pharmaxis

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REGULATORY PATH FOR BRONCHITOL IN BRONCHIECTASIS

Pharmaxis (ASX: PXS, NASDAQ: PXSL) today announced that it has agreed with advice from the U.S. Food and Drug Administration (FDA) on the design of a pivotal Phase 3 trial of the company's mucus clearing agent, Bronchitol, in patients with bronchiectasis.

The trial is a randomized, double-blind investigation of Bronchitol twice daily in approximately 300 adults with bronchiectasis. Participants will be treated for 52 weeks during which they will be assessed for reduction in frequency of exacerbations and quality of life. The trial will be undertaken in Europe and the USA.

This trial is the second Phase III study to be undertaken with Bronchitol in people with bronchiectasis and follows the completion of a successful trial reported during the third quarter of 2007. These trials are expected to form the basis of a marketing application in both the European Union and the U.S. Recruitment of volunteers will begin following receipt of the necessary approvals to begin the trial and is expected to be during the third quarter of 2008.

The clinical trial protocol requires final review by both the U.S. FDA under their Special Protocol Assessment (SPA) process and the European Medicines Agency, the EMEA.

The SPA process allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a New Drug Application, and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA.

Alan Robertson (Pharmaxis CEO) said “To ensure that this pivotal trial can start quickly and be completed efficiently, Pharmaxis has assembled a specific advisory board of opinion leading physicians in bronchiectasis and employed clinical and regulatory staff in the US and EU. There are no products specifically approved for bronchiectasis and Bronchitol remains the only product currently in the later stages of development for bronchiectasis. We are determined to make it available to patients worldwide as soon as possible”.

Pharmaxis is developing Bronchitol as a treatment to improve mucus clearance in the lungs of patients with cystic fibrosis, bronchiectasis and chronic obstructive pulmonary diseases. Bronchitol is a patented, inhalable dry powder formulation of mannitol that is administered directly to the lungs through a convenient, breath activated and easy to use hand held device. The U.S. Food and Drug Administration has granted Bronchitol fast track status and it is designated as an orphan drug in the U.S. and Europe.

A large Phase III trial expected to form the basis of a marketing approval for Bronchitol in Europe in patients with cystic fibrosis is currently actively recruiting.

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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 and immune disorders. Its development pipeline of products include Aridol for the management of asthma, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD) and PXS64 for the treatment of multiple sclerosis.
Founded in 1998, Pharmaxis is listed on the Australian Stock Exchange (symbol PXS), and on NASDAQ Global Market (symbol PXSL). 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 +61 2 9454 7230.

About Bronchitol
Pharmaxis Ltd is developing Bronchitol™ for the management of chronic obstructive lung diseases including cystic fibrosis, bronchiectasis and chronic bronchitis.
Bronchitol is a proprietary formulation of mannitol administered in a convenient hand-held, pocket-sized inhaler. Its formulation as a dry powder with four-way action helps restore normal lung clearance mechanisms.
Clinical studies have shown Bronchitol to be safe, effective and well tolerated in stimulating mucus hydration and clearance in people with chronic obstructive lung diseases. In particular, Bronchitol has been shown to increase mucus clearance from the lungs and significantly improve quality of life for people with bronchiectasis. Additional short term studies have also shown Bronchitol to improve lung function in people affected by cystic fibrosis.

Forward-Looking Statements
The statements contained in this media release that are not purely historical are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. 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 can not guarantee that any product candidate will receive FDA or other regulatory approval or that we will seek any such approval. Factors that could cause or contribute to such differences include, but are not limited to, factors discussed in the "Risk Factors and Other Uncertainties" section of our Form 20-F lodged with the U.S. Securities and Exchange Commission.