Media Release

19 March 2013

PHARMAXIS RECEIVES COMPLETE RESPONSE LETTER FROM FDA ON BRONCHITOL

Pharmaceutical company Pharmaxis (ASX: PXS) today announced it had received a complete response letter from the Food and Drug Administration (FDA) confirming Bronchitol® cannot yet be approved for marketing for the treatment of cystic fibrosis in the United States.

The FDA has concluded its review of the Bronchitol New Drug Application (NDA) and recommended Pharmaxis conduct an additional clinical trial to obtain an approval for Bronchitol. The complete response letter states: *"The submitted data do not provide a favourable benefit-risk balance to support the use of inhaled mannitol in patients with cystic fibrosis 6 years of age and older. The determination of efficacy based on the two clinical trials are not adequate because of the treatment-related frequent early dropouts in trial 301 for which the primary statistical analyses did not account and the lack of statistical significance in trial 302 for the primary endpoint".* In relation to safety, the FDA stated its concern with the occurrence of haemoptysis, particularly in paediatric patients.

Pharmaxis CEO Mr Gary Phillips said, "We are clearly disappointed that Bronchitol cannot yet be made available to patients in the US. The FDA has provided guidance on the necessary measures to gain approval and Pharmaxis will now have a follow up meeting with the FDA. This will be a Type A meeting which I expect will take place next quarter and will examine the parameters of an additional clinical trial including how best to incorporate both adult and paediatric patients.

"At the recent Pulmonary-Allergy Drugs Advisory Committee (PADAC) meeting we received strong support from the US CF Foundation, leading CF clinicians and patients who spoke passionately about the need for Bronchitol. The Company remains committed to bringing Bronchitol to CF patients in the United States and the onus is now on Pharmaxis to work with the FDA to ensure Bronchitol is approved as soon as possible."

The FDA has previously granted Bronchitol Orphan Drug designation for the treatment of patients with cystic fibrosis. The product is approved for marketing for patients aged six years and over in Australia and for patients aged 18 years and over throughout the European Union.

The complete response letter follows a negative recommendation on 30th January from PADAC in its advice to the FDA on the use of Bronchitol for cystic fibrosis patients aged six years and over in the United States.

The FDA submission for Bronchitol is underpinned by two large Phase III clinical trials conducted in 600 patients with cystic fibrosis six years of age and older.

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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 sold in key international markets. Its product Bronchitol® for cystic fibrosis is recently launched in Europe and Australia and its development pipeline of products includes, Bronchitol for bronchiectasis, PXS64 for the treatment of lung fibrosis, ASM8 for asthma and PXS4728 for fibrotic disease. Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company's head office and manufacturing facilities are located in Sydney. 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 is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. Inhaled mannitol hydrates the lungs, helps restore normal lung clearance, and allows patients to clear mucus more effectively.

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 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.