
BRONCHITOL CYSTIC FIBROSIS DOSE TRIAL RESULTS POSITIVE

Bronchitol demonstrates dose-related improvements in lung function of cystic fibrosis patients.

Speciality pharmaceutical company Pharmaxis (ASX:PXS, NASDAQ:PXSL) today announced results from its Phase II trial, DPM-CF-202, in subjects with cystic fibrosis.

The trial achieved its primary end point of demonstrating a dose dependent improvement in lung function as measured by FVC (forced vital capacity) and FEV1 (the amount of air that can be forcibly exhaled in 1 second). At the end of the two-week Bronchitol treatment periods, changes in lung function were as follows:

- 400 mg treatment group: FEV1 increased by 8.6% (139 mls, $p=0.0006$ vs 40 mg)
- 240 mg treatment group: FEV1 increased by 4.6% (87 mls)
- 120 mg treatment group: FEV1 increased by 3.7% (42 mls)
- 40 mg treatment group: FEV1 decreased by -1.6% (-33 mls)

FVC changed by +7.9% on 400 mg ($p=0.0004$ vs 40 mg), +3.9% on 240 mg, +1.5% on 120 mg and -0.6% on 40 mg.

Pharmaxis Chief Executive Officer Alan Robertson said "The excellent result from this trial reaffirms that the 400 mg Bronchitol dose being used in the Phase 3 trials is optimal for its clinical effectiveness. We look forward to the results from the ongoing Phase 3 studies and to bringing Bronchitol to the market as rapidly as possible."

The study was an open, randomised comparison of 400mg, 240 mg, 120 mg and 40 mg of Bronchitol in 48 patients with cystic fibrosis at 12 centres across Canada and Argentina. Bronchitol was administered twice a day for 14 days in a crossover design.

Secondary endpoints of the study included other spirometry and quality of life measures. These measures also showed a positive effect for 400 mg Bronchitol on MMEF (maximum mid expiratory flow) and the respiratory domain of the cystic fibrosis quality of life questionnaire (CFQR).

Additionally, no serious adverse events emerged during the 400 mg treatment period and the adverse event profile was similar across all doses.

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

Pharmaxis has received Orphan Drug Designation and fast track status from the Food and Drug Administration (FDA) for Bronchitol in cystic fibrosis.

Bronchitol is designed to hydrate the airway surface, improve lung hygiene and promote normal lung clearance. Additional data from this trial will be presented 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 due to report preliminary data early in 2009.

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>.

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:

Virginia Nicholls, phone +61 417 610 824 or email virginia.nicholls@pharmaxis.com.au

United States:

Brandon Lewis, Trout Group, phone +1 646 378 2915 or email blewis@troutgroup.com

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-202 (a Phase II study with Bronchitol)
Blinding Status	Open
Design	Crossover, Dose response
Treatment Route	Inhalation
Frequency	Twice daily
Dose levels	400mg, 240 mg, 120 mg, 40 mg for 2 weeks, 1-2 weeks washout between doses
No of subjects	PP population 38
Subject Selection Criteria	diagnosis of cystic fibrosis (sweat test or genotype), of either gender, aged ≥ 7 years, baseline FEV ₁ of between 40% and 80% of the predicted normal value or a decline in FEV ₁ of $\geq 20\%$ in the last 12 months for those $>80\%$ predicted
Study population	Median age: 16 yrs, mean FEV1: 63% predicted
Trial Location	Canada and Argentina
Commercial partners	None

Primary end points:

Change in FEV1	8.6% increase (139 mls) on 400 mg Bronchitol. -1.6% on 40 mg (p=0.0006). 4.6% on 240 mg, 3.7% on 120 mg
Change in FVC	7.9% increase in FVC on 400 mg vs -0.6% on 40 mg (p=0.0004). 3.9% on 240 mg, 1.5% on 120 mg

Secondary end points:

Other lung function measures;	11.9% increase in MMEF on 400 mg (vs -0.3% on 40 mg, change did not reach significance)
CF Questionnaire	Improved 6.3 points on 400 mg vs -0.2 on 40 mg
Safety/adverse events	No serious adverse events on 400 mg Bronchitol

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 and acute respiratory diseases. Our pipeline of products include Aridol for the management of asthma, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD), PXS25 for the treatment of interstitial lung disease and PXS4159 for asthma.

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.