# Media Release

**19th March 2021**

## CHIESI USA ANNOUNCES COMMERCIAL LAUNCH OF PHARMAXIS' CYSTIC FIBROSIS DRUG BRONCHITOL

- **Total of US$10 million in milestones in relation to US approval now received**
- **Bronchitol Phase 3 Study data published in Cystic Fibrosis Journal**

Pharmaxis Ltd (ASX: PXS) today announced that Chiesi USA, Inc. (Chiesi), has launched Bronchitol® (mannitol), an add-on maintenance therapy to improve pulmonary function in cystic fibrosis (CF) patients aged 18 years and older in the United States. Bronchitol, developed by Pharmaxis, is the first dry powder inhaled mucoactive agent providing a compact, portable treatment option for CF patients.

Additionally, Chiesi has announced data from the Pharmaxis Phase 3 global clinical trial (CF303) evaluating the efficacy and safety of Bronchitol in adults with CF has been published online in the Journal of Cystic Fibrosis.

Pharmaxis has so far received a total of US$10 million in Bronchitol milestone payments from Chiesi triggered by FDA approval in October 2020 and the recent first shipment of stock to the USA.

Pharmaxis CEO, Gary Phillips said; "We expect Bronchitol sales in the US to contribute strongly to the product's global sales and profit growth, making the Pharmaxis mannitol respiratory business cash flow positive from FY 2021."

CF is a debilitating genetic disease that causes progressive damage to the lungs and other organs. Bronchitol is approved and PBS listed for the treatment of adults and children in Australia with CF and is also marketed in Europe, Russia and several other countries.

Chiesi is responsible for the commercialisation of Bronchitol in the United States. Bronchitol joins Pharmaxis' first commercial product, Aridol®, in being FDA-approved. Aridol is a lung function test designed to help doctors diagnose and manage asthma by detecting active airway inflammation.

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**SOURCE:** Pharmaxis Ltd, Sydney, Australia

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## About Pharmaxis

Pharmaxis Ltd is an Australian pharmaceutical research company developing drugs for inflammatory and fibrotic diseases, with a focus on myelofibrosis. The company has a highly productive drug discovery engine built on its expertise in the chemistry of amine oxidase inhibitors, with drug candidates in clinical trials. Pharmaxis has also developed two respiratory products which are approved and supplied in global markets, generating ongoing revenue.

Pharmaxis is developing its drug PXS-5505 for the bone marrow cancer myelofibrosis which causes a build up of scar tissue that leads to loss of production of red and white blood cells and platelets. The US Food and Drug Administration has granted Orphan Drug Designation to PXS-5055 for the treatment of myelofibrosis and permission under an Investigational Drug Application (IND) to progress a phase 1c/2 clinical trial that is scheduled to begin recruitment in Q1 2021. PXS-5505 is also being investigated as a potential treatment for other cancers such as liver and pancreatic cancer.

Other drug candidates being developed from Pharmaxis' amine oxidase chemistry platform are targeting fibrotic diseases such as kidney fibrosis, NASH, pulmonary fibrosis and cardiac fibrosis; fibrotic scarring from burns and other trauma; and inflammatory diseases such as Duchenne Muscular Dystrophy.

Pharmaxis has developed two products from its proprietary spray drying technology that are manufactured and exported from its Sydney facility; Bronchitol® for cystic fibrosis, which is approved and marketed in the United States, Europe, Russia and Australia; and Aridol® for the assessment of asthma, which is approved and marketed 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. www.pharmaxis.com.au