

## Media Release

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### PHARMAXIS ANNOUNCES FIRST SALES OF ARIDOL® IN USA

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Pharmaceutical research company Pharmaxis (ASX: **PXS**) today announced the first sales of its asthma diagnostic Aridol® (mannitol bronchial challenge test) in the United States following the relaunch of the product.

Aridol is sold in the US by Pharmaxis' exclusive distribution partner Methapharm Inc., a corporation with extensive experience in the sales channels and specialist centres that conduct lung function testing.

Pharmaxis received approval in August 2018 from the United States Food and Drug Administration (FDA) for its manufacturing facility in Sydney to produce Aridol for the US market and recently supplied the first shipment of Aridol to Methapharm.

Gary Phillips, Chief Executive Officer commented, "Aridol was approved by the FDA in 2011 to identify bronchial hyperresponsiveness and commercialised by Pharmaxis in the US until its withdrawal from the market in 2013 as part of a corporate restructuring when we closed the facility used to manufacture Aridol for the US. Two years ago Pharmaxis partnered with Methapharm to re-enter the US market and commenced the validation work required to have our remaining manufacturing facility approved by the FDA for Aridol. Both Methapharm and Pharmaxis believe there remains a strong need in the US for objective tests to aid physicians in diagnosing asthma. It's good to be back."

Aridol was clinically trialled and developed by Pharmaxis. It is available as a standardised test kit containing pre-filled mannitol capsules and a hand-held dry powder inhaler. During a mannitol challenge test, the subject inhales increasing doses of mannitol with their lung function (Forced Expiratory Volume in one second- FEV) measured after each dose to determine the level of bronchial hyperresponsiveness.

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**SOURCE:** Pharmaxis Ltd, Sydney, Australia

**Media:** Felicity Moffatt: T +61 418 677 701, E [felicity.moffatt@pharmaxis.com.au](mailto:felicity.moffatt@pharmaxis.com.au)

**Investor relations:** David McGarvey: T +61 438 880 106, E [david.mcgarvey@pharmaxis.com.au](mailto:david.mcgarvey@pharmaxis.com.au)

#### 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 under clinical development 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](http://www.pharmaxis.com.au)

#### About Aridol

Aridol is an innovative lung function test designed to help doctors diagnose and manage asthma by detecting active airway inflammation through measuring airway hyper-responsiveness. Patients inhale increasing doses of Aridol (dry powder mannitol) via a simple hand-held device. Respiratory clinicians administering the test measure the patient's lung function to identify airway inflammation which can assist doctors in providing appropriate asthma treatment. Aridol is approved for sale in Australia, major European countries, South Korea and the United States. It is the first and only approved indirect challenge test for asthma, a condition which affects 52 million people worldwide.

## **About Methapharm**

Methapharm is a privately held specialty pharmaceutical company with over twenty years of experience in the marketing of direct challenge agents to pulmonary function laboratories and clinics in the United States. In addition to its respiratory expertise, Methapharm carries a diverse portfolio of hospital products, including neo-natal intensive care, imaging, organ preservation and cancer care.

## **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.