Media Release

02 August 2012

U.S. FDA Accepts Bronchitol New Drug Application for Review

Pharmaceutical company Pharmaxis (ASX: PXS) is pleased to announce it has received notification from the United States Food and Drug Administration (FDA) that the New Drug Application (NDA) for its cystic fibrosis product, Bronchitol®, has been accepted for standard review.

The FDA has assigned the Bronchitol application a Prescription Drug User Fee Act (PDUFA) goal date of 18 March, 2013. If the application is approved, Pharmaxis anticipates Bronchitol could be available for US patients with cystic fibrosis in the second quarter of 2013.

Pharmaxis is seeking approval for Bronchitol for the management of cystic fibrosis patients 6 years of age or older to improve pulmonary function. Cystic fibrosis is a disease that affects around 30,000 people in the United States and is the most common life-limiting genetic disease.

The NDA includes results from two Phase III trials, conducted by Pharmaxis, the results of which were presented at the 2011 North American Cystic Fibrosis annual meeting and recently at the 2012 European Cystic Fibrosis Society annual meeting.

Pharmaxis CEO Dr Alan Robertson said, "The Company is pleased that the FDA has accepted the Bronchitol marketing application and we are looking forward to discussions with the FDA as we work to make Bronchitol available to patients in the U.S."

Bronchitol has Orphan Drug Designation in the U.S. and is approved for marketing in Australia and throughout the European Union.

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SOURCE: Pharmaxis Ltd, Sydney, Australia
CONTACT: Alan Robertson – Chief Executive Officer
Ph: +61 2 9454 7200 or email alan.robertson@pharmaxis.com.au

RELEASED THROUGH:
Australia:
Felicity Moffatt, phone +61 418 677 701 or email felicity.moffatt@pharmaxis.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 disorders. Its product Aridol® for the assessment of asthma is sold in key international markets. Its product Bronchitol® for cystic fibrosis is recently launched in Europe and Australia and its development pipeline of products includes, Bronchitol for bronchiectasis, PXS64 for the treatment of lung fibrosis, ASM8 for asthma and PXS4728 for fibrotic disease. Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company's head office and manufacturing facilities are located in Sydney. For more information about Pharmaxis, go to www.pharmaxis.com.au or contact Investor Relations on phone +61 2 9454 7200.

About Bronchitol
Bronchitol has been developed to help clear mucus (a major source of lung infections), improve lung function and reduce exacerbations in patients with cystic fibrosis.

Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. Bronchitol hydrates the lungs, helps restore normal lung clearance, and allows patients to clear mucus more effectively. Clinical studies have shown Bronchitol to be safe, effective, and well tolerated in treating patients cystic fibrosis.

About Cystic Fibrosis
In a healthy person, there is a constant flow of mucus over the surfaces of the air passages in the lungs, removing debris and bacteria. In CF, an inherited disease, a defective gene disrupts ion transport across the epithelial membrane within cells. In the lungs, this leads to a depletion of the airway surface liquid that normally bathes the cilia, and a resultant reduction in mucociliary clearance. The result is thick, sticky mucus that clogs the lungs, severely restricting the natural airway-clearing process. It also increases the potential for bacteria to become trapped and for inflammation, thus creating an unhealthy lung environment that leads to life-threatening lung infections.

Forward-Looking Statements
Forward-looking statements in this media release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the potential for Aridol and/or Bronchitol. All forward-looking statements included in this media 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 cannot guarantee that any product candidate will receive regulatory approval or that we will seek any such approval.