# Media Release

**26 March 2019**

## US FDA CONVENES ADVISORY COMMITTEE TO ADVISE ON USE OF BRONCHITOL

Pharmaceutical research company Pharmaxis Ltd (ASX: PXS) today announced the US Food and Drug Administration (FDA) will convene a Pulmonary-Allergy Drugs Advisory Committee (PADAC) on 8 May 2019 (US time) to make recommendations on the use of Bronchitol® for adult cystic fibrosis patients in the United States.

The Bronchitol New Drug Application was resubmitted to the FDA in December 2018 by Pharmaxis licensee, Chiesi Group (Chiesi) who are responsible for the regulatory approval process. Pharmaxis is supporting Chiesi in its preparations for the PADAC meeting.

PADAC 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 and makes appropriate recommendations to the Commissioner of Food and Drugs. The Committee consists of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner from among authorities knowledgeable in the fields of pulmonary medicine, allergy, clinical immunology, and epidemiology or statistics.

The specific questions to be asked of the Committee will be advised by the FDA closer to the meeting date.

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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.