

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

**Commencement of Phase II Proof of Concept Clinical Trial
with Inhaled Interferon beta in Asthmatic Subjects**

Southampton, UK – 1 April 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’), announces the commencement of its first Phase II study of inhaled interferon beta (‘IFN-beta’) for the treatment of exacerbations of asthma caused by respiratory viruses including influenza.

The Phase II study, known as SG005, uses the Company’s exclusively in-licensed formulation of inhaled IFN-beta (SNG001) and aims to assess the efficacy and safety of inhaled SNG001 compared to placebo administered to asthmatic subjects after the onset of respiratory viral infection for the prevention or attenuation of asthma symptoms caused by respiratory viruses. Following on from the announcement in November 2009 that SNG001 significantly reduced the ability of influenza to infect lung cells, the SG005 study has now been broadened to include patients who contract influenza as well as common cold viruses.

Respiratory viral infections (primarily caused by common cold and influenza viruses) are recognised as the key triggers of exacerbations (rapid worsening of symptoms), which are the major contributor to the significant healthcare burden in asthma.

Confidence in the outcome of SG005 is strengthened by the results of Synairgen’s Phase I study in moderate asthmatics (SG004), which showed that inhaled SNG001 was well tolerated and the biomarker analysis which confirmed activation of antiviral defences in the lung.

The SG005 study is being conducted at a number of clinical trial sites in the United Kingdom. The first volunteers were entered into the study on 31 March and the trial is expected to be completed during the summer of 2011.

Richard Marsden, Chief Executive Officer, commented, *“We are delighted to have been able to commence this study on schedule. In this study we are aiming to correct an antiviral (IFN-beta) deficiency. We have shown the drug is well tolerated in a safety trial (SG004) and we have evidence that we have successfully primed the antiviral defences; now we will test SNG001 in the presence of virus infections.”*

-Ends-

For further information, please contact:

Synairgen plc
Richard Marsden, Chief Executive Officer
John Ward, Finance Director

Tel: + 44 (0) 23 8051 2800

Matrix Corporate Capital LLP

Tel: + 44 (0) 20 3206 7000

Alastair Stratton
Anu Tayal

Threadneedle Communications
Graham Herring
Josh Royston

Tel: + 44 (0) 20 7653 9850

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) was 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. 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. Synairgen has 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.

Patent granted

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

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 year⁵
- Rhinovirus infections are the major cause of asthma exacerbations, accounting for 50% to 80% of all such attacks in both children and adults⁶

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 yearly⁷

References

1. P. Wark et al. Asthmatic bronchial epithelial cells have a deficient innate immune response to infection with rhinovirus. *J Exp Med.* 2005; 201: 937-947
2. American Lung Association. Trends in Asthma Morbidity and Mortality. January 2009 www.lungusa.org
3. V. Krishnan et al. Mortality in patients hospitalized for asthma exacerbations in the United States. *Am J Respir Crit Care Med* 2006 174, 633-638
4. P.J. Barnes, B. Johnson, J.B. Klim. The Costs of Asthma. *Eur Respir J* 1996 9, 636-642
5. American Lung Association: Cold and Flu Guidelines: The Common Cold www.lungusa.org
6. J.T. Kelly et al. Host immune responses to rhinovirus: Mechanisms in asthma. *J Allergy Clin Immunol* 2008; 122: 671-682
7. www.fluFACTS.com