



ASX/NASDAQ Media release

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**PHARMAXIS REPORTS END OF PHASE II MEETING WITH FDA AND EMEA  
PROTOCOL ASSISTANCE MEETING**

***Bronchitol Proceeding to Phase III Trials in Cystic Fibrosis***

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Pharmaxis Ltd (ASX:PXS, NASDAQ:PXSL), a specialist pharmaceutical company, today announced that it had successfully concluded an End of Phase II meeting with the U.S. Food and Drug Administration (FDA) and a Protocol Assistance meeting with the European Medicines Agency (EMA) for Bronchitol. As a result of these discussions, Pharmaxis will expedite initiation of its Phase III clinical program for Bronchitol in cystic fibrosis.

The FDA and EMA meetings follow Pharmaxis' successful completion of its Phase II clinical program. Results from the Phase II trial of Bronchitol demonstrated significant improvement in lung function in patients with cystic fibrosis.

Alan Robertson, Pharmaxis chief executive officer said 'We are extremely excited about the opportunity to accelerate development plans for Bronchitol. We believe that Bronchitol is an important new treatment for cystic fibrosis patients, and look forward to working diligently with the FDA and the EMA as we finalise the details of the Phase III program.'

Based on the meetings with the regulatory agencies, Pharmaxis plans to initiate two pivotal Phase III clinical trials with the same end point that was used in the Phase II studies, lung function as assessed by FEV1. Pharmaxis will announce the initiation of these studies when the program design has been finalized.

The Phase III clinical trials are the final studies before submitting applications to market Bronchitol in the U.S., the European Union and elsewhere.

Bronchitol is a patented, inhalable dry powder that is administered by a convenient, hand-held, pocket sized device. Both the FDA and the EMA have granted orphan drug status for Bronchitol for the treatment of cystic fibrosis.

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

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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 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.

### **About Bronchitol**

Pharmaxis Ltd is developing Bronchitol for the management of chronic obstructive lung diseases including cystic fibrosis, bronchiectasis and chronic bronchitis. Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. It is designed to hydrate the lungs, restore normal lung clearance mechanisms, and help patients clear mucus more effectively.

The topline results from a Phase II clinical study in cystic fibrosis were reported last year ([http://www.pharmaxis.com.au/library/2005\\_08\\_31\\_CF201\\_results.pdf](http://www.pharmaxis.com.au/library/2005_08_31_CF201_results.pdf)) and the full results will be presented at the American Thoracic Society annual meeting in San Diego, California on May 23<sup>rd</sup> 2006.

### **About cystic fibrosis**

Cystic Fibrosis is a hereditary, life-limiting disease that affects the body's exocrine glands which produce mucus, saliva, sweat and tears. In this disease, a genetic mutation disrupts the delicate balance of sodium, chloride and water within cells, causing the exocrine glands to secrete fluids that are thick, sticky and poorly hydrated. This leads to chronic problems in various parts of the body, particularly the lungs.

The thick mucus in the lungs severely affects the natural airway-clearing processes and increases the potential for bacteria to become trapped, resulting in respiratory infections that often require hospitalisation.

There are approximately 75,000 cystic fibrosis patients in the eight major pharmaceutical markets.

### **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.