



ASX/NASDAQ Media release

06 October 2006

**PHARMAXIS RECEIVES UK APPROVAL FOR PHASE III CYSTIC FIBROSIS TRIAL**

---

Specialist pharmaceutical company Pharmaxis Ltd (ASX:PXS, NASDAQ:PXSL) has received approval from the U.K. Medicines Healthcare products Regulatory Agency (MHRA) to begin the UK arm of an international Phase III clinical trial to evaluate Bronchitol in patients suffering from cystic fibrosis.

Alan Robertson, Pharmaxis Chief Executive Officer said: 'This Phase III trial for Bronchitol is the final clinical step before we seek registration for Bronchitol in the European Union and follows the successful Phase II cystic fibrosis trial reported late last year. When successfully completed, the results of the study should provide sufficient data for a European marketing application to be lodged.'

The trial design has been constructed following meetings with the European regulatory agencies and will investigate the effectiveness of Bronchitol in the treatment of cystic fibrosis. It will be conducted across Europe and Australia and subjects will be assessed for improvements in lung function, exacerbations, and quality of life.

Dosing of subjects is expected to commence in the first quarter of 2007 and full patient recruitment is expected to take about 12 months. Subjects will receive treatment for 6 months. Results are expected to be available mid 2008.

Bronchitol is a patented, inhalable dry powder formulation of mannitol that can be administered by a convenient, hand-held, pocket sized device. Both the United States Food and Drug Administration and the European Medicines Agency have granted orphan drug status for Bronchitol for the treatment of cystic fibrosis.

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

*ends#*

**SOURCE:** Pharmaxis Ltd, Sydney, Australia  
**CONTACT:** Alan Robertson - Chief Executive Officer  
Ph: +61 2 9454 7200, Fax +61 2 9451 3622

**RELEASED THROUGH:**

**United States:**

Brandon Lewis, Trout Group, +1 212 477 9007 or email [blewis@troutgroup.com](mailto:blewis@troutgroup.com)

**Australia:**

Ashley Rambukwella, Financial & Corporate Relations Pty Ltd. Ph: +61 2 8264 1004 or +61 407 231 282 or [a.rambukwella@fcr.com.au](mailto:a.rambukwella@fcr.com.au)

### **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 CF301 - a Phase III multicentre, randomised, parallel, controlled, double-blind study to investigate the safety and efficacy of the long term administration of Bronchitol (inhaled dry powder mannitol) in cystic fibrosis.
Blinding Status	Double blind
Placebo Controlled	Yes
Ratio treatment:placebo	2:1
Treatment Method	
Route	Inhalation
Frequency	Twice daily for 26 weeks
Dose levels	50% of active stream on 400mg, 50% on 200mg
No of subjects	300
Subject Selection Criteria	<ul style="list-style-type: none"><li>• Known diagnosis of cystic fibrosis</li><li>• Aged 6 years and over, male and female</li><li>• FEV1 30 - 90% of the predicted value</li><li>• Absence of uncontrolled asthma or other unstable systemic diseases</li></ul>
Trial Location	Europe and Australia
Commercial partners involved	Pharmaxis only
Expected duration	18 months
Primary end points	<ul style="list-style-type: none"><li>• To assess whether Bronchitol improves lung function</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>• Pulmonary exacerbations</li><li>• Quality of life</li><li>• Other measures of lung 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. An international Phase III trial in bronchiectasis is expected to complete recruitment of its target 350 subjects by the end of 2006.

### **About Cystic Fibrosis**

Cystic Fibrosis (CF) is a hereditary, life-limiting disease that affects the body's exocrine glands which produce mucus, saliva, sweat and tears. In this disease, a genetic mutation disrupts the delicate balance of sodium, chloride and water within cells, causing the exocrine glands to secrete fluids that are thick, sticky and poorly hydrated. This leads to chronic problems in various body systems, especially the lungs and pancreas, and the digestive and reproductive systems.

The thick mucus in the lungs severely affects the natural airway-clearing processes and increases the potential for bacteria to become trapped, resulting in respiratory infections that may require hospitalisation. Impairments to these essential lung defence mechanisms typically begin in early childhood and often result in chronic secondary infections, leading to progressive lung dysfunction and deterioration.

World wide approximately 75,000 people are living with CF.

### **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.