ASX / NASDAQ Media release

4 September 2008

SECOND PIVOTAL PHASE 3 TRIAL IN CYSTIC FIBROSIS BEGINS

Pharmaceutical company Pharmaxis (ASX:PXS, NASDAQ:PXSL) today announced that it has enrolled the first subject into its second pivotal Phase 3 clinical trial evaluating Bronchitol in cystic fibrosis sufferers.

The Phase 3 trial is being conducted in 41 hospitals across North America, Argentina and Germany, and is the final clinical step before Pharmaxis seeks approval to market Bronchitol for cystic fibrosis in the United States.

Pharmaxis Chief Executive Officer Dr Alan Robertson said: "We are delighted to commence this trial following helpful discussions with the FDA and with assistance from the U.S. Cystic Fibrosis Foundation. This trial follows the recent closure to recruitment of the first Phase 3 trial involving 325 subjects. Bronchitol has been awarded fast-track status in the U.S., and orphan drug designation in both the U.S. and EU and we look forward to bringing Bronchitol to the international cystic fibrosis community as rapidly as we can."

This trial is being conducted under the Food and Drug Administration's Special Protocol Assessment (SPA) scheme. The SPA process ensures the clinical trial protocol is acceptable to the U.S. FDA when the results are submitted to support a marketing application for Bronchitol.

The Phase III clinical trial is designed to include a 26-week efficacy treatment period, followed by a 26-week safety period. The efficacy component of the trial is a randomized, double-blind investigation of Bronchitol twice daily in approximately 300 patients with cystic fibrosis. The trial is enrolling cystic fibrosis patients aged six years and older. Participants will be assessed for improvements in lung function, infectious episodes, antibiotic use, quality of life and a range of health economic measures.

Pharmaxis is developing Bronchitol as a treatment to improve mucus clearance in the lungs of patients with cystic fibrosis, bronchiectasis and chronic obstructive airway diseases. Bronchitol is a patented, inhalable dry powder formulation of mannitol that can be administered by a convenient, hand-held pocket sized device. Cystic fibrosis is a fatal disease, affecting more than 75,000 people worldwide.

-ends-

SOURCE: Pharmaxis Ltd, Sydney, Australia
CONTACT: Alan Robertson - Chief Executive Officer
Ph: +61 2 9454 7200 or email alan.robertson@pharmaxis.com.au

RELEASED THROUGH:

Australia:
Virginia Nicholls, phone +61 417 610 824 or email virginia.nicholls@pharmaxis.com.au
United States:
Brandon Lewis, Trout Group, phone +1 646 378 2915 or email blewis@troutgroup.com

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 CF302 – Long Term Administration of Inhaled Mannitol in Cystic Fibrosis – A Safety and Efficacy Study.
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 of administration:	Inhalation
Frequency:	Twice daily for 52 weeks
Dose levels:	400mg
No. of subjects:	300
Subject Selection Criteria:	• Known diagnosis of cystic fibrosis • Aged 6 years and over, male and female • FEV1 40 - 90% of the predicted value • Absence of uncontrolled asthma or other unstable systemic diseases
Trial Location:	U.S., Canada, Argentina and Europe
Commercial partners involved:	Pharmaxis only
Expected enrollment period:	12 months
Primary end points:	To assess whether Bronchitol improves lung function
Secondary end points:	To assess the impact of Bronchitol on: • Pulmonary exacerbations • Quality of life • Other measures of lung function • A range of health economic measures 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 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), PXS25 for the treatment of lung fibrosis and PXS4159 for asthma.
Founded in 1998, Pharmaxis is listed on the Australian Securities 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 Investor Relations on phone +61 2 9454 7200.

Forward-Looking Statements

The statements contained in this media 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 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 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.