ASX/ Media release **14 November 2005**

BRONCHITOL GRANTED ORPHAN DRUG STATUS IN EUROPE

Pharmaxis Ltd (ASX:PXS, NASDAQ:PXSL) announced today that the European Medicines Agency (EMEA) has granted Orphan designation to the company's product Bronchitol™, for the treatment of cystic fibrosis.

Orphan designation has been granted on the basis of Bronchitol's potential to treat cystic fibrosis, a genetic disease which, for the patient, is characterised by recurring respiratory complications.

Alan Robertson, Pharmaxis chief executive officer said: "This European Orphan designation is another major step forward in the development of Bronchitol. The assistance from the EMEA in the final development of Bronchitol will be invaluable in bringing this product to the cystic fibrosis community."

Our recent Phase II trial in cystic fibrosis patients was successful, and demonstrated statistically significant improvements in lung function for patients being treated with Bronchitol. Pharmaxis is conducting an additional Phase II trial aimed at determining the optimal Bronchitol dose for cystic fibrosis and is planning to commence the final international Phase III clinical trials in 2006.

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

European Orphan designation is granted to those products intended for the diagnosis, prevention and treatment of diseases that affect not more than five in 10,000 people in the European Community, or conditions where no current therapy exists. European Orphan designation entitles Pharmaxis to a range of incentives including a ten-year period of market exclusivity, protocol assistance to optimise drug development in the designated indication, reduction in registration fees and eligibilty for grants and initiatives supporting research and development.

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

ends#

SOURCE: Pharmaxis Ltd.
14 November 2005
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

Australia
Ashley Rambukwella, Financial & Corporate Relations Pty Ltd, +61 2 8264 1004 or +61 407 231 282 or email: a.rambukwella@fcr.com.au

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 or call +61 2 9451 7200.

About Orphan Drug Designation

The European Medicines Agency's (EMEA) orphan medicinal product designations are based on various criteria that may include: the seriousness of the condition, the availability of other effective therapies, and the rarity of the condition. An investigational drug is granted orphan designation on the basis of potential activity. An orphan designation is not a marketing authorization, which can only be granted after the quality, safety and efficacy of the product are demonstrated.

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.