

Synairgen plc

('Synairgen' or the 'Company')

Phase II asthma study (SG005) – Interim Review and update

Southampton, UK – 28 June 2011: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company with a particular focus on viral defence of the lungs, provides an update on its Phase II asthma study.

We have previously announced that we would review the sample size calculation during Q2 (calendar) for our Phase II proof of concept asthma trial. We are pleased to announce that the outcome of this review does not require us to alter the total number of subjects required to be dosed in the study, which remains at 140. The recent fundraising has allowed us to take steps to accelerate recruitment through the addition of 10 new sites, so that we can dose the last subjects during this autumn's rhinovirus season. The interim review also included a review of blinded safety related data and this data suggested that the drug remains well tolerated. At 24 June 2011, 197 subjects had been recruited into the pre-treatment pool and, of these, 74 had been dosed. The results of the trial are expected early in Q1 (calendar) 2012.

Richard Marsden, Chief Executive, commented: "We are delighted that the asthma study is progressing well. As a result of the recent fundraising we have been able to accelerate the recruitment of this study, which we expect to complete prior to the end of this autumn's rhinovirus season when we anticipate at least 40% of the subjects in the pre-treatment pool will develop colds or flu symptoms."

The preclinical influenza programme is progressing well, with preliminary results of efficacy against H1N1 'swine' flu expected around the end of Q3 (calendar) this year.

Ends

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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 boosting anti-viral defences in the lungs of asthma and COPD patients, and, in the case of influenza, patients admitted to hospital with severe viral lung infections. Synairgen is listed on AIM (LSE: SNG).

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 November 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 and H5N1 'Bird' flu.

In May 2010, Synairgen presented data from its *in vitro* lung re-infection model showing for the first time that SNG001 can prevent the spread of infection from cell to cell, even after an influenza infection has taken hold. This data is particularly significant for hospitalised patients with pulmonary complications due to influenza-like illness. These patients can continue to generate new virus in the lungs long after it has cleared from the nose. This may adversely affect outcomes (including mortality) as there are limited treatments currently available.

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 study started in 2010 and is due to complete in 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 for COPD in the USA 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 there are in excess of 200,000 hospitalisations¹¹ each year associated with influenza and the total economic cost of influenza is estimated to be in excess of \$80 billion per year¹². During the period 1976 to 2007, there were an average of 23,000 deaths per year in the USA associated with seasonal influenza¹³.

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