



Media Release

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EUROPEAN REGULATORY UPDATE ON BRONCHITOL

Pharmaxis is pleased to advise that it has received notification from the European Commission that processing of the Marketing Authorisation application for Bronchitol to treat cystic fibrosis is nearing completion.

The European Commission procedure is expected to conclude next month and Pharmaxis is proceeding with plans for a commercial launch of Bronchitol later in the second quarter in anticipation of a successful outcome. The first commercial launch will be in Germany and the UK, and will be followed by other countries as pricing and reimbursement negotiations are concluded.

Pharmaxis CEO Dr Alan Robertson said, "While this final European Commission ratification process has been concluding, we have completed preparations for the Bronchitol launch in Europe. Sales teams have been fully recruited and trained in Germany and the UK and stock will be in markets within weeks of receipt of the Marketing Authorisation."

"A European Marketing Authorisation provides access to 29 European countries and we intend to expand the use of Bronchitol beyond the important UK and German markets, which together make up 40% of the EU market by value. Many of these countries were part of our clinical trial program and there is already awareness of the product amongst clinicians and patients."

Pharmaxis continues to progress the completion of its New Drug Application (NDA) for Bronchitol which is to be filed with the US Food and Drug Administration (FDA) in the second quarter of this year.

The NDA will seek approval to market Bronchitol in the USA for people affected by cystic fibrosis age 6 years and older. It is an essential part of Pharmaxis' global expansion strategy for Bronchitol and will be applied to other key markets including South America, Canada, Middle East and non EU European countries.

Dr Robertson said, "We are committed to ensuring that the value of Bronchitol, which is now an important pharmaceutical asset, is maximised. While the immediate commercial focus is on the European Union, in parallel, the company is exploring a range of options to make Bronchitol available in all markets in the shortest possible time and with the fastest possible penetration."

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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 and bronchiectasis, PXS25/64 for the treatment of lung fibrosis and ASM8 and PXS4728 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 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 with 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.

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.
