Media Release

24 April 2013

PHASE 3 CLINICAL TRIAL IN BRONCHIECTASIS (B305) FAILS PRIMARY ENDPOINT

MEETS KEY SECONDARY ENDPOINTS ON EFFICACY AND SAFETY

Pharmaceutical company Pharmaxis (ASX: PXS) today announced its Phase 3 clinical trial (B305) assessing the effectiveness of Bronchitol® in people with bronchiectasis had not met the trial's primary endpoint of demonstrating a significant difference in the rates of defined pulmonary exacerbations in patients treated over a 12 month period.

Top line results of the double blind, placebo controlled, randomised trial showed an eight (8) per cent reduction in exacerbation rates among patients treated with Bronchitol compared with control which was not statistically significant.

The positive trend in the primary endpoint was supported by a number of statistically significant secondary endpoints. These included a delay in the time to a first exacerbation, reduced days on antibiotics and improved quality of life.

The trial results show Bronchitol has an acceptable safety profile in the patient population studied with no overall difference in the numbers of patients experiencing adverse events or serious adverse events in the Bronchitol and control groups.

The 52 week study of 485 subjects was the largest ever undertaken in bronchiectasis and the first to look at the rate of exacerbations over 12 months. The study took place across 84 hospitals in Europe, North America, South America, Canada, Australia and New Zealand.

Pharmaxis Chief Executive Officer, Mr Gary Phillips said, "It is disappointing not to have achieved the primary endpoint in this trial. We will therefore not be proceeding immediately with a regulatory submission for bronchiectasis. This trial, however, was a global first and is valuable both to Pharmaxis and the health professionals treating patients with bronchiectasis. The very large data set contains more than 43 thousand electronic pages of patient information. A full analysis will take some time but encouragingly, available data suggests that Bronchitol performs better in some patients with high disease burden.

"Bronchiectasis is a heterogeneous disease and, while there is more analysis to be undertaken, it seems likely that a clinically meaningful subgroup of Bronchitol patients can be identified to form the basis for discussions with regulatory authorities on approvable clinical trial designs.

"Over the coming months Pharmaxis will explore the options available for advancing the clinical development program in bronchiectasis. I would like to thank the patients in the trial, their clinicians and the team at Pharmaxis. This was a large scale undertaking in a disease that is difficult to assess and I am proud of the effort made in working towards a treatment for this difficult and potentially fatal disease."

Dr Diana Bilton, Consultant Respiratory Physician at Royal Brompton Hospital, London, said, "Bronchiectasis is a serious and disabling lung condition for which there are very few treatment

options. Historically, reducing exacerbations in respiratory conditions like COPD and bronchiectasis has proven difficult. The secondary endpoints in this study of improving quality of life and increasing the time to suffering an exacerbation are highly clinically relevant and the data suggests that Bronchitol is worth developing in a well-defined patient population."

Mr Phillips said, "A presentation of the findings of the B305 study will be made at an international scientific respiratory conference where I expect it will attract significant attention. B305 is a pioneering study in this disease which affects 600,000 people in the major pharmaceutical markets but for which no products have been approved to assist with mucus clearance."

Bronchitol (mannitol) is an inhaled dry power designed to hydrate the lung and restore normal lung clearance mechanisms. It is approved in Australia and Europe (adults) for the treatment of the genetic disease cystic fibrosis. Bronchitol has orphan drug designation for bronchiectasis in the US.

Trial Design			
Name of trial	DPM B305 - A Phase III multicenter, randomized, parallel group, controlled, double blind study to investigate the safety and efficacy of inhaled mannitol (Bronchitol) over 12 months in the treatment of bronchiectasis		
Blinding status	Double blind		
Comparator controlled	Yes		
Ratio – Bronchitol to control	1:1		
Treatment route	Inhalation		
Treatment frequency	Twice daily for 52 weeks		
Dose level	400mg mannitol or comparator (50mg mannitol)		
No of subjects	485		
Study withdrawal rate	Bronchitol: 18.0% Comparator: 17.1%		
Subject selection criteria	•Known diagnosis of bronchiectasis (diagnosed by HRCT) •Ages 18 – 85 years, male and female •FEV1 40% - 85% of the predicted value and greater than 1.0L •Clinically stable bronchiectasis for a period of 2 weeks prior to study • ≥ 2 exacerbations in past year, and ≥ 4 in the past 2 years •Sputum per day ≥ 10g •SGRQ ≥ 30 •Pass mannitol tolerance test		
Trial Location	Australia, New Zealand, United Kingdom, Argentina, Chile, Canada, USA, Belgium, Netherlands, Germany		
Trial Results			
Primary endpoint	To show a significant difference in the rates of graded pulmonary exacerbations, in patients with bronchiectasis treated with Bronchitol compared to control. Exacerbations are defined as a worsening in respiratory signs and symptoms requiring a change in treatment.		8% difference (Rate ratio 0.92) Not significant (p=0.31)
Secondary endpoints	•Time to first exacerbation (Hazard ratio) •Days of antibiotic use – duration (rate ratio) •Quality of life: Change in St Georges Respiratory Questionnaire •Sputum weight: 24 hour collection (g) •Spirometric lung function •Epworth Sleep Score •Hospitalisations for exacerbations (rate ratio)	Improved 28% Improved 24% Improved 28% Improved 29% Not achieved Not achieved Improved 39%	0.78 (p=0.022) 0.76 (p=0.0496) -2.4, (p=0.046) +2.8 (p=0.036) Not significant Not significant Not significant
Safety	•Similar overall rates of AE's and SAE's between treatment groups •Acceptable safety profile		

Ends

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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), ASM8 for the treatment of severe asthma, PXS25 for the treatment of lung fibrosis and PXS4159 for lung inflammation.
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 treatment of chronic obstructive lung diseases, including cystic fibrosis, bronchiectasis, and chronic bronchitis. Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. It is designed to hydrate the lungs, restore normal lung clearance mechanisms, and help patients clear mucus more effectively.

About Bronchiectasis
Bronchiectasis is a condition in which damage to the airways causes them to dilate, lose their tone and become scarred. Bronchiectasis is often caused by an infection or other condition that injures the walls of the airways or prevents the airways from clearing mucus. Mucus helps remove inhaled dust, bacteria, and other small particles from the lung.
In bronchiectasis, the airways slowly lose their ability to clear mucus. The mucus builds up, and bacteria begin to grow, which leads to repeated, serious lung infections. Each infection (or exacerbation) causes more damage to the airways. Over time, the airways can't properly move air in and out of the lungs. As a result, the body's vital organs do not get enough oxygen and this can lead to serious health problems such as respiratory failure.

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 can not 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.