Pharmaceutical research company Pharmaxis (ASX: PXS) today announced it has completed the preclinical package on its anti-fibrotic Lysyl Oxidase (LOX) program focused on pancreatic cancer and will this week file an ethics submission to enable progress into a Phase 1 clinical trial in healthy volunteers. The trial is planned to commence in the first quarter of 2019. It is the third program from the Company’s amine oxidase chemistry platform to reach the important stage of entering human clinical trials.

Pharmaxis is the first company to progress a small molecule LOX inhibitor into clinical development. The compound is an oral once-a-day drug that inhibits all lysyl oxidase family members (LOX, LOXL1, 2, 3 & 4). It successfully cleared preclinical safety and toxicity studies in the third quarter of 2018 and has shown significant reductions in fibrosis in in-vivo models of kidney fibrosis, lung fibrosis, myelofibrosis and pancreatic cancer. Whereas the Pharmaxis selective LOXL2 inhibitors that are currently completing phase 1 studies are suited to chronic fibrotic conditions such as IPF and NASH, this all-encompassing LOX inhibitor is well positioned for the treatment of severe fibrosis as well as cancer with prominent stroma (connective tissue) or fibrotic metastatic niches. Pharmaxis plans to initially develop the compound for pancreatic cancer.

Pharmaxis is collaborating with Garvan Institute of Medical Research to investigate the therapeutic potential of LOX inhibition in pancreatic cancer.

Thomas R. Cox, Leader of the Matrix and Metastasis Team, Garvan Institute of Medical Research, who is leading the academic collaboration said, “Pancreatic cancer has proved difficult to treat with chemotherapy in part because fibrotic stroma limits access to, and efficacy of current drug treatments against tumour cells. An anti-fibrotic may enhance accessibility and provide additional benefit against not only tumour cells at the primary tumour, but also those cells which have spread from the pancreas to other parts of the body”. Researchers at the Garvan Institute have evidence in mouse models that inhibition of the LOX family alters the tumour microenvironment rendering tumours more susceptible to existing therapies. The team has also generated positive results in in vitro and in-vivo models of the pancreatic cancer using the Pharmaxis LOX inhibitor.

Pharmaxis CEO Gary Phillips said, “Moving another a drug into the clinic further validates the productivity and expertise of our Drug Discovery and Development team. This latest drug has shown real promise in pre-clinical testing and our ambition is to move it into pancreatic cancer patients as soon as possible and demonstrate clinical proof of concept in a disease which has a very high unmet need. The clinical program we envisage in pancreatic cancer is very efficient relative to other fibrotic indications so the opportunity to add significant value to the asset by taking it into phase 2 clinical trials prior to partnering is very attractive.”

The Garvan Institute’s research on the role of LOX enzymes in pancreatic cancer and the potential of Pharmaxis compounds in this disease will be the subject of presentations at upcoming international scientific symposia in 2019.
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 Ar idol® for the assessment of asthma is sold in Europe, Australia, the United States and Asia. The company's development pipeline is centred on its expertise in amine oxidase chemistry and includes Lysyl Oxidase Like 2 (LOXL2) inhibitors under clinical development for fibrotic diseases of the heart, kidney, liver and lung, and Lysyl Oxidase (LOX) inhibitors under clinical development for severe fibrotic diseases including pancreatic cancer and myelofibrosis. In May 2015, Boehringer Ingelheim acquired the first Pharmaxis investigational drug PXS-4728A from the amine oxidase platform, a potent inhibitor of Semicarbazide-Sensitive Amine Oxidase (SSAO), and is developing it for the treatment of two diseases - the liver-related condition Non-alcoholic Steatohepatitis (NASH) and diabetic retinopathy. 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

About Garvan
The Garvan Institute of Medical Research is one of Australia’s largest medical research institutions and is at the forefront of next-generation genomic sequencing in Australia. Garvan’s main research areas are: cancer, diabetes and metabolism, genomics and epigenetics, immunology and inflammation, osteoporosis and bone biology, and neuroscience. Garvan’s mission is to make significant contributions to medical science that will change the directions of science and medicine and have major impacts on human health.

Forward-Looking Statements
Forward-looking statements in this media release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the potential of products and drug candidates. All forward-looking statements included in this media release are based upon information available to us as of the date hereof. Actual results, performance or achievements could be significantly different from those expressed in, or implied by, these forward-looking statements. These forward-looking statements are not guarantees or predictions of future results, levels of performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this document. Except as required by law we undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise.