



Media Release

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PHARMAXIS SUBMITS U.S. NEW DRUG APPLICATION FOR BRONCHITOL

Pharmaceutical company Pharmaxis (ASX: PXS) is pleased to announce it has submitted a New Drug Application (NDA) to the Food and Drug Administration (FDA) seeking approval for Bronchitol® for the treatment of patients with cystic fibrosis in the United States. The FDA has previously granted Bronchitol Orphan Drug designation for the treatment of patients with cystic fibrosis.

The FDA submission for Bronchitol is supported by two large Phase III clinical trials conducted in 600 patients with cystic fibrosis six years of age and older. The integrated data of the two pivotal, randomized, double-blind, controlled, multi-centre trials reported significant improvements in lung function combined with reductions in exacerbation incidence. Bronchitol is well tolerated and, consistent with all studies evaluating Bronchitol, the adverse events reported in the Phase III program were mostly mild in nature. Additionally, in the clinical trial setting, sustained improvement in lung function has been seen out to 18 months.

Pharmaxis CEO Dr Alan Robertson said, “The submission marks the second of two key milestones for the Bronchitol program following approval last month to market the product in Europe. Cystic fibrosis patients have a life-limiting disease. It starts at birth because of genetic mutations that impair the airway surface liquid lining of the lung leading to irreversible damage to the lung structure. Currently approved therapies for the majority of cystic fibrosis patients work on thinning mucus secretions, or on targeting the bacteria that infect the lung. Bronchitol targets restoration of the airway surface liquid and, by improving mucociliary clearance, positively impacts the cascade of events that otherwise lead to lung function loss.”

“We look forward to working with the U.S. regulatory authorities to bring this treatment to people in need and acknowledge and appreciate the support of the cystic fibrosis community during the development of Bronchitol” said Dr Howard Fox, Chief Medical Officer of Pharmaxis.

Bronchitol is set to be introduced this quarter into the largest European market, Germany. Additionally, Bronchitol is approved for marketing in Australia and is awaiting listing on the Pharmaceutical Benefits Scheme by the Minister for Health and Ageing. This step is necessary before reimbursement can be made available for Australian patients with cystic fibrosis.

#ENDS#

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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 launched in a number of key markets. Its development pipeline of products includes, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD), PXS25 for the treatment of lung fibrosis and ASM8 and PXS4159 for asthma. Pharmaxis is listed on the Australian Securities Exchange (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 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.
