
CYSTIC FIBROSIS TRIAL IN CHILDREN RETURNS POSITIVE DATA

Pharmaxis Ltd (ASX:PXS; NASDAQ: PXSL) announced today that a Phase II clinical trial in children with cystic fibrosis demonstrated excellent lung function improvement following three months treatment with Bronchitol that matched that achieved by the current marketed product rhDNase¹. The improvement in lung function after three months on Bronchitol reflects that seen in a previous study following two weeks of treatment.

The study was an independent investigator initiated study conducted in the United Kingdom in 20 children with a mean age of 13 years. Those children enrolled in the trial completed three months treatment with each of three different therapies – Bronchitol alone, both Bronchitol and rhDNase together and rhDNase alone. The trial measured changes in lung function, airway inflammation, infections, and quality of life.

At the end of the treatment period, lung function as determined by measuring FEV1 (the amount of air that can be forcibly exhaled in 1 second) improved by:

- 7% while the subjects were on Bronchitol
- 7% while subjects were on rhDNase and
- 2% while subjects were on both agents together.

The study had insufficient numbers to reach a definitive statistical conclusion.

People affected by cystic fibrosis typically experience a decline in lung function of 1-2% every year of their life, as measured by FEV1.

Pharmaxis Chief Executive Officer Alan Robertson said: 'While not on the regulatory approval path, this is the first time we have had an opportunity to measure the performance of Bronchitol following 3 months continuous treatment and it bodes well for the pivotal 6 month Phase 3 trial that is currently in progress. Although the two agents worked less well when taken together, the patient numbers are low and a previous study has shown a benefit to using both therapies together.'

Bronchitol is designed to hydrate the airway surface, improve lung hygiene and promote normal lung clearance. rhDNase is designed to improve mucus viscosity. Additional data from this trial will be presented by the independent investigator at a forthcoming scientific congress. A European, Pharmaxis sponsored, regulatory Phase III clinical trial, designed to lead to a marketing application for Bronchitol in adults and children with cystic fibrosis, is currently enrolling subjects.

Approximately 75,000 people in the major pharmaceutical markets are affected with cystic fibrosis and no products have been approved to improve lung hydration. To find out more about Pharmaxis, go to <http://www.pharmaxis.com.au>.

1: *rhDNase is marketed as Pulmozyme, which is a trade mark of Genentech Inc.*

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About the Trial

The following information is provided in accord with the ASX and AusBiotech Code of Best Practice for Reporting by Biotechnology, Medical Device and other Life Sciences Companies.

Name of Trial	DPM - CF-203 (A phase II study with Bronchitol)
Blinding Status	Open label
Placebo Controlled	No
Treatment Method	
Route	Inhalation
Frequency	Twice per day
Dose levels	400 mg
Number of Subjects	20 evaluable
Subject Selection Criteria	Subjects with a known diagnosis of cystic fibrosis, FEV1 < 70% of predicted, of either gender, aged between 8 and 19 years of age and currently receiving rhDNase or eligible to receive rhDNase.
Primary End Points	To compare and contrast the effect on FEV1 of: 1: Bronchitol to rhDNase 2: Bronchitol + rhDNase to rhDNase
Secondary End Points	To assess whether: 1: the effects of Bronchitol are additive to rhDNase 2: Bronchitol reduces the bacterial load in the lung 3: the effects of Bronchitol are beneficial to quality of life
Trial Location	United Kingdom
Commercial partners	Pharmaxis Ltd
Sponsor	Investigator initiated, Pharmaxis supported

About Bronchitol

Pharmaxis Ltd is developing Bronchitol for the management of chronic obstructive lung diseases including bronchiectasis, cystic fibrosis and chronic bronchitis. Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. It is designed to hydrate the lungs, restore normal lung clearance mechanisms, and help patients clear mucus more effectively. Clinical studies have shown Bronchitol to be well tolerated, to improve quality of life, and to stimulate mucus hydration and clearance in people with bronchiectasis and cystic fibrosis.

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 and autoimmune diseases. Its development pipeline of products include Aridol for the management of asthma, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD) and PXS64 for the treatment of multiple sclerosis. Founded in 1998, Pharmaxis is listed on the Australian Stock Exchange (symbol PXS), and on NASDAQ Global Market (symbol PXSL). 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 +61 2 9454 7200.

Forward-Looking Statements

The statements contained in this media release that are not purely historical are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. 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 can not guarantee that any product candidate will receive FDA or other regulatory approval or that we will seek any such approval. Factors that could cause or contribute to such differences include, but are not limited to, factors discussed in the "Risk Factors and Other Uncertainties" section of our Form 20-F lodged with the U.S. Securities and Exchange Commission.