Media Release

13 May 2020

FDA ACKNOWLEDGES RECEIPT OF BRONCHITOL NDA RESUBMISSION DECISION REVIEW DATE 1 NOVEMBER 2020

Pharmaceutical research company Pharmaxis Ltd (ASX: PXS) today announced its US licensee Chiesi Farmaceutici S.p.A. (Chiesi) has received acknowledgement of receipt of the Bronchitol NDA resubmission from the US Food and Drug Administration (FDA). The receipt of this communication from the FDA indicates that the submission responds to all issues raised in the complete response letter received in June 2019.

However, the FDA have classified the resubmission as Class 2 which changes the FDA review period from an expected two months to six months and sets a Goal Action Date of 1 November 2020.

Pharmaxis CEO Gary Phillips said, "While I am pleased that the FDA has confirmed Chiesi's submission to be complete, I am disappointed the FDA has exercised its discretion to set a six month review timetable. The US$10 million launch milestone payable by Chiesi subsequent to an approval of Bronchitol by the FDA therefore moves from the fourth quarter of 2020 to the first quarter of 2021."

Chiesi Group is responsible for the regulatory approval and commercialisation of Bronchitol in the United States. If Bronchitol is approved by the FDA, Pharmaxis will receive the US$10 million milestone payment on the supply of Bronchitol for the US commercial launch and additional 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 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. Boehringer Ingelheim acquired the Pharmaxis anti-inflammatory AOC3 inhibitor in 2015 to develop it (BI 1467335) for two diseases: the liver condition Non-alcoholic Steatohepatitis (NASH) and diabetic retinopathy (DR).

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, a systemic pan-LOX inhibitor for acute fibrosis and cancer that will enter a phase 2 study in 2020 and a topical pan-LOX inhibitor for scarring that is expected to commence phase 1 studies in 2H 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/

About Chiesi Group

Based in Parma, Italy, Chiesi Farmaceutici is an international research-focused healthcare group with 85 years of experience in the pharmaceutical industry and a global presence in 29 countries. Chiesi researches, develops, and markets innovative drugs in the respiratory therapeutics, specialist medicine, and rare disease areas. Its R&D organization is headquartered in Parma (Italy), and is integrated with R&D groups in France, the USA, the UK, and Sweden to advance Chiesi's pre-clinical, clinical, and registration programs. Chiesi employs nearly 6,000 people. Chiesi Group is a certified Benefit Corporation.

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.