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### PHARMAXIS ANNOUNCES RUSSIAN APPROVAL FOR BRONCHITOL LARGEST MARKET ACCESSED TO DATE

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Pharmaceutical research company Pharmaxis (ASX: PXS) is pleased to announce its drug Bronchitol® has been approved for marketing in Russia for the treatment of both paediatric and adult cystic fibrosis (CF) patients. Russia is the largest market accessed to date for Bronchitol.

In a landmark decision Bronchitol today became the first medicine to be processed under new Russian laws to provide patients access to innovative medicines. The new orphan drug legislation was announced by the Russian Ministry of Health in January 2016, and Bronchitol was designated as an orphan drug the following month.

There are approximately 7,400 CF patients on the Russian Cystic Fibrosis Registry, but it is estimated there are between 3,000 and 6,000 CF patients living in rural regions not currently included on the registry. Last year the Russian market for CF drugs to deal with mucus clearance was approximately US\$29 million. The first Russian sales of Bronchitol are expected before the end of 2016.

Pharmaxis CEO Mr. Gary Phillips said, "This is an important milestone for the company and a noteworthy achievement for Australian innovation. Bronchitol will be manufactured and exported to Russia from our purpose-built factory in Sydney. It will be used to treat children aged 6 and above and adults throughout Russia who are suffering from the debilitating symptoms of cystic fibrosis. This development demonstrates both the clinical research and commercial expertise of the Pharmaxis team. We have successfully translated an Australian clinical discovery into an approved therapy for patients in the EU, Australia and now Russia.

"I am also proud of the work we have done in having Bronchitol become the first drug to be granted marketing approval under the new Russian legislation. We were instrumental in demonstrating the need for the new legislation and this will ultimately mean better access to a range of medicines for Russian patients in need."

Russia's Ministry of Health Orphan Committee will now consider Bronchitol's application for reimbursement under the country's program for guaranteed funding of seven orphan diseases known as the 7 Nosologies Program. CF drugs are purchased by the Russian Ministry of Health by way of an annual tender.

Pharmaxis Chairman Mr. Malcolm McComas said, "Russia is the largest market accessed for Bronchitol so far and a significant amount of work was led by Pharmaxis CEO Gary Phillips whose experience and long standing relationships in Eastern Europe were a key factor in successfully navigating the complexities involved in achieving this milestone."

There are 40 cystic fibrosis centres for children and 3 for adult patients in Russia. Additionally, some small centers are located within the pulmonology departments of pediatric hospitals.

President of the Russian Association of patients with cystic fibrosis Professor Nikolay Kapranov welcomed the approval saying, "The staff of the Russian and Moscow centres of cystic fibrosis are very pleased that Bronchitol has state registration in Russia and that our patients will have access to a new innovative

product . We believe the vast majority of our CF patients will be able to have free access to this modern product once it is included in the 7 Nosologies Program.”

Elena Amelina, Head of CF laboratory Scientific Research Center of Pulmonology MOH Russia said, “State registration of Bronchitol in Russia is a very important and timely step in the treatment of cystic fibrosis in this country. Bronchitol is an effective product in the treatment of cystic fibrosis giving improved drainage of the bronchus-pulmonary system. Given the process of state registration and inclusion in the list of orphan drugs is now complete, we urgently wait for Bronchitol’s inclusion in the 7 Nosologies Program and the supply of the product in Russia so it can be included in the basic treatment of our patients.”

Bronchitol is a precision spray-dried form of mannitol, delivered to the lungs by a specially designed, portable inhaler. The product is approved for marketing for patients aged 6 years and over in Australia and for patients aged 18 years and over throughout the European Union.

Pharmaxis has been supported in its Russian application by its Russian distributor who will provide in-country logistical support for Bronchitol. Pharmaxis will engage the services of four CF medical specialists to support the use of Bronchitol in the clinic.

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#### **About Pharmaxis**

Pharmaxis (ACN 082 811 630) is an Australian research pharmaceutical company with a portfolio of products at various stages of development and approval. Its product Bronchitol® for cystic fibrosis is marketed in Europe and Australia and a phase 3 trial to enable completion of an NDA for the US market is underway. Its product Aridol® for the assessment of asthma is sold in Europe, Australia and Asia. The company’s development pipeline is centred on its expertise in amine oxidase chemistry and includes Semicarbazide-Sensitive Amine Oxidase Inhibitors (SSAO) for Non-alcoholic Steatohepatitis (NASH) and inflammatory diseases including Chronic Obstructive Pulmonary Disease (COPD), and Lysyl Oxidase Inhibitors (LOX) targeting fibrotic diseases including pulmonary fibrosis and some cancers. In May 2015, Boehringer Ingelheim acquired the Pharmaxis investigational drug PXS4728A, to develop it for the treatment of the liver-related condition NASH. 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).

#### **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.