Media Release

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RE-EXAMINATION OF EU BRONCHITOL MARKETING APPLICATION REQUESTED

Pharmaceutical company Pharmaxis (ASX: PXS) today announced that a formal request has been submitted to the Committee for Medicinal Products for Human Use (CHMP) requesting a re-examination of the European Bronchitol marketing application for cystic fibrosis.

This request follows dialogue between the Company and the European Medicines Agency and discussions with the Company's external advisors.

At the forthcoming July meeting of the CHMP, two new Rapporteurs will be appointed to lead the re-examination process. The new Rapporteurs usually comprise one individual who voted for the approval of Bronchitol and one individual who voted against the approval of Bronchitol.

Importantly, the Company has the right to request that a Scientific Advisory Group be established to assist with the re-examination process and to make a recommendation to the CHMP. The Scientific Advisory Group is appointed by the CHMP and should include clinicians and experts in the field of respiratory medicine. Patient groups may also be invited to join. A change of label from the original marketing application may occur during the re-examination process.

The Company must submit the detailed grounds for re-examination before the end of August and these should be based on the grounds for refusal outlined in the negative opinion. During September and October the company will work with the Rapporteurs and the Scientific Advisory Group of the CHMP in preparing a recommendation for the CHMP. According to its published guidelines, we expect the CHMP to vote on the re-examination at its October meeting.

Dr Alan Robertson, Pharmaxis Chief Executive Officer, commented: "Bronchitol was designed to rehydrate the surface lining of the lung which is the basic pharmacological defect for people with cystic fibrosis. This defect leads to excessive mucus accumulation, chronic bacterial colonisation and lung function decline. In clinical trials, Bronchitol has been shown to improve lung function and reduce the incidence of infectious exacerbations. We believe Bronchitol will be recognised by the CHMP's Scientific Advisory Group as an important new treatment option in a disease for which new medicines are urgently required. We now look forward to working with the CHMP over the coming months 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 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.

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.

About Procedural Advice on the Re-Examination of CHMP Opinions

Refer to the EMA website:
ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004024.pdf

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.