Media Release

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RE-EXAMINATION DOCUMENTS SUBMITTED FOR EU BRONCHITOL MARKETING APPLICATION

Pharmaceutical company Pharmaxis (ASX: PXS) today announced that it had submitted detailed grounds for re-examination of its Bronchitol EU marketing application for cystic fibrosis to the Committee for Medicinal Products for Human Use (CHMP). The documents have been lodged following the formal request for re-examination submitted last month and subsequent dialogue between the Company and the new Rapporteurs appointed to lead the process.

The new Rapporteurs comprise one individual who previously voted for the approval of Bronchitol and one individual who voted against the approval of Bronchitol. As the re-examination proceeds, the CHMP will have the benefit of expert advice from a Scientific Advisory Group. The Scientific Advisory Group is appointed by the CHMP and will include clinicians and experts in the field of cystic fibrosis. Patient groups may also be invited to join. Following an initial review of Pharmaxis' submission by the Rapporteurs, the CHMP can refer questions of the Scientific Advisory Group and will receive its recommendation prior to a final determination. Pharmaxis expects a decision at the October CHMP meeting.

Dr Alan Robertson, Pharmaxis Chief Executive Officer, commented: "Following the appointment of the new Rapporteurs at the CHMP meeting in July, we have had the opportunity to discuss the grounds for re-examination. That interaction, and discussions with senior cystic fibrosis clinicians, has been valuable in developing a submission which addresses the concerns that the CHMP expressed in June. The submission focuses on demonstrating that the improvements in lung function and reductions in exacerbation incidence are clinically relevant for cystic fibrosis patients. Pharmaxis has also provided further evidence to demonstrate that the side effect profile of Bronchitol is acceptable and, in particular, that the incidence of haemoptysis is in line with that reported as the background level in this disease, and that any risk of bronchospasm is low and manageable."

Dr Robertson continued: "At the recent European cystic fibrosis conference in Germany, Felix Ratjen (Professor, Department of Paediatrics, University of Toronto) outlined the unique benefits of Bronchitol as a mucociliary clearance agent and highlighted its position alongside currently available therapies, while Moira Aitken (Professor of Medicine, University of Washington) summarised the clinical results from the two pivotal clinical trials of Bronchitol and compared the results favourably with historical data from other studies of current therapies. Pharmaxis appreciates the support it has received from the international CF community.

"There will be further opportunities to discuss Bronchitol at the forthcoming Scientific Advisory Group and CHMP meetings in October and we are optimistic that Bronchitol will be recognised as an important new treatment option for cystic fibrosis. We look forward to continuing working with the CHMP over the coming weeks with the goal of making Bronchitol available in Europe in a timely fashion."

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

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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 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, thick, sticky mucus that clogs the lungs and severely restricts the natural airway-clearing process. It also increases the potential for bacteria to become trapped, thus creating an unhealthy lung environment that makes CF patients vulnerable to lung infection and inflammation which leads to permanent lung damage, significant losses in lung function, and in shortened life expectancy.

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 is an osmotic agent formulated as a respirable dry powder contained in capsules that are delivered via a small hand held inhaler. Once delivered to the lungs Bronchitol increases hydration of the airway surface liquid and changes the properties of the mucus making it easier to clear.

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.

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.