



Press release

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

LOXL2 Inhibitor Update

- Successful completion of LOXL2 preclinical studies
- Phase I trial on track to commence in Q4 2017

Southampton, UK – 6 September 2017: Synairgen (LSE: SNG), the respiratory drug discovery and development company, is pleased to announce that, following the successful completion of preclinical pharmacology and toxicology studies, a compound from its anti-fibrotic Lysyl Oxidase type 2 (LOXL2) inhibitor programme, PXS-5382A, is being prepared to commence Phase I clinical development.

PXS-5382A is being developed in partnership with Pharmaxis (ASX: PXS) to target the fatal lung disease idiopathic pulmonary fibrosis (IPF) and other fibrotic conditions including non-alcoholic steatohepatitis (NASH), kidney fibrosis and heart fibrosis.

Synairgen will progress PXS-5382A through the Phase I trial, the results of which are expected mid-2018. Thereafter Synairgen and Pharmaxis plan to out-license PXS-5382A to a suitable partner to fully realise the commercial value of this compound given the potential size and number of indications it could address.

Richard Marsden, CEO of Synairgen, commented: *“We believe PXS-5382A is a very valuable candidate with potential applications in a number of fibrotic conditions including lung, liver, cardiac and kidney fibrosis. These diseases represent areas of high unmet medical need and consequently present very substantial market opportunities.*

“The effect of this novel inhibitor across different model types is very exciting, with the latest supporting data suggesting that PXS-5382A can significantly reduce lung fibrosis and therefore has the potential to improve lung function in severely ill patients. These data build on the encouraging results seen to date and further support the rationale behind bringing this promising inhibitor to clinic.

“Based on PXS-5382A’s potential across a number of disease areas and the promising data seen to date, we have received significant interest from companies looking to license the programme for multiple indications. We look forward to progressing these discussions as PXS-5382A advances through the clinic. This outcome has been the result of a successful collaboration with Pharmaxis, through the combination of their expertise in small molecule drug development and Synairgen’s expertise in translational research in lung diseases.”

LOXL2 is a pro-fibrotic enzyme believed to play a significant role in the collagen cross-linking formation process in fibrotic diseases such as NASH, cardiac fibrosis, kidney fibrosis and IPF; all of which are areas of high unmet need that could have substantial

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.

potential. The LOXL2 inhibitor PXS-5382A is a potent and selective inhibitor of LOXL2 and has consistently been shown to significantly reduce and inhibit cross-linking formation in *in vitro* and *in vivo* models of lung, liver and cardiac fibrosis. These findings have been the subject of presentations at numerous international scientific conferences and more data will be presented at similar upcoming events as the Phase I trial proceeds.

The Company continues to analyse the data from the INEXAS trial and expects to make a further announcement regarding the potential of its inhaled interferon-beta drug (SNG0010) shortly.

-Ends-

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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. 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.

About IPF

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.

About NASH:

NASH is a serious progressive liver disease caused by excessive fat accumulation in the liver that induces chronic inflammation, resulting in progressive fibrosis (scarring) that can lead to cirrhosis, eventual liver failure, cancer and death. There are currently no medications approved for the treatment of NASH. The proportion of liver transplants attributable to NASH has increased rapidly in past years and by 2020 the disease is projected to become the leading indication for liver transplant.

Current research has reported the prevalence of NASH to range from 1.5% to 6.45%, a number twice as high as 20 years ago and the market has been forecast by Deutsche Bank to be worth in excess of \$35 billion by 2025.