



## ASX/NASDAQ Media Release

14 May 2009

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### U.S. FDA ACCEPTS ARIDOL™ NEW DRUG APPLICATION FOR REVIEW

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Pharmaxis (ASX:PXS, NASDAQ:PXSL) today announced it had received notification from the United States Food and Drug Administration (FDA) that the New Drug Application (NDA) for its mannitol bronchial challenge test Aridol™ has been accepted for standard review. The FDA will advise the result of the review on 27 December 2009.

Pharmaxis is seeking approval for Aridol for "the assessment of bronchial hyperresponsiveness to aid in the diagnosis of patients with symptoms of or suggestive of asthma." Asthma affects more than 34 million people in the U.S. with an annual economic cost of \$19.7 billion. When approved, Aridol will be the first dry powder bronchial challenge test available in the U.S.

Alan Robertson, Pharmaxis Chief Executive Officer said: "We have been greatly encouraged by the interest respiratory physicians have shown in Aridol at recent U.S. scientific conferences. We estimate that 200,000 bronchial hyper-responsiveness tests are performed in the US each year and hope that the introduction of a dry powder test kit will encourage more physicians to utilize this test when diagnosing asthma. We look forward to working with the FDA to complete the review."

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.

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**About Pharmaxis**

Pharmaxis (ACN 082 811 630) is a respiratory specialty 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™ (mannitol bronchial challenge test) which is a tool to diagnosis and assess for asthma; Bronchitol™ (mannitol inhalation powder) 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 with regional offices in the US, Europe, and Asia-Pacific. For more information about Pharmaxis, go to [www.pharmaxis.com.au](http://www.pharmaxis.com.au) or contact Investor Relations on: +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 in assessing airway inflammation in patients with asthma. The easy to administer Aridol 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.