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NeuroDerm Announces Positive Results of a Phase I Study of ND0612 for the Treatment of Parkinson's Disease

Ness Ziona, March 4th, 2013 / -- <u>NeuroDerm</u>, Ltd. announced today the results of a Phase I safety and pharmacokinetic trial of ND0612, a novel drug formulation for the treatment of Parkinson's disease. ND0612 is a proprietary levodopa/carbidopa liquid formula administered continuously sub-cutaneously through a patch pump. It is designed to provide steady levodopa blood levels for the reduction of motor complications in Parkinson's disease. Results of this study support the continued development of ND0612 for the treatment of Parkinson's disease.

In this double-blind, placebo controlled, dose-escalation trial in young, healthy volunteers, ND0612 was shown to be safe and tolerable in all of the tested doses. Furthermore, clinically meaningful levodopa concentrations were reached and, for the first time in man, steady state levodopa concentrations were maintained in a practical manner both day and night. The full results of this study will be presented at a future scientific meeting.

"ND0612's success in its first phase I trial means that clinically significant steady state levodopa concentrations can, for the first time, be maintained, both day and night, through a conveniently administered drug. With ND0612, steady state levodopa levels, the elusive holy grail of Parkinson's levodopa therapy, should be available to all PD patients. Moreover, as ND0612 bypasses the gastrointestinal tract, steady state levodopa levels should be little influenced by intestinal absorption or oral ingestion of food or drugs. We believe that ND0612 could become a breakthrough treatment option that may establish a new, significantly higher standard of care for Parkinson's patients".

About Parkinson's Disease

Parkinson's disease affects approximately 6 million patients in the world. It is caused by decreasing dopamine signaling in the brain as dopaminergic brain cells die off. Levodopa is the "Gold Standard" therapy for Parkinson's disease and virtually all patients receive it together with a levodopa degradation inhibitor (usually, carbidopa). When administered through the oral route, however, levodopa plasma concentrations undergo sharp fluctuations reaching high peaks and low troughs that contribute to the clinical and motor complications in Parkinson's patients.

About ND0612

ND0612 is a proprietary formulation of levodopa and carbidopa administered through a pump patch that enables, for the first time, to conveniently achieve steady state levodopa plasma levels. Levodopa and carbidopa (traditionally co-administered with levodopa to prevent its breakdown) are nearly always administered orally and suffer from an unfavorable pharmacokinetic profile due to short half life and low bioavailability. Continuous subcutaneous delivery of levodopa and carbidopa is a novel approach designed to improve their pharmacokinetic profile and maintain stable, therapeutic levodopa plasma concentrations, thereby significantly ameliorating motor fluctuations and non-motor complications in Parkinson's disease.

About NeuroDerm

NeuroDerm is an emerging pharmaceutical company that develops therapies for the treatment of CNS diseases. NeuroDerm's technology is based on proprietary reformulations of well established oral drugs whose low bio-availability is the major impediment to better efficacy. The company's lead products are ND0612 and ND0611, revolutionary SC drugs for the treatment of Parkinson's disease and ND0801, a combination patch for the treatment of ADD/ADHD. Other programs focused at other diseases, including schizophrenia and Alzheimer's disease, are in different stages of development. NeuroDerm is headquartered in the Weizmann Science Park, Ness Ziona, Israel.

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