

Press release

Synairgen plc (‘Synairgen’ or the ‘Company’)

Synairgen announces successful outcome of Phase I safety and antiviral ‘proof of mechanism’ biomarker study of inhaled interferon beta in asthmatic subjects

Southampton, UK – 12 November 2009: Synairgen plc (LSE: SNG), the respiratory company with a particular focus on viral defence in asthma and chronic obstructive pulmonary disease (‘COPD’), announces the successful outcome of its second Phase I clinical study (SG004) for inhaled interferon beta (‘IFN-beta’), which the Company is developing for the treatment of viral infection in asthma and COPD sufferers.

The aims of the study were to assess the safety of inhaled IFN-beta in the target population and to establish that it activates antiviral defences in the lungs of asthmatics.

Safety data

In SG004, conducted jointly by Synairgen in Southampton and The Medicines Evaluation Unit in Manchester, 40 moderate asthmatics received a range of doses of inhaled IFN-beta or placebo over a period of up to two weeks.

Inhaled IFN-beta was well-tolerated, causing no adverse effect on standard measures of lung function and inflammation.

“We are pleased that inhaled IFN- β was well tolerated at a dose level that we predict will be efficacious in asthma and COPD”, said Prof. Ratko Djukanovic, Synairgen Co-Founder and Director of the Southampton NIHR Respiratory Biomedical Research Unit, who was the Chief Investigator for the study.

Antiviral activity

Neopterin is a well-recognised marker of IFN-beta antiviral activity. Synairgen has developed and validated a test for measuring neopterin in airway secretions. Analysis of the study samples shows statistically significant and dose dependant increases in neopterin levels indicating that antiviral defences have been activated in the lung.

Furthermore there were increases of between 4 fold and 64 fold in the gene expression of three antiviral proteins (MxA, 2-5-OAS and IP-10) in the lung cells of these asthmatic volunteers 24 hours after inhaling IFN-beta. This indicates that inhaled IFN-beta stimulated a broad antiviral response in the lung.

Prof. Stephen Holgate, Co-Founder and non-executive director of Synairgen, commented *"We are very pleased with the exciting results from this study in moderate asthmatics. The safety data is most reassuring and also to see four markers of the antiviral response greatly increases our confidence ahead of the Phase II efficacy studies due to commence in the spring next year."*

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Notes to editors

About Synairgen

Synairgen is a drug discovery and development company founded by Professors Stephen Holgate, Donna Davies and Ratko Djukanovic, focused on identifying and out-licensing new pharmaceutical products which address the underlying causes of asthma and COPD. Synairgen is listed on AIM (LSE: SNG).

Synairgen's researchers use advanced cell models incorporating human tissue and cells drawn from its biobank of clinical samples, which are obtained from well-characterised healthy control, asthma or COPD volunteers.

For more information about Synairgen please see www.synairgen.com.

Synairgen's interferon beta ('IFN-beta') programme

Synairgen is developing inhaled IFN-beta as a therapy to combat viral-induced asthma and COPD exacerbations.

Using *in vitro* human models, it was discovered that epithelial cells (cells which line the airways) from both subjects with asthma¹ and COPD have significantly weaker anti-viral responses to the common cold virus than healthy control subjects. The addition of low levels of IFN-beta into the models restored anti-viral responses (simulating aerosolised IFN-beta therapy). This suggests that local delivery of IFN-beta to the lungs could limit the spread of virus to lungs in subjects with respiratory disease and the consequent worsening of their symptoms.

Synairgen has entered into a supply and licence agreement for a patent-protected formulation of IFN-beta from the Rentschler Group in Germany.

SG004

SG004, a placebo-controlled Phase I study in controlled asthmatics taking inhaled corticosteroids, used the Company's exclusively in-licensed Rentschler formulation of inhaled IFN-beta and was designed to establish its safety at four different dose regimens, over a period of up to 14 days. In addition, biomarker activity (see below) was measured as an indicator of antiviral activity. The SG004 study was conducted by Synairgen in Southampton and the Medicines Evaluation Unit in Manchester, both sites with renowned expertise in advanced respiratory trials. The first volunteer was entered into the study in July 2008 and the trial was completed in September 2009.

Biomarkers

Neopterin is a recognised IFN-beta biomarker and has been measured in blood during IFN-beta studies in multiple sclerosis. Synairgen has developed a technique for measuring neopterin in airway secretions (sputum), which reflects antiviral activity locally in the lung. Biomarker levels have been monitored in SG004 to confirm the biological activity of IFN-beta delivered to the lungs. Successful biomarker data further supports the original dosing rationale and helps the Company to set the dose for Phase II.

In June 2009, Synairgen raised £6 million to finance two Phase II proof of concept studies of inhaled IFN-beta in asthma and COPD.

In August 2009, the patent for inhaled IFN-beta to treat rhinovirus infections in asthma and COPD was granted in the USA. The patent forms part of a patent portfolio owned by the University of Southampton, which is exclusively licensed to Synairgen.

Asthma statistics

- There are approximately 23 million asthmatics in the USA²
- The economic cost to the USA of asthma is \$19.7 billion per year²
- Asthma accounts for 1.7 million emergency department visits per year in the USA²
- The cost of emergency department visits and in-patient care in relation to asthma in the USA is \$4.7 billion²
- The average duration of a hospitalisation for an asthma exacerbation in the USA is 2.7 days at a cost of \$9,078³
- 50% of the total cost of the asthma is apportioned to 10% of the asthmatic population with the severest disease⁴

COPD statistics

- COPD includes chronic bronchitis and emphysema
- COPD is forecast to be the third leading cause of death worldwide (after heart attack and stroke) by 2030⁵
- 12 million adults in the USA have reported a physician diagnosis of COPD and it is estimated that another 12 million may have COPD but do not realise it⁶
- The economic cost to the USA of COPD is \$42.6 billion per year⁷
- Hospital care cost \$11.3 billion² and in 2006 there were 672,000 hospitalizations for COPD in the USA⁸

Rhinovirus (common cold virus) and exacerbations (worsening of symptoms) of asthma and COPD

- Adults get an average of two to four colds per year, mostly between September and May. Young children suffer from an average of six to eight colds per year⁹
- Rhinovirus infections are the major cause of asthma exacerbations, accounting for 50% to 80% of all such attacks in both children and adults¹⁰
- 80-85% of COPD exacerbations are associated with viral or bacterial respiratory tract infections with rhinovirus and Haemophilus influenzae thought to be the major contributors¹¹

References

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