ASX / NASDAQ Media Release

04 May 2009

PHARMAXIS ANNOUNCES POSITIVE RESULTS OF PHASE 3 CYSTIC FIBROSIS TRIAL

Pharmaceutical company Pharmaxis (ASX:PXS, Nasdaq:PXSL) is pleased to announce positive results of its recently completed international Phase III trial of Bronchitol™ in people with cystic fibrosis. The study represents one of the largest clinical trials conducted in cystic fibrosis.

The primary endpoint of the trial was to assess whether Bronchitol improves lung function as measured by a change in Forced Expiratory Volume in 1 second (FEV_1) when administered 400 mg twice per day for six months. The clinical trial comfortably met this endpoint. Patients treated with Bronchitol had a statistically significant improvement in lung function from baseline of 6.6% ($p=0.001$ versus placebo). Lung function improved at week 6 and was sustained through to week 26.

The key secondary endpoint of the trial was to assess whether Bronchitol further improves lung function in patients already being treated with the most commonly used CF therapeutic, dornase alfa (Pulmozyme™). This endpoint was also successfully achieved. For patients being treated with concurrent dornase alfa, FEV_1 improved after 6 months by 5.2% from baseline ($p=0.002$ versus placebo).

Over the 6 month treatment period, there was significant lung function improvement for both those patients being treated with Bronchitol and dornase alfa ($p=0.008$ versus placebo) and those being treated with Bronchitol alone ($p=0.015$ versus placebo).

Consistent loss of lung function, is the leading cause of death for people with cystic fibrosis and this deterioration now averages 1-2% per year.

Dr Alan Robertson, Pharmaxis Chief Executive Officer said: ”We are delighted that Bronchitol performed so well in this important long term study and we now know that it can change the therapeutic landscape for many of the 75,000 people with this disease. In a trial which recruited a wide range of patients with varying disease severity, Bronchitol showed significant health benefits. As the first dry powder formulation to publish positive results in cystic fibrosis it promises convenience for patients who have complex daily schedules dominated by difficult treatment regimens.”

For the 324 subjects randomized, the treatment groups were balanced with respect to key demographic and background characteristics: the average age was approximately 23 years old, the mean lung function on entry to the trial was 62% of the predicted normal FEV_1, and 55% of the population were using dornase alfa. The ages ranged from 6 years to 56 years and the lung function ranges were from 26% to 94% of the predicted FEV_1.

In the trial subjects, Bronchitol was well-tolerated overall and had a favourable safety profile. At screening, only 7% of recruited subjects were unable to tolerate Bronchitol and were therefore not entered into the study. There was no difference in adverse events or serious

adverse events between the treatment groups. The most common adverse event was cough, which was mild to moderate in most cases and similar between the treatment arms.

The trial was conducted in 40 centres in the United Kingdom, Ireland, Australia and New Zealand. It was a double blind, placebo controlled study designed in consultation with the European Medicines Agency (EMEA) with the objective of seeking a marketing authorisation for Bronchitol for treating cystic fibrosis in Europe and elsewhere. Pharmaxis will now move to file a marketing application later this year.

The first scientific presentation of the results will be made at the June European Cystic Fibrosis Society meeting in France. In addition a more detailed account of the results of the trial is planned to be presented at the North American Cystic Fibrosis conference in Minneapolis in October.

Bronchitol has received Orphan Drug Designation and development fast track status from the U.S. Food and Drug Administration and Orphan Drug Designation from the European Medicines Agency.

Bronchitol is designed to hydrate the airway surface of the lungs, and promote normal lung mucus clearance. No new products have been approved anywhere in the world for cystic fibrosis for more than 10 years.

Dr Alan Robertson said: "We recognise that many people have been involved in the development of Bronchitol and their assistance has been invaluable. The trial was complex and challenging and this landmark result is a tribute to their efforts."

#ENDS#

Dr Alan Robertson will host a teleconference to discuss the results on Tuesday 5th May at 8.00am (Sydney), (Monday 4th May at 6.00pm U.S. East Coast, 3.00pm U.S. West Coast).

Telephone access (toll free) details are below:

- Australia: 1800 131 617
- USA/Canada: 866 746 2596
- UK: 0800 376 8339
- NZ: 0800 446 958
- Switzerland: 0800 001 230

Online (global access): http://services.choruscall.com/links/pharmaxis090505.html

#ends#

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:
Australia:
Felicity Moffatt, phone +61 418 677 701 or email felicity.moffatt@pharmaxis.com.au

United States:
Brandon Lewis, Trout Group, phone +1 646 378 2915 or email blewis@troutgroup.com

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 diagnosis 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 action on mucus helps restore normal lung clearance mechanisms. Clinical studies have shown Bronchitol to be 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

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.