ASX/ Media release **26 October 2004**

Pharmaxis Aridol asthma trial successful

Pharmaxis (ASX:PXS) is pleased to announce the Phase III clinical trial of Aridol™ achieved its endpoints. The trial was designed to evaluate Aridol as a test for asthma. The positive results mean the company will apply for marketing authorisation later this year in Australia, and early in 2005 in Europe. Subject to regulatory approval, sales of Aridol are expected to commence in 2005. The annual revenue potential of Aridol as a management tool for Asthma is estimated to be in excess of $250 million.

Aridol is designed to identify patients with active asthma and provide information on the severity of their disease and the effectiveness of their current treatment. In the trial, Aridol correlated well with patients diagnosed as asthmatic by an expert physician. Importantly, preliminary analysis of the Aridol test results also suggests that 25% of the asthmatic patients studied should have their medication increased or changed to improve control of their disease, and up to 17% could have their medication decreased without adverse effects.

Alan Robertson, Pharmaxis chief executive officer said, ”The results provide evidence that Aridol can improve current best practice for diagnosis and management of asthma and ultimately offer a better health outcome for asthma patients. We are continuing to invest globally in studies that will establish Aridol as the yardstick by which asthma is assessed.”

Asthma is a public health problem affecting 52 million people worldwide and 2.2 million people in Australia, and patients often need daily medication for its life-long effects. The diagnosis and management of asthma is most commonly based on observation of symptoms. Recent surveys indicate that only 5% of patients achieve optimum control of their asthma[1]. For a long time, a new tool such as Aridol has been needed that can reduce the cost of asthma to healthcare systems and improve patients well being. Asthma cost the US healthcare system alone US$15 billion last year. In 2003, 400 lives in Australia and 4,500 in the United States were lost to asthma.

The study demonstrated the safety of Aridol as a test for assessing the presence and severity of airway inflammation, and its sensitivity and specificity in identifying children and adults with asthma.

The trial also demonstrated that Aridol compared well with hypertonic saline (HS), a test used to confirm asthma amongst athletes at the recent Olympic games. No serious adverse events occurred in any subject.

Brett Charlton, Pharmaxis medical director said, “The consistent feedback from trial participants was that Aridol was easy and comfortable to use. We have much more data from the trial that we are still analysing, but even at this early stage we can say that Aridol has proven itself as a useful and practical new tool for clinicians treating asthma”

The Phase III, open label, blinded, randomised crossover trial commenced in January 2004, and studied 646 asthmatic and non-asthmatic subjects aged from 6 to 83 years, at 12 hospitals in Sydney, Melbourne, Brisbane, Newcastle and Canberra.

The trial was conducted in accordance with the International Committee of Harmonisation (ICH) guidelines for Good Clinical Practice (GCP).

Aridol is a patented, inhalable, dry powder that can be administered using a convenient, hand-held device. The test does not require specialist equipment and can be performed in a general practitioner’s surgery. It is manufactured by Pharmaxis in the company’s TGA-approved manufacturing facility.

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

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[1] *J Allergy Clin Immunology 2004, 114(1);40-47*

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About Pharmaxis (ACN 082 811 630)

Pharmaxis develops innovative pharmaceutical products to treat human respiratory and autoimmune diseases. Its 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 and is traded under the symbol PXS. The company is chaired by Denis Hanley and is headquartered in Sydney at its TGA-approved manufacturing facilities.

For more information about Pharmaxis, go to www.pharmaxis.com.au or call +61 2 9451 5961.

About the Trial

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

Name of Trial	**DPM- A-301**
Blinding Status	**Operator blinded, open label**
Placebo Controlled	**No**
Treatment Method	
Route	**Inhalation**
Frequency	**Repeat administration on a single occasion**
Dose levels	**0-635 mg**
Number of Subjects completing a test	**646**
Dropout Rate	**Nil**
Subject Selection Criteria	**Either gender, ≥ 6 years, with a baseline FEV1 > 70% for asthmatics or >80% for non asthmatics of predicted**
Primary End Points	
Safety	**No serious adverse events**
Sensitivity compared to existing HS test **Specificity compared to existing HS test**	**81%** **87%**
Secondary End Points	
Sensitivity compared to diagnosis (in patients not on inhaled corticisteroids) **Specificity compared to diagnosis**	**Up to 91%** **95%**
Other	**Additional analysis in progress**

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.

Australia has the highest rate of asthma in the world. The disease affects one in four children, one in seven teenagers and one in 10 adults. It is the most common medical cause for hospitalisation among children aged five to 14. It is estimated that one in five Australians with asthma are undiagnosed. Furthermore, many people with asthma are also misdiagnosed.

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.

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 diagnose a patient's asthma.

The innovative Aridol™ lung function test, developed by Australian researchers and Pharmaxis Ltd, will help doctors more accurately diagnose 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. This change in the airways is simply detected by measuring the amount of air a person can exhale in one second (FEV1). The smaller the dose required to cause contraction, the more severe the patient's asthma diagnosis. People without asthma 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.