
BRONCHITOL RECEIVES NEGATIVE RECOMMENDATION FROM PADAC

Pharmaceutical company Pharmaxis (ASX: PXS) today announced it has received a negative recommendation from a Committee advising the US Food and Drug Administration (FDA) on the use of Bronchitol® for cystic fibrosis patients in the United States.

The Pulmonary-Allergy Drugs Advisory Committee (PADAC) voted on three questions (listed below) relating to Bronchitol's safety and efficacy in cystic fibrosis patients aged 6 years and over, with a negative result on all questions.

Pharmaxis CEO Dr Alan Robertson said, "The Committee vote is disappointing, however, we are aware that these recommendations are not binding on the FDA and we will continue the process of working with the FDA to bring Bronchitol to patients in the US. It is important to remember that we are in a process and that opportunities remain to discuss the issues that were raised by the Committee before the FDA makes its final decision on 18 March 2013."

PADAC reviews and evaluates available data concerning the safety and effectiveness of new products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms and makes recommendations to the FDA. The Committee comprises 14 voting members including the Chair. The Committee's deliberations on Bronchitol took place over 7 hours in Washington concluding early this morning AEDT.

Dr Alan Robertson said, "The Committee meeting was rigorous and I thank the CF Foundation, patients and expert clinicians who came to the meeting and shared their personal experiences and specialised knowledge."

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

The questions considered by the Committee were:

Considering the totality of the data, is there substantial evidence of efficacy for DPM (Bronchitol) at a dose of 400 mg twice daily for improvement of pulmonary function in patients 6 years and older with cystic fibrosis? If not, what further efficacy data should be obtained?

Is the safety profile for DPM (Bronchitol) for the maintenance treatment of patients with cystic fibrosis sufficient to support approval? If not, what further safety data should be obtained?

Do the efficacy and safety data provide substantial evidence to support approval of DPM (Bronchitol) at a dose of 400 mg twice daily for the management of cystic fibrosis in patients aged 6 years and older to improve pulmonary function? If not, what further data should be obtained?

As Pharmaxis is in an ongoing process with the FDA, the Company does not intend to comment further on the Bronchitol NDA until the FDA announces its decision on 18 March 2013.

#ENDS#

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About Pharmaxis

Pharmaxis Ltd (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.
