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**CYSTIC FIBROSIS TRIAL REACHES TARGET RECRUITMENT**

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Pharmaxis (ASX:PXS) announced today that the recruitment target has been reached for its Phase II clinical trial of Bronchitol in patients with cystic fibrosis. The study was designed to evaluate the effects of inhaled Bronchitol compared with a placebo.

The trial commenced in 2004 and is being conducted at hospitals in Australia and New Zealand. Patients who volunteered for the study receive either Bronchitol or an inactive placebo twice a day for two weeks. A two-week drug-free period follows, and patients then receive either a placebo or Bronchitol for a fortnight, depending on their first course of treatment.

A scheduled interim assessment of trial progress was undertaken by the independent statistician and the Medical Director without knowing whether the patients were being treated with Bronchitol or placebo. This assessment revealed better than expected variance in the data, enabling results to be achieved with fewer patients. The target recruitment for the trial has therefore been revised downwards from 51 patients to 30 patients and this target has now been surpassed.

As the trial is now at full recruitment, the independent statistician has advised that premature unblinding of the data could bias the study results. The trial will be unblinded after the last patient has completed the study, which is expected to be in July.

Alan Robertson, Pharmaxis chief executive officer said: "We are delighted that Bronchitol has reached this milestone for treating cystic fibrosis and are very grateful to the patients and their families for their participation in this study. We believe that Bronchitol is an important new medicine that will positively impact people's lives and look forward to reporting the trial results shortly."

Cystic Fibrosis is a genetic disease affecting approximately 30,000 children and adults in the United States and 2,500 people in Australia. A defective gene causes the body to produce an abnormally thick, sticky mucus that clogs the lungs and leads to life-threatening lung infections and there is no cure.

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

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### **About Pharmaxis**

**Pharmaxis (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 since listing 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 application for Aridol in Australia**
- **Award of an AusIndustry Pharmaceuticals Partnerships Program (P3) grant.**
- **Orphan drug status granted by the US FDA to Bronchitol for the treatment of bronchiectasis**

**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](http://www.pharmaxis.com.au) or call +61 2 9451 5961.**

### **About Bronchitol**

**Pharmaxis Ltd is developing Bronchitol™ for the management of chronic obstructive lung diseases including cystic fibrosis, bronchiectasis and chronic bronchitis. In early 2005, Pharmaxis reported approval had been granted to conduct a clinical study in London designed to evaluate Bronchitol against the market leading treatment for enhancing mucus clearance in cystic fibrosis.**

**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 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 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