



## Media release

27 April 2010

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### Pharmaxis provides FDA resubmission for Aridol U.S. marketing application

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Pharmaxis (ASX:PXS) today announced that the U.S. Food and Drug Administration (FDA) has acknowledged receipt of the resubmission of its New Drug Application (NDA) for Aridol™ (mannitol inhalation powder). The resubmission follows an action letter received from the FDA dated 23 December 2009.

Included in the Pharmaxis resubmission is a safety information update, revised labelling and further information regarding the Chemistry Manufacturing and Control (CMC).

Dr. Alan Robertson, Pharmaxis' Chief Executive Officer, said "We believe that this resubmission fully addresses all of the issues raised in the action letter and we look forward to working with the FDA to conclude the Aridol NDA".

The matter is scheduled to complete within 6 months.

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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). 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 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. This process 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**

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 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" section of our Statutory Annual Report available on the Pharmaxis website.