



## ASX/NASDAQ Media release

14 March 2007

### **PHARMAXIS REPORTS PHASE II RESULTS FOR ARIDOL IN COPD**

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Pharmaceutical company Pharmaxis (ASX:PXS, NASDAQ:PXSL) today announced the results from its Phase II trial for Aridol in subjects with Chronic Obstructive Pulmonary Disease (COPD), a respiratory disease affecting over 30 million people worldwide.

The trial was conducted in 79 diagnosed COPD patients at 12 centres in Australia. The primary objective of the trial was to determine if subjects that were positive to an Aridol challenge test would demonstrate an improvement in lung function, as measured by spirometry, following a 3 month course of inhaled corticosteroids.

A secondary objective was to determine the effect of inhaled corticosteroids on hyper-responsive airways as measured by a positive Aridol test.

In this group, with predominantly mild to moderate COPD, Aridol response was positive in 76.5% of cases. There were no related serious adverse events and Aridol was shown to have an acceptable safety profile.

As the inhaled corticosteroid did not improve lung function, as measured by spirometry, in either the Aridol positive or the Aridol negative group of subjects, the primary hypothesis could not be satisfactorily tested.

However, in subjects with a positive Aridol challenge test, treatment with inhaled corticosteroids led to a highly statistically significant improvement in hyper-responsive airways as judged by a subsequent Aridol challenge test ( $p < 0.004$ ). In COPD, the severity of hyper-responsive airways is associated with the severity of the disease and is a major risk factor for the development of respiratory symptoms and worsening of the patients health.<sup>1</sup>

Pharmaxis CEO Dr Alan Robertson said: "The finding that airway hyper-responsiveness improved in trial subjects after taking a short course of inhaled steroids is important, and new, and clinically valuable. The presence of hyper-responsive airways is becoming accepted as an important measure in determining the prognosis of patients with COPD<sup>3</sup> and a simple test such as Aridol to identify hyper-responsiveness and monitor the effects of treatment is needed.

"Spirometry is not a good enough indicator of disease progression in COPD patients. Major international studies have also shown that inhaled corticosteroids fail to affect lung function, as measured by spirometry, in patients with mild to moderate COPD<sup>2</sup>."

To further enhance the role of Aridol in COPD management, Pharmaxis is therefore supporting an additional, and larger, study in subjects with COPD to be run in Switzerland. In the forthcoming trial, subjects with COPD and no previous exposure to inhaled corticosteroids will be treated according to the global prescribing guidelines<sup>4</sup> and tested with Aridol before and after three months treatment with an inhaled bronchodilator and an inhaled steroid. The Swiss trial will use Aridol and not spirometry as the principal measure of disease control. The first patient is expected to be enrolled into this study in April 2007 and the study should conclude during the first half of 2008.

There are more than 30 million COPD sufferers in the developed world. Deaths from COPD have risen by 14% in men and 185% in women between 1984 and 2000. COPD is the fourth leading cause of death in the U.S. and the only major cause of death that continues to rise.

For more details about the current trial, refer to the trial's disclosure summary below.

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

1: *Chest*: (2003) **124**, 449-458

2: *British Medical Journal* (2000) **320**, 1297-1303

3: *Respiratory Medicine*: (2007) **doi: 10.1016/j.rmed.2007.01.08**

4: *Global initiative for chronic Obstructive Lung Disease (GOLD) 2006* (<http://www.goldcopd.com/>)

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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 autoimmune diseases. Its development pipeline of products include Aridol (inhaled dry powder mannitol) 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 was listed on the Australian Stock Exchange in November 2003 (symbol PXS), and on NASDAQ (symbol PXSL) in August 2005. The company is headquartered in Sydney at its TGA-approved manufacturing facilities. For more information about Pharmaxis, go to [www.pharmaxis.com.au](http://www.pharmaxis.com.au) or contact Jane Sugden, Investor Relations +61 2 9454 7230.

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### **About the trial**

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

Name of Trial	DPM-COPD-201 (a Phase II study with Aridol)
Blinding Status	Open
Placebo Controlled	No
Treatment Method	
Route	Inhalation
Frequency	Twice.
Dose level	0 – 635mg inhaled mannitol
No of subjects	79 (safety), 68 (efficacy)
Key Subject Selection Criteria	Aged 45-80 years. Diagnosis of COPD. No corticosteroids for 6 weeks, FEV <sub>1</sub> greater than 60% predicted.
Trial Location	12 sites in Australia
Commercial partners involved	None
Primary efficacy end points	Ability of Aridol to predict improved FEV <sub>1</sub> after ICS treatment in mild-moderate COPD
Primary safety end points	To demonstrate the safety of Aridol in COPD (adverse events, vital signs, spirometry)
Main Secondary efficacy end points	Impact of ICS on response to mannitol Other lung function COPD clinical control Quality of life Exacerbation frequency

### **Study results**

#### Primary efficacy end points

Ability of Aridol to predict improved FEV <sub>1</sub> after ICS treatment in mild-moderate COPD	No improvement in FEV <sub>1</sub> in Aridol +ve or -ve groups
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#### Primary safety end points

To demonstrate the safety of Aridol in COPD	No related serious adverse events. Adequate safety profile
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#### Secondary efficacy end points

Impact of ICS on response to mannitol	Reduced Aridol positivity (P<0.004)
Other lung function	No significant change
COPD clinical control	No significant changes
Quality of life	No significant changes
Exacerbation frequency	No significant change

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**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.

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