ASX/ Media release **22 November 2004**

Pharmaxis files Aridol IND in the USA

Pharmaxis (ASX:PXS) announced today the filing of an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA). The IND is the first formal step in conducting a US clinical trial which will support a marketing application for Aridol in the USA in 2005.

Alan Robertson, Pharmaxis chief executive officer said that the filing of the IND was an important event in the continuing globalisation of Aridol: "The recently completed Australian Aridol trial allows us to apply for marketing authorisation in Europe and Australia. This study has been designed to extend our authorisation to the American market," he said.

"The filing of the IND represents the culmination of a significant effort by very many people and is indicative of the quality and expertise of the team we have assembled. The results from this trial and the recently completed, successful Phase III Australian trial will form the basis of a marketing application to be submitted to the FDA in 2005." said Dr Robertson.

The Phase III clinical trial will be conducted over ten sites in the US and will recruit 130 subjects. The objective of the trial is to determine sensitivity and specificity of Aridol with respect to clinical diagnosis of asthma.

Asthma is a public health problem affecting over 20 million people in the USA. The diagnosis and management of asthma is most commonly based on observation of symptoms. New tools are needed that can reduce the cost of asthma on healthcare systems and improve patient well being. In the USA, asthma cost the healthcare system US$15 billion last year and 4,500 people died from the condition.

The trial will be 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 facility.

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

ends#

For further information, please contact:

Alan Robertson - Pharmaxis Chief Executive Officer

Ph: (02) 9454 7202 or alan.robertson@pharmaxis.com.au

Released through:

Ashley Rambukwella – Financial & Corporate Relations

Ph: (02) 8264 1004 / m. 0407 231 282 or a.rambukwella@fcr.com.au

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 the IND

An IND application has to be approved before a clinical trial can be conducted in the USA and typically follows a pre-IND meeting with the FDA. At this meeting the proposed contents of the IND are discussed and broadly agreed. Pharmaxis met with the FDA in July of this year.

There are three main sections to the Aridol IND:

- **The chemistry, manufacturing and controls**
- **The pharmacology and toxicology section which deals with the safety profile of Aridol**
- **The clinical section which addresses the clinical trial and contains the Investigator's brochure and the clinical trial protocol.**

Following successful completion of the clinical programme, Pharmaxis will be in a position to apply for approval for a New Drug Application (NDA) with the FDA. The FDA will review the NDA and based on an assessment of Aridol's safety and effectiveness may grant approval for marketing.

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.

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.

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.