Media release

23 October 2009

Pharmaxis commences pivotal bronchiectasis study and aligns global Bronchitol™ registration strategy

Pharmaceutical company Pharmaxis (ASX:PXS) today announced that it has commenced screening patients in its pivotal twelve month Phase 3 trial of Bronchitol for bronchiectasis and has moved to streamline its global regulatory strategy for this indication. As part of this strategy, Pharmaxis has voluntarily withdrawn its marketing application to the Therapeutic Goods Administration (TGA) in Australia for the use of Bronchitol to treat bronchiectasis. This application was submitted in September 2008 based on a 3 month clinical trial that used quality of life and mucus clearance as the co-primary endpoints.

Dr Alan Robertson, Pharmaxis Chief Executive Officer said; "Pharmaxis first successful Phase 3 clinical trial remains one of the largest completed in bronchiectasis, however, the quality of life improvements may not be adequate on their own to claim other than symptomatic relief of bronchiectasis in worldwide markets."

"Bronchiectasis is a disease where there are currently no registered products, limited epidemiological data and no validated endpoints that have been accepted by the majority of regulatory authorities. The reduction in antibiotic use in our first Phase 3 trial has given us the confidence to commit to a longer trial with reduction of exacerbations as its primary endpoint. This study has now commenced recruiting and based on our discussions with the FDA and EMEA will support a robust label claim in bronchiectasis patients where there remains a high unmet medical need."

"Australia represents less than 2% of the worldwide market for bronchiectasis. As well as different clinical endpoints, the Australian submission used a product with a different dosage from that used in the current pivotal 12 month study. We now need to align Australia with the global bronchiectasis regulatory strategy."

Pharmaxis has confirmed that it will continue its dialogue with the TGA and resubmit the bronchiectasis indication as soon as possible. In the meantime Bronchitol will continue to be available to bronchiectasis patients in Australia through the special access scheme.

Separately, it is planned to file a marketing application with the TGA for the use of Bronchitol in people with cystic fibrosis before the end of 2009 following positive results from an international phase 3 clinical trial.

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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.