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US FDA GRANTS BRONCHITOL ORPHAN DRUG STATUS FOR TREATMENT OF CYSTIC FIBROSIS

Pharmaxis (ASX:PXS) announced today that the United States Food and Drug Administration (FDA) has expanded the orphan drug designation for the company's product Bronchitol™. Bronchitol has been granted the additional indication of facilitating mucus clearance in patients with cystic fibrosis.

The orphan drug status entitles Pharmaxis to a range of incentives; these include a seven-year period of market exclusivity, assistance from the FDA with clinical trial design and an exemption from FDA User fees. Many orphan products receive expedited review or accelerated approval because they are for serious or life-threatening diseases. Cystic fibrosis is a life threatening condition.

In February 2005, the FDA granted orphan drug designation for Bronchitol™ as a treatment for patients with bronchiectasis.

Alan Robertson, Pharmaxis chief executive officer said, "Pharmaxis now has a terrific opportunity to make a real difference to people with cystic fibrosis. There have been no therapeutic advances to help clear congested lungs for patients with cystic fibrosis in the past ten years. We are looking forward to working with the FDA on getting this important product to patients not just in the USA, but worldwide."

Pharmaxis has closed enrolment for its Phase II clinical trial for Bronchitol in cystic fibrosis in Australia. The company is conducting two further Phase II studies in cystic fibrosis patients to help determine the optimal dose of Bronchitol and examine the effects of using Bronchitol compared with existing treatments.

Orphan drug status is granted by the FDA to those products intended for the diagnosis, prevention and treatment of rare diseases, or conditions where no current therapy exists or would be improved. There are 33,000 diagnosed cystic fibrosis patients in the United States. 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 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
- Commencement of Aridol US Phase III study
- Lodgement of marketing application for Aridol in Australia and Europe
- 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 US Orphan Drug status
The term "orphan drug" in the USA refers to a product that treats a rare disease affecting fewer than 200,000 Americans. The Orphan Drug Act was signed into US law in 1983. The intent of the Orphan Drug Act is to stimulate the research, development, and approval of products that treat rare diseases and is accomplished through several mechanisms:

- Sponsors are granted seven years of marketing exclusivity after approval of its orphan drug product.
- Sponsors also are granted US tax incentives for clinical research they have undertaken.
- FDA's Office of Orphan Products Development coordinates research study design assistance for sponsors of drugs for rare diseases. The Office of Orphan Products Development also encourages sponsors to conduct open protocols, allowing patients to be added to ongoing studies.
- Grant funding is available to defray costs of qualified clinical testing expenses incurred in connection with the development of orphan products.

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 dry powdered mannitol administered in a convenient hand-held, pocket-sized inhaler.

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.