



Media release

09 February 2010

Pharmaxis completes clinical trial with the antifibrotic agent, PXS25

Pharmaxis (ASX:PXS) today announced it had completed the first Phase I clinical trial in healthy volunteers with its new drug candidate, PXS25. The trial was designed to determine the tolerance and pharmacokinetic profile of PXS25 following intravenous administration. The trial investigated five ascending doses of PXS25 in 40 subjects. At all doses, PXS25 was found to be safe and well tolerated with a pharmacokinetic profile consistent with a drug that could be delivered once per day.

Dr Alan Robertson, Pharmaxis' Chief Executive Officer, said "We have seen encouraging results from PXS25 in pre clinical testing that suggests it will be active in a range of fibrotic diseases. I am therefore delighted that, based on the results from this Phase I study, PXS25 fulfils many of the other criteria we look for in a drug. I'd like to thank those involved in this study and we look forward to developing PXS25 further."

Additional Phase I trials will be completed before PXS25 is evaluated in patients with lung disease.

PXS25 is being developed as a potential new treatment for pulmonary fibrosis which has a mortality rate that exceeds many cancers and affects over 5 million people worldwide.

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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 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). 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.

About PXS25

PXS25 is a new anti-fibrotic agent under investigation for the treatment of pulmonary fibrosis. It inhibits the function of a key regulatory protein responsible for scarring in the lung and elsewhere. PXS25 will be delivered to the lungs as a once per day administration.

About Pulmonary Fibrosis

Pulmonary fibrosis is a condition in which tissue in the lung becomes thick and stiff, or scarred, over time. The development of the scarred tissue is called fibrosis. As the lung tissue becomes thicker, the lung loses its ability to move oxygen into the bloodstream.

There are 5 million people worldwide affected by pulmonary fibrosis. In the United States there are over 200,000 patients and, as a consequence of misdiagnosis, the actual numbers may be significantly higher. Typically, patients are in their forties and fifties when diagnosed but getting a diagnosis between the ages of seven and eighty is also possible. There is no known cure and patients will typically live for 3 to 5 years following diagnosis.

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	PXS25-101 (a Phase I trial with PXS25)
Blinding Status	Double blind
Placebo Controlled	Yes
Treatment Method	
Route	Intravenous
Frequency	Single dose
Dose levels	0.3 mg/kg; 1.0 mg/kg; 3.0 mg/kg; 6.4 mg/kg; 9.6 mg/kg
No of subjects enrolled	40
No of subjects treated	40
Subject Selection Criteria	Healthy volunteers
Trial Location	Australia
Commercial partners involved	None
Duration	3 months
<u>Primary end point:</u>	
<input type="checkbox"/> Safety	No serious adverse events. The reported adverse events were mild and inconsistent.
<input type="checkbox"/> Pharmacokinetic parameters	Consistent with once a day dosing

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 Aridol and/or Bronchitol or PXS25. 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 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" section of our Statutory Annual Report available on the Pharmaxis website.