



Media Release

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PHARMAXIS' BRONCHITOL RECEIVES TGA APPROVAL FOR AUSTRALIANS WITH CYSTIC FIBROSIS

Pharmaceutical company Pharmaxis (ASX: PXS) today announced that the Australian Therapeutic Goods Administration (TGA) has approved Bronchitol (inhaled dry powder mannitol) for marketing in Australia for the treatment of cystic fibrosis and it is now to be included in the Australian Register of Therapeutic Goods (ARTG).

Bronchitol has been approved for the treatment of cystic fibrosis (CF) in both adult and paediatric patients aged over six years as either an add-on therapy to dornase alfa or in patients intolerant of, or inadequately responsive to, dornase alfa.

Mr Terry Stewart, CEO of CF Australia, said: "We welcome the approval of Bronchitol and congratulate Pharmaxis on its commitment to helping patients and in getting a long awaited new treatment to this point. There is a great need for new medicines for people with CF. We must not forget that this is a genetic condition; people have cystic fibrosis from their first breath, so anything new that can improve patients' way of living, their quality of life and potentially their length of life is a wonderful step forward."

Dr Alan Robertson, Pharmaxis Chief Executive Officer, said: "The TGA's decision is the first approval for Bronchitol anywhere in the world and is an historic milestone for the company. It is fitting for a product that has been discovered and developed in Australia to be made available first to Australian patients. We are extremely pleased to have concluded the regulatory review process for Bronchitol with the TGA, one of the world's leading regulatory bodies. This approval is a testament to the hard work of many people in Pharmaxis and those in the CF community worldwide who have assisted in the clinical development of Bronchitol."

Bronchitol has been the subject of two pivotal clinical trials in cystic fibrosis in over 600 people involving 93 hospitals around the world. In April 2009 Bronchitol was awarded Orphan Drug designation in Australia for the treatment of patients with cystic fibrosis to improve lung function and reduce exacerbations.

Bronchitol has received Orphan Drug Designation and fast track status from the US Food and Drug Administration and Orphan Drug Designation from the European Medicines Agency.

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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 development pipeline of products includes Aridol for the assessment of asthma, 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

Pharmaxis Ltd is developing Bronchitol for the management of chronic obstructive lung diseases including cystic fibrosis, and bronchiectasis. Bronchitol is a proprietary dry-powder mannitol, precision formulated for delivery to the lungs through an easy-to-use, pocket-size, portable inhaler. Once inhaled its five-way action on mucus helps restore normal lung clearance mechanisms. Bronchitol has received Orphan Drug Designation and fast track status from the US Food and Drug Administration and Orphan Drug Designation from the European Medicines Agency and the Australian Therapeutic Goods Administration.

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.
