



Media Release

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PHARMAXIS ANNOUNCES MAJOR MILESTONE: POSITIVE BRONCHITOL OPINION FOR EUROPE

Pharmaceutical company Pharmaxis (ASX: PXS) today announced the Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the granting of a Marketing Authorisation for Bronchitol, clearing the way for the product to be used in Europe “for the treatment of cystic fibrosis in adults as an add-on therapy to best standard of care.”

Pharmaxis expects the European Commission to confirm this opinion and grant the Marketing Authorisation for Bronchitol in January 2012.

Pharmaxis CEO Dr Alan Robertson welcomed the decision saying, “This outcome from the CHMP meeting is an important milestone for the company. It is good news for the cystic fibrosis (CF) community which has supported us throughout the development of Bronchitol. As the life expectancy of CF patients has lengthened, the size of the adult population in Europe has increased. Bronchitol will be used for CF patients aged 18 and above, which represents about two thirds of all patients who could potentially benefit from the drug. Pharmaxis will undertake a short term clinical trial in children (age 6-17) with a view to extending the license to this age group.

“Bronchitol is a drug which was discovered and developed in Australia. It is approved for marketing in Australia and is now set to become available throughout the 27 countries of the European Union. This outcome represents the culmination of a great deal of work by many people.

“Pharmaxis will move quickly to commercialise Bronchitol in Europe. We have established our supply and logistics arrangements and advanced launch preparations and pricing applications with our marketing partner, Quintiles. The awareness of Bronchitol’s clinical data amongst CF clinicians has increased through publications and presentations at scientific conferences. European clinicians provided valuable support to the CHMP decision and are looking forward to Pharmaxis bringing this new therapeutic treatment option to their patients in the near future.” Dr Robertson said.

Professor Stuart Elborn, President of the European Cystic Fibrosis Society, stated; “Life expectancy in cystic fibrosis is improving but there remains an urgent need for new therapies which can improve lung function and reduce exacerbations. Bronchitol increases mucociliary clearance and will be the first approved therapy in Europe with this mechanism of action and has been shown to improve both lung function and reduce exacerbations when added to standard medications in use today. I welcome this decision by the CHMP.”

Robert J. Beall, Ph.D, President and CEO of the American Cystic Fibrosis Foundation said; “The Cystic Fibrosis Foundation is delighted to see an important new CF medicine being made available to patients in Europe. It takes a lot of dedication from industry and the CF community to develop a drug to this point. We are proud to have played a part in this process through our clinical trial group and look forward to Bronchitol being submitted to the FDA early next year.”

Bronchitol's approval for the treatment of cystic fibrosis patients in Australia and the European Marketing Application are based on the results of two Phase 3 clinical trials involving more than 600 people and conducted in 95 centres throughout the world.

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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), ASM8 for asthma, PXS25 for idiopathic pulmonary fibrosis and a new oxidase inhibitor for lung disease. 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 is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. Bronchitol hydrates the lungs, helps restore normal lung clearance, and allows patients to clear mucus more effectively. Clinical studies have shown Bronchitol to be safe, effective, and well tolerated in treating patients cystic fibrosis.

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.
