Media Release

9th February 2021

PHARMAXIS STARTS EXPORTING ITS CYSTIC FIBROSIS DRUG TO THE USA FOLLOWING FDA APPROVAL

- **US$3 million milestone payment triggered**
- **Manufactured and packaged by Pharmaxis in Australia**

Pharmaceutical research company Pharmaxis Ltd (ASX: PXS) has announced it has exported the first shipment of its locally developed and manufactured drug Bronchitol®(mannitol) to the USA. The cystic fibrosis (CF) treatment was approved by the US Food and Drug Administration (FDA) on 30 October 2020. Following receipt of an initial payment of US$7 million (~A$10 million) from its exclusive US distributor Chiesi, Pharmaxis will now receive a further US$3 million (~A$4 million) milestone payment.

After ramping up production at its purpose-build factory in the Sydney suburb of Frenchs Forest, Pharmaxis has now dispatched the first shipment of Bronchitol to Atlanta, Georgia. The drug has been manufactured and prepared for export by Pharmaxis employees at the company's high tech TGA and FDA approved facility in French Forest.

Pharmaxis CEO Gary Phillips said, "This represents a proud and very rare achievement for a home-grown pharmaceutical research company. Not only did the team at Pharmaxis design, lead and complete the three large scale international clinical trials which established Bronchitol as a safe and effective medication for CF patients, we have now manufactured the drug to be used by adult CF patients in the USA.

"Production of drugs for delivery to the lungs is one of the most difficult processes undertaken in medicine manufacturing. Our factory is equipped with the technology to engineer a powder with precise control of the particle size, suitable for delivery via a hand-held inhaler. The powder is put into capsules, and then packaged with all the information required for use by CF patients who will take the drug twice a day. I'd like to thank our production staff for their unwavering dedication and we look forward to servicing the US market with a new treatment option in CF."

Pharmaxis expects 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, a debilitating genetic disease 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 Group, will be 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.

#ENDS#

SOURCE: Pharmaxis Ltd, Sydney, Australia

AUTHORISED FOR RELEASE TO ASX BY:

David McGarvey, Chief Financial Officer and Company Secretary: T +61 2 9454 7203,
E david.mcgarvey@pharmaxis.com.au

CONTACT:

Media: Felicity Moffatt: T +61 418 677 701, E felicity.moffatt@pharmaxis.com.au
Investor relations: Rudi Michelson (Monsoon Communications) T +61 411 402 737,
E rudim@monsoon.com.au

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