

Pharmaxis announces positive results from Phase II trial of Bronchitol™

Pharmaxis (ASX:PXS) today announced that the Phase II Bronchitol™ clinical trial has demonstrated the safety and feasibility of using Bronchitol in longer term Phase III clinical trials in patients with bronchiectasis, a respiratory disease affecting more than 600,000 people worldwide.

Dr Alan Robertson, Pharmaxis CEO said that results from the study were very impressive.

“The success of this bronchiectasis trial is a very significant milestone in the development of Bronchitol. The positive outcome from this exploratory study takes us an important step closer to getting Bronchitol into the marketplace,” he said.

Bronchitol is a patented, inhalable, dry powder that can be administered by a convenient, hand-held, pocket sized device. It is manufactured by Pharmaxis in the company's TGA-approved manufacturing facility. Bronchitol is being developed for the management of various chronic obstructive lung diseases, in particular bronchiectasis, chronic bronchitis and cystic fibrosis.

Brett Charlton, Pharmaxis Medical Director, said: “the positive results from this and earlier studies, and feedback from many patients in the study that their lives were improved after only 2 weeks therapy, is very encouraging in this difficult to treat disease”.

The double blind, placebo controlled, crossover trial enrolled 60 adults aged from 18 to 75 who suffer from bronchiectasis, a form of chronic obstructive lung disease. It commenced in November 2003 and was conducted at hospitals in Sydney and Melbourne in Australia, and Auckland in New Zealand. A statistically significant improvement in a quality of life score was observed after two weeks treatment with Bronchitol and statistically significant improvements were also seen in sleep quality as reflected in a ‘sleepiness’ score. The improvement in quality of life was considered clinically significant. Patients with an unclear chest at commencement of treatment had a highly significant improvement in their bronchiectasis symptoms score on Bronchitol compared with placebo.

Out of the 60 patients recruited, 3 withdrew during the study; 2 whilst on placebo and one whilst on Bronchitol. Adverse events occurred with similar frequency on both Bronchitol

and placebo treatments. No serious adverse events were recorded and no deleterious effects on lung function or infections were observed.

The primary objective of the trial was to compare the effects of twice daily treatment of Bronchitol on the disability and handicap associated with bronchiectasis before and after treatment and against placebo. Disability and handicap was assessed by quality of life and symptom questionnaires, as well as exercise testing. The trial was conducted in accordance with the International Committee of Harmonisation (ICH) guidelines for Good Clinical Practice (GCP).

Bronchiectasis is an irreversible dilation of the main airways to the lungs, commonly accompanied by chronic infection. There are many causes of bronchiectasis and the disease can develop at any age, although symptoms may not be apparent until later in life. Most patients are affected by chronic cough and phlegm. The symptoms often begin quietly, usually after a respiratory infection, and tend to worsen gradually over a period of years.

Pharmaxis is aiming to have all studies completed to enable submission of a general marketing approval for bronchiectasis with the TGA by 2006.

To find out more about Pharmaxis, go to <http://www.pharmaxis.com.au>.

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For further information, please contact:

Alan Robertson - Pharmaxis Chief Executive Officer

Ph: (02) 9454 7216 or alan.robertson@pharmaxis.com.au

Released through:

Ashley Rambukwella – Financial & Corporate Relations

Ph: (02) 8264 1004 / m. 0407 231 282 or a.rambukwella@fcr.com.au

About Pharmaxis

Pharmaxis is a developer of innovative pharmaceutical products to treat human respiratory and autoimmune diseases. Its pipeline of products include Aridol™ for asthma management, which is nearing completion of a Phase III clinical trial, Bronchitol™ for cystic fibrosis and chronic obstructive pulmonary disease and PXS25 for the treatment of multiple sclerosis.

Founded in 1998, Pharmaxis was listed on the Australian Stock Exchange in November 2003 and is traded under the symbol PXS. The company is chaired by Denis Hanley, former Chairman and CEO of Memtec Limited. Pharmaxis employs 28 staff at its Sydney headquarters and TGA-approved manufacturing facilities, and at Canberra.

About bronchiectasis

Pronounced 'brong-kee-eck-tah-sis', bronchiectasis is one of the chronic obstructive pulmonary diseases, or COPD's, and affects children and adults. It is often mistaken for asthma or pneumonia and misdiagnosis is common. In this disease, the bronchial tubes become irreversibly enlarged, forming pockets that can become infected. The bronchi walls are damaged, causing impairment to the lung's complex cleaning system. The tiny hairs, or cilia - which line the bronchial tubes and sweep them free of dust, germs and excessive mucus are unable to function properly. The result is that matter such as mucus and bacteria accumulates affecting the performance of the lungs and the quality of life of the individual.

About the Trial

The following information is provided in accord with the draft ASX and AusBiotech Code of Best Practice for Reporting by Biotechnology, Medical Device and other Life Sciences Companies.

Name of Trial	DPM- B-201/202
Blinding Status	Double blinded – investigator and subject
Placebo Controlled	Yes
Treatment Method	
Route	Inhalation
Frequency	Twice per day for 14 days
Dose levels	400 mg
Number of Subjects	60
Dropout Rate	3/60 (2 on placebo)
Subject Selection Criteria	Known diagnosis of bronchiectasis of either gender, aged 18 to 75 and clinically stable 30 days prior to entry
Primary End Points	
Quality of life	Significant improvement on Bronchitol (p<0.05)
Sleepiness	Significant improvement Bronchitol over placebo (p<0.05)
Bronchiectasis symptoms	Highly significant improvement Bronchitol over placebo (p<0.005)
Exercise capacity	No change
Adverse Events	
Active	Two considered significant None considered serious
Placebo	Two considered significant None considered serious
Secondary End Points	
Lung Function	No changes
Sputum microbiology	No changes
Sputum rheology	In progress
Sputum volume	No changes
Other	Post hoc analysis in progress