

Pharmaxis successfully completes enrolment for its 600-patient Phase III trial of Aridol™ in asthma

Pharmaxis (ASX:PXS) today announced that enrolment is complete for the 600-patient Phase III trial of its asthma management product, Aridol™. The trial was designed to demonstrate that Aridol is a safe and effective challenge test for people with signs and symptoms of asthma. It is being developed to allow people with asthma to determine the severity of their disease and to better manage their asthma medication.

Over 600 children and adults aged from 6 years who suffer from asthma were enrolled in the Phase III, open label, operator blinded, randomised crossover trial. Enrolment commenced in January 2004. The trial was conducted at 12 hospitals in Sydney, Melbourne, Brisbane, Newcastle and Canberra.

Asthma is a disease of the airways that affects more than 52 million people worldwide. The cause of asthma is not known. In Australia, which has one of the highest incidences of asthma in the world, 1 in 6 children and 1 in 10 adults have been diagnosed with asthma. It ranks among the 10 most common reasons for seeing a general practitioner. It can be fatal and in 2002, 397 people in Australia died from asthma*.

The primary objectives of the trial were:

- to demonstrate the safety of Aridol as a test for assessing airway inflammation, and
- to measure the sensitivity and specificity of Aridol in identifying people with asthma.

Dr Alan Robertson, Pharmaxis CEO said that the company expected to release the trial results in September.

“Completion of enrolment in the Aridol trial represents an important milestone in the commercial development of Aridol and in the development of Pharmaxis. This is one of the few Phase III studies undertaken by an Australian company and represents a significant effort from a large number of people. A positive outcome from this study will allow us to finalise our registration documents for the Australian and European authorities.” he said.

People affected by asthma have sensitive airways. When triggered, the inside of the airways become inflamed, the airways tighten and breathlessness results. The sources that trigger asthma symptoms are different for every person, and can include exercise, colds, flu, and inhaled allergens. No matter what the potential cause Aridol can detect the

potential for inflammation. Without Aridol a medical practitioner's diagnosis of asthma is commonly made on the basis of a questionnaire and physical examination and there is a potential for the diagnosis to be incorrect, and more importantly, imprecise.

In spite of advances made in treating asthma, the number of people with asthma continues to rise and, therefore, the need for an evidence based diagnosis continues to grow.

Aridol represents an opportunity to both provide medical practitioners with an accurate tool for asthma management, and sufferers with an improved understanding of the extent of their condition, allowing better use of their preventative medication. The result of which, will be a better health outcome for the patient.

Aridol is a patented, inhalable, dry powder that can be administered using a convenient, hand-held device. The test does not require specialist equipment and can be performed in a general practitioner's surgery. It is manufactured by Pharmaxis in the company's TGA-approved manufacturing facility.

Pharmaxis expects to lodge a registration application seeking approval to market Aridol with the Australian and European authorities during the fourth quarter of 2004. Subject to regulatory approval, sales of Aridol are forecast to commence during 2005.

To find out more about Pharmaxis, go to <http://www.pharmaxis.com.au>.

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*Source: The Asthma Foundation of NSW

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About Pharmaxis

Pharmaxis is a developer of innovative pharmaceutical products to treat human respiratory and autoimmune diseases. Its pipeline of products include Aridol™ for asthma management, which is nearing completion of a Phase III clinical trial, Bronchitol™ for cystic fibrosis and chronic obstructive pulmonary disease and PXS25 for the treatment of multiple sclerosis.

Founded in 1998, Pharmaxis was listed on the Australian Stock Exchange in November 2003 and is traded under the symbol PXS. The company is chaired by Denis Hanley, former Chairman and CEO of Memtec Limited. Pharmaxis employs 26 staff at its Sydney headquarters and TGA-approved manufacturing facilities, and at Canberra.