

Press release

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

Synaigen announces *in vitro* antiviral activity of interferon beta against 2009 H1N1 (‘swine flu’)

Southampton, UK – 9 November 2009: Synaigen plc (LSE: SNG), the respiratory drug discovery and development company with a particular focus on viral defence in asthma and chronic obstructive pulmonary disease (‘COPD’), announces that, as part of its development programme for inhaled interferon beta (‘IFN-beta’) in asthma and COPD, laboratory experiments have been completed which confirm the antiviral potency of IFN-beta against 2009 H1N1.

In the experiments, performed for Synaigen by the Health Protection Agency’s Centre for Emergency Preparedness and Response (Porton Down, Salisbury), lung cells were grown in cell culture. These cells were then exposed to the 2009 H1N1 (Strain: Influenza A/California/04/2009(H1N1)), resulting in around 70% of cells becoming infected. In the presence of IFN-beta, the proportion of cells infected with the virus was reduced by at least 94% over 3 experiments. This suggests that IFN-beta may have the potential to prevent H1N1-induced respiratory exacerbations of asthma and COPD.

Inhaled IFN-beta is being developed by Synaigen to prevent respiratory viruses spreading from the nose and throat to the lungs, where the exacerbations of asthma and COPD patients occur. On the basis of these promising H1N1 data, Synaigen is evaluating the further potential of this therapy.

Professor Stephen Holgate, Co-founder and non-executive director of Synaigen, commented, *“This shows how broad an antiviral therapy interferon beta could be. The key point is that interferon beta acts by protecting the host cells rather than targeting any one incoming specific virus, which is the strategy of other therapies in development. 28% of patients admitted to hospital in the USA with 2009 H1N1 have been asthmatics. These exacerbation-prone patients need the kind of protection that interferon beta might provide.”*

Richard Marsden, Chief Executive Officer, commented, *“This is very exciting news for our inhaled interferon beta programme. In our asthma Phase II trial we intend to treat patients with inhaled interferon beta who have developed respiratory virus symptoms. Having already shown interferon beta activity against the main common cold viruses, rhinovirus and respiratory syncytial virus (RSV), we can now add H1N1 to our existing body of evidence, and will be continuing further experiments with other flu viruses.”*

Professor Stephen Holgate and Richard Marsden will comment further on this announcement at the Synaigen Investor Conference on Thursday 12 November. Contact Threadneedle Communications for more information.

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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 antiviral responses to the common cold virus than healthy control subjects. The addition of low levels of IFN-beta into the models restored antiviral 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 levels over a 14 day period. In addition biomarker activity (see below) is being measured as an indicator of antiviral activity. The SG004 study has been 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 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 will further support the original dosing rationale and help the Company set the dose for Phase II.

SG004 results

Synairgen will be announcing the safety and biomarker results of SG004 on 12 November 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

H1N1 and asthma

Asthma is the most common underlying condition for hospitalised H1N1 patients - In the USA, 28%% of hospitalised 2009 H1N1 flu patients had asthma¹²

References

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