



Media Release

12 July 2011

PHARMAXIS BRONCHITOL RESUBMITTED TO AUSTRALIAN PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE

Pharmaceutical company Pharmaxis (ASX: PXS) today announced that it has resubmitted an application for its cystic fibrosis product Bronchitol to the Pharmaceutical Benefits Advisory Committee (PBAC) for reimbursement on the Australian Pharmaceutical Benefits Scheme (PBS). The PBAC is an independent expert body appointed by the Australian Government to provide advice on the listing of subsidised prescription medicines.

The PBAC will consider the application at its November meeting. If approved Bronchitol will then be subject to consideration by the Pharmaceutical Benefits Pricing Authority and the Australian Government.

The Company's first submission to list Bronchitol for the treatment of cystic fibrosis was considered at the March meeting of the PBAC and was not recommended for inclusion on the PBS due to what the Committee 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."

Dr Alan Robertson, Pharmaxis CEO, said; "The Company is committed to a successful listing of this new treatment and has worked closely with the PBAC secretariat in dealing with issues raised by the Committee. In addition Pharmaxis has been working with the cystic fibrosis community to provide firm evidence on the use of CF drugs so that an unambiguous understanding of the position of Bronchitol in cystic fibrosis emerges and that the appropriate comparator for patients not responding to currently available therapies can be agreed."

Dr Robertson added, "This is a challenging climate for new PBS submissions. Bronchitol is the first new drug for cystic fibrosis in its class since Pulmozyme® was introduced over 15 years ago and establishing a common treatment guideline to suit the very wide variety of CF patients today presents some issues. However, we have worked hard to provide an improved understanding of how Bronchitol will be used and I look forward to the conclusion of this part of the reimbursement 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

RELEASED THROUGH:

Australia:

Felicity Moffatt, phone +61 418 677 701 or email 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 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 has been the subject of a number of clinical trials. In two major Phase 3 clinical trials, Bronchitol improved mucus clearance by 3 fold relative to control ($p < 0.0001$). In addition, lung function after the 6 month trial, as measured by Forced Expiratory Volume in 1 second (FEV_1), improved by 7.3% relative to baseline ($p < 0.001$) and by 3.8% relative to control ($p < 0.001$) and that Bronchitol achieved this on top of existing cystic fibrosis treatments. Patients with cystic fibrosis will normally lose 1-2% of their lung function annually.

In addition, treatment with Bronchitol reduced overall pulmonary exacerbation incidence by 29% ($p = 0.039$) relative to control. Pulmonary exacerbations are associated with subsequent FEV_1 decline in both adults and children with cystic fibrosis. The incidence of adverse events in the clinical trials were similar between the control group and the Bronchitol group and were comparable to adverse events reported for currently approved cystic fibrosis medicines.

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.
