

Press release

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

Additional Positive Data in Lung Fibrosis

- Phase I clinical trial scheduled to start in H2 2017

Southampton, UK – 10 March 2017: Synairgen plc (LSE: SNG), the respiratory drug discovery and development company, today announces further positive data from its LOXL2 (lysyl oxidase-like 2 enzyme) inhibitor programme against the lung disease idiopathic pulmonary fibrosis (IPF), being conducted in collaboration with Pharmaxis (ASX: PXS). Successful completion of toxicology studies will enable commencement of Phase I clinical trials in H2 this year as planned.

Using cells from IPF patients, Synairgen has previously reported that these inhibitors can reduce cross-linking of collagen fibres in an *in vitro* model of IPF developed in collaboration with the University of Southampton and the Company has now demonstrated that this results in a reduction in tissue stiffness of around 50%. Today Synairgen also reports that oral administration of one of these compounds significantly inhibited cross-link formation, reduced fibrosis score and improved lung function (elastance) in a preclinical model of lung fibrosis (note 1). Together these results suggest that inhibition of LOXL2 using these novel inhibitors has the potential to improve lung function in patients with lung fibrosis by reducing tissue stiffness.

IPF is a fatal lung disease which, with a median survival of 2 to 3 years¹, carries a worse prognosis than many cancers. It affects up to 132,000 people in the US and approximately 50,000 new cases are diagnosed each year². The current products for IPF have generated global revenues in excess of \$1 billion in 2016³. Whilst the underlying cause of the disease is not fully understood, IPF results from the relentless build-up of scar tissue which, in turn, damages the structure of the lung affecting normal uptake of oxygen into the blood. The resultant stiffening of the lungs makes it increasingly difficult to breathe. Scar tissue is formed largely of collagen. LOXL2 is a member of a family of enzymes that stiffen scar tissue by forming cross-links between the collagen molecules.

Synairgen and Pharmaxis are collaborating to develop small molecule inhibitors of LOXL2 for the treatment of IPF and other fibrotic conditions including non-alcoholic steatohepatitis (NASH), kidney fibrosis and cardiac fibrosis.

Commenting on the results, Richard Marsden, CEO of Synairgen, said: *“The effect of these inhibitors across different model types is very exciting, suggesting that inhibition of LOXL2 has the potential to improve lung function in severely ill patients with lung fibrosis by reducing tissue stiffness.*

“2017 will be an important year for Synairgen. Subject to the successful completion of on-going pre-clinical work, we expect to commence Phase I clinical trials of the LOXL2 inhibitor during the second half of 2017. The window for licensing the LOXL2 programme to a pharmaceutical partner will open at the end of Phase I. We also expect to hear the outcome of the AstraZeneca Phase II trial of interferon beta during the first half of 2017.”

Note 1: The inhibitor was profiled in a model of progressive lung fibrosis initiated by local expression of the pro-fibrotic mediator TGF- β in the lungs using a non-replicating adenoviral vector. The study was conducted at McMaster University (Hamilton, Canada).

References

1. Ley B *et al.* Clinical course and prediction of survival in idiopathic pulmonary fibrosis. *Am J Respir Crit Care Med.* 2011 Feb 15;183(4):431-40
2. Boehringer Ingelheim – www.BreathlessIPF.com. Accessed 9 March 2017.
3. Sourced from Roche Finance Report 2016 and Boehringer Ingelheim press release 3 August 2016.

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Notes for Editors

About Synairgen

Synairgen is a respiratory drug discovery and development company founded by University of Southampton Professors Stephen Holgate, Donna Davies and Ratko Djukanovic. The business, focused primarily on asthma and COPD, uses its differentiating human biology BioBank platform and world-renowned international academic KOL network to discover and develop novel therapies for respiratory disease. Leveraging its scientific and clinical facilities at Southampton General Hospital, the Company uses *in vitro* and *ex vivo* models to progress opportunities into clinical development. The BioBank of human samples is used in these models to increase confidence in the likelihood of successful drug development. Core to Synairgen's business strategy is the realisation of value via licensing transactions. This approach has been validated by the licensing agreement formed with AstraZeneca in June 2014 for Synairgen's SNG001 (AZD9412) programme in asthma/COPD. In August 2015 the Company entered into a collaboration with Pharmaxis to develop an oral LOXL2 inhibitor to reduce fibrosis in patients with idiopathic pulmonary fibrosis (IPF). Synairgen is quoted on AIM (LSE: SNG). For more information about Synairgen, please see www.synairgen.com

About Pharmaxis

Pharmaxis is an Australian research pharmaceutical company with a portfolio of products at various stages of development and approval. The company's development pipeline is centred on its expertise in amine oxidase chemistry and includes Semicarbazide-Sensitive Amine Oxidase Inhibitors (SSAO) for Non-alcoholic Steatohepatitis (NASH) and inflammatory diseases including Chronic Obstructive Pulmonary Disease (COPD), and Lysyl Oxidase Inhibitors (LOX) targeting fibrotic diseases including pulmonary fibrosis and some cancers. Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). For more information about Pharmaxis, please see www.pharmaxis.com.au.