



ASX/ Media release

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US FDA GRANTS PHARMAXIS' BRONCHITOL ORPHAN DRUG STATUS

Pharmaxis (ASX:PXS) announced today that the United States Food and Drug Administration (FDA) has granted an Orphan Drug status for the company's product Bronchitol™, for the treatment of bronchiectasis.

Orphan drug status has been granted to Pharmaxis on the basis of Bronchitol's ability to aid the treatment of bronchiectasis, an incurable, degenerative and chronic inflammatory condition of the lungs affecting over half a million people worldwide.

Orphan drug status is granted by the US 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. Orphan drug status entitles Pharmaxis to a range of incentives including a seven-year period of market exclusivity and study design assistance that will substantially contribute to rapid approval.

Alan Robertson, Pharmaxis chief executive officer said: "We are extremely pleased that Bronchitol has been granted Orphan Drug status by the FDA. With these concessions Bronchitol will proceed more quickly towards the international trials required for approval, and patients will receive benefits sooner."

In late 2004, Pharmaxis reported positive results from a two week Bronchitol study in patients with bronchiectasis. Most cases of bronchiectasis develop during childhood, some rare cases are present from birth. Bronchiectasis can be the result of infections such as pneumonia or the inhalation of irritating substances, causing inflammation of the bronchial wall.

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
- 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 9451 5961.

About Orphan Drug status

The term "orphan drug" 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 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 bronchiectasis

Pronounced 'brong-kee-eck-tah-sis', bronchiectasis is one of the chronic obstructive pulmonary diseases, or COPDs, and affects children and adults. It is often mistaken for asthma or pneumonia and misdiagnosis is common. In this disease the bronchial tubes become irreversibly enlarged, forming pockets that can become infected. The bronchi walls are damaged, causing impairment to the lung's complex cleaning system. The tiny hairs, or cilia, which line the bronchial tubes and sweep them free of dust, germs and excessive mucus are unable to function properly. The result is that matter such as mucus and bacteria accumulates affecting the performance of the lungs and the quality of life of the individual.