## ASX/Nasdaq Media Release 20 June 2008

**PHARMAXIS CONCLUDES SPECIAL PROTOCOL ASSESSMENT WITH FDA FOR BRONCHITOL PHASE 3 TRIAL**

Pharmaxis (ASX: PXS, Nasdaq: PXSL) today announced that the company and the U.S. Food and Drug Administration (FDA) have reached agreement on the phase 3 registration trial of Bronchitol for bronchiectasis via the Special Protocol Assessment process.

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 previously agreed on the trial design with the European regulatory agency (EMEA). This trial will therefore form the basis of a marketing application in both the U.S. and Europe.

The phase 3 trial has been designed in collaboration with internationally renowned experts in the field of bronchiectasis and will be a randomized, placebo controlled, double-blind investigation of Bronchitol twice daily in approximately 350 adults with bronchiectasis. Participants will be treated for 52 weeks and the primary endpoints are reduction in frequency of exacerbations and improvement in quality of life. Secondary endpoints include time to first exacerbation and duration of exacerbation. Additional secondary endpoints are antibiotic use, sputum volume, exercise tolerance and lung function measurements. The trial includes health economic analysis and will be conducted in centers across Europe and the U.S.

This trial is the second Phase III study to be undertaken for Bronchitol in bronchiectasis and follows the completion of a successful shorter trial reported last year.

Pharmaxis CEO, Alan Robertson, said the company was pleased to have concluded its discussions with the FDA and the EMEA.

“We believe this phase 3 trial design will allow us to thoroughly demonstrate the clinical benefits of Bronchitol in a patient population for which mucus build up and clearance is a daily problem. Our bronchiectasis program follows closely behind our work in cystic fibrosis where a phase 3 clinical trial is expected to soon close recruitment.”

Pharmaxis is developing Bronchitol as a treatment to improve mucus clearance in the lungs of patients with cystic fibrosis, bronchiectasis and other acute and chronic pulmonary conditions. The U.S. FDA has granted Bronchitol fast track status and it is designated as an orphan drug in the U.S.

***- ends -***

**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:**
**United States:**
Brandon Lewis, Trout Group, phone +1 646 378 2915 or email blewis@troutgroup.com
**Australia:**
Virginia Nicholls, phone +61 417 610 824 or email virginia.nicholls@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 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.