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**PHARMAXIS ANNOUNCES SIGNIFICANT BUSINESS MILESTONES  
COMMERCIALISATION OF BRONCHITOL® (MANNITOL) IN USA  
NOVAQUEST DISPUTE SETTLED**

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Pharmaceutical company Pharmaxis (ASX: PXS) today announced it has entered into an exclusive distribution and supply agreement with global pharmaceutical company Chiesi Farmaceutici SpA (Chiesi) for the commercialisation of Bronchitol® (mannitol) in the United States. As a precursor to this agreement Pharmaxis has settled its dispute with NovaQuest Pharma Opportunities Fund III (NovaQuest) and entered an Amended and Restated Financing Agreement.

Under the terms of the commercialisation agreement Chiesi is responsible for funding up to US\$22 million of the cost of the phase 3 clinical trial of Bronchitol which recently enrolled its first patient. Subject to approval in the United States, Bronchitol will be sold as part of Chiesi's cystic fibrosis portfolio which includes Bethkis® (tobramycin inhalation solution) and Pertzye® (pancrelipase) delayed-release capsules, both launched in the US earlier this year. Milestones totaling up to US\$25 million are payable tied to the launch of Bronchitol, and on achieving certain annual sales levels.

Pharmaxis will manufacture Bronchitol on commercial terms for Chiesi but should it be independently sourced in the future by Chiesi, the Agreement provides for an ongoing share of sales revenue for Pharmaxis.

Under the terms of the amended Financing Agreement, NovaQuest will receive reduced financial terms on its existing US\$20 million investment and no further investment by NovaQuest is required.

Pharmaxis CEO Mr Gary Phillips said, "This is a significant milestone in the transformation of the Pharmaxis business model. We are delighted to have Chiesi as a partner to develop and commercialise Bronchitol in the US market. Chiesi has a global capability, a growing presence in the US and importantly is a well-established and respected partner to the CF community. Our two companies will now work together to meet the requirements specified by the FDA in its Complete Response Letter with Pharmaxis taking the lead on managing the phase 3 study and Chiesi responsible for the final FDA submission and subsequent commercialisation. Chiesi's agreement to fund the costs of the phase 3 study made it possible to renegotiate financial and other terms with NovaQuest and thereby end legal action initiated by Pharmaxis in August 2014."

Mr Phillips added, "While partnering and other negotiations progressed we continued to advance the Bronchitol phase 3 study using our own resources, confident that an acceptable outcome was possible. We continue to work on partnering activities for the Pharmaxis business in the EU and Drug Discovery programs where ongoing discussions are well advanced."

**#ends#**

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### **About Pharmaxis**

Pharmaxis (ACN 082 811 630) is a specialist pharmaceutical company involved in the research, development and commercialisation of therapeutic products for chronic respiratory disorders. Its product Bronchitol® for cystic fibrosis is marketed in Europe and Australia. Its product Aridol® for the assessment of asthma is sold in key international markets. The company's development pipeline of products includes Lysyl Oxidase Inhibitors (LOX) targeting fibrotic diseases including pulmonary fibrosis and some cancers and Semicarbazide-Sensitive Amine Oxidase Inhibitors (SSAO) for inflammatory disease including Chronic Obstructive Pulmonary Disease (COPD) and Non-alcoholic steatohepatitis (NASH). Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company's head office and manufacturing facilities are located in Sydney, Australia.

### **About Chiesi**

Chiesi Farmaceutici is a research-focused international group, with nearly 80 years of experience, headquartered in Parma (Italy). Chiesi researches, develops and commercializes innovative pharmaceutical solutions in the respiratory therapeutics and specialist medicine areas. In 2014, Chiesi achieved sales of over 1.3 billion Euros, constituting 8% growth over 2013. Its R&D centers in Parma (Italy), Paris (France), Frederick (USA), Chippenham (UK) and the R&D team of the acquired Danish company Zymenex, integrate their efforts to advance Chiesi's pre-clinical, clinical and registration programs. The Chiesi Group employs approximately 4200 people, 500 of which are dedicated to R&D activities. For more information please visit [www.chiesi.com](http://www.chiesi.com)

### **About Bronchitol (mannitol)**

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 the treatment of cystic fibrosis for patients aged over six years in Australia and for patients aged 18 years and over throughout the European Union and in Israel.

### **About Bethkis (Tobramycin Inhalation Solution)**

BETHKIS® is indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*. Safety and efficacy have not been demonstrated in patients under the age of six years, patients with FEV<sub>1</sub> less than 40% or greater than 80% predicted, or patients colonized with *Burkholderia cepacia*.

### **Important Safety Information About Bethkis (tobramycin inhalation solution)**

BETHKIS is contraindicated in patients with a known hypersensitivity to any aminoglycoside. Bronchospasm can occur with inhalation of BETHKIS. Bronchospasm and wheezing should be treated as medically appropriate. Caution should be exercised when prescribing BETHKIS to patients with known or suspected auditory, vestibular, renal, or neuromuscular dysfunction. Audiograms, serum concentration, and renal function should be monitored as appropriate. Avoid concurrent and/or sequential use of BETHKIS with other drugs with neurotoxic or ototoxic potential. BETHKIS should not be administered concurrently with ethacrynic acid, furosemide, urea, or mannitol. Aminoglycosides may aggravate muscle weakness because of a potential curare-like effect on neuromuscular function. Fetal harm can occur when aminoglycosides are administered to a pregnant woman. Advise women of the potential hazard to the fetus. Common adverse reactions (more than 5%) occurring more frequently in BETHKIS patients are forced expiratory volume decreased, rales, red blood cell sedimentation rate increased, and dysphonia. BETHKIS full Prescribing Information is available at [www.chiesiusa.com](http://www.chiesiusa.com).

### **About Pertzye (Pancrelipase) Delayed-Release Capsules**

PERTZYE (pancrelipase) is approved by the U.S. Food and Drug Administration (FDA) for the treatment of Exocrine Pancreatic Insufficiency due to cystic fibrosis or other conditions. Limitation of Use: PERTZYE is not interchangeable with any other pancrelipase product.

### **Important Safety Information About Pertzye**

Fibrosing colonopathy is associated with high-dose use of pancreatic enzyme replacement. Exercise caution when doses of PERTZYE exceed 2,500 lipase units/kg of body weight per meal (or greater than 10,000 lipase units/kg of body weight per day). To avoid irritation of oral mucosa, do not chew PERTZYE or

retain in the mouth. Hyperuricemia may develop. Consider monitoring uric acid levels in patients with hyperuricemia, gout, or renal impairment. There is theoretical risk of viral transmission with all pancreatic enzyme products including PERTZYE. Exercise caution when administering pancrelipase to a patient with a known allergy to proteins of porcine origin. The most common adverse reactions ( $\geq 10\%$  of patients treated with PERTZYE) are diarrhea, dyspepsia, and cough. PERTZYE full Prescribing Information and Medication Guide are available at [www.pertzyecf.com](http://www.pertzyecf.com).

#### **Trademarks**

BRONCHITOL® (mannitol) is owned by Pharmaxis Ltd. PERTZYE® (pancrelipase) is owned by Digestive Care, Inc. and is licensed to Chiesi USA, Inc. for sales and marketing purposes in the United States. BETHKIS® (tobramycin inhalation solution) is owned by Chiesi Farmaceutici S.p.A. and is licensed to Chiesi USA, Inc. for sales and marketing purposes in the United States.

#### **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 for Bronchitol. All forward-looking statements included in this media release are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. We cannot guarantee that any product candidate will receive regulatory approval or that we will seek any such approval.