

## Media Release

20 December 2018

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### PHARMAXIS ANNOUNCES RESUBMISSION OF BRONCHITOL® NDA IN USA

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Pharmaceutical research company Pharmaxis (ASX: **PXS**) today announced the resubmission of the Bronchitol New Drug Application with the United States Food and Drug Administration (FDA) by its licensee Chiesi Group (Chiesi).

The resubmission responds to the matters raised by the FDA in its Complete Response Letter issued in March 2013 and includes the results of the phase 3 clinical trial conducted after consultation with the FDA. The trial reported in June 2017.

Pharmaxis expects the FDA review process to take between six and twelve months to conclude. 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, and Pharmaxis will be the exclusive supplier of Bronchitol for the US market.

Gary Phillips, Chief Executive Officer commented, "The resubmission of the Bronchitol NDA concludes a substantial investment and effort by Pharmaxis and Chiesi over an extended period of time. We will continue to support Chiesi in progressing the application with the FDA and look forward to the conclusion of the review in the second half of 2019."

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**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 Europe, the United States, 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), 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](http://www.pharmaxis.com.au)

#### About Bronchitol

Bronchitol is a precision spray-dried form of mannitol, delivered to the lungs by a specially designed, portable inhaler. Bronchitol works by rehydrating the airway/lung surface and promoting a productive cough. The product is approved for marketing for the treatment of cystic fibrosis patients aged over six years in Australia and Russia and for patients aged 18 years and over throughout the European Union.

#### 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. 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.