
FDA Advisory Committee Recommends Approval of Pharmaxis' Aridol

Pharmaxis (ASX:PXS) today announced that an advisory committee of the U.S. Food and Drug Administration (FDA) has voted to recommend the approval of Aridol™ (mannitol bronchial challenge test) for use as a bronchial test to assess bronchial hyperresponsiveness to aid in diagnosing patients who have symptoms of asthma or symptoms that are suggestive of asthma.

The recommendation was made by the FDA's Pulmonary-Allergy Drugs Advisory Committee following a meeting on 20 November 2009.

"Pharmaxis is pleased that the committee has recognised the effectiveness and safety profile of Aridol," said Dr Alan Robertson, Pharmaxis' Chief Executive Officer. "Today's discussion marks an important step in expanding the role of pulmonary function tests for patients suspected of having asthma and we look forward to working with the FDA to further address the points raised by the panel."

The questions considered by the Pulmonary-Allergy Drugs Advisory Committee and the votes were as follows:

Do the data provide substantial and convincing evidence to support the use of the mannitol bronchial challenge test to assess bronchial hyperresponsiveness to aid in diagnosing patients who have symptoms of asthma or symptoms that are suggestive of asthma?

- a) In patients 18 years of age and older: the vote was 12 – 3 – 1 (for – against - abstain)*
- b) In patients 12 to 17 years of age: the vote was 14 – 2 – 0 (for – against - abstain)*
- c) In patients 6 to 11 years of age: the vote was 11 – 5 – 0 (for – against - abstain)*

Aridol is approved for sale in major European countries, Korea and Australia. It is an indirect lung function challenge test that relies on the presence of active airway inflammation to register a response.

In making its decision, the Advisory Committee reviewed efficacy and safety data from two Phase 3 trials that were conducted in more than 1000 people.

The FDA often seeks the advice of its advisory committees when evaluating potential new products but is not required to follow its recommendation. If approved, the FDA will determine final prescribing information. Pharmaxis filed an NDA for Aridol in March 2009 and the FDA is scheduled to advise the result of its review by 27 December 2009.

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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 Aridol

Asthma is among the top 10 most commonly cited reasons for consulting a General Practitioner (GP) yet GPs currently rely upon older tests that are often inaccurate and cumbersome in assessing airway inflammation in patients with asthma. The easy to administer Aridol test uses a patented formulation of mannitol processed into a breathable powder. The test requires the patient to inhale increasing doses of Aridol, which causes the airways to narrow and contract. This process is simply detected by measuring the amount of air a person can exhale in one second. The smaller the dose required to cause contraction, the more severe the patient's asthma diagnosis. People without airway inflammation do not respond to an Aridol challenge test.

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.