



## Media Release

25 May 2011

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### PHARMAXIS RECEIVES NEGATIVE TREND VOTE FROM THE CHMP ON BRONCHITOL

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Pharmaceutical company Pharmaxis (ASX: PXS) today announced that the Company had presented an oral explanation at the Committee for Medicinal Products for Human Use (CHMP) meeting last week as part of its European Union marketing application for Bronchitol® for the treatment of cystic fibrosis. The oral explanation is an opportunity for the Company to address any outstanding issues raised during the marketing application review process prior to the CHMP formally voting to approve or reject the current marketing application for Bronchitol at its next scheduled meeting which concludes on 23 June 2011.

Following the oral presentation, the members of the CHMP undertook a trend vote intended to show whether they were orientated to vote for, or against, the approval of Bronchitol. The outcome of this trend vote was negative.

While not a final decision, the trend vote indicates that the CHMP's current orientation is not to approve Bronchitol based on the existing application when it meets in June 2011. Pharmaxis considers it unlikely that this position will change before the formal vote is undertaken next month.

The Company is in the process of reviewing its alternatives with respect to the European Union marketing application.

If there are adequate grounds, the Company may appeal a negative decision. Any such appeal would have to be filed by September 2011 and the Company believes the outcome of the appeal would be known by the end of November 2011. An appeal would involve a re-examination of the application and must be based on the data already submitted. If an appeal is unsuccessful, the Company could conduct an additional clinical trial and resubmit an application for the European Union. As an alternative, the Company may choose to withdraw its application before any final decision is made in June 2011 and resubmit an application for regulatory approval of Bronchitol in the EU at a later date.

While any EU appeal is in progress, Pharmaxis would slow preparation of its US FDA marketing application.

Pending the outcome of any appeal, the Company will refocus its operations and manage its cash resources in such a way to enable it to support its regulatory applications in the Europe and US and, if required, undertake a further clinical trial. At the end of the March 2011 quarter, the Company had cash on hand of \$56 million. Pharmaxis will be taking immediate steps to reduce its cash burn and to preserve its cash resources.

Dr Alan Robertson, Pharmaxis Chief Executive Officer, commented: "Although this is not the final stage in the application process, we are clearly disappointed with the outcome of this trend vote. All patients with cystic fibrosis have difficulty in breathing and in clearing their lungs and people born with cystic fibrosis will die at an unacceptably early age from respiratory failure; so there is evidently a high unmet medical need. Pharmaxis remains steadfastly positive about the benefit of Bronchitol and will work to address the Committee's concerns, with the goal of making this important medication available to CF patients in the Europe Union."

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The Company will provide a further update on the Company's regulatory strategy after considering and working through the implications of a final decision on the application from the CHMP June 2011 meeting.

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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 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 improve lung function and reduce exacerbations in patients with cystic fibrosis. In cystic fibrosis, lungs become infected and colonised with bacteria that results in excessive mucus secretion and, over time, lung function declines making breathing difficult and the lungs more susceptible to bacterial assault. A drug such as Bronchitol that helps improve mucus clearance, reduce exacerbations and improve lung function should have an impact on the progression of the disease.

Bronchitol has been the subject of extensive clinical trials. In two major Phase 3 clinical trials, run in different hospitals, in different countries, at different times, after 12 months treatment, Bronchitol improved lung function by 8.1% in one instance and 8.2% in the second instance ( $p < 0.001$ ). Bronchitol achieved this feat in patients that were being treated with the latest drugs and subject to the latest techniques for keeping their lungs clear. It is important to bear in mind that patients with cystic fibrosis will normally lose 1-2% of their lung function annually. This data and this consistency of performance gives us hope that Bronchitol will change the course of the disease over time.

#### **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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