

ASX/ Media release

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PHARMAXIS TO COMMENCE UK PHASE II TRIAL FOR BRONCHITOL IN CYSTIC FIBROSIS

Pharmaxis Limited (ASX:PXS) has received approval to commence a Phase II clinical study in the United Kingdom with its therapeutic for the management of cystic fibrosis, Bronchitol.

Authorisation provided by the UK regulatory authority, the Medicines and Healthcare Products Regulatory Agency (MHRA) and the hospital ethics committee means that the dosing phase of the study can begin. The study is designed to determine the effects of Bronchitol on mucus clearance and lung performance in patients with cystic fibrosis over a three month period.

The study will be run by Imperial College London, the Royal Brompton Hospital and the Great Ormond Street Hospital for Children in London, and will compare the effects of twice daily administration of Bronchitol with treatment by pulmozyme, the market-leading medication for enhancing lung clearance. Forty two patients are to be enrolled in the study, which is expected to conclude in 2006.

Pharmaxis chief executive officer Dr Alan Robertson said: "This important clinical trial is part of a group of studies designed to test the effectiveness of Bronchitol in treating patients with cystic fibrosis. At present, patients have few treatment options, and we are looking forward to bringing this new medicine to the cystic fibrosis community as rapidly as possible. We are excited to be working on this product with London's world renowned clinical research groups."

In late 2004, Pharmaxis reported positive results from a two week study in patients with bronchiectasis, and an Australian clinical trial in patients with cystic fibrosis is in progress. Over 75,000 people worldwide are affected by cystic fibrosis, and there is no cure. In Australia, 2,500 people suffer from the disease, a fifth of whom are children under five years of age.

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 draft 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 label
Placebo Controlled	No
Treatment Method	
Route	Inhalation
Frequency	Twice per day for 12 weeks
Dose levels	400 mg
Number of Subjects	42 to complete protocol
Subject Selection Criteria	Subjects with a known diagnosis of cystic fibrosis, of either gender, aged between 9 and 18 years of age and currently receiving pulmozyme (RhDNase) or eligible to receive pulmozyme.
Primary End Points	To compare and contrast the effect on FEV1of: 1: Bronchitol to Pulmozyme 2: Bronchitol + Pulmozyme to Pulmozyme
Secondary End Points	To assess whether: 1: the effects of Bronchitol are additive to Pulmozyme 2: Bronchitol reduces the bacterial load in the lung 3: the effects of Bronchitol are beneficial to quality of life 4: Bronchitol affects the lungs
Trial Location	London, England
Commercial partners involved	None
Expected duration	18 months

About Pharmaxis Ltd

Pharmaxis (ACN 082 811 630) develops innovative pharmaceutical products to treat human respiratory and autoimmune diseases. Its pipeline of products include AridolTM for the management of asthma, BronchitolTM 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 and is traded under the symbol PXS. The company is headquartered in Sydney at its TGA-approved manufacturing facilities.

For more information about Pharmaxis, go to www.pharmaxis.com.au or call +61 2 9454 7200.

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, and eventually, death.

The average life expectancy for people with CF is only 31 years of age, with most patients dying from respiratory failure. In Australia, 2,500 people are living with CF, half of whom are children under five years of age.

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 in a convenient hand-held, pocketsized inhaler. Its formulation as a dry powder with a four-way action helps restore normal lung clearance mechanisms.

Clinical studies, have shown Bronchitol to be safe, effective and well tolerated in stimulating mucus hydration and clearance in people with chronic obstructive lung diseases. In particular, Bronchitol has been shown to dramatically increase mucus clearance from the lungs and significantly improve quality of life for people with bronchiectasis. Additional pilot studies have also shown a benefit for people affected by cystic fibrosis.

Longer-term clinical studies involving Bronchitol in chronic obstructive lung diseases are underway. These studies aim to demonstrate a reduction in the number of bacterial infections and the need for physiotherapy and hospitalisation; an improvement in oxygen delivery from the lungs, exercise capacity and quality of sleep; and an overall improvement in lung function.

About Imperial College London

Consistently rated in the top three UK university institutions, Imperial College London is a world leading science-based university whose reputation for excellence in teaching and research attracts students (11,000) and staff (6,000) of the highest international quality. Innovative research at the College explores the interface between science, medicine, engineering and management and delivers practical solutions that enhance the quality of life and the environment - underpinned by a dynamic enterprise culture. Website: www.imperial.ac.uk.

Cystic Fibrosis at Royal Brompton Hospital

The first adult cystic fibrosis clinic in Europe was set up in 1965 by Sir John Batten at the Royal Brompton Hospital and the largest cystic fibrosis centre in Europe is now based there. Nearly a thousand patients currently attend the hospital, around 650 adult CF patients and a little over 350 children. The Royal Brompton hosts training programmes for doctors, surgeons, physiotherapists, social workers, dietitians and other health care professionals in the management of cystic fibrosis. The post of clinical nurse specialist for cystic fibrosis, which was pioneered at the Royal Brompton, has become a model for approximately 50 similar posts in the UK and many more worldwide. Many new advances in the treatment of the condition have been pioneered at the hospital.

Cystic Fibrosis at Great Ormond Street Hospital

Great Ormond Street Hospital for Children has the widest range of children's specialists in the UK and with the Institute of Child Health, is the largest research centre into childhood illness outside the United States. GOSH is one of the leading tertiary centres for treating cystic fibrosis. The hospital see more than 150 inpatients and some 600 outpatients with cystic fibrosis each year and holds 6 CF clinics around the country.