



## **D-Pharm completes enrollment for the Phase IIb trial of DP-b99 in acute stroke patients**

***(Rehovot, Israel) August 1st 2006 -***

D-Pharm announced today completion of enrollment in its Phase IIb clinical trial of DP-b99. DP-b99 is a unique neuroprotective drug that addresses the array of damaging processes occurring in the brains of stroke patients. The Phase IIb trial results are expected to be available towards the end of 2006 following completion of the 3 month follow-up period.

"Patient enrollment into stroke trials is notoriously difficult to plan, therefore, I'm very satisfied that we've managed to complete enrollment without major delays. D-Pharm is indebted to all the investigators and other team members in the study sites in Germany, Israel and South Africa, whose dedicated efforts and meticulous work enabled the timely completion of this task" said Dr Gilad Rosenberg, D-Pharm's VP, Clinical Development.

The current double blind, placebo controlled, multi-center, international trial is designed to reconfirm the efficacy and beneficial effect of DP-b99 previously observed in stroke patients, as well as to strengthen and extend the safety data obtained from the Phase IIa study. The study enrolled patients with ischemic stroke accompanied by language dysfunction, visual field defect or inattention with a baseline NIHSS score of 7 to 20. Patients were recruited in 25 centers in Germany, Israel and latterly also in South Africa. In this trial DP-b99 was administered intravenously, once daily, over 4 days with the first administration up to 9 hours following stroke onset. The patient group is stratified into those treated within six hours or within six to nine hours following stroke onset. Thus, in addition to confirming safety and efficacy, D-Pharm expects this study to clearly define the optimal patient population and therapeutic window for DP-b99.

Clinical, laboratory and electrocardiographic safety data has been monitored throughout the trial by an independent Drug Safety Monitoring Board. To date, no differences have been found between the placebo and active drug groups with respect to adverse events or other safety measures, and following each of the Board's reviews the recommendation was to continue the study as planned. Cato Research served as the clinical research organization for this study.

Stroke is the leading cause of neurological disability worldwide and reflects a considerable unmet need in effective acute stroke therapy, which DP-b99 aims to address.

### **DP-b99**

DP-b99 is a discovery product, rationally designed using D-Pharm's proprietary technology, Membrane Active Chelators (MAC). Considerable evidence suggests that redistribution of metal ions and disturbances in metal ion homeostasis are key components in the cascade of events underlying cell damage in stroke. In the first hours

post-stroke, ion disturbances cause excitatory cell damage and in the days and weeks following they contribute to edema, inflammation and cell death. D-Pharm is developing a novel approach to neuroprotection based on selective modulation of calcium, zinc, copper and iron homeostasis in the vicinity of cell membranes.

In earlier Phase I and II clinical trials DP-b99 was proven to be safe both in healthy young and elderly volunteers and in stroke patients. Efficacy evaluation in Phase IIa demonstrated noteworthy improvements in clinical stroke outcome assessed with the NIH Stroke Scale (NIHSS) 2, 7 and 30 days after stroke in patients treated with DP-b99 within 12 hours of the onset of stroke symptoms.

#### **About D-Pharm Ltd.**

D-Pharm ([www.dpharm.com](http://www.dpharm.com)) is a biopharmaceutical company pioneering the development of lipid-like therapeutics and has generated a rich product pipeline from its drug targeting and discovery technologies, Regulated Activation of Prodrugs (D-RAP™) and Membrane Active Chelators (MAC). These technologies control drug activity via built-in 'switch-on/switch-off' mechanisms. The company's business strategy is to seek a partner for continued global development of DP-b99 early in 2007. In addition, D-Pharm's pipeline includes DP-VPA, a new chemical entity that is a modified and targeted version of valproic acid for epilepsy, bipolar disorder treatment and migraine prophylaxis. DP-VPA is currently in an advanced stage of a clinical Phase II program. In preclinical development is DP-109, an oral, disease-modifying therapy for Alzheimer's disease. DP-109 has demonstrated impressive efficacy in a transgenic mice model of Alzheimer's disease. For further information visit our web site: [www.dpharm.com](http://www.dpharm.com).