Media Release

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FDA PROVIDES GUIDANCE ON BRONCHITOL APPROVAL STEPS
FDA EXPECTED TO COMPLETE REVIEW Q2 2020

Pharmaceutical research company Pharmaxis Ltd (ASX: PXS) today announced its US licensee Chiesi Group (Chiesi) has received detailed advice from the US Food and Drug Administration (FDA) on its plan to fulfil the requirements necessary to approve Bronchitol® (mannitol) for the treatment of adult cystic fibrosis patients in the United States. Based on this feedback Chiesi has added an additional month to its timetable. The FDA review of the Bronchitol NDA is therefore now expected to be completed in the second quarter of 2020.

In a Complete Response Letter received by Chiesi in June 2019, the FDA required Chiesi revise the product packaging and user instructions for Bronchitol and then conduct a human factor study (HFS) demonstrating that the revisions would enable healthcare professionals to properly administer the mannitol tolerance test. Chiesi submitted a protocol for the HFS last quarter to ensure the FDA's requirements were fully incorporated in the study. Chiesi has now received the FDA's advice to increase the size of the HFS as well as other FDA recommendations that have been incorporated into the final study design.

Pharmaxis CEO Gary Phillips said, "This important regulatory step has now been completed and the study can commence. While the timetable has extended by a month, importantly the FDA advice sought and received by Chiesi ensures the HFS is conducted in accordance with the FDA's expectations."

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 supply of Bronchitol for the US commercial launch 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 Limited is an Australian pharmaceutical research company and a global leader in drug development for inflammation and fibrotic diseases. The company has a highly productive drug discovery engine, drug candidates in clinical trials and significant future cash flows from partnering deals.

Leveraging its small-molecule expertise and proprietary amine oxidase chemistry platform, Pharmaxis has taken four in-house compounds to Phase 1 trials in just five years. Global pharmaceutical company Boehringer Ingelheim acquired the Pharmaxis anti-inflammatory AOC3 inhibitor in 2015 and is developing it (BI 1467335) for two diseases: the liver condition Non-alcoholic Steatohepatitis (NASH) and diabetic retinopathy (DR). Total potential milestone payments to Pharmaxis from these programs is €419 million ($625 million).

The company's successor amine oxidase program has developed an oral anti-fibrotic LOXL2 inhibitor, aimed at NASH, pulmonary fibrosis (IPF) and other high-value fibrotic heart and kidney diseases, with a commercial partnering process underway. Two further new drugs from the same program are expected to begin proof-of-efficacy trials in 2020. Pharmaxis' Mannitol platform has yielded the products Bronchitol® for cystic fibrosis, which is marketed in Europe, Russia and Australia, with United States FDA approval pending; and Aridol® for the assessment of asthma, which is sold in the United States, Europe, Australia and Asia.

Pharmaxis is listed on the Australian Securities Exchange (PXS). Its head office, manufacturing and research facilities are in Sydney, Australia. http://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.