NeuroDerm Initiates Phase 2 Study of ND0611 Dermal Patch in Patients with Parkinson’s Disease

Ness Ziona, March 9, 2011 / -- NeuroDerm, Ltd. announced today the enrollment of the first group of patients in its Phase I/II clinical trial of ND0611, a new patch for the treatment of Parkinson’s disease. ND0611, a proprietary carbidopa liquid formula administered via a dermal patch, is designed to increase the bioavailability and efficacy of orally- administered levodopa and thus improve treatment of Parkinson’s disease.

In pre-clinical studies, plasma concentrations of orally-administered levodopa showed markedly less fluctuation, higher area-under-the-curve values, and higher trough concentrations after continuous administration of ND0611 together with standard levodopa products (Sinemet®, Stalevo® and Sinemet® CR). A phase I trial in young, healthy volunteers demonstrated that ND0611, co-administered with Sinemet®, was safe and tolerable. It also showed that ND0611 increased levodopa clearance half-life, the duration of levodopa concentration in excess of a typical threshold for anti-Parkinsonian effect (1000ng/ml in plasma), and the area-under-the-concentration-time-curve of levodopa.

This double-blind, randomized, six-way crossover Phase I/II trial is designed to evaluate ND0611’s safety, tolerability, levodopa bioavailability, and preliminary clinical efficacy when administered with the three most commonly-used levodopa therapies (immediate-release Sinemet®, Sinemet®-CR, and Stalevo®) in 24 advanced Parkinson’s disease patients. The company expects to complete this study by the end of 2011. This trial is supported by a grant of $1M by The Michael J. Fox Foundation for Parkinson's Research as part of the Foundation’s prestigious Clinical Intervention Awards 2010 program.

"ND0611 is a simple yet original approach for improving levodopa drug therapy in Parkinson's patients,” said Todd Sherer, PhD, Chief Program Officer, The Michael J. Fox Foundation. “Since levodopa is the best currently available drug therapy for Parkinson's disease, increasing its efficacy would be significant for many Parkinson's disease patients.

“This first trial in patients is an important step forward in the development of ND0611 as a new treatment alternative for Parkinson’s disease” said Oded S. Lieberman, PhD, NeuroDerm’s Chairman and CEO. “While levodopa has for many years been the leading Parkinson’s disease drug therapy, low oral levodopa bioavailability means that, even under the best current standard of care, advanced Parkinson’s patients suffer from debilitating motor complications. If ND0611 is shown to improve oral levodopa’s bioavailability in patients - it should improve the efficacy of oral levodopa treatment and should reduce these motor complications”.

About Parkinson’s Disease

Parkinson’s disease affects approximately 6M 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. Levodopa is always co-administered with a degradation inhibitor (usually, carbidopa). When administered through the oral route, however, levodopa suffers from a short clearance half-life and low bioavailability that contributes to motor complications in Parkinson’s patients.

About ND0611

ND0611 is based on a proprietary formulation that enables, for the first time, the continuous administration of carbidopa in a practical manner via a subcutaneous dermal patch. Carbidopa, conventionally co-administered with levodopa orally to prevent its breakdown, suffers from low bioavailability in itself. Continuous subcutaneous delivery of carbidopa should thus improve the bioavailability of oral levodopa, permit more continuous levels of levodopa to be maintained in the brain, improve the management of motor fluctuations in Parkinson’s disease patients and result in a higher levodopa usage efficacy in Parkinson’s disease therapy.

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 ND0611, a revolutionary skin patch 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 obesity, 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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