Media release

17 December 2009

Pharmaxis lodges TGA application to market Bronchitol™ for cystic fibrosis in Australia

Pharmaceutical company Pharmaxis (ASX:PXS) today announced that it had submitted an application with the Therapeutic Goods Administration (TGA) to market Bronchitol in Australia for the treatment of cystic fibrosis.

The marketing application follows the filing of an application to market Bronchitol for the treatment of cystic fibrosis with the European Medicines Agency (EMEA) in October. Both applications are based on a successful international Phase 3 clinical trial reported in May with headline results showing a 6.5% improvement in the lung function of patients treated with Bronchitol.

Pharmaxis Chief Executive Officer, Dr Alan Robertson, said: "This has been an important year for Pharmaxis and I am delighted that 2009 is ending with another step towards bringing Bronchitol to the cystic fibrosis community in Australia.

"Pharmaxis has prepared a comprehensive brief for the TGA based on a well designed global study carried out across 40 centres – including Australia.

"Bronchitol is designed to hydrate the airway surface of the lungs and promote normal lung mucus clearance in people with cystic fibrosis. We believe that Bronchitol has the capacity to modify the course of the disease and are looking forward to working with the TGA over the coming months," Dr Robertson said.

Bronchitol has received Orphan Drug Designation and fast track status from the U.S. Food and Drug Administration and Orphan Drug Designation from the European Medicines Agency.

The TGA will advise by mid February 2010 if the marketing application is accepted for evaluation. A final decision on the application is expected in the first half of 2011.

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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 Bronchitol

Pharmaxis Ltd is developing Bronchitol for the management of chronic obstructive lung diseases including bronchiectasis, cystic fibrosis 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. Clinical studies have shown Bronchitol to be well tolerated, to improve lung function and quality of life, and to stimulate mucus hydration and clearance in people with bronchiectasis and cystic fibrosis.

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. 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.