospital Southampton NHS Foundation Trust and Director of the Southampton Respiratory

Biomedical Research Unit, was the Chief Investigator of the trial. He comments: "This trial, conducted by several UK academic respiratory experts, provides the first evidence of an effective anti-viral drug that can boost the asthmatic patient's immune system to fight viruses and thus significantly reduce the impact of [virus infections](#) on asthma control. Scientists at the University of Southampton, who made the discovery of innate immune deficiency in asthma, have long suspected that the need to correct the deficiency is greatest in patients with severe asthma: we now have compelling evidence that this is the case."

Richard Marsden, Chief Executive of Synairgen, adds: "This is a great result for the development of our programme. To put SNG001's potential into context, it is estimated that in the US alone there are some 2 to 4 million difficult to treat (Step 4 and 5) adult asthma sufferers who could benefit from this therapy. Children, who get more colds than adults, represent an additional asthma market opportunity. We believe that there will be even greater potential in COPD. We continue to analyse the wealth of data generated by this important trial and to plan the next phase of its development, ideally alongside an industry partner."

Leanne Metcalf, Assistant Director of Research at Asthma UK, says: "This has the potential to be one of the biggest breakthroughs in asthma treatments in the past 20 years. We are incredibly excited by the possibilities this research could bring to reduce hospital admissions and deaths as a result of asthma attacks. Over 80% of asthma attacks are triggered by cold and flu viruses, and until now we haven't had any effective treatments that can stop this from happening. This clinical trial demonstrates the potential of this anti-viral drug to prevent asthma attacks for thousands of people with severe asthma. We are incredibly proud to have played a part in the realisation of this research programme which should benefit people with asthma in a really significant way."

Provided by University of Southampton

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