

# ASX/Media Release

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## PHARMAXIS ANNOUNCES IMPROVED PBS LISTING OF BRONCHITOL

Pharmaceutical company Pharmaxis (ASX: PXS) today announced it has received approval for simplified access to Bronchitol® for the treatment of cystic fibrosis (CF) under the Australian government's Pharmaceutical Benefits Scheme (PBS) in a decision that brings criteria for reimbursement in line with current clinical practice.

Pharmaxis has been advised of a positive decision on its application to the Pharmaceutical Benefits Advisory Committee (PBAC) to change the wording of the PBS listing for Bronchitol, removing a requirement for patients to demonstrate a 10% increase in a spirometric measure of lung function in order to secure continued PBS reimbursement.

The new listing will see the "10% Continuation Rule" removed and replaced with a new set of clinician and patient-determined criteria which are intended to allow flexibility in clinical decision-making.

Under the improved listing arrangement lung health will continue to be measured objectively to ensure patients are continuing to receive treatment benefit. Furthermore, it will be measured at 3 months, a time better aligned with clinical decision-making in keeping with routine patient visits to clinics.

Pharmaxis CEO Mr Gary Phillips said, "This is welcome news for cystic fibrosis patients in Australia. It simplifies the process for patients and allows clinicians more flexibility in managing people being treated with Bronchitol. The PBAC decision recognises the fact that Bronchitol patients in Australia are well managed by a team of CF specialists who provide close and ongoing assessment of their treatment."

Mr David Jack, CEO of Cystic Fibrosis Australia, the peak patient body representing CF patients in Australia said: "This is a positive step for CF patients in Australia, providing more appropriate access for some patients-especially people in rural areas and younger patients".

Bronchitol® is a precision spray-dried form of mannitol, delivered to the lungs by a portable inhaler. Bronchitol® is approved in Australia for the treatment of cystic fibrosis in adults and paediatric patients aged over six years as either an add-on therapy to dornase alfa, or in patients intolerant of, or inadequately responsive to, dornase alfa.

#ENDS#

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#### **About Pharmaxis**

Pharmaxis (ACN 082 811 630) is a specialist pharmaceutical company involved in the research, development and commercialization of therapeutic products for chronic respiratory disorders. Its product Aridol® for the assessment of asthma is sold in key international markets. Its product Bronchitol® for cystic fibrosis is recently launched in Europe and Australia and its development pipeline of products includes, Bronchitol for bronchiectasis, PXS64 for the treatment of lung fibrosis, ASM8 for asthma and PXS4728 for fibrotic disease. Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company's head office and manufacturing facilities are located in Sydney. For more information about Pharmaxis, go to www.pharmaxis.com.au or contact Investor Relations on phone +61 2 9454 7200.

#### **About Bronchitol**

Bronchitol has been developed to help clear mucus (a major source of lung infections), improve lung function and reduce exacerbations in patients with cystic fibrosis. Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. Inhaled mannitol hydrates the lungs, helps restore normal lung clearance, and allows patients to clear mucus more effectively.

### **About Cystic Fibrosis**

In a healthy person, there is a constant flow of mucus over the surfaces of the air passages in the lungs, removing debris and bacteria. In CF, an inherited disease, a defective gene disrupts ion transport across the epithelial membrane within cells. In the lungs, this leads to a depletion of the airway surface liquid that normally bathes the cilia, and a resultant reduction in mucociliary clearance. The result is thick, sticky mucus that clogs the lungs, severely restricting the natural airway-clearing process. It also increases the potential for bacteria to become trapped and for inflammation, thus creating an unhealthy lung environment that leads to life-threatening lung infections.

## **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.