

Pharmaxis Ltd

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02:12 26 Mar 2019

Pharmaxis prepares for advisory committee meeting on use of Bronchitol in the US

Pharmaxis Ltd (ASX:PXS) is preparing for an important meeting that will make recommendations on the possible use of its Bronchitol® product for adult cystic fibrosis patients in the United States.

The company is supporting its licensee Chiesi Group in preparing for a meeting with the Pulmonary-Allergy Drugs Advisory Committee (PADAC) which will take place in May.

Chiesi, which is responsible for the regulatory approval process, has been advised by the US Food and Drug Administration (FDA) that the PADAC meeting will take place in the US on May 8.

READ: Pharmaxis sees progress in Boehringer Ingelheim's clinical trial in patients with NASH

Pharmaxis is an Australian pharmaceutical research company focused on inflammation and fibrosis. It has a portfolio of products at various stages of development and approval.

One of these products, Bronchitol, for treatment of cystic fibrosis, is marketed in Europe, Russia and Australia and the company is seeking to market it in the large US market.

As part of this process, Chiesi resubmitted the Bronchitol New Drug Application to the FDA in December of 2018.

Used in treatment of cystic fibrosis patients

Bronchitol is a precision spray-dried form of mannitol, delivered to the lungs by a specially designed, portable inhaler.

It works by rehydrating the airway/lung surface and promoting a productive cough. Bronchitol is used for the treatment of cystic fibrosis patients.

Price: 0.115

Market Cap: \$45.39 m

1 Year Share Price Graph



Share Information

Code: PXS

Listing: ASX

52 week High Low
 0.305 0.105

Sector: Pharma & Biotech

Website: www.pharmaxis.com.au

Company Synopsis:

Pharmaxis Ltd (ASX:PXS) is a specialty pharmaceutical company focused on the development of new products for the diagnosis and treatment of chronic respiratory and immune disorders.

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READ: Pharmaxis begins phase one clinical trial of compound targeting pancreatic cancer

PADAC, which is convened by the FDA, reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

Through this process, PADAC makes appropriate recommendations to the Commissioner of Food and Drugs in the US.

The committee comprises a core of 11 voting members including the chair.

These members are selected by the Commissioner from among authorities knowledgeable in the fields of pulmonary medicine, allergy, clinical immunology, and epidemiology or statistics.

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