

Pharmaxis Ltd

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Pharmaxis welcomes US FDA committee's recommendation on use of Bronchitol in CF

Pharmaxis Ltd (ASX:PXS) (FRA:UUD) (OTCMKTS:PXSLY) US licensee Chiesi Farmaceutici S.p.A. has received a positive US Food and Drug Administration advisory committee recommendation for use of the inhaled powder Bronchitol in adult patients with cystic fibrosis (CF).

The recommendation is a positive milestone for international commercialisation of the drug the Australian company developed.

Overnight in Washington, nine of the 16-member Pulmonary/Allergy Drugs Advisory Committee (PADAC) voted yes to the question : "Is the benefit/risk profile adequate to support approval of DPM (dry powder mannitol) for the proposed indication of the management of cystic fibrosis to improve pulmonary function in patients 18 years of age and older in conjunction with standard therapies?"

PADAC is responsible for reviewing and evaluating safety and effectiveness data for proposed new products for treating pulmonary disease and conditions with allergic and/or immunologic mechanisms and makes recommendations to the US FDA.

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

Pharmaxis chief executive officer Gary Phillips called the committee's vote for a recommendation "very encouraging" while noting it was not binding on regulators.

Phillips highlighted the company's next steps and expected timetable in a market release, saying: "Pharmaxis will continue to support Chiesi to work with the FDA to bring Bronchitol to patients in the US.

"We expect the FDA to make its final decision by mid-year."

If the FDA approves the drug for marketing, its manufacturer and exclusive supplier Pharmaxis is set to receive a US\$10 million payment on the product's commercial launch in the US market.

US market approval has long been a goal for the dry-powder therapeutic which studies have shown helps CF patients clear mucus from their lungs and improve their lung function.

Three large-scale global clinical trials of Bronchitol have been undertaken by Pharmaxis.

The company's efforts have resulted in regulatory approvals in a variety of geographic markets, and marketing in Europe, Russia, Australia and a number

Price: 0.088

Market Cap: \$34.92 m

1 Year Share Price Graph



Share Information

Code: PXS

Listing: ASX

52 week High Low
0.285 0.053

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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