Media release

29 December 2009

Pharmaxis receives response letter from the FDA on Aridol application

Pharmaxis (ASX:PXS) today announced it had received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) in relation to its New Drug Application (NDA) for Aridol™ (mannitol inhalation powder). The FDA has determined that the NDA cannot be approved in its present form.

The Complete Response Letter sets out the reasons for the FDA's action. The letter listed deficiencies observed at three subcontract manufacturing and testing facilities; submission of revised labelling; and agreement to post marketing requirements.

Dr Alan Robertson, Pharmaxis' Chief Executive Officer, said "The Complete Response Letter provides us with a clear outline of the FDA's requirements. Importantly, we have not been requested to undertake any additional clinical studies prior to product approval. We look forward to working with the FDA to satisfactorily address the matters raised and progress to approval as soon as possible."

Pharmaxis filed an NDA for Aridol in February 2009. Following a meeting on 20 November 2009 the FDA's Pulmonary-Allergy Drugs Advisory Committee voted to recommend the approval of Aridol.

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SOURCE: Pharmaxis Ltd, 20 Rodborough Rd, Sydney, Australia

CONTACT: Alan Robertson - Chief Executive Officer
Ph: +61 2 9454 7200 or email alan.robertson@pharmaxis.com.au

RELEASED THROUGH:
Australia:
Felicity Moffatt, phone +61 418 677 701 or email felicity.moffatt@pharmaxis.com.au

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.

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.