



## ASX/NASDAQ Media release

20 August 2008

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### 12 MONTH PHASE 3 TRIAL FINDS BRONCHITOL SAFE IN BRONCHIECTASIS

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Pharmaceutical company Pharmaxis (ASX:PXS, NASDAQ:PXSL) today announced that the Phase 3 clinical trial evaluating the long term safety of Bronchitol in subjects with bronchiectasis has concluded with no serious adverse events attributed to the drug following 12 months of treatment.

A total of 123 subjects started treatment with 320 mg Bronchitol twice per day and 99 subjects completed the full 12 months of the trial. Of the 24 withdrawals, only seven were a result of adverse events (three related to lung infections and two related to cough).

The most common adverse events attributed to treatment were cough in 9% of the subjects and sore throat in 5%. Other reported adverse events related to treatment were infrequent, mild in severity and in most cases were a consequence of the underlying disease.

Pharmaxis CEO Alan Robertson said: "Pharmaxis intends to file a marketing application in Australia for Bronchitol as soon as possible now that this study has concluded satisfactorily.

"Bronchitol has created a great deal of interest among people suffering with bronchiectasis and we continue to respond to requests from trial participants and others interested in Bronchitol. We are looking forward to bringing Bronchitol to the market place and are delighted this trial has concluded successfully."

This 12 month treatment period was an open label extension to a three month efficacy trial which reported in the second half of 2007.

**The conclusion from this trial is that Bronchitol improves quality of life and mucus clearance following three months of treatment and is safe and well tolerated following 12 months of treatment.** The open label component of the trial reported today supports the efficacy reported earlier in the blinded phase of the trial.

Bronchitol is being initially developed as a twice daily inhalation therapy for people with the incurable lung conditions bronchiectasis and cystic fibrosis.

It is estimated that more than 600,000 in the major pharmaceutical markets suffer from bronchiectasis and Pharmaxis expects Bronchitol to be the first targeted medication for this patient group in 20 years, addressing an important medical need. Total U.S. medical care expenditure is US\$13,000 per bronchiectasis patient, double that of patients without the disorder; and an increased overall cost to the US health system of US\$630 million.

**SOURCE:** Pharmaxis Ltd, Sydney, Australia

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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), PXS25 for the treatment of lung fibrosis and PXS4159 for asthma.

Founded in 1998, Pharmaxis is listed on the Australian Securities 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](http://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 and acute 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 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.