Media Release

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PHARMAXIS ANNOUNCES RESULTS FOR SECOND PHASE III TRIAL OF BRONCHITOL IN CYSTIC FIBROSIS

Pharmaceutical company Pharmaxis (ASX:PXS) is pleased to announce top line results from the second large-scale global Phase III trial (CF302) of Bronchitol® (mannitol inhalation powder) in patients with cystic fibrosis (CF).

The results support the early and sustained improvement in lung function in cystic fibrosis patients seen in the first phase III study (CF301) and Pharmaxis will now move forward to meet the U.S. Food & Drug Administration (FDA) later this year to discuss a New Drug Application (NDA) for Bronchitol.

Patients treated with Bronchitol had an 8.2 % (107mL) improvement in lung function (FEV_1) compared to baseline over the 26 weeks of the study which was highly significant ($p<0.001$) and similar to the 6.3% improvement seen in the earlier study (CF301). Significant improvements from baseline were seen on Bronchitol at 6, 14 and 26 weeks of treatment ($p\leq0.001$).

The primary endpoint comparing the FEV_1 mL improvement of Bronchitol to control over the 26 weeks, narrowly missed statistical significance ($p=0.059$). This was despite the overall treatment effect across 26 weeks expressed as a percentage being similar to that reported in CF301. In fact, the FEV_1 percentage improvement of Bronchitol compared to control in CF302 over the 26 weeks was significant ($p=0.029$). Secondary endpoints targeting other measures of lung function also showed significant[a] improvement in patients on Bronchitol compared with control, including forced vital capacity (FVC) ($p=0.022$), and FEV_1 % predicted ($p=0.024$).

Pharmaxis Chief Operating Officer Gary Phillips said, “This second large-scale trial completes our pre-marketing clinical development program in CF. Patients who are already receiving current best standard of care have shown improvement in their lung function in both multi-centre trials and this effect has recently been shown to be sustained over 18 months. CF patients are frequently burdened with multiple treatments including nebulisers and we hope that Bronchitol’s formulation as a dry powder delivered by a small portable inhaler has the potential to bring an effective therapy to CF patients in a way that assists them in managing their disease.”

A total of 318 patients were recruited in the USA and 6 other countries. The treatment groups were balanced with respect to key demographic and background characteristics; the average age was approximately 20 years, the mean lung function on entry to the trial was 65% of the predicted normal FEV_1, and 75% of the population were using dornase alpha. The ages ranged from 6 years to 53 years and the lung function ranges were from 34% to 96% of the predicted FEV_1.

a. No adjustment for multiplicity

In trial subjects, Bronchitol was well-tolerated overall and demonstrated a similar rate of adverse events across treatment groups. Similar to the earlier study, only 7% of recruited subjects were unable to tolerate Bronchitol and were not entered into the study, whilst the withdrawal rate during the study was only 15%. The most common treatment related adverse event was cough, which was similar between the treatment arms.

Mr Phillips concluded, "CF302 is an important trial that allows us to complete the regulatory dossier that will be discussed with the FDA later this year. It is also important for our submission to the European regulatory authority (EMA) which has requested the safety data from CF302 as part of its review process. Pharmaxis will be submitting this additional information shortly and remains on track to receive a decision later this year. We extend our sincere thanks to the U.S. Cystic Fibrosis Foundation Therapeutics Development Network, the investigators, healthcare staff and patients who have taken part in this study."

Additional data from the trial will be presented at the forthcoming North American Cystic Fibrosis Conference in Baltimore, Maryland on 21 – 23 October, 2010.

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About the Clinical Trial

Demographics

Criteria	CF301	CF302
Patients failing mannitol tolerance test	7%	7%
Patients randomised	324	318
Received treatment	295	305
Withdrawal rate^	33%	14.8%
Average age	23	20
Age range	6 - 56	6 - 53
Mean predicted FEV_1 on entry	62%	65%
Predicted FEV_1 range	26% - 94%	34% - 96%
% patients on dornase alfa	55%	75%

^Withdrawal post start of randomised study treatment

Results

Criteria	CF301		CF302	
	Data	P value	Data	P value
FEV_1 Mannitol post-baseline vs. Baseline (mL)				
• Week 26 (mL)	121	<0.001	105	<.001
• Week 26 (%)	6.6%		8.6%	
• Week 6 – 26	119	<0.001	107	<.001
• Week 6 – 26 (%)	6.3%	<0.001	8.2%	<0.001
FEV_1 Mannitol vs Control (mL)				
• Week 26 (mL)	93	0.003	72	0.059
• Week 6 – 26 (mL)	86	<0.001	54	0.059
• Week 6 – 26 (%)	3.7%	0.003	3.8%	0.029
FVC Mannitol vs. Control (mL) at week 26	113	0.002	71	0.022
FEV% predicted Mannitol vs Control at week 26	2.52	0.0016	2.42	0.024

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 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. Bronchitol 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.

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.