

**BRONCHITOL COMMERCIAL PROGRESS IN EUROPE**

- **NICE DRAFT RECOMMENDATION ON COST EFFECTIVENESS**
- **LAUNCHED IN THE UK**
- **GERMAN PRICE PUBLISHED**

Pharmaceutical company Pharmaxis (ASX:PXS) today announced that the National Institute for Health and Clinical Excellence (NICE) in the UK has issued a preliminary opinion that Bronchitol (inhaled dry powder mannitol) could not yet be considered a cost-effective use of NHS resources for the treatment of cystic fibrosis in England and Wales. This opinion is not NICE's final guidance on Bronchitol and the recommendations may change following consultation and receipt of stakeholder comment.

The Committee appreciated that CF is a multi-faceted condition, with a complex treatment pathway that must be tailored to the needs of the individual patient. The high quality of the two Phase III clinical studies was acknowledged, and the Committee accepted the evidence of the clinical and patient experts on the advantages for patients in having a choice of treatments, and that Bronchitol has the potential to ease the disease burden. The Committee's view at this stage is that the calculation of cost effectiveness is associated with considerable uncertainty and dependent on a variety of imputed assumptions.

Pharmaxis CEO Dr Alan Robertson said, "We believe that the cost effectiveness ratios in our submission are correctly positioned to gain a positive recommendation from NICE. The Committee has clearly identified a number of areas of uncertainty and we will be working with NICE and other patient and professional stakeholders over coming weeks to supply further analyses and clarification. We look forward to further progress and the forthcoming Committee meeting, which will consider the comments received during the consultation period. The closing date for comments on the draft opinion is 3 July 2012, the second appraisal committee meeting will likely be held in September and the process will be finalized sometime during Q4 2012."

**UK LAUNCH**

Bronchitol has been introduced in the United Kingdom at a retail price of £16.55 per day and notification has been received from the UK Department of Health that this price is acceptable.

"No CF drugs currently available in the UK other than Bronchitol have ever been reviewed by NICE. The decision to fund Bronchitol remains in the hands of the local health authorities with whom we have been liaising over recent months. Bronchitol is now available in pharmacies and we will be pursuing the negotiations with local payors to fund treatment for CF patients in their area," Dr Robertson said.

**PRICE IN GERMANY**

Pharmaxis today officially published the retail price of Bronchitol in Germany at €35.65 per day. Germany's Federal Joint Committee (G-BA) has a modified procedure for orphan drug assessments such that only

products with annual sales in Germany of more than €50 million will be subject to an early benefit assessment from the Institute for Quality and Efficiency in Health Care (IQWiG).

Dr Robertson said, “Bronchitol has demonstrated significant reductions in the incidence of exacerbations when used on top of standard therapy in addition to its effects on improving and maintaining lung function. This retail price is in line with guidance we have provided in relation to the German market and pricing research conducted by Pharmaxis amongst German physicians and insurance funds.

“We now look forward to introducing Bronchitol to UK and German CF clinics following the formal European launch, which will take place at the European CF symposium in Dublin from June 6<sup>th</sup> – 9<sup>th</sup> 2012.”

**#ENDS#**

**SOURCE:** Pharmaxis Ltd, Sydney, Australia

**CONTACT:** Alan Robertson – Chief Executive Officer

Ph: +61 2 9454 7200 or email [alan.robertson@pharmaxis.com.au](mailto:alan.robertson@pharmaxis.com.au)

**RELEASED THROUGH:**

**Australia:**

Felicity Moffatt, phone +61 418 677 701 or email [felicity.moffatt@pharmaxis.com.au](mailto:felicity.moffatt@pharmaxis.com.au)

**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 launched in a number of key markets. Its development pipeline of products includes, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD), PXS25 for the treatment of lung fibrosis and ASM8 and PXS4159 for asthma. Pharmaxis is listed on the Australian Securities Exchange (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 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. Bronchitol hydrates the lungs, helps restore normal lung clearance, and allows patients to clear mucus more effectively. Clinical studies have shown Bronchitol to be safe, effective, and well tolerated in treating patients cystic fibrosis.

**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 Aridol and/or 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.