pharmaxis

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PHARMAXIS COMPLETES U.S. FDA SPECIAL PROTOCOL ASSESSMENT

Pharmaxis (ASX: PXS, NASDAQ: PXSL) today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) under the Special Protocol Assessment process (SPA) on the design of a pivotal Phase 3 trial of the company's novel mucus clearing agent, Bronchitol, in patients with cystic fibrosis.

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.

Pharmaxis Chief Executive Officer Dr Alan Robertson said: "We are pleased that the FDA has completed the Special Protocol Assessment, and we can initiate our second pivotal trial in cystic fibrosis. We now have a clear path toward gaining regulatory approval in the U.S. for Bronchitol in this important indication and continue on track to begin patient enrolment in this trial during the first quarter of 2008."

The Phase III clinical trial treats subjects for 26 weeks. The trial is a randomized, double-blind investigation of Bronchitol twice daily in approximately 250 adults and children with cystic fibrosis. Participants will be assessed for improvements in pulmonary function, infectious episodes and quality of life.

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.

This trial is the second Phase III trial being undertaken with Bronchitol in people with cystic fibrosis. The first trial is being undertaken in Europe and Australia and commenced recruitment during the second quarter of 2007. Recruitment of volunteers is on track to close during the second quarter of 2008.

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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 Jane Sugden, Investor Relations +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.