

# Media Release

25 January 2011

# **UPDATE: BRONCHITOL EU MARKETING AUTHORISATION FOR CYSTIC FIBROSIS**

Pharmaceutical company Pharmaxis (ASX: PXS) made an oral presentation to last week's meeting of the European Committee for Medicinal Products for Human Use (CHMP). Subsequent to the meeting the CHMP has now provided the company with its outstanding issues and advised that the review timetable will conclude in Q2 2011.

"We are pleased with the ongoing discussions with the CHMP and believe we are in a good position to provide our response to their outstanding issues in a timely manner", said Dr Alan Robertson, Chief Executive Officer of Pharmaxis.

Bronchitol has been the subject of two international Phase 3 clinical trials and is the only new product in registration to treat 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 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.

#### **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.