
SECOND CYSTIC FIBROSIS TRIAL PASSES RECRUITMENT TARGET

Pharmaxis (ASX:PXS) today announced that its second pivotal Phase 3 clinical trial of Bronchitol for the treatment of cystic fibrosis has now passed its recruitment target of 300 subjects.

The first efficacy data from the trial is expected to be available during the first half of 2010.

This trial is the second of two trials in cystic fibrosis, required by the U.S. FDA, before a marketing application can be submitted in the U.S. When complete, more than 600 cystic fibrosis patients will have been recruited into the two Bronchitol Phase 3 clinical trials.

The trial is taking place across 58 sites in 7 countries and is a double blind, placebo controlled, randomised study comparing 400 mg of Bronchitol twice a day to placebo. The trial includes a 26-week efficacy and safety component, with an optional 26 week open-label Bronchitol safety extension.

Pharmaxis Chief Executive Officer, Alan Robertson said: "I am excited about this trial: the recruitment has gone well and the compliance rate is good and the support from the patients and clinical centres has been excellent. My expectation is that this trial, and the one that has gone before, will show that Bronchitol has the opportunity to fundamentally impact the way people with cystic fibrosis manage the disease."

The primary efficacy end-point is change in lung function from baseline as determined by FEV₁ (forced expiratory volume in one second) over 26 weeks.

Approximately two thirds of the subjects entering the study were being treated with rhDNase.

This trial is being conducted under the FDA's Special Protocol Assessment (SPA) scheme. Pharmaxis has received Orphan Drug Designation and fast track status from the FDA for Bronchitol.

More than 75,000 people in the major pharmaceutical markets are affected by cystic fibrosis and no products have been approved to improve lung hydration.

Pharmaxis will file a marketing authorization application with the European Medicines Agency shortly based on the first pivotal trial reported in May of 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 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.