

**BRONCHITOL™ EUROPEAN CYSTIC FIBROSIS 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 commenced its dosing phase. The study, which aims to determine the benefits of Bronchitol in children also receiving the market leading treatment, rhDNase, is being conducted at 2 sites in the United Kingdom.

Pharmaxis Chief Executive Officer Alan Robertson said: 'Our previous clinical study demonstrated that Bronchitol offers significant benefit for people with cystic fibrosis. This trial will enable us to understand how Bronchitol performs in conjunction with the leading treatment for mucus clearance and help position Bronchitol in the marketplace. It's an important study that will run in parallel with our final Phase III program.'

Patients enrolled in the study will receive three months treatment with each of three different therapies – Bronchitol alone, both Bronchitol and rhDNase together and rhDNase alone. The trial will measure changes in lung function, airway inflammation, infections, and quality of life. Full patient recruitment is expected to take about eight months.

Approximately 75,000 people in the major pharmaceutical markets are affected with cystic fibrosis and no products have been approved to improve lung hydration.

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

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## **About the trial**

The following information is provided in accord with the ASX and AusBiotech Code of Best Practice for Reporting by Biotechnology, Medical Device and other Life Sciences Companies.

Name of Trial	DPM-CF-203 (a Phase II study with Bronchitol)
Blinding Status	Open
Placebo Controlled	No
Treatment Method	
Route	Inhalation
Frequency	Twice daily
Dose level	400mg twice daily
No of subjects	42
Subject Selection Criteria	Confirmed diagnosis of cystic fibrosis, either gender, aged 8 - 18 years, currently receiving rhDNase or having a FEV <sub>1</sub> <70% of mean predicted normal value and eligible to receive RhDNase. Able to perform acceptable spirometry. Subjects will be asked to discontinue rhDNase therapy for 2 weeks prior to commencing the first treatment arm.
Trial Location	United Kingdom
Commercial partners involved	None
Expected duration	18 months
Primary end point	FEV <sub>1</sub>
Secondary end points	<ul style="list-style-type: none"><li>• FVC, FEF<sub>25-75</sub></li><li>• Airway inflammation</li><li>• Sputum microbiology</li><li>• Quality of Life score</li><li>• Treatment effects scores</li><li>• Respiratory symptoms scores</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 PXS25 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, about one fifth of whom are children under five years of age. In the U.S., over 30,000 people are affected.

Pharmaxis is dedicated to developing products to treat this debilitating disease

### **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 or to obtain orphan drug exclusivity in the U.S. 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.