ASX / Nasdaq Media Release

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PHASE 3 CYSTIC FIBROSIS TRIAL RESULTS PRESENTED AT EUROPEAN CONFERENCE

Pharmaceutical company Pharmaxis (ASX:PXS, Nasdaq:PXSL) is pleased to announce that additional results of its recently completed international Phase III trial of Bronchitol in patients with cystic fibrosis have been presented at the 2009 European Cystic Fibrosis Conference in Brest, France.

The results were presented to the conference on Friday 12 June by Dr Diana Bilton of the Royal Brompton Hospital, London.

The trial was a multi-centre, randomised, double blind, placebo controlled, 26 week study, with an optional further 6 month open label uncontrolled period. It was conducted in 40 centres in the United Kingdom, Ireland, Australia and New Zealand.

The primary endpoint of the trial was to assess whether Bronchitol improves lung function as measured by a change in FEV_1 when administered twice per day for six months.
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, rhDNase. Additional endpoints included changes in the Forced Vital Capacity of the lung, pulmonary exacerbations and antibiotic use.

Safety evaluation included the incidence of adverse events and the microbiology of sputum samples.

Clinical Results

- There was a clinically meaningful change from baseline (119mL) and placebo (93mL) at week 26 with Bronchitol for FEV1 ($p<0.001$). Importantly, treatment with Bronchitol showed an immediate and sustained improvement in lung function (FEV1) over the 26 weeks ($p<0.001$).
- For the subgroup of patients on concomitant rhDNase there was also a significant improvement in FEV1 from baseline (88mL) and from placebo (109mL) at week 26 with Bronchitol ($p=0.001$). Again, there was an immediate and sustained improvement in FEV1 over the 26 week period of the study ($p=0.003$).
- While the study was not powered to show a reduction in the secondary endpoint of exacerbation, the rate of a protocol defined pulmonary exacerbation (PDPE) per subject for the 26 weeks was lower for Bronchitol versus control: overall reduction in rate of 25% ($p=0.2$).
- There was a non significant increase in time to first PDPE ($p=0.1$) for the Intention to Treat group, however, for the Per Protocol population, i.e. those who were mostly compliant with therapy and stayed in the study, there was a significant increase in time to first PDPE ($p=0.026$).

- There was a clinically meaningful change from baseline (129mL) and control (113mL) at week 26 with Bronchitol for Forced Vital Capacity (FVC) of the lung ($p=0.002$). Additionally, treatment with Bronchitol showed an immediate and sustained improvement in lung capacity (FVC) over the 26 week treatment period ($p<0.001$).

Safety

- There was a similar number of adverse events and serious adverse events per treatment group, with no deaths in the study.
- Respiratory adverse events that were more common with Bronchitol compared with placebo, included cough (25.4% versus 20.3%), haemoptysis (11.9% versus 8.5%) and pharyngolaryngeal pain (13.6% versus 4.2%).
- There were similar rates between the groups for adverse events of particular interest including: wheezing, asthma, bronchospasm (Bronchitol 4.5% versus 5.9%).
- At screening 7% of patients were ineligible to participate due to suspected undiagnosed hyperreactive airway disease.
- Overall infections were lower in the Bronchitol group (39% versus 47.5%).
- There was no difference in microbial growth for specific microorganisms between treatment groups, confirming that Bronchitol does not contribute to the bacterial load in the lung.

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

A more detailed account of the results of the trial are planned to be presented at the North American Cystic Fibrosis conference in Minneapolis in October.

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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 it's 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

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.