# Media Release

**14 May 2013**

## PHARMAXIS MEETING FDA TO DISCUSS BRONCHITOL FOR CYSTIC FIBROSIS BUSINESS REVIEW ANNOUNCEMENT END OF MAY

Pharmaceutical company Pharmaxis (ASX: PXS) announced it will meet this week with representatives of the Food and Drug Administration (FDA) to discuss the key parameters of the clinical trial necessary to secure approval for Bronchitol® (mannitol) for the treatment of cystic fibrosis in the USA.

The Type A meeting with the Division of Pulmonary, Allergy and Rheumatology Products (DPARP) will be attended by members of Pharmaxis' medical and regulatory teams and will take place in Maryland, USA.

Pharmaxis CEO Mr Gary Phillips said, "This meeting is an opportunity for a structured discussion with the FDA on key points of its evaluation of the Company's New Drug Application and the pathway for approval of Bronchitol. Pharmaxis is seeking guidance so it can design a clinical trial to meet the FDA's requirements for substantial evidence of the efficacy of Bronchitol in patients with cystic fibrosis.

"Defining the pathway for regulatory approval for Bronchitol in the USA is important for the 30,000 CF patients who still have an unacceptably short life expectancy and who need new products that are both efficacious and safe. It will also remove uncertainty about the time and investment required to access the valuable US market where Bronchitol has orphan drug designation providing for seven years of market exclusivity from approval.

"The outcome of the FDA meeting will allow Pharmaxis to finalise a business review and implement a phased restructuring based around the expected delay to US revenue and the approval paths for Bronchitol in cystic fibrosis and bronchiectasis. The results of this review will be announced by the end of May 2013."

Bronchitol is approved in Europe for adults and in Australia for patients aged six years and over. These approvals were based on data collected in two large scale global Phase III clinical trials conducted in 600 patients with cystic fibrosis six years of age and older. Bronchitol is reimbursed for patients in Australia and the United Kingdom.

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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 disorders. Its product Aridol® for the assessment of asthma is sold in key international markets. Its product Bronchitol® for cystic fibrosis is recently launched in Europe and Australia and its development pipeline of products includes, Bronchitol for bronchiectasis, PXS64 for the treatment of lung fibrosis, ASM8 for asthma and PXS4728 for fibrotic disease. Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company's head office and manufacturing facilities are located in Sydney. For more information about Pharmaxis, go to www.pharmaxis.com.au or contact Investor Relations on phone +61 2 9454 7200.

**About Bronchitol**
Bronchitol has been developed to help clear mucus (a major source of lung infections), improve lung function and reduce exacerbations in patients with cystic fibrosis. Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. Inhaled mannitol hydrates the lungs, helps restore normal lung clearance, and allows patients to clear mucus more effectively.

**About Cystic Fibrosis**
In a healthy person, there is a constant flow of mucus over the surfaces of the air passages in the lungs, removing debris and bacteria. In CF, an inherited disease, a defective gene disrupts ion transport across the epithelial membrane within cells. In the lungs, this leads to a depletion of the airway surface liquid that normally bathes the cilia, and a resultant reduction in mucociliary clearance. The result is thick, sticky mucus that clogs the lungs, severely restricting the natural airway-clearing process. It also increases the potential for bacteria to become trapped and for inflammation, thus creating an unhealthy lung environment that leads to life-threatening lung infections.

**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 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.