

Media Release

15 December 2010

PHARMAXIS HOLDS PRE-NDA MEETING WITH FDA FOR BRONCHITOL

Pharmaceutical company Pharmaxis (ASX: PXS) today announced that the Company held a pre-NDA meeting with the US Food and Drug Administration (FDA) on Friday 10 December 2010. The purpose of the meeting was to discuss the proposed new drug application (NDA) for Bronchitol for the treatment of cystic fibrosis.

Dr Alan Robertson, Pharmaxis Chief Executive Officer, commented: "This meeting provides us with the guidance we need to submit the Bronchitol NDA. We appreciate the advice of the FDA and look forward to working with the FDA."

Two, long term, Phase 3 trials of Bronchitol in patients with cystic fibrosis demonstrated a clinically important improvement in lung function – in addition to an improvement in a variety of other measures. Loss of lung function is the principal reason for reduced life expectancy for people with cystic fibrosis.

Pharmaxis plans to submit the NDA during the second quarter of 2011.

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SOURCE: Pharmaxis Ltd, Sydney, Australia

CONTACT: Alan Robertson – Chief Executive Officer

Ph: +61 2 9454 7200 or email alan.robertson@pharmaxis.com.au

RELEASED THROUGH:

Australia:

Felicity Moffatt, phone +61 418 677 701 or email felicity.moffatt@pharmaxis.com.au

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 development pipeline of products includes Aridol for the assessment of asthma, 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 Bronchitol

Pharmaxis Ltd is developing Bronchitol for the management of chronic obstructive lung diseases including cystic fibrosis, and bronchiectasis. Bronchitol is a proprietary dry-powder mannitol, precision formulated for delivery to the lungs through an easy-to-use, pocket-size, portable inhaler. Once inhaled its five-way action on mucus helps restore normal lung clearance mechanisms. Bronchitol has received Orphan Drug Designation and fast track status from the US Food and Drug Administration and Orphan Drug Designation from the European Medicines Agency and the Australian Therapeutic Goods Administration.

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.
