



ASX/ Media release

12 May 2005

---

***BRONCHITOL™ APPROVED FOR PATIENT USE UNDER THE SPECIAL ACCESS SCHEME***

---

Pharmaxis (ASX:PXS) announced today that the Therapeutic Goods Administration (TGA) has approved several requests to supply its unapproved drug, Bronchitol, to patients with bronchiectasis who participated in recent clinical trials.

The TGA requires that pharmaceuticals are approved and registered before they can be supplied. Exemptions are occasionally granted under the Special Access Scheme (SAS) for the supply of unapproved pharmaceuticals such as Bronchitol, to seriously ill patients. Each request is considered individually, on a patient-by-patient basis.

Under the SAS, a patient's doctor applies to the TGA for approval to request the needed drug from the manufacturer. Patients, doctors and the manufacturer are all obliged to carefully monitor and report the safety of the drug and the balance of its benefits and risks.

In these cases, Pharmaxis will supply Bronchitol to a number of patients in NSW and Victoria.

Pharmaxis CEO Alan Robertson said 'This is a wonderful opportunity for Pharmaxis to help people living with bronchiectasis. To breathe easily is something most people take for granted: making that possible for these patients is very gratifying.'

Bronchitol is still in development. Clinical studies have shown it to be well tolerated, safe and effective in stimulating mucus hydration and clearance in people with chronic obstructive lung diseases. In particular, Bronchitol has been shown to dramatically increase mucus clearance from the lungs and significantly improve quality of life for people with bronchiectasis. Pharmaxis' Phase II clinical trials for bronchiectasis are complete and Phase III pre-registration trials are beginning.

To find out more about Pharmaxis, go to <http://www.pharmaxis.com.au>.

***ends#***

---

**For additional information, please contact:**

Alan Robertson - Pharmaxis Chief Executive Officer  
Ph: (02) 9454 7202 or alan.robertson@pharmaxis.com.au

**Released through:**

Ashley Rambukwella – Financial & Corporate Relations  
Ph: (02) 8264 1004 / m. 0407 231 282 or a.rambukwella@fcr.com.au

**About Pharmaxis Ltd**

Pharmaxis (ACN 082 811 630) develops innovative pharmaceutical products to treat human respiratory and autoimmune diseases. Its pipeline of products include Aridol™ for the management of asthma, Bronchitol™ for cystic fibrosis and chronic obstructive pulmonary disease (COPD) and PXS64 for the treatment of multiple sclerosis.

Founded in 1998, Pharmaxis was listed on the Australian Stock Exchange in November 2003 and is traded under the symbol PXS. The company is headquartered in Sydney at its TGA-approved manufacturing facilities.

For more information about Pharmaxis, go to [www.pharmaxis.com.au](http://www.pharmaxis.com.au) or call +61 2 9454 7200.

**About Bronchitol™**

Pharmaxis Ltd is developing Bronchitol™ for the management of chronic obstructive lung diseases including cystic fibrosis, bronchiectasis and chronic bronchitis.

Bronchitol is a proprietary formulation of mannitol administered in a convenient hand-held, pocket-sized inhaler. Its formulation as a dry powder with a four-way action helps restore normal lung clearance mechanisms.

**About bronchiectasis**

Pronounced 'brong-kee-eck-tah-sis', bronchiectasis is one of the chronic obstructive pulmonary diseases, or COPDs, and affects children and adults. It is often mistaken for asthma or pneumonia and misdiagnosis is common. In this disease the bronchial tubes become irreversibly enlarged, forming pockets that can become infected. The bronchi walls are damaged, causing impairment to the lung's complex cleaning system. The tiny hairs, or cilia, which line the bronchial tubes and sweep them free of dust, germs and excessive mucus are unable to function properly. The result is that matter such as mucus and bacteria accumulates affecting the performance of the lungs and the quality of life of the individual.