

***BRONCHITOL CYSTIC FIBROSIS DOSE FINDING STUDY COMMENCES***

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Pharmaxis Ltd (ASX:PXS; NASDAQ: PXSL) announced today that a Phase II clinical trial in patients with cystic fibrosis has dosed its first patients. The study is designed to determine the optimal dose of the mucus clearing agent, Bronchitol™, and is being conducted in seven hospitals throughout Canada.

Pharmaxis Chief Executive Officer Alan Robertson said: 'This Canadian trial builds on our previously reported Australian study with Bronchitol, which demonstrated a significant clinical benefit for people with cystic fibrosis. Our objective is to find the most suitable dose of Bronchitol for the important Phase III clinical trials which are scheduled to commence mid-2006.'

All patients in the study will receive the same dose of Bronchitol twice daily for 2 weeks, then will be randomised into three groups. Once randomised, patients will receive 2 weeks treatment at one of three different doses followed by a week without Bronchitol, until all three doses have been evaluated. The trial will measure changes in respiratory function, quality of life and the general health of the patient at each dose. Full patient recruitment is expected to take about six months.

Approximately 75,000 people in the major pharmaceutical markets are affected with cystic fibrosis. The major difficulty in living with the disease is chronic lung congestion caused by poor lung hydration. Bronchitol is designed to tackle this problem, for which no products are currently available.

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

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**SOURCE: Pharmaxis Ltd.**

CONTACT: Alan Robertson, Chief Executive Officer, +61 2 9454 7202, fax +61 2 9451 3622

Web site: <http://www.pharmaxis.com.au>

## **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, +61 2 8264 1004 or +61 407 231 282 or email: [a.rambukwella@fcr.com.au](mailto:a.rambukwella@fcr.com.au)

## **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-CF-202 (a Phase II study with Bronchitol)
Blinding Status	Open, then blinded for variable doses.
Placebo Controlled	No
Treatment Method	
Route	Inhalation
Frequency	Twice daily
Dose level	Variable
No of subjects	42
Subject Selection Criteria	Confirmed diagnosis of cystic fibrosis, either gender, aged $\geq 7$ years, baseline FEV <sub>1</sub> between 40% and 80% of predicted normal value or a decline in FEV <sub>1</sub> of $\geq 20\%$ in the last 12 months for those $>80\%$ predicted. Subjects concurrently using mucolytic agents are not eligible to join the study.
Trial Location	Canada
Commercial partners involved	None
Expected duration	11 months
Primary end point	FEV <sub>1</sub> , FVC
Secondary end points	<ul style="list-style-type: none"><li>• FEF<sub>25-75</sub>, PEF</li><li>• Sputum volume and microbiology</li><li>• Adverse events</li><li>• Quality of Life</li><li>• Treatment effects</li><li>• Respiratory symptoms</li></ul>

## **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 9451 7230.

## **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 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.

In Australia, 2,500 people are living with CF, and about one fifth are children under five years of age. In the U.S., over 30,000 people are affected.

### **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 safety and effectiveness of Bronchitol in treating cystic fibrosis or the timing or ability of the Company to obtain regulatory approval of 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 and risks disclosed from time to time in reports filed with the Securities and Exchange Commission, including our Registration Statement on Form F-1.