



## Media Release

21 April 2011

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### PHARMAXIS' BRONCHITOL DEFERRED BY AUSTRALIAN PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE

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Pharmaceutical company Pharmaxis (ASX: PXS) today announced a delay to the listing of Bronchitol on the Australian Pharmaceutical Benefits Scheme (PBS). The company's first submission to list Bronchitol for the treatment of cystic fibrosis was reviewed at the March meeting of the Pharmaceutical Benefits Advisory Committee (PBAC) and was not recommended for inclusion in the PBS, at that time, due to what the PBAC described as "uncertainties in where Bronchitol will fit in clinical practice and consequent difficulties in identifying the right comparator in one clinical setting that leads to uncertain cost-effectiveness."

A resubmission has been prepared to address the issues raised by the PBAC and will be made at the earliest opportunity.

Dr Alan Robertson, Pharmaxis CEO, said, "Cystic fibrosis is a disease where there have been no new treatments approved for more than 18 years and Bronchitol will have an effect on the way other products are used. We are working with the CF community to more accurately predict these likely changes and remove any ambiguities." Dr Robertson added, "It is a difficult climate for new drug submissions but we are committed to the process and to securing satisfactory reimbursement for patients with cystic fibrosis. The majority of new drugs take at least two submissions before being recommended for PBS listing and, while I am disappointed by this outcome, I am confident we will soon be able to finalise the process."

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. It was approved for marketing by the Therapeutic Goods Administration in February this year.

Australia has approximately 2,800 people living with cystic fibrosis.

#ENDS#

**SOURCE:** Pharmaxis Ltd, Sydney, Australia

**CONTACT:** Alan Robertson – Chief Executive Officer

Ph: +61 2 9454 7200 or email [alan.robertson@pharmaxis.com.au](mailto:alan.robertson@pharmaxis.com.au)

**RELEASED THROUGH:**

**Australia:**

Felicity Moffatt, phone +61 418 677 701 or email [felicity.moffatt@pharmaxis.com.au](mailto:felicity.moffatt@pharmaxis.com.au)

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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](http://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.

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