

PHARMAXIS APPLIES FOR REGULATORY APPROVAL TO MARKET ARIDOL

Pharmaxis Ltd (ASX:PXS) announced today the submission of a marketing authorisation application for Aridol to the Therapeutic Goods Administration (TGA). If approved, registration will grant Pharmaxis the rights to sell Aridol in Australia.

Aridol is a patented, inhalable, dry powder which is administered to the lungs through an inhaler to test for asthma, measure its severity and the effectiveness of current medication. It can also help predict whether patients with chronic obstructive pulmonary disease (COPD) will receive a clinical benefit from inhaled steroids. Results from clinical testing show Aridol can improve current best practice for patient diagnosis and asthma management.

Alan Robertson, Pharmaxis chief executive officer said: "Aridol represents a new approach to asthma management, and the submission for marketing authorisation is the culmination of a rigorous program of testing to ensure high standards of safety and quality to the Australian community."

"Pharmaxis is dedicated to the development of safe and effective treatments for airway diseases, and we will work closely with regulatory authorities worldwide to bring Aridol to patients as quickly as possible."

Testing with Aridol does not require specialist equipment, and can be performed in a general practitioner's surgery. Aridol is manufactured by Pharmaxis at its TGA-approved facilities in Sydney, Australia. The annual revenue potential of Aridol as a management tool for asthma is estimated to be in excess of \$250 million.

Pharmaxis's application is supported by data from Phase II and Phase III studies of Aridol in patients with asthma. The pivotal Phase III clinical study involving over 600 patients was conducted in Australia and completed in 2004. In the trial, Aridol correlated well with patients diagnosed as asthmatic by an expert physician. Importantly, analysis of the Aridol test results indicated that 25 per cent of the asthmatic patients studied should have their medication increased or changed to improve control of their disease, and up to 17 per cent could have their medication decreased without adverse effects.

It is estimated that more than two million Australians currently have asthma. Asthma is the leading cause of children being sent to hospital and is one of the main reasons for employees to miss days at work.

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 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.