
PHARMAXIS COMPLETES TREATMENT PHASE IN PIVOTOL BRONCHITOL CYSTIC FIBROSIS CLINICAL TRIAL FOR US MARKET

Pharmaceutical research company Pharmaxis (ASX: PXS) today announced that the last of 423 patients has concluded treatment in its international clinical trial evaluating Bronchitol® (mannitol) for cystic fibrosis (CF). The topline results of the trial are expected to be reported in the second quarter of this year.

The Phase 3 trial known as DPM-CF-303 has been conducted in accordance with the requirements of the US Food and Drug Administration (FDA) to gain marketing approval for Bronchitol to treat adult CF patients in the United States. Subject to a positive trial outcome, a response will be submitted to the FDA and a decision on approval can be expected in the second half of 2018.

The trial is a 26 week randomised, double-blind parallel group investigation of Bronchitol administered twice daily in cystic fibrosis patients aged 18 and over to assess improvements in lung function, pulmonary exacerbations and safety. The trial recruited a total of 423 patients across 126 sites in 21 countries in North and South America, Western and Eastern Europe.

Pharmaxis has partnered its work on Bronchitol for the United States with global pharmaceutical company Chiesi Farmaceutici SpA (Chiesi). Chiesi has funded US\$22 million of the expected total US\$26 million cost of the trial. Chiesi is also responsible for completing the Bronchitol New Drug Application with the FDA. Subject to approval in the United States, Bronchitol will be sold as part of Chiesi's cystic fibrosis portfolio. Milestones totaling up to US\$25 million are payable including US\$10 million on the launch of Bronchitol.

Pharmaxis will manufacture Bronchitol in Australia on commercial terms for Chiesi with Pharmaxis retaining a high teens percent share of sales revenue as its margin.

Pharmaxis Chief Executive Officer Mr. Gary Phillips said "Having the last of more than 400 participants at 126 sites in 21 countries complete their last clinic visit is a very significant milestone for the Bronchitol business unit. The US is the largest CF market and we are looking forward to the trial results and working to make Bronchitol available in clinics across the USA. This trial has been made possible by the clinicians, patients and CF community who have participated and we again thank them sincerely for their support."

The trial design was guided by the FDA and follows two large scale clinical trials already undertaken by Pharmaxis (CF 301 and CF 302) in which a post hoc analysis of the subgroups of adult patients (307 in total) showed a statistically significant improvement in FEV₁. The CF303 trial is being managed by INC, a global contract research organisation with significant experience running international trials in the cystic fibrosis community.

Bronchitol is a precision spray-dried form of mannitol, delivered to the lungs by a specially designed, portable inhaler. The product is approved for marketing for the treatment of cystic fibrosis patients aged over six years in Australia and Russia and for patients aged 18 years and over throughout the European Union and in Israel.

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SOURCE: Pharmaxis Ltd, Sydney, Australia

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

About Pharmaxis

Pharmaxis (ACN 082 811 630) is an Australian research pharmaceutical company with a portfolio of products at various stages of development and approval. Its product Bronchitol® for cystic fibrosis is marketed in Europe and Australia and a phase 3 trial to enable completion of an NDA for the US market is underway. Its product Aridol® for the assessment of asthma is sold in Europe, Australia and Asia. The company's development pipeline is centred on its expertise in amine oxidase chemistry and includes Semicarbazide-Sensitive Amine Oxidase Inhibitors (SSAO) for Non-alcoholic Steatohepatitis (NASH) and inflammatory diseases including Chronic Obstructive Pulmonary Disease (COPD), and Lysyl Oxidase Inhibitors (LOX) targeting fibrotic diseases including pulmonary fibrosis and some cancers. In May 2015, Boehringer Ingelheim acquired the Pharmaxis investigational drug PXS4728A, to develop it for the treatment of the liver-related condition NASH. Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company's head office, manufacturing and research facilities are located in Sydney, Australia. For more information about Pharmaxis, please see www.pharmaxis.com.au.

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 of products and drug candidates. All forward-looking statements included in this media release are based upon information available to us as of the date hereof. Actual results, performance or achievements could be significantly different from those expressed in, or implied by, these forward-looking statements. These forward-looking statements are not guarantees or predictions of future results, levels of performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this document. Except as required by law we undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise.