# Media Release

**28 September 2011**

## EUROPEAN BRONCHITOL MARKETING APPLICATION UPDATE

Pharmaceutical company Pharmaxis (ASX: PXS) today announced that the re-examination of the European Bronchitol marketing application for cystic fibrosis by the Committee for Medicinal Products for Human Use (CHMP) is proceeding according to schedule.

The CHMP has adopted a list of questions to be considered by the ad hoc Scientific Advisory Group which was appointed by the CHMP and includes clinicians and experts in the field of cystic fibrosis. Pharmaxis will present to the Scientific Advisory Group in early October and the Scientific Advisory Group will make its recommendations directly to the CHMP.

An opinion on the re-examination of Bronchitol for the treatment of cystic fibrosis is due to be reached by the CHMP at its forthcoming meeting which will be held between 17th and 20th October.

Dr Alan Robertson, Pharmaxis Chief Executive Officer, commented: "Bronchitol operates higher on the pathophysiological cascade than any approved medicine for cystic fibrosis and represents an exciting new treatment option. Re-hydration of the surface lining of the lung is an important clinical goal and leads to a reduction of mucus accumulation, improved mucus clearance and a reduction in the incidence of pulmonary exacerbations. In two Phase III clinical trials, Bronchitol has been shown to improve lung function – the loss of which ultimately leads to the early death of people with cystic fibrosis. We look forward to working with the CHMP over the coming weeks with the goal of making Bronchitol available to patients in Europe with cystic fibrosis."

Bronchitol has received Orphan Drug Designation from the European Medicines Agency and is approved for marketing in Australia.

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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 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 6 month treatment, as measured by Forced Expiratory Volume in 1 second ($FEV_1$), improved by 7.3% relative to baseline ($p<0.001$) and this improvement was maintained out to 12 months ($FEV_1$ increase of 8%). Bronchitol achieved this on top of existing cystic fibrosis treatments - including antibiotics. On average, patients with cystic fibrosis will lose 1-2% of their lung function each year.

Furthermore, 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.

**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). 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.