
US FDA ADVISORY COMMITTEE MAKES POSITIVE RECOMMENDATION ON USE OF BRONCHITOL FOR ADULT CF PATIENTS

Pharmaceutical company Pharmaxis (ASX: PXS) today announced its US licensee Chiesi has received a positive recommendation from a Committee advising the US Food and Drug Administration (FDA) on the use of Bronchitol® for adult cystic fibrosis patients in the United States.

The deliberations of the Pulmonary-Allergy Drugs Advisory Committee (PADAC) took place over eight hours in Washington concluding early this morning AEDT. After voting separately on the efficacy evidence and the safety profile, 9 members of the 16 person committee 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?”*

Pharmaxis CEO Gary Phillips said, “The Committee vote is very encouraging, however, we are aware that these recommendations are not binding and 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.”

PADAC reviews and evaluates available data concerning the safety and effectiveness of new products for use in the treatment of pulmonary disease and conditions with allergic and/or immunologic mechanisms and makes recommendations to the FDA.

Chiesi is responsible for the regulatory approval and commercialisation of Bronchitol in the United States. If Bronchitol is approved by the FDA, Pharmaxis will receive a US\$10 million milestone payment on the commercial launch of Bronchitol in the US and mid to high teen percentage royalties on in-market net sales. Pharmaxis will manufacture and be the exclusive supplier of Bronchitol for the US market.

Bronchitol® is an inhaled dry powder for the treatment of cystic fibrosis and has been the subject of three large scale global clinical trials conducted by Pharmaxis. It is approved and marketed in Europe, Russia, Australia and several other countries.

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About Pharmaxis

Pharmaxis (ACN 082 811 630) is an Australian pharmaceutical research company focused on inflammation and fibrosis with a portfolio of products at various stages of development and approval. Its product Bronchitol® for cystic fibrosis is marketed in Europe, Russia and Australia. Its product Aridol® for the assessment of asthma is sold in the United States, Europe, Australia and Asia. The company's development pipeline is centred on its expertise in amine oxidase chemistry and includes a series of Lysyl Oxidase Inhibitors under clinical development targeting fibrotic diseases of the heart, kidney, liver and lung. In May 2015, Boehringer Ingelheim acquired the Pharmaxis investigational drug PXS-4728A, a potent inhibitor of Semicarbazide-Sensitive Amine Oxidase (SSAO) (also known as amine oxidase, copper containing 3 (AOC3)), to develop it for the treatment of the liver-related condition Non-alcoholic Steatohepatitis (NASH) and other inflammatory diseases. Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company's head office, manufacturing and research facilities are located in Sydney, Australia. For more information about Pharmaxis, please see www.pharmaxis.com.au

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 of products and drug candidates. All forward-looking statements included in this media release are based upon information available to us as of the date hereof. Actual results, performance or achievements could be significantly different from those expressed in, or implied by, these forward-looking statements. These forward-looking statements are not guarantees or predictions of future results, levels of performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this document. For example, despite our efforts there is no certainty that we will be successful in partnering our LOXL2 program or any of the other products in our pipeline on commercially acceptable terms, in a timely fashion or at all. Except as required by law we undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise.