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PHARMAXIS ANNOUNCES ANTI FIBROTIC LOXL2 PROGRAM CLEARS PRECLINICAL DEVELOPMENT AND SET TO COMMENCE PHASE 1 TRIALS

- Small molecule LOXL2 inhibitor with proven efficacy in multiple pre-clinical models of fibrosis set to commence phase 1 trials in Q4 2017.
- Pharmaxis consolidates its position as a significant competitor in the NASH market as the LOXL2 inhibitor joins its SSAO inhibitor in the clinic.

Pharmaceutical research company Pharmaxis (ASX: PXS) and its collaborator UK biotechnology company Synairgen plc (AIM: SNG) today announced completion of the preclinical development stage of their anti-fibrotic Lysyl Oxidase type 2 (LOXL2) inhibitor program allowing the first compound to commence human clinical phase I studies in Q4 2017.

The Pharmaxis drug discovery group has developed a number of selective small molecule inhibitors to the LOXL2 enzyme utilising the same amine oxidade platform that delivered PXS-4728A, an anti-inflammatory drug that was acquired by Boehringer Ingelheim in 2015. The LOXL2 enzyme is fundamental to the fibrotic cascade that follows chronic inflammation in the liver disease NASH, cardiac fibrosis, kidney fibrosis, and idiopathic pulmonary fibrosis (IPF), and it also plays a role in some cancers.

Pharmaxis CEO Gary Phillips said, “The extensive pre-clinical program performed on our program compounds has confirmed that they have all the characteristics of a successful once a day, oral drug. They have shown excellent efficacy in several different in vivo fibrosis models including fibrosis of the liver, lung, kidney and heart. These findings have been the subject of presentations at a number of international scientific conferences and more data will be presented at similar upcoming events as the phase 1 studies proceed. In regulatory toxicity studies, our compounds have been well tolerated and shown a good safety profile.”

NASH is a major cause of fibrosis and cirrhosis of the liver and is an area of high unmet medical need with no treatments currently available. 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. The potential for the LOXL2 program to be developed as a therapeutic for NASH positions Pharmaxis as a key player in this important and growing disease. In addition to its anti-fibrotic LOXL2 program, Pharmaxis also has an ongoing interest in the anti-inflammatory SSAO/VAP-1 inhibitor PXS-4728A with which its partner Boehringer has just commenced a NASH phase 2 study.

Mr Phillips said, “NASH is clearly a growing and valuable market for the future. It’s a disease that is attracting a variety of well-funded research strategies and it is anticipated that a combination approach that tackles the metabolic, inflammatory and fibrotic drivers of NASH, will be necessary in order to reduce the long term effects of this disease. As lysyl oxidase type 2 is the key enzyme in the fibrotic cascade we anticipate that our LOXL2 program will be attractive to many of the multinational pharmaceutical companies that are building a portfolio approach to treating NASH and some other fibrotic diseases such as IPF.”

The amine oxidase platform at Pharmaxis has generated lead candidate small molecule enzyme inhibitors to a range of important disease targets that are at various stages of development. The SSAO inhibitor PXS-4728A acquired by Boehringer is in phase 2, the LOXL2 inhibitor program is about to enter phase 1 trials
whilst a drug inhibiting both myeloperoxidase (MPO) and SSAO and one inhibiting all the LOX family of enzymes are in the final stages of pre-clinical testing before being entered into the toxicity studies necessary before phase 1 trials can commence in 2018.

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About Pharmaxis
Pharmaxis (ACN 082 811 630) is an Australian pharmaceutical research company focused on inflammation and fibrosis with a portfolio of products at various stages of development and approval. Its product Bronchitol® for cystic fibrosis is marketed in Europe, Russia and Australia. Its product Aridol® for the assessment of asthma is sold in Europe, Australia and Asia. The company’s development pipeline is centred on its expertise in amine oxidase chemistry and includes a series of Lysyl Oxidase Inhibitors that will enter clinical development in 2017 targeting fibrotic diseases of the heart, kidney, liver and lung. In May 2015, Boehringer Ingelheim acquired the Pharmaxis investigational drug PXS-4728A, a potent inhibitor of Semicarbazide-Sensitive Amine Oxidase (SSAO), to develop it for the treatment of the liver-related condition Non-alcoholic Steatohepatitis (NASH) and other inflammatory diseases. Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company’s head office, manufacturing and research facilities are located in Sydney, Australia. For more information about Pharmaxis, please see www.pharmaxis.com.au

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