



ASX/ Media release

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**PHARMAXIS APPLIES TO MARKET ARIDOL™ IN EUROPE**

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Specialty pharmaceutical company Pharmaxis Ltd (ASX:PXS) announced today that it has submitted the marketing authorisation application for its asthma management product Aridol to the Swedish Medicinal Products Agency (MPA), the national authority responsible for the regulation and surveillance of drugs and other medicinal products in Sweden.

Authorisation can take from six to eighteen months and, if granted, will allow Pharmaxis to sell Aridol in the 25 member countries of the European Union.

Alan Robertson, Pharmaxis chief executive officer said: "This European submission is a further important step in the commercialisation of Aridol. Additionally, we have a number of investigator led Aridol clinical studies in progress in Europe. Together with our initiatives in the United States and Australia, this is a key step in making Aridol available worldwide."

The results from a comprehensive program of clinical testing show that Aridol can improve best practice for asthma management and provide a better outcome for the patient. Presently, there are no registered tests available in Europe, and Aridol will fill an important and unmet medical need.

Pharmaxis' application is supported by data from Phase II and Phase III studies of Aridol in patients with asthma. More than 600 patients participated in the pivotal Phase III clinical study, which was conducted in Australia and completed in 2004.

Aridol has been developed as a challenge test for diagnosing and managing asthma, and is being manufactured by Pharmaxis at its TGA approved facility in Frenchs Forest in Sydney, Australia. Asthma is a major health problem affecting more than 52 million people around the world. The annual revenue potential of Aridol as a management tool for asthma is estimated to be in excess of \$250 million.

In January 2005, Pharmaxis submitted an Aridol marketing application to the Australian Therapeutic Goods Administration. If approved, registration will grant Pharmaxis the rights to sell Aridol in Australia.

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

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**About Pharmaxis**

Pharmaxis (ACN 082 811 630) develops innovative pharmaceutical products to treat human 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.

Achievements since listing include:

- Successful completion of Bronchitol Phase II study for bronchiectasis
- Successful completion of Aridol Phase III study for asthma testing
- Acceptance by the US FDA of Aridol as an Investigational New Drug (IND)
- Lodgement of marketing application for Aridol in Australia
- An AusIndustry's Pharmaceuticals Partnerships Program (P3) grant
- Orphan drug status granted in the USA for Bronchitol in bronchiectasis

Founded in 1998, Pharmaxis was listed on the Australian Stock Exchange in November 2003 and is traded under the symbol PXS.

For further information, go to [www.pharmaxis.com.au](http://www.pharmaxis.com.au) or call +61 2 9454 7200.

**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.