



## Media Release

9 November 2011

---

### PHARMAXIS ANNOUNCES PBAC DECISION ON BRONCHITOL

---

Pharmaceutical company Pharmaxis (ASX: PXS) today announced that, on this occasion, its new drug for treating cystic fibrosis, Bronchitol, has not been recommended for listing on the Australian Pharmaceutical Benefits Scheme (PBS) by the government's expert advisory body, the Pharmaceutical Benefits Advisory Committee (PBAC).

Pharmaxis has been verbally advised of the decision made at the Committee's November meeting, the minutes of which will be published on the PBAC website next month. Pharmaxis will meet with the Chair of PBAC in early December to discuss the outstanding concerns of the Committee.

Pharmaxis CEO Dr Alan Robertson said, "This decision comes just weeks after a positive opinion on Bronchitol by European regulators and days after a positive additional reimbursement decision for Aridol in the USA, and highlights the fact that Australia is one of the most challenging reimbursement environments in the world. In response to issues raised by the PBAC during its previous review, Pharmaxis provided extensive additional data covering centres that serve more than half of all the Australian CF patients. In addition, expert testimony was provided by the Thoracic Society of Australia on the role of Bronchitol in the management of cystic fibrosis. We will continue to work with the PBAC to understand what further information it still requires in order to make Bronchitol available on a subsidised basis for Australians living with cystic fibrosis."

Bronchitol is an Australian discovered and developed product which was approved for marketing in Australia in February and recently received a positive opinion by a European regulatory committee, clearing the way for its marketing in 29 countries in Europe.

#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)

---

**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](http://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.

---