



ASX/NASDAQ Media release

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**PHARMAXIS ENROLS FIRST PATIENT IN PHASE III BRONCHIECTASIS TRIAL**

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Specialist pharmaceutical company Pharmaxis Ltd (ASX:PXS, NASDAQ:PXSL) is pleased to announce that the first of 350 patients has enrolled in its Phase III Bronchitol trial to treat the chronic obstructive lung disease, bronchiectasis; an incurable, degenerative and chronic inflammatory condition of the lungs affecting more than half a million people worldwide.

The trial will investigate the safety and effectiveness of Bronchitol in the treatment of bronchiectasis. It is being conducted at 22 hospitals across Australia, New Zealand, the United Kingdom and Northern Ireland. Two thirds of trial volunteers will receive Bronchitol and the remaining one third will receive a placebo. Patients will be assessed for mucus clearance and quality of life as measured by symptoms, cough severity, exercise capacity and lung function.

This trial follows a successful Phase II study in patients with bronchiectasis and the trial design has been constructed following meetings with the European regulatory agencies.

Alan Robertson, Pharmaxis Chief Executive Officer said 'This pivotal trial for Bronchitol is the final step before registration in Australia, New Zealand and the European Union. When complete, the results of the study should provide sufficient data for a marketing application to be lodged.'

Full patient recruitment is expected to take about 8 months and treatment approximately 4 months. Results are expected to be available in the June quarter of 2007.

Bronchitol is a patented, inhalable dry powder that can be administered by a convenient, hand-held, pocket sized device. The United States Food and Drug Administration granted orphan drug status for Bronchitol for the treatment of bronchiectasis in 2005.

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

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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 autoimmune diseases. Its development pipeline of products include Aridol™ for the management of asthma, Bronchitol™ for cystic fibrosis and chronic obstructive pulmonary disease (COPD) and PXS64 for the treatment of multiple sclerosis.

Founded in 1998, Pharmaxis was listed on the Australian Stock Exchange in November 2003 (symbol PXS), and on NASDAQ (symbol PXSL) in August 2005. 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 Jane Sugden, Investor Relations +61 2 9454 7230.

## **About the trial**

The following information is provided in accord with the ASX and AusBiotech Code of Best Practice for Reporting by Life Science Companies.

Name of Trial	DPM B301 - a Phase III multicentre, randomised, parallel, placebo-controlled, double-blind study to investigate the safety and efficacy of Bronchitol™ (dry powder mannitol) in the symptomatic treatment of bronchiectasis.
Blinding Status	Double blind
Placebo Controlled	Yes
Ratio treatment:placebo	2:1
Treatment Method	
Route	Inhalation
Frequency	Twice daily for 12 weeks
Dose level	320mg mannitol or placebo
No of subjects	354
Subject Selection Criteria	<ul style="list-style-type: none"><li>• Known diagnosis of bronchiectasis (diagnosed by HRCT)</li><li>• Ages 15 – 80 years, male and female</li><li>• FEV1 50 - 80% of the predicted value and greater than 1.0L</li><li>• Absence of uncontrolled asthma or other unstable systemic diseases</li><li>• Clinically stable bronchiectasis for a period of 2 weeks prior to study entry</li><li>• Evidence of chronic sputum production</li><li>• Chronic cough and chronic chest congestion</li></ul>
Trial Location	Australia, New Zealand, United Kingdom, Northern Ireland
Commercial partners involved	Pharmaxis only
Expected duration	12 months
Primary end points	<ul style="list-style-type: none"><li>• To assess whether Bronchitol improves health related quality of life</li><li>• To assess the impact of Bronchitol on 24 hour sputum volume.</li></ul>
Secondary end points	<ul style="list-style-type: none"><li>• To assess the impact of Bronchitol on:<ul style="list-style-type: none"><li>• Bronchiectasis symptoms</li><li>• Cough severity</li><li>• Exercise capacity</li><li>• Lung function, including gas transfer</li><li>• Antibiotic use</li><li>• Bronchial wall thickening and inflammation</li><li>• Peripheral airway function</li></ul></li><li>• To demonstrate the safety profile of Bronchitol</li></ul>

### **About Bronchitol**

Pharmaxis Ltd is developing Bronchitol for the management of chronic obstructive lung diseases including cystic fibrosis, bronchiectasis 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 cystic fibrosis and bronchiectasis. Longer term clinical studies involving Bronchitol in cystic fibrosis and bronchiectasis are underway. These studies aim to demonstrate an improvement in lung function and quality of life, and a reduction in infection and physiotherapy needs.

### **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 are prone to infection. The bronchi walls become damaged, causing impairment to the lung's complex cleaning system. The result is that mucus and bacteria accumulate affecting the performance of the lungs and the quality of life of the patient.

### **Forward-Looking Statements**

The statements contained in this press 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 press 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 press 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.