



## Media Release

24 June 2011

---

### EUROPEAN CHMP CONFIRMS NEGATIVE OPINION ON BRONCHITOL FOR CYSTIC FIBROSIS

---

Pharmaceutical company Pharmaxis (ASX: PXS) today announced it has been advised by the European Medicines Agency that the June meeting of the Committee for Medicinal Products for Human Use (CHMP) has adopted a negative opinion in relation to the Company's marketing application for Bronchitol for cystic fibrosis. This confirms the negative trend vote, taken by the CHMP at its May meeting that was advised by Pharmaxis on 25 May 2011.

The Company expects to receive further information and will update the market as appropriate.

Pharmaxis considers it has appropriate grounds upon which to request a re-examination of its European Bronchitol marketing application. The Company will complete a review of the CHMP opinion, which will include further discussions with the European Medicines Agency and advice from external specialist regulatory consultants, before formally requesting a re-examination.

Pharmaxis has 15 days to request a re-examination and until 21 August to lodge a detailed submission.

The Company will provide additional information and details of the re-examination as the European regulatory approval process continues.

#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, improve lung function and reduce exacerbations in patients with cystic fibrosis. Bronchitol has been the subject of a number of clinical trials. In two major Phase 3 clinical trials, Bronchitol improved lung function after one year, as measured by Forced Expiratory Volume in 1 second (FEV1), by 8.1% in one instance and 8.2% in the second instance ( $p < 0.001$ ). Bronchitol achieved this in patients that were being treated with the latest drugs and subject to the latest techniques for keeping lungs clear. Patients with cystic fibrosis will normally lose 1-2% of their lung function annually. In the two Phase 3 trials, treatment with Bronchitol led to an increase in mucus clearance ( $p < 0.0001$ ) and reduced overall pulmonary exacerbation incidence by 29% ( $p = 0.039$ ).

**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.

**About the Committee for Medicinal Products for Human Use (CHMP)**

The CHMP meets once a month. The meetings of the CHMP are not public. Currently, no agendas or minutes of the meetings are published. After each CHMP meeting, a meeting report and a press release are published on the Agency's website ([www.ema.europa.eu](http://www.ema.europa.eu)). In addition, summaries of opinions adopted during each meeting in respect of specific medicines are published on the Agency's website. These express the opinion of the CHMP on new marketing application dossiers from pharmaceutical companies, on referral procedures and on other issues on which the Committee is required to provide an opinion.

**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.

---