ASX/ Media release **21 July 2005**

APPROVAL TO BEGIN CANADIAN CYSTIC FIBROSIS TRIAL GRANTED

Pharmaxis Ltd (ASX:PXS) announced today that Health Canada has granted it approval to conduct a clinical trial of Bronchitol in patients with cystic fibrosis.

The approval, granted following the acceptance of product information, manufacturing and safety data and trial protocols, allows Pharmaxis to enrol patients with cystic fibrosis for its Phase II dosing study. Recruitment will begin shortly and is expected to take around six months.

As well as determining the optimum dose of Bronchitol, the study will measure and record changes in the participants' quality of life and lung capacity. Cystic fibrosis patients often have difficulty sleeping and breathing due to accumulated mucus in their lungs.

Alan Robertson, Pharmaxis chief executive officer said: "This is very good news for Pharmaxis and for cystic fibrosis patients. The approval is the Canadian equivalent of the US FDA's Investigative New Drug, and helps to make Bronchitol available to a much wider population."

Pharmaxis was recently granted US FDA orphan drug status for Bronchitol in cystic fibrosis and in bronchiectasis. It is conducting two separate Phase II studies in cystic fibrosis patients. The Canadian study will look for the optimal dose of Bronchitol, the other UK-based study will compare the effects of existing treatments against those of Bronchitol. During April, Pharmaxis reached the recruitment target for its first Australian clinical trial in cystic fibrosis.

For more detail concerning the trial, refer to the trial's disclosure summary below.

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-202 (a Phase II study with Bronchitol)
Blinding Status	Open label
Placebo Controlled	No
Treatment Method	
Route	Inhalation
Frequency	Twice daily for 2 weeks at each dose
Dose levels	400mg for 2 weeks, then randomization to each of 40mg, 120mg and 240mg
Number of Subjects	42
Subject Selection Criteria	Known diagnosis of cystic fibrosis; either gender; aged 7 or older; have current baseline FEV1 40-80% of normal or a decline of 20% in the last 12 months if greater than 80%; not using RhDNase or other mucolytics.
Primary End Points	Change in FEV1 and FVC
Secondary End Points	Mean changes in FEV1/FVC, FEF25-75, PEF; Presence of acquired bacteria in sputum; Adverse events; Quality of life score; Change in treatment effects scores; Change in respiratory symptoms scores; Change in expectorated sputum volume.
Trial Location	Canada
Commercial partners involved	None
Expected duration	Up to 12 months

About Pharmaxis

Pharmaxis Ltd (ACN 082 811 630) develops innovative pharmaceutical products to treat human 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.

Achievements to date include:

- **Successful completion of Bronchitol Phase II study in bronchiectasis patients**
- **Successful completion of Aridol Phase III study in asthma patients**
- **Acceptance by the US FDA of Aridol as an Investigational New Drug (IND)**
- **Lodgement of marketing applications for Aridol in Australia and European Union**

- **Awarding of AusIndustry's Pharmaceuticals Partnerships Program (P3) grant.**

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 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, pocket-sized inhaler. Its formulation as a dry powder with 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 signifcantly 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 an improvement in the quality of life, 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 the quality of sleep; and an overall improvement in lung function.

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.

Pharmaxis is dedicated to developing products to treat this debilitating disease