

# **Media Release**

## 13 December 2010

## **BRONCHITOL RECOMMENDED FOR APPROVAL BY AUSTRALIAN ADVISORY COMMITTEE**

Pharmaceutical company Pharmaxis (ASX: PXS) today announced that the Australian Advisory Committee on Prescription Medicines (ACPM) has recommended approval of Bronchitol (inhaled dry powder mannitol) for marketing in Australia for the treatment of cystic fibrosis.

Dr Alan Robertson, Pharmaxis Chief Executive Officer, said: "We are delighted to have received this recommendation from the Advisory Committee on Prescription Medicines and look forward to the prospect of making Bronchitol available to people with cystic fibrosis. For all concerned, this is a difficult disease, so we are excited to be another step closer to making this new treatment alternative available. We are working with the Therapeutics Goods Administration (TGA) to complete the review process early in 2011."

The ACPM (formerly ADEC) is appointed by the Australian Federal Minister for Health and Ageing to advise on the suitability of drugs for marketing in Australia. The Committee includes eminent physicians, pharmacologists, toxicologists and pharmacists and provides independent, scientific advice on new drugs to the TGA. Their review and subsequent recommendation by the Committee at its most recent meeting follows the TGA evaluation of clinical, pharmacological quality and safety data submitted by Pharmaxis in December 2009, in addition to consultation between the company and the TGA.

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.

## #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 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 Therapeutics 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.