

**ENROLMENT COMMENCED IN ARIDOL™ COPD STUDY**

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Pharmaxis (ASX:PXS; NASDAQ: PXSL) is pleased to announce that its Aridol™ Phase II clinical trial in 140 patients with chronic obstructive pulmonary disease (COPD) has enrolled its first patient. The study is designed to assess the ability of Aridol to predict the usefulness of inhaled corticosteroids as a treatment for COPD. It is being conducted in 12 sites throughout Australia.

All patients in the study will receive an Aridol test at the beginning of the trial, and then begin a 12 week course of inhaled corticosteroids. The trial will record differences in lung function, quality of life and general health of the patient. Full patient recruitment is expected to take about six months and, with a treatment period of three months, results are not expected before the quarter ending September 30, 2006.

Alan Robertson, Pharmaxis chief executive officer said: 'This latest trial will assess the potential second use for Aridol. According to our preliminary data, only one in five COPD patients respond to inhaled steroids. Our expectation is that Aridol will be able to identify the responders. If successful, Aridol has the potential to cut the consumption of inhaled steroids and reduce expense and unnecessary side effects for a large number of patients.'

COPD is the world's fourth largest cause of death, and is estimated to affect about 30 million people in the western world.

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-COPD-201 (a Phase II study with Aridol)
Blinding Status	Open
Placebo Controlled	No
Treatment Method	
Route	Inhalation
Frequency	Once only, before treatment with inhaled corticosteroids
Dose level	0 – 635mg inhaled mannitol
No of subjects	140
Subject Selection Criteria	Aged 45 - 80 years, male and female, ≥ 10 pack years smoking history, spirometry consistent with COPD (pre-bronchodilator FEV <sub>1</sub> ≥60% (and >1.4L) and FEV <sub>1</sub> /FVC <70%), symptoms of dyspnoea and/or chronic cough and/or excess sputum production, untreated with ICS or oral steroids for a period of 6 weeks, clinically stable for 14 days prior to study entry.
Trial Location	Australia
Commercial partners involved	None
Expected duration	12 months
Primary end point	FEV <sub>1</sub> for Aridol positive vs Aridol negative patients
Secondary end points	Aridol dose provoking a fall in FEV <sub>1</sub> of 10% and 15% Response dose ratio Lung function parameters Quality of life Exacerbations

## **About Pharmaxis**

Pharmaxis (ACN 082 811 630) is a specialist pharmaceutical company involved in the research, development and commercialization 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 PXS25 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 cause 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 COPD**

Chronic Obstructive Pulmonary Disease (COPD) comprises many serious conditions affecting the lung, including emphysema, chronic bronchitis and bronchiectasis. More than 30 million people are living with COPD worldwide. COPD is the fourth leading cause of death after heart disease, cancer and stroke and is responsible for more than 100,000 deaths a year in the US and Western Europe alone. The disease costs the US healthcare system US\$40 billion per year.

People with COPD are affected by a breakdown in the natural mechanism (cleansing, hydrating and protecting) of the mucus lining of the airways. They face the ongoing challenge of clearing excessive and thickened secretions from their congested lungs, usually by constant coughing. Current treatments are designed to assist this natural process of keeping the mucus hydrated and clearing it from the lungs. Management of the disease generally involves bronchodilators and steroids. Regrettably however, only one in five patients respond positively to steroids.

Breathing problems, respiratory infections, poor sleep, general discomfort, lifestyle limitations and the gradual deterioration of lung function over the years makes living with COPD a challenge.

Pharmaxis is dedicated to developing products to treat this debilitating disease.

## **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 COPD. 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 20-F filed with the U.S. Securities and Exchange Commission on August 22, 2005.