Media Release

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PHARMAXIS ANNOUNCES SUSTAINED BENEFIT WITH BRONCHITOL IN PHASE 3 CYSTIC FIBROSIS TRIAL

Pharmaceutical company Pharmaxis (ASX:PXS) today announced significant headline results for the second six month dosing of its international Phase III trial of Bronchitol in people with cystic fibrosis. The lung function of patients treated with Bronchitol for a full twelve months improved from 6.5% at six months to 8.0% ($p<0.001$) at the end of twelve months treatment. In addition, the lung function of patients who were on placebo for the first six months of the study improved by 10.3% ($p<0.001$) when switched to Bronchitol.

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 Forced Expiratory Volume in 1 second (FEV1) by a statistically significant 6.5% ($p=0.003$ versus placebo).

The second six month unblinded, non-placebo controlled phase was to determine the safety of Bronchitol in patients with cystic fibrosis following twelve months of treatment and to assess the long term effects on lung function. In addition, those patients who had been treated with placebo during the initial six month blinded phase of the trial were switched to Bronchitol during the subsequent six month open phase.

Dr Alan Robertson, Pharmaxis Chief Executive Officer said: “These results are very impressive and are of significant clinical relevance. 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 a 12 month period hold out the promise that, with longer usage, Bronchitol can change the course of cystic fibrosis. Bronchitol is the first dry powder formulation to report results of this nature in CF and 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 tribute to their dedication and effort.”

A total of 170 subjects (Bronchitol=97, placebo=73) consented to participate in the open label phase and of these, 81 (83.5%) and 49 (67.1%) completed the six month open label phase. For the 170 subjects that entered the open label phase, the average age was 23 years and the mean lung function on entry was 63% of the predicted normal FEV1. The ages ranged from 6 years to 56 years and the lung function ranges were from 26% to 92% of the predicted FEV1.

Reported treatment related adverse events were experienced by 40 subjects. Four of these events related to the condition being aggravated; cough, haemoptysis, or wheezing were experienced by 3 subjects each. 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.

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 and effects on exacerbation will be presented at a forthcoming scientific meeting.

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 accepted for review by the EMEA.

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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 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.