

Media Release

20 June 2013

EUROPEAN CF CLINICAL TRIAL IN PAEDIATRIC PATIENTS BEGINS

Pharmaceutical company Pharmaxis (ASX:PXS) today announced that it has enrolled the first subject into its European paediatric clinical trial evaluating Bronchitol® in cystic fibrosis.

The Phase 2 trial being conducted in Europe and Canada is a requirement of Bronchitol's earlier European marketing approval for adults and if positive will form part of an application to extend this approval to treat children and adolescents in the EU with cystic fibrosis.

The trial is a 27 week randomised, double-blind crossover investigation of Bronchitol administered twice daily in approximately 160 patients with cystic fibrosis. The trial is enrolling cystic fibrosis patients aged 6 to 17 years and will assess improvements in lung function, treatment induced sputum weight and safety.

Pharmaxis Chief Executive Officer Mr Gary Phillips said: "This clinical trial includes patients aged 6-17 who make up approximately one third of patients in the EU who could potentially benefit from Bronchitol. It utilizes a number of different design features to overcome some of the issues seen in this age group in the earlier phase 3 studies. We expect it will provide important additional evidence on the performance of Bronchitol in the paediatric and adolescent population."

Bronchitol is a precision spray-dried form of mannitol, delivered to the lungs by a specially designed, portable inhaler. The product is approved for marketing for patients aged over six years in Australia and for patients aged 18 years and over throughout the European Union.

Trial Design	
Name of trial	DPM-CF-204: A randomised, multicentre, double-blind, placebo-controlled, crossover trial determining the efficacy of dry powder mannitol in improving lung function in subjects with cystic fibrosis aged six to seventeen years
Primary endpoint	The absolute change from each baseline to week 8 of each treatment period in percentage of predicted FEV ₁ .
Secondary endpoints	• Change in percentage of predicted FVC between placebo and mannitol treatment • Change in percentage of predicted FEF₂₅₋₇₅ between placebo and mannitol treatment (exploratory endpoint) • Adverse events, vital signs and physical examination • Treatment induced sputum weight
Blinding status	Double blind
Placebo controlled	Yes
Trial design	Randomised, multicentre, double-blind, placebo-controlled, crossover. 8 weeks on drug/placebo; 8 weeks washout; 8 weeks on placebo/drug
Treatment route	Inhalation
Treatment frequency	Twice daily
Dose level	400mg mannitol or placebo
Number of subjects	Minimum: 160
Subject selection criteria	• Confirmed diagnosis of cystic fibrosis • Be aged ≥ 6 years and < 18 years, male and female • Predicted FEV₁ of ≥ 30% and ≤ 90% • Pass mannitol tolerance test

Trial locations	Europe (seven countries) and Canada
Commercial partners involved	No commercial partner
Expected enrolment period	18 months

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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 product Aridol® for the assessment of asthma is sold in key international markets. Its product Bronchitol® for cystic fibrosis is launched in Europe and Australia and its development pipeline of products includes Bronchitol for bronchiectasis, ASM8 for asthma and preclinical assets in inflammatory and fibrotic diseases. Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company's head office and manufacturing facilities are located in Sydney. For more information about Pharmaxis, go to www.pharmaxis.com.au or contact Investor Relations on phone +61 2 9454 7200.

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 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.