ASX / NASDAQ Media release

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PHASE III TRIAL FINDS PHARMAXIS' BRONCHITOL EFFECTIVE

Pharmaxis (ASX: PXS, NASDAQ: PXSL) today announced that its Phase III B301 study of Bronchitol for the treatment of people with bronchiectasis has met its two primary efficacy endpoints: quality of life and mucus clearance.

Data from the 362 subject study demonstrated a highly significant improvement in quality of life after 12 weeks of treatment with Bronchitol as assessed by the St George Respiratory Questionnaire, a patient reported outcome tool for measuring health-related quality of life, (p-value less than 0.005) and a significant improvement in quality of life compared to placebo (p-value less than 0.05).

In addition, there was a highly significant difference in mucus clearance at 12 weeks for patients receiving Bronchitol versus those patients receiving placebo (p-value less than 0.001).

There were no serious adverse events attributable to treatment and the incidence of adverse events did not significantly differ between the placebo and the Bronchitol groups. The dropout rate overall was less than 10% indicating that treatment was well accepted.

The trial was conducted at 22 hospitals across Australia, New Zealand and the United Kingdom. Participants received either Bronchitol or placebo for 12 weeks, after which participants were provided with Bronchitol for a total of 12 months to determine the safety of long term treatment.

"The completion of this study and the achievement of its primary endpoints is a major advance towards our goal of having Bronchitol available for patients with bronchiectasis" said Pharmaxis Chief Executive Officer Dr Alan Robertson.

"This is the largest single study ever conducted in bronchiectasis and we have collected a large amount of data on a variety of secondary endpoints which are still being analyzed. With no products currently indicated for bronchiectasis we look forward to discussing our complete data set and next steps with the regulators."

Bronchiectasis is an incurable, degenerative and chronic lung condition. Pharmaxis expects Bronchitol to be the first targeted medication for this patient group in over 20 years – addressing an important medical need.

Over 600,000 patients worldwide suffer from bronchiectasis including 110,000 in the United States and 20,000 in Australia. 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 of US$630 million. Widespread availability of high resolution scanners is leading to increasing diagnosis and the understanding that bronchiectasis is more common than previously thought. Pharmaxis is developing Bronchitol as a daily treatment administered by inhalation to the patient's lungs.

Earlier this month, Pharmaxis requested a Special Protocol Assessment review with the U.S. Food and Drug Administration to commence a U.S. Phase III trial with Bronchitol.

Full study results will be submitted for presentation at an upcoming international scientific meeting.

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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
Brad Miles, BMC Communications Group, phone +1 212.477.9007, email brad@bmcommunication.com

Australia:
Virginia Nicholls, phone +61 417 610 824 or email virginia.nicholls@pharmaxis.com.au

About the trial
The following information is provided in accord with the ASX and AusBiotech Code of Best Practice for Reporting by Life Science Companies.

Name of Trial	DPM B301 - a Phase III multicentre, randomised, parallel, placebo-controlled, double-blind study to investigate the safety and efficacy of Bronchitol™ (dry powder mannitol) in the symptomatic treatment of bronchiectasis.	
Blinding Status	Double blind	
Placebo Controlled	Yes	
Ratio treatment:placebo	2:1	
Treatment Method		
Route	Inhalation	
Frequency	Twice daily for 12 weeks	
Dose level	320mg mannitol or placebo	
No of subjects	362	
Subject Selection Criteria	• Known diagnosis of bronchiectasis (diagnosed by HRCT) • Ages 15 – 80 years, male and female • FEV1 >50% of the predicted value and greater than 1.0L • Clinically stable bronchiectasis for a period of 2 weeks prior to study • Evidence of chronic sputum production • Chronic cough and chronic chest congestion	
Trial Location	Australia, New Zealand, United Kingdom	
Primary end points	• To assess whether Bronchitol improves health related quality of life	p<0.005 (baseline) p<0.05 (placebo)
	• To assess the impact of Bronchitol on 24 hour sputum volume.	p<0.001 (placebo)
Secondary end points	To assess the impact of Bronchitol on:	
	• Bronchiectasis symptoms (questionnaire)	Not yet available
	• Cough severity (questionnaire)	Not yet available
	• Exercise capacity (shuttle)	Not yet available
	• Lung function, including gas transfer	Not yet available
	• Antibiotic use	Not yet available
	• Bronchial wall thickening and inflammation	Not yet available
	• Peripheral airway function	Not yet available
	• To demonstrate the safety profile of Bronchitol	Same as placebo

About Bronchitol
Pharmaxis Ltd is developing Bronchitol for the management of chronic obstructive lung diseases including bronchiectasis, cystic fibrosis 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. Clinical studies have shown Bronchitol

to be well tolerated, to improve quality of life, and to stimulate mucus hydration and clearance in people with bronchiectasis and cystic fibrosis.

About Bronchiectasis
Bronchiectasis is one of the chronic obstructive pulmonary diseases, or COPDs, and affects children and adults. It is often mistaken for asthma or pneumonia and misdiagnosis is common. In this disease the bronchial tubes become irreversibly enlarged, forming pockets that can become infected. The bronchi walls are damaged, causing impairment to the lung's complex cleaning system. The tiny hairs, or cilia, which line the bronchial tubes and sweep them free of dust, germs and excessive mucus are unable to function properly. The result is that matter such as mucus and bacteria accumulates affecting the performance of the lungs and the quality of life of the individual.

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 autoimmune diseases. 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.

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.