



ASX/NASDAQ Media release

16 November 2006

PHARMAXIS REPORTS PHASE III RESULTS FOR ARIDOL

Pharmaceutical company Pharmaxis (ASX:PXS, NASDAQ:PXSL) today announced the results from its US-based Phase III trial for Aridol. The trial was conducted in 30 U.S. centers in more than 500 patients under an FDA approved protocol who were suspected of having asthma but who did not have a firm diagnosis.

In this group with predominantly very mild symptoms, Aridol was able to identify patients with exercise induced bronchoconstriction in 58% of cases (sensitivity). In comparison methacholine, an approved lung function test in the U.S., identified 54% of cases. The difference between the two tests was not statistically significant. Aridol also had similar specificity to methacholine, (66% versus 70% respectively) in subjects without exercise induced bronchoconstriction. In addition Aridol was proven to have an acceptable safety profile.

Based on this study and an earlier Phase III trial that was the basis of the marketing approval in Sweden and Australia, Pharmaxis plans to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the second quarter of 2007.

Pharmaxis CEO Dr Alan Robertson said 'This is the largest study of its kind in this patient group with such mild symptoms. **The result underscores that there is no gold standard with which to compare Aridol and it was gratifying to see that it performed as well, or better, than an existing FDA approved test.** We plan to discuss the results of the study and the rest of our substantial clinical evidence data base with the FDA at a pre-NDA meeting to be held during Q1 2007. The current study collected a vast amount of data which will be analyzed in the weeks to come and which we expect will further demonstrate the clinical application and usefulness of Aridol. Aridol is the world's first indirect dry powder challenge test and we expect it to become firmly established in the management of asthma in the future.'

A detailed presentation of the data from the study will be presented at a forthcoming international scientific congress. Aridol is already approved and available in Sweden and Australia, and is currently going through the European regulatory approval system which should see it approved in most of Europe in 2007.

There are more than 52 million asthma sufferers in the developed world. According to the Global Initiative for Asthma (GINA), asthma accounts for 1 in every 250 deaths worldwide and many of the deaths are preventable being due to suboptimal long-term medical care.

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

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

ends#

SOURCE: Pharmaxis Ltd, Sydney, Australia
CONTACT: Alan Robertson - Chief Executive Officer
Ph: +61 2 9454 7200, Fax +61 2 9451 3622

RELEASED THROUGH:

United States:

Brandon Lewis, Trout Group, +1 212 477 9007 or email blewis@troutgroup.com

Australia:

Virginia Nicholls, +61 417 610 824 or email virginia.nicholls@pharmaxis.com.au

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 or contact Jane Sugden, Investor Relations +61 2 9454 7230.

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-A-305 (a Phase III study with Aridol)
Blinding Status	Operator blinded
Placebo Controlled	No
Treatment Method	
Route	Inhalation
Frequency	Once only.
Dose level	0 – 635mg inhaled mannitol
No of subjects	501
Key Subject Selection Criteria	Aged 6 – 50 years. Current symptoms suggestive of asthma but without a definitive diagnosis or an exclusion of the diagnosis of asthma. No inhaled corticosteroids for 4 weeks, FEV ₁ greater than 70% predicted.
Trial Location	United States of America
Commercial partners involved	None

Primary efficacy end points	Sensitivity of Aridol for exercise challenge positivity (more than 10% fall in FEV ₁ from baseline) Comparative specificity of Aridol and methacholine for exercise negativity
Primary safety end points	To demonstrate the safety of Aridol (ECG, adverse events, vital signs, spirometry)
Secondary efficacy end points	Comparative sensitivity and specificity of Aridol and methacholine for clinician's diagnosis Correlation of FEV ₁ falls on Aridol, exercise and methacholine

Study results

Primary efficacy end points

Sensitivity of Aridol for exercise challenge positivity (more than 10% fall in FEV₁ from baseline) 58% (51,66) vs 54% (46,62) for methacholine]

Comparative specificity of Aridol and methacholine for exercise negativity 66% (59,72) vs 70% (63,76) for methacholine

Primary safety end points

To demonstrate the safety of Aridol No related serious adverse events. Adequate safety profile

Secondary efficacy end points

Comparative **sensitivity and specificity** of Aridol and methacholine for clinician's diagnosis
Aridol 55% (49,61): methacholine 50% (44,56)
Aridol 74% (66,81): methacholine 77% (70,84)

Correlation of FEV₁ falls on Aridol, exercise and methacholine
FEV₁ falls, measured as baseline-minimum, were significantly smaller ($p < 0.05$) for Aridol for exercise positive and exercise negative subjects indicating improved safety.
Aridol 12.4% (11.3,13.5); 10.1% (9.2,11.0)
Methacholine 19.5% (17.7,21.3); 14.4% (13.0,15.9)

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.
