



## ASX Media Release

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### PHARMAXIS ANNOUNCES MILESTONE IN PHASE 3 TRIAL FOR CYSTIC FIBROSIS

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Pharmaceutical company Pharmaxis (ASX: PXS) today announced completion of its second six month, Phase 3 international trial assessing the effectiveness of Bronchitol in people with cystic fibrosis.

The last participant has completed the final clinical visit and the trial has run on time and on budget. The first patient entered the trial in September 2008.

The double blind, placebo controlled, randomised study comparing 400 mg of Bronchitol twice a day to control included 305 participants, and was conducted across 53 sites in 7 countries.

In addition to this now completed blinded efficacy and safety period, an optional 26 week open-label uncontrolled Bronchitol extension is still running.

This trial is the second of two trials in cystic fibrosis, required by the FDA, before a marketing application can be submitted in the United States. A total of 600 cystic fibrosis patients have now been recruited into the two Bronchitol Phase 3 clinical trials.

Pharmaxis Chief Executive Officer, Alan Robertson said: "We are very pleased to announce this important milestone. The support of the U.S. Cystic Fibrosis Foundation has been important in conducting this trial efficiently and there has been considerable enthusiasm from patients and the clinical centres involved. It is hoped this trial will confirm that Bronchitol has the opportunity to impact the way people with cystic fibrosis live their lives."

The primary efficacy end-point is change in lung function from baseline as determined by FEV<sub>1</sub> (forced expiratory volume in one second) over 26 weeks. Consistent loss of lung function is the main reason for shortening the life of people with cystic fibrosis.

The results of the trial will be available shortly after data review and statistical analysis of the various endpoints have been completed.

The trial has been designed under the FDA's Special Protocol Assessment (SPA) scheme. Pharmaxis has received Orphan Drug Designation and fast track status from the FDA for Bronchitol in cystic fibrosis.

Approximately 75,000 people in the major pharmaceutical markets have cystic fibrosis and no products have been approved to improve lung hydration.

Based on the results of the first Phase III trial reported in May 2009, Pharmaxis filed a marketing authorization application with the European Medicines Agency in October 2009. The regulatory review is expected to conclude during the second half of 2010.

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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 includes Aridol for the management of asthma, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD), ASM8 for the treatment of severe asthma, PXS25 for the treatment of lung fibrosis and PXS4159 for lung inflammation.

Founded in 1998, 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](http://www.pharmaxis.com.au) or contact Investor Relations on phone +61 2 9454 7200.

**About Bronchitol**

Pharmaxis Ltd is developing Bronchitol for the treatment of chronic obstructive lung diseases, including cystic fibrosis, bronchiectasis, and chronic bronchitis. Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. It is designed to hydrate the lungs, restore normal lung clearance mechanisms, and help patients clear mucus more effectively. Extensive clinical studies have shown Bronchitol to be well tolerated, to improve lung function and quality of life, and to stimulate mucus hydration and clearance in people with cystic fibrosis and bronchiectasis.

**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 can not guarantee that any product candidate will receive 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" section of our Statutory Annual Report available on the Pharmaxis website.