
PHARMAXIS ANNOUNCES FDA FACTORY APPROVAL AND RELAUNCH OF ARIDOL® IN US MARKET

Highlights:

- FDA approves Pharmaxis manufacturing facility in Sydney, Australia to produce Aridol® for the US market
- Aridol was first approved by the FDA in 2011 to identify bronchial hyperresponsiveness as an aid to diagnosing asthma, and commercialised by Pharmaxis in the US until its withdrawal from the market in 2013 as part of a corporate restructuring
- Aridol will commence US commercial sales in Q4 2018 via Pharmaxis' exclusive distributor in North America, Methapharm Inc., who are experts in the specialist respiratory diagnostic market

Pharmaceutical research company Pharmaxis (ASX: **PXS**) today announced the company has received approval from the United States Food and Drug Administration (FDA) for its manufacturing facility to produce the asthma diagnostic product Aridol for the US market.

The approval follows a recent onsite FDA inspection of the Pharmaxis manufacturing facility in Sydney where the company currently manufactures Aridol for Europe, Australia, and South Korea as well as Bronchitol® for Europe, Australia and Russia.

Pharmaxis will relaunch Aridol into the US market later in 2018 via its exclusive distribution partner Methapharm who have extensive experience in the sales channels and specialist centres that conduct respiratory testing. Global sales of Aridol (ex-US) are currently A\$2 million per annum and Pharmaxis believes that the addition of the US market offers an opportunity to at least double that revenue.

Aridol was approved by the FDA in 2011 to identify bronchial hyperresponsiveness, as part of a physician's assessment of asthma in patients 6 years of age and over, and commercialised by Pharmaxis in the US until its withdrawal from the market in 2013 as part of a corporate restructuring. Recent US market research suggests that there remains a strong need for objective tests to aid physicians in diagnosing asthma and that Aridol's mechanism of action and ease of use will be highly valued by respiratory specialists.

Gary Phillips, Chief Executive Officer commented, "Aridol has proven to be a valuable diagnostic aid in respiratory function laboratories in many global markets. I am delighted that the FDA, having inspected our Sydney manufacturing facility, has given approval to recommence supply of the product to the US market. We are also very pleased to have Methapharm, who have many years of experience in the US, to commercialise the product. This partnership will bring the benefits of this indirect bronchial challenge test kit to US patients with respiratory symptoms and add a valuable income stream to this business segment of Pharmaxis."

Craig Baxter, CEO of Methapharm said, "We are very excited to add Aridol (mannitol inhalation powder) to our growing portfolio. We see the commercialisation of Aridol as an integral part of our continued efforts to demonstrate the value of objective testing for patients suspected of having asthma or other respiratory disorders. Through our planned investments in education and training, and by combining Aridol with our existing product offering, we believe we will be able to ensure maximum usage and market penetration."

First approved by the Australian regulatory agency in 2012, the Pharmaxis factory in Sydney is a unique purpose built facility which manufactures, packages and exports Pharmaxis products. It is equipped with one of the largest pharmaceutical grade spray driers in the world, which is capable of producing highly refined inhalable powder for the diagnosis and treatment of respiratory conditions.

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SOURCE: Pharmaxis Ltd, Sydney, Australia

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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 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

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 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 and South Korea. 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

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