

Media Release

27 June 2011

EUROPEAN MARKETING AUTHORISATION APPLICATION REVIEW OF BRONCHITOL

Pharmaceutical company Pharmaxis (ASX: PXS) announced today that the Committee for Medicinal Products for Human Use (CHMP) have, at this point, refused the marketing authorisation for Bronchitol® for the treatment of cystic fibrosis and have now provided the reasoning behind reaching this opinion. This opinion is consistent with the trend vote taken by the CHMP at its May meeting, and advised publically by Pharmaxis on 25 May 2011.

The major concern of the CHMP that led to the refusal was their view that the effectiveness and benefit of Bronchitol had not been established. In particular, that it was not clear to the CHMP that the improvement in lung function would be sufficient to improve the patient's condition and that the extent of the improvement was difficult for them to ascertain since the results of the studies were, in their view, inconsistent across the different age groups.

Pharmaxis does not concur with this opinion and considers it has appropriate grounds upon which to request a re-examination of the European Bronchitol marketing application. The Company will complete a review of the CHMP opinion, including further discussions with the European Medicines Agency and will obtain advice from external specialist regulatory consultants, before requesting a re-examination. The company has 15 days in which to lodge a request for re-examination.

Dr Alan Robertson, Pharmaxis Chief Executive Officer, commented: "Bronchitol is a new treatment option for patients with cystic fibrosis and we are disappointed by the committee opinion. We believe that Bronchitol addresses a real and urgent need for drugs that help to restore and repair the airway surface liquid of the lung. Bronchitol improves lung function and is responsible for a significant reduction in the incidence of exacerbations. Furthermore, the sustained improvements in lung function now seen out to 12 months with Bronchitol are crucial in a disease where an accelerated loss of lung function is largely responsible for the early death of the patient. We remain committed to advancing Bronchitol for patients affected by cystic fibrosis and will focus on addressing the concerns of the CHMP in the months ahead. We have a clear understanding of the task in hand and are well advanced in our preparation."

The company will provide additional advice and details of the re-examination as the European regulatory approval process proceeds but it is anticipated that the process will conclude by November 2011.

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 FEV₁ 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 those adverse events reported for currently approved cystic fibrosis medicines.

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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 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.
