



ASX/NASDAQ/Media release

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***U.S. PHASE III ARIDOL TRIAL ENROLS FIRST PATIENT***

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Pharmaxis Ltd (ASX:PXS NASDAQ:PXSL) is pleased to announce that the Aridol Phase III clinical trial in patients with suspected asthma has enrolled its first patients. The trial is designed to compare the sensitivity and specificity of Aridol (mannitol) to identify exercise induced bronchoconstriction. The trial design is based on discussions with the U.S. Food and Drug Administration (FDA) and compares Aridol with acknowledged methods for diagnosing airway responsiveness in patients suspected of having asthma. It is being conducted in 28 sites throughout the United States.

Alan Robertson, Pharmaxis chief executive officer said: 'Despite being treated by expert physicians and receiving state-of-the-art drugs, an alarming number of patients with moderate to severe asthma remain poorly controlled. The diagnosis of asthma only on the basis of patient history of symptoms is not best practice and leads to poor control of the disease. At the conclusion of this trial, we intend to file for authorisation to market Aridol in the U.S with the FDA in 2006.'

The opportunity to have an easy to administer and objective tool for determining whether or not a patient has asthma is significant. Based on independent market research, the annual addressable market for Aridol in the U.S. and Europe includes the existing 400,000 bronchial challenge tests performed yearly, 2 million new tests for assisting the diagnosis of asthma and 16 million new tests performed by pulmonary specialists and primary care physicians for assisting the management of asthma.

All patients in the study will have symptoms suggestive of asthma but will be without a definitive diagnosis. Each will receive an Aridol test and will undergo a methacholine challenge test and an exercise challenge test. The trial will record changes in lung function, safety and vital signs as compared to both methacholine and exercise challenges. Full patient recruitment is expected to take about 6 months.

Asthma affects more than 50 million people in the western world, and is one of the most common reasons for hospital admission and emergency room care.

To find out more about Pharmaxis, go to <http://www.pharmaxis.com.au>.

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**About the trial**

The following information is provided in accord with the ASX and AusBiotech draft Code of Best Practice for Reporting by Biotechnology, Medical Device and other Life Sciences Companies.

Name of Trial	DPM-A305 (a Phase III study with Aridol)
Blinding Status	Open
Placebo Controlled	No
Treatment Method	
Route	Inhalation
Frequency	Once only.
Dose level	0 – 635mg inhaled mannitol
No of subjects	280
Subject Selection Criteria	Aged 6 – 40 years, male and female. Current symptoms suggestive of asthma but without a definitive diagnosis or an exclusion of the diagnosis of asthma. No inhaled corticosteroids for 4 weeks prior to screening, skin test negative to aeroallergens. FEV <sub>1</sub> greater than 70% predicted value and remaining within 10% of value at all other visits.
Trial Location	United States of America
Commercial partners involved	None
Expected duration	6 months
Primary end point	Concordance of Aridol positivity with exercise challenge positivity (more than 10% fall in FEV <sub>1</sub> from baseline within 30 minutes, after 8 minutes of standardised exercise)
Primary safety end points	Safety (ECG, adverse events, vital signs, spirometry) as compared to methacholine and to exercise challenge tests

## **About Pharmaxis**

Pharmaxis (ACN 082 811 630) is a specialist pharmaceutical company involved in the research, development and commercialisation of therapeutic products for chronic respiratory and autoimmune diseases. Its development pipeline of products include Aridol for the management of asthma, Bronchitol for cystic fibrosis and chronic obstructive pulmonary disease (COPD) and PXS64 for the treatment of multiple sclerosis. Founded in 1998, Pharmaxis was listed on the Australian Stock Exchange in November 2003 (symbol PXS), and on NASDAQ (symbol PXSL) in August 2005. The company is headquartered in Sydney at its TGA-approved manufacturing facilities.

## **About Aridol**

Asthma is among the top 10 most commonly cited reasons for consulting a General Practitioner (GP). Yet GPs currently rely upon older tests that are often inaccurate and cumbersome to assess airway inflammation in patients with asthma.

The innovative Aridol lung function test, developed by Australian researchers and Pharmaxis Ltd, will help doctors more accurately determine the severity of a patient's disease and allow prescription of the right amount of medication.

The simple 15 minute test uses a patented formulation of mannitol processed into a respirable powder. The test requires the patient to inhale increasing doses of Aridol, which causes the airways to narrow and contract that is simply detected by measuring the amount of air a person can exhale in one second. The smaller the dose required to cause contraction, the more severe the patient's asthma diagnosis. People without airway inflammation do not respond to an Aridol challenge test.

Doctors can use the results of this test to measure how severe a patient's asthma is and the medication and dose required to bring it under control.

## **About asthma**

Asthma is a common, chronic lung disease that affects people of all ages. It is characterised by ongoing breathing problems and symptoms of wheezing, breathlessness, chest tightness and coughing. Although the causes of the disease are not fully understood, often there is a family history of asthma, eczema or hay fever.

Asthma is most commonly triggered by colds and flu, exercise, inhaled allergens (pollens, moulds, animal hair and dust mites), cigarette smoke, changes in temperature and weather, particular drugs (including aspirin and some blood pressure medications), chemicals and strong smells and some foods, food preservatives, flavourings and colourings.

When asthma is not effectively diagnosed and treated, it can lead to a decrease in quality of life and poor participation in exercise activities, school and workplace absenteeism, hospitalisation, and in some cases, death.

Published estimates indicate that asthma affects over 20 million people in the U.S. It is estimated that each year in the U.S., 4.7 out of every 1,000 people under the age of 16 are newly diagnosed with asthma and two out of every 1,000 people aged 16 to 44 are newly diagnosed with the disease. Only about 30% of U.S. asthma patients receive inhaled

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corticosteroids despite evidence that uncontrolled asthma is common. Poorly controlled asthma can lead to irreversible damage to the airways.

Although there is no cure for asthma, people with asthma can effectively control their symptoms and enjoy a better quality of life by taking asthma medication, continuing to monitor their symptoms, staying active and healthy, avoiding triggers if and when possible, having an asthma action plan and visiting their doctor regularly.

**Forward-Looking Statements**

The statements contained in this press release that are not purely historical are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements in this press release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the potential for Aridol to be used in the treatment of asthma. All forward-looking statements included in this press release are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. We can not guarantee that any product candidate will receive FDA or other regulatory approval or that we will seek any such approval. Factors that could cause or contribute to such differences include, but are not limited to, factors discussed in the "Risk Factors and Other Uncertainties" section of our Form F-1 filed with the U.S. Securities and Exchange Commission.

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