



## ASX/NASDAQ Media Release

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### PHARMAXIS ANNOUNCES NEW DRUG APPLICATION SUBMISSION FOR ARIDOL™

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Pharmaceutical company Pharmaxis (ASX:PXS, NASDAQ:PXSL) today announced it had submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for Aridol, a bronchial challenge test. Bronchial challenge tests are designed to help in the correct diagnosis and assessment of asthma. The structure and content of the NDA was based on a pre-NDA meeting with the FDA and follows the completion of two international randomized pivotal Phase 3 trials with Aridol involving over 1,000 subjects.

The NDA application is the vehicle through which Pharmaxis formally proposes that the FDA approve a new pharmaceutical for sale and marketing in the U.S. There is currently no FDA approved dry powder bronchial challenge test available in the U.S. and Aridol is the first test of this kind that comes complete and ready to use.

Alan Robertson, Pharmaxis Chief Executive Officer said: "We are delighted to announce this major milestone for Pharmaxis especially in light of the fact that this is believed to be the first such NDA submitted by an Australian company for a drug designed and developed in Australia. Pharmaxis is committed to the development of safe and effective products to help people living with lung diseases, and we look forward to working closely with the FDA over the coming months".

Asthma affects more than 34 million people in the U.S.<sup>1</sup> with an annual economic cost in the U.S. of \$19.7 billion<sup>1</sup> and has a substantial impact on the health of a nation. Aridol was developed to assist with improving existing management strategies that help to control asthma and prevent worsening of its symptoms.

Aridol is approved for sale in most major European countries, Australia and Korea. Aridol has been included in the Global Initiative for Asthma guidelines, and in the U.S. Asthma Management Guidelines. It is one of the tests recommended by the World Anti-Doping Agency, and other sports governing bodies to ensure elite athletes who are asthmatic are properly diagnosed and treated.

#### *Reference*

*1.American Lung Association. Epidemiology & Statistics Unit, Trends in Asthma Morbidity and Mortality 2007*

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**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 immune disorders. Its development pipeline of products includes Aridol for the management of asthma, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD), PXS25 for the treatment of lung fibrosis and PXS4159 for asthma. Founded in 1998, Pharmaxis is listed on the Australian Securities Exchange (symbol PXS), and on NASDAQ Global Market (symbol PXSL). The company is headquartered in Sydney at its TGA-approved manufacturing facilities. For more information about Pharmaxis, go to [www.pharmaxis.com.au](http://www.pharmaxis.com.au) or contact Investor Relations on phone +61 2 9454 7200.

**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.

**Forward-Looking Statements**

The statements contained in this media 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 media 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 media 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.