

## Media Release

6 October 2010

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### US FOOD AND DRUG ADMINISTRATION APPROVES ARIDOL

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Pharmaceutical company Pharmaxis (ASX:PXS) is pleased to announce the US Food and Drug Administration (FDA) has approved Aridol™ (mannitol inhalation powder) Bronchial Challenge Test Kit for marketing.

Pharmaxis Acting Chief Executive Officer Mr Gary Phillips said, “We are extremely pleased with this achievement. An FDA submission is a complex task requiring involvement from almost all divisions of the company and this positive outcome has shown Pharmaxis’ ability to successfully work with the FDA to achieve a positive outcome.

“The US represents one of the world’s largest markets for bronchial challenge tests. Aridol offers a new type of test with improved levels of convenience and efficiency and we believe it will find an important place in the overall assessment of bronchial hyperresponsiveness (BHR) when asthma is suspected. We are well prepared for a US launch of Aridol with a commercial team in place and pre-marketing activities underway with the respiratory community. We anticipate commencing sales in Quarter 1, 2011”, Mr Phillips said.

The FDA have approved Aridol for the assessment of bronchial hyperresponsiveness in patients 6 years of age or older who do not have clinically apparent asthma. Aridol should not be used as a standalone tool to assess asthma, but as part of a physician’s overall assessment of asthma.

Asthma currently affects more than 23 million people in the US and annually causes over 13 million visits to see a physician and almost half a million hospitalizations. Aridol is endorsed by several international organisations and guidelines including: the International Olympic Committee Medical Commission’s Independent Panel, the US Asthma Management Guidelines, and the Global Initiative for Asthma (GINA) Report on Global Strategy for Asthma Management and Prevention.

“Aridol is an important step in the advancement of bronchial challenge testing because it induces constriction through the release of endogenous inflammatory mediators,” said Bill Storms, MD, Clinical Allergist, Colorado Springs, USA. “We believe that indirect challenges such as Aridol, correlate better with airway inflammation, a hallmark of asthma.”

Pharmaxis has already received approval for Aridol in key world markets including parts of Asia, Europe and now the USA. Aridol is manufactured at Pharmaxis’ FDA approved GMP facility in Sydney, Australia which is capable of large scale production of the challenge test.

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**About Pharmaxis**

Pharmaxis Ltd (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 Aridolga, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD), PXS25 for the treatment of lung fibrosis and, ASM8 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 yet physicians currently rely upon older tests that are often inaccurate and cumbersome in assessing airway hyperresponsiveness 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 are less likely to respond to an Aridol challenge test. Aridol is approved for sale in the United States, most major European countries, Australia and South Korea

**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 cannot guarantee that any product candidate will receive regulatory approval or that we will seek any such approval.