



## **Independent Report Received on PBT2 Phase I Clinical Trial**

**Melbourne, Australia – 5 May 2006: Prana Biotechnology Limited (NASDAQ: PRAN, ASX: PBT)**, has received an independent report in respect of the Phase I trials with its lead proprietary compound, PBT2, under development as a therapy for Alzheimer's disease.

The Phase I clinical trial program for PBT2 investigated the safety/tolerability and pharmacokinetics of single and multiple oral doses of PBT2, in 55 young male volunteers (18-45 years) and 32 older male and female volunteers (45 to 75 years). Full data analysis for both clinical studies is complete and the data is being prepared for publication. Plans are underway for a Phase II clinical trial.

“Having reviewed the safety and pharmacokinetic profile for PBT2 from the two Phase I studies, it certainly appears that the drug is generally well tolerated at doses to 800mg. In both studies, there were no significant differences in overall rates of adverse effects between PBT2 and the placebo groups and there appears to be no relationship between dose and rate of adverse effects. Of the adverse effects that were seen, the vast majority of these were thought to be unrelated to PBT2 treatment. Of the few that were possibly related, they appeared mild and self limiting. The Phase I results provide the confidence needed to move forward to formal Phase II testing in people with Alzheimer's disease” said Dr. Craig Ritchie, psychiatrist and Director of Mental Health Clinical Trials at University College London and Prana clinical advisor.

The data from the two studies indicate that after oral administration, in healthy human volunteers, PBT2 is rapidly absorbed ( $T_{max} \leq 3$ hrs), achieves good blood levels (in the micromolar range), is primarily metabolised to PBT2-glucuronide and is renally cleared. PBT2 exposure was seen to increase in a linear fashion with increasing single doses, with relatively little accumulation on repeat dosing. Dosing in the clinical trials did not exceed 800mg once daily for 7 days. The terminal elimination rate (Apparent clearance) appeared relatively consistent across all doses tested. There appears little, if any, gender or age difference in the tolerability or pharmacokinetics. The most common adverse effects noted were headache, gastrointestinal disturbance and somnolence. Dosing did not appear to reach the maximum tolerated dose for healthy volunteers.

Geoffrey Kempler, Executive Chairman and CEO, added, “PBT2 is performing well, and its overall profile supports once-a-day dosing. The Phase I safety/tolerability and pharmacokinetic profiles provide us with the confidence to initiate the Phase II clinical trial program for PBT2 and reinforce our belief that PBT2 possesses the attributes to allow it to be the first drug on the market that targets the a-beta pathway to treat Alzheimer's disease”.

### **About Prana Biotechnology Limited**

Prana Biotechnology was established to commercialise research into Alzheimer's disease and other major age-related degenerative disorders. The company was incorporated in 1997 and listed on the Australian Stock Exchange in March 2000 and listed on NASDAQ in September 2002. Researchers at prominent international institutions including the University of Melbourne

and Massachusetts General Hospital, a teaching hospital of Harvard Medical School, discovered Prana's technology.

For further information, please visit our web site at [www.pranabio.com](http://www.pranabio.com).

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