ASX/ Media release **23 December 2004**

US FDA GRANTS APPROVAL FOR ARIDOL™ PHASE III TRIAL

Pharmaxis (ASX:PXS) announced today that the United States Food and Drug Administration (FDA) has accepted an Investigational New Drug Application (IND) for the clinical testing of the company's asthma management product, Aridol.

The IND allows the start of a Phase III asthma clinical study in the US in about 150 patients. Results from the study will supplement the recent successful 600 patient Aridol Phase III trial undertaken in Australia and help the company apply for registration to market Aridol in the US.

The IND has been granted on the basis of satisfying FDA criteria regarding preclinical, chemistry, manufacturing and safety data from the completed and ongoing clinical studies.

Alan Robertson, Pharmaxis chief executive officer said: "This IND is a significant step towards registering Aridol for sale in the US. The new trial will commence in 2005, and we expect its completion during the second half of that year. A successful outcome will open up the major US market for Pharmaxis and further expand the global reach of Aridol."

It is estimated that more than 20 million Americans currently have asthma. Close to 1.9 million emergency room visits were attributed to asthma in the US in 2002[1].

The recently completed Australian Phase III trial of Aridol enables Pharmaxis to apply for marketing authorisation in Australia and Europe. Subject to regulatory approval, sales of Aridol are expected to commence here in 2005. The annual revenue potential of Aridol as a management tool for asthma is estimated to be in excess of $250 million worldwide.

Recent surveys indicate that only 5% of patients achieve optimum control of their asthma[2]. New tools such as Aridol are needed that can reduce the cost of asthma on healthcare systems and improve patients well being. Asthma cost the US healthcare system alone US$15 billion last year. In 2003, 4,500 lives in the United States were lost to asthma.

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 at Frenchs Forrest, Sydney.

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

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[1] American Lung Association *[2] J Allergy Clin Immunology 2004, 114(1);40-47*

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About Pharmaxis

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 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 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 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 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