
BRONCHITOL REDUCES RISK OF EXACERBATIONS IN PATIENTS WITH CYSTIC FIBROSIS ADDITIONAL DATA PRESENTED AT EUROPE CF MEETING

Pharmaceutical company Pharmaxis (ASX: PXS) today presented a new analysis of its two Phase 3 clinical studies of Bronchitol® showing positive trends in reducing exacerbations in all age sub groups of cystic fibrosis patients.

The analysis which focuses on adult patients, has been presented at the European Cystic Fibrosis Meeting taking place in Ireland. Its release coincides with the commercial launch of Bronchitol in the UK and Germany following the approval by the European Medicines Agency of Bronchitol earlier this year for the treatment of cystic fibrosis in adults as an add-on therapy to best standard of care.

The two phase 3 studies contained 341 adult patients and their results were broadly consistent with those from the overall population of 600 patients which included adolescents and children.

- Adult patients who showed an increase in lung function on Bronchitol had 59% fewer exacerbations than patients who showed no improvement (p=0.03).
- Exacerbation incidence was reduced by 29% in the overall population (p=0.039) and there were consistent improvements in all age groups with a 24% reduction in adults (NS).
- Sputum weight in adult patients was significantly increased at both 6 and 14 weeks
- Lung function in adults showed significant improvements over the 6 months of the study and were sustained out to 12 months.
- For adults, there was no increase in treatment burden after taking Bronchitol for 6 months.

Exacerbations in CF patients are a distinct worsening of symptoms and the most common reason for hospitalisation. The exacerbations recorded in the Bronchitol studies were serious events that all necessitated the use of IV antibiotics.

Dr Moira Aitken, Division of Pulmonary and Critical Care Medicine, University of Washington Medical Centre, commented, "There remains a significant need for new treatments in cystic fibrosis and the results from the Bronchitol Phase 3 studies suggest this is a very useful drug. These studies contained a heavily treated patient group, very representative of the CF patients we see in our clinics, with more than 60% positive for *Pseudomonas aeruginosa*. Fifty nine percent of the adults in the trials were receiving chronic rhDNase treatment and 56% were taking chronic inhaled antibiotics. Thus these trials clearly demonstrate that Bronchitol's action in increasing mucociliary clearance augments other chronic therapies, improves lung function and reduces acute pulmonary exacerbations".

The 35th European Cystic Fibrosis Conference is being attended by CF clinicians, healthcare professionals and patient organisations from all over the world. Bronchitol features in 4 posters, oral presentations and a dedicated symposium.

Dr Alan Robertson, Pharmaxis CEO, said "We are now engaged with CF centres across Europe and the clinical responses possible with Bronchitol have been well received by both patients and clinicians. In the 6 month Phase 3 studies, 45% of patients had an improvement in FEV1 relative percent predicted

of 5% or more above baseline and 29% of participants improved by 10% or more. These results suggest Bronchitol is a significant drug for the CF community. At the same time, other clinical benefits with Bronchitol are being explored and, in an early research investigation presented for the first time at the European meeting, Bronchitol has been shown to increase the potency of tobramycin to clear pseudomonas infections. While still at the investigational stage, these results hold out exciting possibilities for the future”.

Bronchitol is approved throughout the European Union for people with cystic fibrosis aged 18 and over.

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SOURCE: Pharmaxis Ltd, Sydney, Australia

CONTACT: Alan Robertson – Chief Executive Officer

Ph: +61 2 9454 7200 or email alan.robertson@pharmaxis.com.au

RELEASED THROUGH:

Australia: Felicity Moffatt, phone +61 418 677 701 or email felicity.moffatt@pharmaxis.com.au

USA: Seth Lewis- Vice President, The Trout Group, LLC

PH: +1 (646) 378 2952 or email slewis@troutgroup.com

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 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.
