



ASX/NASDAQ Media release

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US FAST-TRACKS PHARMAXIS CYSTIC FIBROSIS DRUG

Pharmaceutical company Pharmaxis (ASX:PXS, NASDAQ:PXSL) today announced that the US Food and Drug Administration (FDA) has designated Bronchitol as a fast-track product for cystic fibrosis.

The FDA fast-tracks the New Drug Application (NDA) process if a therapy can potentially address an unmet medical need for a life-threatening disease. Designation as a fast-track product is designed to expedite regulatory review of the Bronchitol NDA. The FDA and European Medicines Agency have both previously granted Bronchitol orphan drug status for treating cystic fibrosis.

Pharmaxis chief executive officer Dr Alan Robertson said: "The FDA decision is encouraging news for thousands of cystic fibrosis patients. It recognises the positive clinical data for Bronchitol in treating cystic fibrosis, which is a lethal inherited condition.

"This designation will speed the process of bringing this potentially life-saving drug to cystic fibrosis sufferers.

"Phase II studies show Bronchitol significantly improves lung function and wellbeing in patients with cystic fibrosis. We look forward to working with the FDA on introducing Bronchitol to the U.S. market as rapidly as possible."

Pharmaxis is currently conducting Phase III and II clinical trials of Bronchitol in cystic fibrosis patients at sites in Europe, Canada, Argentina and Australia.

Cystic fibrosis affects approximately 75,000 people in the developed world, including 33,000 US patients and 2,500 Australians - a fifth of whom are children under five years old. There have been no treatment advances in over a decade, and no products are approved to improve lung hydration.

Designation as a fast track product enables Pharmaxis to file the new drug application on a rolling basis as data becomes available, allowing the FDA to review the application in sections ahead of receiving the complete submission. A complete submission is expected to be made in 2008.

Pharmaxis is developing Bronchitol as a treatment to improve mucus clearance in the lungs of patients with cystic fibrosis, bronchiectasis and chronic obstructive pulmonary diseases. Bronchitol is a patented, inhalable dry powder formulation of mannitol administered by a hand-held, pocket sized device.

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

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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.
