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Media Release

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FIRST PATIENTS DOSED IN TRIAL OF PHARMAXIS SCAR REDUCTION DRUG

- Collaboration with research team led by Professor Fiona Wood AM doses first patients in trial of 50 patients with established scars
- 3-month placebo-controlled study to report safety and tolerability endpoints as well as measures of scar structure and appearance in 2H 2022
- PXS-6302 is a first in class topical inhibitor of the lysyl oxidase enzymes that are involved in formation and maintenance of scars; a potential breakthrough treatment for patients with problematic scars in a market estimated at US$3.5 billion per year

Pharmaxis (ASX: PXS) today announced that a phase 1c trial of its novel topical drug treatment for scarring, has commenced dosing in patients with established scars. The study, led by renowned surgeon Professor Fiona Wood AM and researchers at The University of Western Australia (UWA), will assess the safety and tolerability of a once daily application of Pharmaxis drug PXS-6302 applied to areas of established scars on adult patients. Skin biopsies will be taken in order to study the impact on scar structure as well as visual and physical assessments of the scar tissue.

PXS-6302 is a first in class inhibitor of the lysyl oxidase enzymes (LOX) that are involved in formation and maintenance of scars and is a potential breakthrough treatment for patients with problematic scars.

Professor Wood commented, “Scars are a constant reminder of trauma with both physical and psychological impact. Our aim is to reduce the scar and reduce the impact. Long-term scars are notoriously hard to improve, so it is potentially ground-breaking that a simple cream may make a difference.”

Scar formation following a burn or skin injury is a considerable health issue worldwide. After an injury, people are unable to regenerate normal skin, instead the repair process leads to scar formation. Scars are both aesthetically and functionally inferior to normal skin, leading to significant psychological and physical problems. Key factors in the poor appearance and pliability of scars, and in particular hypertrophic scars, are the changes to the structure and quantity of collagen in the dermal layer. Current treatments in a global market valued at US$3.5 billion, aim to rectify the scar in the acute phase (i.e. during wound healing and scar maturation) through options such as compression therapy, silicone gel sheeting or later when the scar is established by cryotherapy, scar revision or laser.

LOX plays a critical role in scar formation by crosslinking the collagen fibres. The resulting changes in collagen structure and increased rigidity of the tissue stimulates greater production of collagen and LOX which in turn leads to more scar tissue. Pharmaxis and its collaborators at UWA will now test if inhibiting LOX in established scar tissue with PXS-6302 can safely and effectively improve scarring when administered as a cream once a day for a 3-month period.

Dr Mark Fear, Senior Research Fellow at the Stan Perron Centre for Excellence in Childhood Burns noted, “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. It is really exciting to be commencing studies with PXS-6302 in people with established scars as a next step towards better scar treatment.”

Gary Phillips, Pharmaxis CEO, added, “We place enormous value on our collaboration with Fiona Wood and the team at UWA. They identified the opportunity of utilising our expertise in drug development and extensive knowledge of lysyl oxidase enzymes to help patients with scars and have

provided the clinical leadership to get this study underway. I look forward to reporting on the results later this year for a project that has significant potential both clinically and commercially."

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 Fiona Stanley Hospital in Perth with financial support from Pharmaxis.

Trial Design	
Name of trial	PXS-6302 SOLARIA2: A Phase 1c, Single Centre Study Investigating the Safety and Tolerability of a Lysyl Oxidase Inhibitor (PXS-6302) vs Placebo in the Amelioration of Established Scars.
Trial number	ACTRN12621001545853
Primary endpoint	To investigate the safety and tolerability of multiple applications of PXS-6302 vs placebo in a target cohort.
Secondary endpoints	• Characterize pharmacokinetic and pharmacodynamic parameters • Physical and visual skin and scar assessments
Blinding status	Blinded
Placebo controlled	Yes
Trial design	Placebo controlled, single centre, 12-week duration phase 1c study incorporating a sentinel cohort on active drug who will be assessed at 4 weeks prior to expanding the study with cohort 2 who are randomised 1:1 on active or placebo.
Treatment route	Topical
Treatment frequency	Once daily
Dose level	One dose
Number of subjects	Cohort 1: 8 patients on active treatment Cohort 2: 42 patients; 21 on active treatment and 21 on placebo
Subject selection criteria	Adult patients aged between 18 and 60 years with a scar between 1-5 years of duration (includes all surgery types).
Trial locations	Fiona Stanley Hospital, Murdoch, Western Australia
Commercial partners involved	No commercial partner

Ends

SOURCE: Pharmaxis Ltd, Sydney, Australia

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About Pharmaxis

Pharmaxis Ltd is an Australian clinical stage drug development 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 (FDA) 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 began recruitment in Q1 2021. PXS-5505 is also being investigated as a potential treatment for other cancers such as pancreatic cancer. The FDA has granted an IND for a phase 1c/2a clinical trial in liver 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; and inflammatory diseases such as Duchenne Muscular Dystrophy. PXS-6302 is being studied as a first in class topical drug that inhibits the enzymes involved in formation and maintenance of scars

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.