



ASX/NASDAQ Media release

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PHARMAXIS BEGINS PHASE III CYSTIC FIBROSIS TRIAL

Pharmaxis (ASX: PXS, NASDAQ: PXSL) today announced that it has enrolled its first patient in its international Phase III clinical trial evaluating Bronchitol in cystic fibrosis sufferers.

The Phase III trial is being conducted initially in 40 hospitals across Australia, the UK and Ireland, and is the final clinical step before Pharmaxis seeks approval to market Bronchitol for cystic fibrosis in the European Union, Australia and elsewhere.

Pharmaxis Chief Executive Officer Dr Alan Robertson said: "It's great news to get this trial underway and it represents significant progress for our cystic fibrosis programme. For the first time, we are offering the convenience of dry powder inhalation technology to help restore normal lung clearance and normal lung defence to patients with cystic fibrosis. This trial follows the successful Phase II trial where Bronchitol led to a demonstrable improvement in patients lung function."

The trial design has been constructed following consultation with the European and Australian regulatory agencies and will assess the effectiveness and safety of Bronchitol in treating cystic fibrosis.

The Phase III clinical trial is designed to include a 26-week efficacy treatment period, followed by a 26-week safety extension period. The efficacy component of the trial is a randomized, double-blind investigation of Bronchitol twice daily in approximately 250 patients with cystic fibrosis. The trial is enrolling cystic fibrosis patients aged six years and above. Participants will be assessed for improvements in lung function, infectious episodes and quality of life.

Pharmaxis is developing Bronchitol as a treatment to improve mucus clearance in the lungs of patients with cystic fibrosis, bronchiectasis and chronic obstructive pulmonary diseases. Bronchitol is a patented, inhalable dry powder formulation of mannitol that can be administered by a convenient, hand-held pocket sized device. The U.S. Food and Drug Administration has granted Bronchitol fast track status and it is designated as an orphan drug in the U.S. and Europe.

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

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About the trial

The following information is provided in accordance with the ASX and AusBiotech Code of Best Practice for Reporting by Life Sciences Companies.

Name of Trial	DPM CF301 - a Phase III multicentre, randomised, parallel, controlled, double-blind study to investigate the safety and efficacy of the long term administration of Bronchitol (inhaled dry powder mannitol) in cystic fibrosis.
Blinding Status	Double blind for 26 weeks followed by open label for 26 weeks
Placebo Controlled	Yes
Ratio treatment:placebo	3:2
Treatment Method	
	Route
	Inhalation
	Frequency
	Twice daily for 26 weeks
	Dose levels
	400mg
No. of subjects	250+
Subject Selection Criteria	<ul style="list-style-type: none"> • Known diagnosis of cystic fibrosis • Aged 6 years and over, male and female • FEV1 30 - 90% of the predicted value • Absence of uncontrolled asthma or other unstable systemic diseases
Trial Location	Europe and Australia
Commercial partners involved	Pharmaxis only
Expected enrollment period	12-18 months
Primary end points	To assess whether Bronchitol improves lung function
Secondary end points	To assess the impact of Bronchitol on: <ul style="list-style-type: none"> • Pulmonary exacerbations • Quality of life • Other measures of lung function • To demonstrate the safety profile of Bronchitol

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 autoimmune diseases. Its development pipeline of products include Aridol for the management of asthma, Bronchitol for cystic fibrosis and chronic obstructive pulmonary disease (COPD) and PXS64 for the treatment of multiple sclerosis.

Founded in 1998, Pharmaxis is listed on the Australian Stock Exchange (symbol PXS), and on NASDAQ Global Market (symbol PXSL). 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 Jane Sugden, Investor Relations +61 2 9454 7230.

Forward-Looking Statements

The statements contained in this press release that are not purely historical are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements in this press 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 press 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 FDA or other 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 and Other Uncertainties" section of our Form 20-F lodged with the U.S. Securities and Exchange Commission.