

**PHARMAXIS ANNOUNCES SUSTAINED BENEFIT IN CYSTIC FIBROSIS  
FOLLOWING LONG TERM BRONCHITOL TREATMENT**

Pharmaceutical company Pharmaxis (ASX:PXS) today announced significant headline results for the final stage of its international Phase III trial of Bronchitol (inhaled mannitol) in people with cystic fibrosis.

The lung function, as measured by Forced Expiratory Volume in 1 second (FEV1), of Bronchitol treated patients improved by 129 mL (7.9%) after 18 months relative to their lung function on entering the trial ( $p < 0.01$ ).

Pharmaxis Chief Executive Officer Dr Alan Robertson said: "These sustained results are impressive and of significant clinical importance. For cystic fibrosis patients, consistent loss of lung function, averaging 1-2% per year, is the leading cause of death. The improvements now shown with Bronchitol treatment over an 18 month period hold out the promise that Bronchitol can modify the course of this disease.

The lung function data is as follows:

	<b>Time (weeks)</b>	<b>Δ FEV1 (mL)</b>	<b>Δ FEV1 (%)</b>	<b>Significance</b>
Blinded phase	0	0	0	-
	26	119	6.5	P<0.001
Unblinded phase	52	156	8.1	P<0.001
	78	129	7.9	P<0.01

This clinical trial of Bronchitol was conducted in two phases. The first six month, placebo controlled blinded phase reported in May 2009 and met its primary endpoint by improving lung function as measured by a change in FEV1 by a clinically significant 6.5% ( $p < 0.001$  versus control). In an extension to the regulatory Phase III trial, patients were invited to continue on active drug, or be switched from control to drug for up to a year after the first 6 month blinded phase had concluded. Accordingly, some patients finished the trial having been on Bronchitol for 18 months.

The second twelve month unblinded, non-placebo controlled phase was to determine the safety of Bronchitol in patients with cystic fibrosis following eighteen months of treatment and to assess the long term effects on lung function.

Dr Robertson said, "Bronchitol is the first inhaled drug, formulated as a dry powder to report results of this nature in CF. It offers convenience for patients who otherwise have to deal with complex daily treatment regimens. Many people have been involved in the development of Bronchitol and this result is a measure of their dedication and effort."

A total of 97 subjects consented to participate in the open label phase and of these, 81 (83.5%) completed the first six months of the open label phase. Not all subjects were entered into the second 6 months of the open label phase - 42 subjects were entered into this phase. Of these 38 completed the trial (90%). For the 97 subjects that entered the open label phase, the average age was 23 years and the mean lung function on entry was 65.5% of the predicted normal FEV1.

The majority of adverse events were mild to moderate in severity and many of the frequently reported adverse events were a consequence of the underlying disease. Reported possible treatment related adverse events of interest included: condition being aggravated (4.1%): cough (5.3%), haemoptysis (5.3%).

The trial was conducted in 40 centres in the United Kingdom, Ireland, Australia and New Zealand.

Additional data from the trial including other lung function parameters will be presented at the forthcoming European Cystic Fibrosis Conference in Valencia, Spain on 16-19 June.

Bronchitol is designed to hydrate the airway surface of the lungs, and promote normal lung mucus clearance. It has received Orphan Drug Designation and fast track status from the U.S. Food and Drug Administration and Orphan Drug Designation from the European Medicines Agency. A marketing application has been submitted and is under review by the EMA.

#ENDS#

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

**CONTACT:** Alan Robertson - Chief Executive Officer

Ph: +61 2 9454 7200 or email [alan.robertson@pharmaxis.com.au](mailto:alan.robertson@pharmaxis.com.au)

**RELEASED THROUGH:**

**Australia:**

Felicity Moffatt, phone +61 418 677 701 or email [felicity.moffatt@pharmaxis.com.au](mailto:felicity.moffatt@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 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),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 obstructive lung diseases including cystic fibrosis, and bronchiectasis. Bronchitol is a proprietary dry-powder mannitol, precision formulated for delivery to the lungs through an easy-to-use, pocket-size, portable inhaler. Once inhaled its five-way action on mucus 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.

**About Cystic Fibrosis**

In a healthy person, there is a constant flow of mucus over the surfaces of the air passages in the lungs, removing debris and bacteria. In CF, an inherited disease, a defective gene disrupts ion transport across the epithelial membrane within cells. In the lungs, this leads to a depletion of the airway surface liquid that normally bathes the cilia, and a resultant reduction in mucociliary clearance. The result is thick, sticky mucus that clogs the lungs, severely restricting the natural airway-clearing process. It also increases the potential for bacteria to become trapped and for inflammation, thus creating an unhealthy lung environment that leads to life-threatening lung infections.

**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 cannot 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.