Media Release

31 August 2021

PHARMAXIS TREATMENT TO PREVENT WOUND AND BURNS SCARS CLEARS PHASE 1 TRIAL

- Topical treatment safe and well tolerated in study of healthy volunteers
- Full inhibition of lysyl oxidase enzymes achieved in skin with minimal systemic exposure
- Collaboration with research team led by Professor Fiona Wood AM planning for trial in patients with established scars to commence in Q4 2021

Pharmaxis (ASX: PXS) today announced that its novel topical drug treatment for scarring has delivered positive Phase 1 clinical trial results and will now advance to the next stage of development in patients. In a study of healthy volunteers led by renowned surgeon Prof Fiona Wood AM the Pharmaxis drug demonstrated good tolerability and full inhibition of the enzymes being targeted to prevent scarring.

The phase 1 trial of the drug known as PXS-6302 tested 4 different strengths formulated as an easy to apply cream in 4 subjects as a single dose, scaling to the highest dose applied daily for 7 days in a further 6 subjects. The positive results from the study have now triggered the next steps in initiating a longer term study in patients with scars.

The study was conducted by a research team at the University of Western Australia (UWA) and Fiona Stanley Hospital. Professor Wood welcomed the early study results saying, “Scars are a constant reminder of trauma with both physical and psychological impact. Our aim is to reduce the scar and reduce the impact. We have two studies planned with Pharmaxis; this first one in established scars and an additional one in patients with burn injuries after they have had surgery.”

Dr Kylie Sandy-Hodgetts, Senior Research Fellow at the School of Biomedical Sciences, UWA, and principal investigator on the study said, “Based on the encouraging results from the phase 1 study in healthy volunteers, we are now preparing for a study in patients with established scars. We will be investigating the safety of 3 months’ treatment with PXS-6302, and exploring if 3 months’ treatment with PXS-6302, at a dose that we now know will significantly inhibit an enzyme implicated in scar formation, can make a difference to both the appearance and structure of their scars.”

The Pharmaxis discovery has shown promising results in pre-clinical models of scar tissue development under the direction of Dr Mark Fear, Senior Research Fellow at the Stan Perron Centre for Excellence in Childhood Burns. Dr Fear commented on the background to the forthcoming study in patients with established scars, “We now understand from our research that even scars which are stable and many years old are in fact replenishing a significant proportion of mature, stiff collagen in a matter of a few months. This presents an opportunity for a drug like PXS-6302 to potentially improve even established scars.”

PXS-6302 was discovered by the Pharmaxis research team at the company’s Frenchs Forest laboratories. The project was supported by a National Health and Medical Research Council (NHMRC) development grant funding extensive pre-clinical work executed in collaboration with UWA. The clinical trials in patients with established scar and patients with burns will both be conducted at the Fiona Stanley Hospital in Perth with financial support from Pharmaxis.

Ends

SOURCE: Pharmaxis Ltd, Sydney, Australia

AUTHORISED FOR RELEASE TO ASX BY:
Pharmaxis Ltd Disclosure Committee. Contact: David McGarvey, Chief Financial Officer and Company Secretary: T +61 2 9454 7203, E david.mcgarvey@pharmaxis.com.au

CONTACTS:

Media: Felicity Moffatt: T +61 418 677 701, E felicity.moffatt@pharmaxis.com.au
Investor relations: Rudi Michelson (Monsoon Communications) T +61 411 402 737, E rudim@monsoon.com.au

Kylie Sandy-Hodgetts (UWA School of Biomedical Sciences) 0435 436 747
Simone Hewett (UWA Media and PR Manager) 08 6488 3229 / 0432 637 716

Join the Pharmaxis mailing list here
Follow us:

About Pharmaxis

Pharmaxis Ltd is an Australian pharmaceutical research company developing drugs for inflammatory and fibrotic diseases, with a focus on myelofibrosis. The company has a highly productive drug discovery engine built on its expertise in the chemistry of amine oxidase inhibitors, with drug candidates in clinical trials. Pharmaxis has also developed two respiratory products which are approved and supplied in global markets, generating ongoing revenue.

Pharmaxis is developing its drug PXS-5505 for the bone marrow cancer myelofibrosis which causes a build up of scar tissue that leads to loss of production of red and white blood cells and platelets. The US Food and Drug Administration has granted Orphan Drug Designation to PXS-5055 for the treatment of myelofibrosis and permission under an Investigational Drug Application (IND) to progress a phase 1c/2 clinical trial that commenced recruitment in Q1 2021. PXS-5505 is also being investigated as a potential treatment for other cancers such as liver and pancreatic cancer.

Other drug candidates being developed from Pharmaxis' amine oxidase chemistry platform are targeting fibrotic diseases such as kidney fibrosis, NASH, pulmonary fibrosis and cardiac fibrosis; fibrotic scarring from burns and other trauma; and inflammatory diseases such as Duchenne Muscular Dystrophy.

Pharmaxis has developed two products from its proprietary spray drying technology that are manufactured and exported from its Sydney facility; Bronchitol® for cystic fibrosis, which is approved and marketed in the United States, Europe, Russia and Australia; and Aridol® for the assessment of asthma, which is approved and marketed in the United States, Europe, Australia and Asia.

Pharmaxis is listed on the Australian Securities Exchange (PXS). Its head office, manufacturing and research facilities are in Sydney, Australia. www.pharmaxis.com.au

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. For example, despite our efforts there is no certainty that we will be successful in developing or partnering any of the products in our pipeline on commercially acceptable terms, in a timely fashion or at all. 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.