Media Release

20 June 2019

PATHWAY TO US APPROVAL CLARIFIED AFTER FDA ISSUES COMPLETE RESPONSE LETTER ON USE OF BRONCHITOL FOR ADULT CF PATIENTS

NDA EXPECTED TO BE COMPLETED Q1 2020

Pharmaceutical company Pharmaxis (ASX: PXS) today announced its US licensee Chiesi Group (Chiesi) has received a complete response letter from the US Food and Drug Administration (FDA) detailing the remaining matters to be addressed before Bronchitol® can be approved for adult cystic fibrosis (CF) patients in the United States. Based upon the clear and achievable path to approval communicated in the FDA complete response letter, Pharmaxis believes that the FDA review of the Bronchitol NDA will be completed in Q1 2020.

The main requirement included in the FDA complete response letter is that Chiesi revise the product packaging and user instructions; and then conduct a human factor study (HFS) demonstrating that the revised user components enable healthcare professionals to properly administer the mannitol tolerance test.

Pharmaxis CEO Gary Phillips said, "We are confident that the FDA complete response letter provides a clear and achievable path to approval. FDA requested changes to the product packaging and user instructions require that an HFS be conducted. This is targeted for completion by the end of 2019. Based on our experience with healthcare professionals in other markets where our training and packaging has supported thousands of mannitol tolerance tests that have been conducted to ensure patients hypersensitive to mannitol are not prescribed Bronchitol, we are very confident the requested FDA changes can be efficiently implemented and will be effective in achieving the desired goal. We have been sharing our experiences in other markets with Chiesi and continue to work collaboratively to prepare for a successful introduction to patients in US cystic fibrosis clinics."

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.

#ENDS#

SOURCE: Pharmaxis Ltd, Sydney, Australia

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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.