Pharmaxis Announces Positive Combined Phase 3 Cystic Fibrosis Trial Results

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BALTIMORE, Oct. 22 /PRNewswire/ -- Pharmaceutical company Pharmaxis (ASX: PXS) today announced significant results of pooled data from its two large scale six month Phase III trials of Bronchitol (inhaled mannitol) in people with cystic fibrosis.

The combined results have been presented for the first time at the North American Cystic Fibrosis Conference (NACFC) currently underway in Baltimore. In addition, more results from the second trial (CF302) have been released to supplement the top line results reported on 22nd June 2010.

The two studies were of similar design and encompass 643 patients from 11 countries. Over the 26 weeks of the two studies, patients treated with Bronchitol had an average 7.3% improvement in lung function (FEV1) compared to baseline ($p<0.001$) and a highly significant improvement compared to patients in the control group ($p<0.001$). In the sub group of patients who were also on rhDNase, patients taking Bronchitol showed a 5.3% improvement from baseline ($p<0.001$), that was again superior to the control group ($p=0.020$). In the sub group of patients who were not on rhDNase, patients taking Bronchitol showed a 9.44% improvement from baseline ($p<0.001$), that was also superior to the control group ($p=0.009$). The overall rate per annum reduction in exacerbations for patients on Bronchitol versus those on control was 25% (NS) and the number of patients experiencing an exacerbation was 29% lower for those taking Bronchitol (NS). This result was achieved in a well treated patient population who overall had a very low rate of exacerbations in the study.

"This comprehensive analysis of the pooled results provides an important insight into the overall benefits Bronchitol can provide to patients who are receiving current best standard of care," said Pharmaxis Chief Executive Officer Dr. Alan Robertson. "The number of exacerbations in the two studies was fairly low, reflecting the aggres
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