

Pharmaxis to launch cystic fibrosis drug in Europe

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Singapore: Australian pharmaceutical company Pharmaxis is all set to launch Bronchitol for cystic fibrosis (CF) patients in the UK and Germany, following the approval by the European Medicines Agency. Pharmaxis has achieved positive result in reducing exacerbations in all age sub groups of cystic fibrosis patients in its two phase III clinical studies of Bronchitol.

The two phase III 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.

Dr Moira Aitken, division of pulmonary and critical care medicine, University of Washington Medical Centre, said, "There remains a significant need for new treatments in cystic fibrosis and the results from the Bronchitol phase III 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 percent positive for *Pseudomonas aeruginosa*. These trials clearly demonstrate that Bronchitol's action in increasing mucociliary clearance augments other chronic therapies, improves lung function and reduces acute pulmonary exacerbations".

Dr Alan Robertson, Pharmaxis CEO, said, "We are now engaged with CF centers across Europe and the clinical responses possible with Bronchitol have been well received by both patients and clinicians. In the six-month phase III studies, 45 percent of patients had an improvement in FEV1 relative percent predicted of 5 percent or more above baseline and 29 percent of participants improved by 10 percent 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".