

Press release

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

IFN-beta Patent Granted in Europe

Southampton, UK – 6 May 2010: Synairgen 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’), is pleased to announce that the patent for inhaled interferon beta (‘IFN-beta’) to treat rhinovirus infections in asthma and COPD has been granted in Europe.

The patent is part of a patent portfolio owned by the University of Southampton, which is exclusively licensed to Synairgen.

Richard Marsden, CEO of Synairgen, commented, *“The European patent grant and the US patent granted last year are key ingredients in the out-licensing package.”*

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Notes for 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 virus-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) was measured as an indicator of antiviral activity. The trial was completed in September 2009 and showed that inhaled IFN-beta was well tolerated, causing no adverse effect on standard measures of lung function and inflammation.

SG004 Biomarkers

Neopterin is a well-recognised marker of IFN-beta antiviral activity. Having developed and validated a test for measuring neopterin in airway secretions, analysis of the SG004 samples showed statistically significant and dose dependant increases in neopterin levels, indicating that antiviral defences had 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 the asthmatic volunteers 24 hours after inhaling IFN-beta, indicating that inhaled IFN-beta stimulated a broad antiviral response in the lung.

Activity of IFN-beta against 2009 H1N1 ('swine flu') and seasonal influenza

Laboratory experiments were undertaken in 2009 for Synairgen by the Health Protection Agency's Centre for Emergency Preparedness and Response (Porton Down, Salisbury) which confirmed the antiviral potency of IFN-beta against 2009 H1N1. In the experiments lung cells were grown in cell culture and 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.

Synairgen has undertaken similar *in vitro* experiments which also confirm the antiviral potency of IFN-beta against seasonal influenza.

SG005

SG005 is a placebo-controlled Phase II study of inhaled interferon beta ('IFN-beta') for the treatment of exacerbations of asthma caused by respiratory viruses including influenza. Following on from the discovery that IFN-beta significantly reduced the ability of influenza to infect lung cells SG005 was broadened to include patients who contract influenza as well as common cold viruses. The first volunteers were entered into the study on 31 March and the trial is expected to be completed during the summer of 2011.

Patents granted

The patents for inhaled IFN-beta to treat rhinovirus infections in asthma and COPD were granted in the USA in August 2009 and in Europe in May 2010. The patents form 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 projected to be \$20.7 billion for 2010³
- 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 for 2010 is projected to be \$5.5 billion³
- The average duration of a hospitalisation for an asthma exacerbation in the USA is 2.7 days at a cost of \$9,078⁴
- 50% of the total cost of the asthma is apportioned to 10% of the asthmatic population with the severest disease⁵

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 2030⁶
- 12 million adults in the USA have reported a physician diagnosis of COPD⁷. However, as many as 24 million adults have some evidence of impaired lung function, implying an under-diagnosis of this disease⁸
- The economic cost to the USA of COPD is projected to be \$49.9 billion for 2010³
- Hospital care is projected to cost \$13.2 billion for 2010³ and in 2006 there were 672,000 hospitalizations for COPD in the USA⁷

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

- 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

Influenza

- In the USA, an estimated 25–50 million cases of the flu are currently reported each year — leading to 150,000 hospitalizations and 30,000–40,000 deaths yearly¹¹

References

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