

## ASX/NASDAQ Media release

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# PHARMAXIS' ARIDOL GAINS EUROPEAN APPROVAL

## ASTHMA PRODUCT NOW APPROVED IN 14 COUNTRIES ACROSS EUROPE

The European Mutual Recognition Procedure has successfully completed evaluating the Pharmaxis (ASX:PXS, NASDAQ:PXSL) lung function test Aridol, allowing the 13 European countries involved to issue a marketing authorisation.

The European approval follows Sweden's acceptance of Aridol late last year.

Pharmaxis CEO Dr Alan Robertson said the decision provides an important new disease management tool to millions of asthma sufferers across Europe. It is the successful culmination of a significant drug registration process by Pharmaxis.

"Aridol is the first lung challenge test to be approved Europe-wide. We are delighted by this validation of Pharmaxis' capability to bring a product from concept to global markets," said Dr Robertson.

"Countries involved in the Mutual Recognition Procedure have agreed to approve the marketing of Aridol for the detection of airway reactivity in patients with asthma and other respiratory diseases."

The 13 approving countries include Germany, France, the United Kingdom, Italy, the Netherlands, Belgium, Denmark, Greece, Spain, Finland, Ireland, Norway and Portugal. Aridol is already being marketed in Sweden and Australia.

Distribution partners have been established for most major markets, with further distributors pending. Pharmaxis is working closely with its European partners to achieve a successful launch of Aridol in these important markets. Pharmaxis distributes Aridol directly to physicians in the UK and Australia.

A simple-to-use airways inflammation test, Aridol is administered as a dry powder in a hand-held inhaler. Doctors can use the results of this test to identify airway hyper-responsiveness – a hallmark of asthma.

Asthma affects 52 million people worldwide, many of whom may be receiving inappropriate medication because of the absence of an objective test - until now. Asthma cost the US healthcare system alone US\$15 billion in 2004. In 2003, asthma claimed 400 Australian and 4,500 US lives.

Clinical trial results suggest that 25% of asthmatic patients are being treated with sub optimal dosages of asthma medication, and up to 17% could reduce their medication without adverse effects.

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

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#### **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 assess airway inflammation in patients with asthma. The easy to administer test uses a patented formulation of mannitol processed into a breathable 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 airway inflammation do not respond to an Aridol challenge test. Doctors can use the results of this test to identify airway hyperresponsiveness – a hallmark of asthma.

### **About Pharmaxis**

Pharmaxis (ACN 082 811 630) is a specialist pharmaceutical company involved in the research, development and commercialization of therapeutic products for chronic respiratory and autoimmune diseases. Its development pipeline of products include Aridol<sup>TM</sup> for the management of asthma, Bronchitol<sup>TM</sup> for cystic fibrosis and chronic obstructive pulmonary disease (COPD) and PXS64 for the treatment of multiple sclerosis.

Founded in 1998, Pharmaxis was listed on the Australian Stock Exchange in November 2003 (symbol PXS), and on NASDAQ (symbol PXSL) in August 2005. The company is headquartered in Sydney at its TGA-approved manufacturing facilities. For more information about Pharmaxis, go to www.pharmaxis.com.au or contact Jane Sugden, Investor Relations +61 2 9454 7230.

## Forward-Looking Statements

The statements contained in this press release that are not purely historical are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements in this press release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the potential for Aridol and/or Bronchitol. All forward-looking statements included in this press release are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. We can not guarantee that any product candidate will receive FDA or other regulatory approval or that we will seek any such approval. Factors that could cause or contribute to such differences include, but are not limited to, factors discussed in the "Risk Factors and Other Uncertainties" section of our Form 20-F lodged with the U.S. Securities and Exchange Commission.