

# ASX/NASDAQ Media Release

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## PHARMAXIS TO APPLY TO MARKET BRONCHITOL IN AUSTRALIA

Pharmaxis (ASX:PXS, NASDAQ:PXSL) today announced that it will apply for Australian marketing approval of Bronchitol for patients with bronchiectasis, following a meeting with the Australian Therapeutic Goods Administration (TGA).

Bronchitol is being developed as a twice daily therapy for people with the incurable lung condition Bronchiectasis. The meeting with the TGA on 12 February was arranged following the successful completion of a Phase III clinical study of Bronchitol in the second half of 2007. The trial demonstrated a significant improvement in the quality of life for patients treated with Bronchitol, and a significant difference in their mucus clearance.

Pharmaxis will submit its marketing authorisation application following the conclusion of the ongoing safety component of the Phase III trial – an optional 12 month extension to determine the safety of long-term Bronchitol treatment. This component of the trial has had a high participation rate and a low withdrawal rate, and will complete mid-year. Pharmaxis will file the marketing application during the third quarter of 2008.

"We are delighted that our discussions with the TGA have provided a path forward for bringing Bronchitol to market in Australia," said Pharmaxis Chief Executive Officer Alan Robertson.

"More than 20,000 Australians suffer from bronchiectasis and Pharmaxis expects Bronchitol to be the first targeted medication for this patient group in over 20 years – addressing an important medical need."

Bronchiectasis is an incurable, degenerative and chronic lung condition that makes breathing difficult through excessive mucus build up in the lungs. Pharmaxis has the only product in Phase III clinical trials for bronchiectasis anywhere in the world.

Over 600,000 patients worldwide suffer from bronchiectasis. Total U.S. medical care expenditure is US\$13,000 per bronchiectasis patient, double that of patients without the disorder; and an increased overall cost of US\$630 million. Widespread availability of high resolution scanners is leading to increasing diagnosis and the understanding that bronchiectasis is more common than previously thought. Pharmaxis is developing Bronchitol as a daily treatment administered by inhalation to the patient's lungs.

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

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#### **About Bronchitol**

Pharmaxis Ltd is developing Bronchitol for the management of chronic obstructive lung diseases including bronchiectasis, cystic fibrosis and chronic bronchitis. Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. It is designed to hydrate the lungs, restore normal lung clearance mechanisms, and help patients clear mucus more effectively. Clinical studies have shown Bronchitol to be well tolerated, to improve quality of life, and to stimulate mucus hydration and clearance in people with bronchiectasis and cystic fibrosis.

#### **About Bronchiectasis**

Bronchiectasis is one of the chronic obstructive pulmonary diseases, or COPDs, and affects children and adults. It is often mistaken for asthma or pneumonia and misdiagnosis is common. In this disease the bronchial tubes become irreversibly enlarged, forming pockets that can become infected. The bronchi walls are damaged, causing impairment to the lung's complex cleaning system. The tiny hairs, or cilia, which line the bronchial tubes and sweep them free of dust, germs and excessive mucus are unable to function properly. The result is that matter such as mucus and bacteria accumulates affecting the performance of the lungs and the quality of life of the individual.

#### **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 for the management of asthma, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD) and PXS64 for the treatment of multiple sclerosis. Founded in 1998, Pharmaxis is listed on the Australian Stock 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 <a href="https://www.pharmaxis.com.au">www.pharmaxis.com.au</a> or contact Investor Relations +61 2 9454 7200

## **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.