
EXTENDED BENEFIT WITH BRONCHITOL IN SECOND PHASE III CYSTIC FIBROSIS TRIAL

Pharmaceutical company Pharmaxis (ASX:PXS) today announced positive first results for the open label component of its second international Phase III trial of Bronchitol in people with cystic fibrosis. In this part of the trial, all participants were treated with Bronchitol, including those that were in the control arm for the first six months. The key findings were:

- Lung function change (FEV1) for those participants treated with Bronchitol for 6 months was 8.2% ($p=0.001$ versus baseline) and this was maintained out to 12 months (FEV1 improvement of 8.2%). The withdrawal rate in the open label phase was 7%.
- Subjects who were switched from control to Bronchitol at the end of the first 6 months had a 6.3% improvement in lung function relative to baseline at the end of 12 months ($p=0.031$).

Dr Alan Robertson, Pharmaxis Chief Executive Officer said: "We are very pleased with this result which confirms the robust clinical response and good safety profile we have demonstrated with Bronchitol over a number of clinical trials. Cystic fibrosis is a disease that leads to slow decline in lung performance over time and, in this trial, Bronchitol was again able to improve lung function at commencement of treatment, at week 26, and maintain that improvement over 52 weeks for patients who were already receiving best standard of care. The repeated demonstration of sustained benefit in this second trial with Bronchitol holds out the promise that long term use of Bronchitol can change the course of the disease."

The trial objective was to determine the safety of Bronchitol in patients with cystic fibrosis following twelve months treatment and to assess the long term effects on lung function. This clinical trial of Bronchitol was conducted in two phases. The first six months was controlled and blinded and designed to assess efficacy and safety. The second six months was open label, unblinded and not controlled. Patients initially randomized to the control group were switched to receive Bronchitol during the subsequent six month open phase.

A total of 260 subjects (Bronchitol=153, placebo=107) participated in the open label phase and of these, 242 subjects (93%) completed this six month phase. For the subjects that entered the open label phase, the average age was 19.6 years and the mean lung function on entry was 64.6% of the predicted normal FEV1. The ages ranged from 6 years to 53 years and the lung function ranges were from 34% to 96% of the predicted FEV1.

In all subjects in the open label phase, the most commonly reported adverse events were haemoptysis (5.7%), headache (4.2%) and cough (8.8%). Haemoptysis and cough are common clinical features of cystic fibrosis.

The trial was conducted in 53 centres in the United States, Argentina, Canada, Belgium, France and Germany. 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 is under review by the European Medicines Agency and it has been recommended for marketing approval by the Advisory Committee on Prescription Medicines in Australia.

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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 disorders. Its development pipeline of products includes Aridol for the assessment of asthma, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD), PXS25 for the treatment of lung fibrosis and ASM8 and PXS4159 for asthma.

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. Bronchitol has received Orphan Drug Designation and fast track status from the US 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.
