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NeuroDerm Presents ND0612H Phase II Trial Results in Late-Breaking Poster Session at the 21st International Congress of Parkinson's Disease and Movement Disorders

-ND0612H achieved a complete reduction of OFF-time to zero in 42% of patients treated for 24 hours -

- Statistically significant and clinically meaningful reduction in OFF-time and increase in the portion of patients "ON" by 8:00am-

REHOVOT, Israel, June 05, 2017 (GLOBE NEWSWIRE) -- NeuroDerm Ltd. (Nasdaq:NDRM), a clinical stage pharmaceutical company developing drug-device combinations for central nervous system (CNS) disorders, today announced final data from trial 006. Sheila Oren, MD, MBA, Chief Medical Officer at NeuroDerm will present the final results from this trial in a poster titled, "Safety, efficacy and tolerability of continuous SC LD/CD (ND0612) infusion in PD patients with motor fluctuations," (Abstract LBA41) in a late-breaking poster session on Wednesday, June 7, from 1:15 p.m. to 2:45 p.m. (P.T.) at the 21st International Congress of Parkinson's Disease and Movement Disorders. The Congress is taking place June 4-8, 2017 in Vancouver, B.C.

Trial 006 was an international open label, blinded rater, phase II study of ND0612H, NeuroDerm's high dose continuous, subcutaneously delivered levodopa/carbidopa (LD/CD) liquid formulation, in patients with advanced Parkinson's disease. In March 2017, NeuroDerm announced that a preliminary analysis of trial 006 demonstrated that the trial successfully met its primary, key secondary and additional secondary endpoints, with many patients experiencing a complete reduction of OFF-time to zero.

"The significant increase in Good ON time coupled with a significant reduction in OFF time, including a complete resolution of OFF time to zero in 42% of patients in the first of our two regimens, demonstrates the substantial potential of 24-hour administration of ND0612H," said Oded S. Lieberman, PhD, CEO of NeuroDerm. "The results of this study offer additional evidence that this innovative therapy can transform the care and outcome for patients with advanced Parkinson's disease, and suggest that ND0612 can provide significant patient benefit without the surgical risks associated with deep brain stimulation and LD/CD intestinal gel."

Trial 006 Design

Trial 006 was a 28-day multicenter, international (U.S., EU and Israel), parallel-group, blinded rater, randomized phase II study that investigated the efficacy, safety, tolerability and pharmacokinetics of two dosing regimens (R1 and R2) of ND0612H and compared them to the baseline of standard optimized oral therapy:

- R1: 24-hour administration of ND0612H (720/90mg LD/CD) at a high day rate for 18 hours and a low night rate for 6 hours.
- R2: 14-hour administration of ND0612H during the waking hours (538/68mg LD/CD) complemented by a morning dose of 150/15mg oral LD/CD.

All patients could add oral LD/CD therapy at any time as needed. The trial enrolled 38 patients with advanced Parkinson's disease.

Tamar Rachmilewitz MD, Medical Director at NeuroDerm will present additional baseline patient characteristic data from trial 006 in an abstract titled, "Baseline characteristics of the population enrolled to a randomized clinical study of subcutaneous levodopa/carbidopa (ND0612) infusion in patients with advanced PD," (Abstract 1377) in a poster session on Thursday, June 8, from 1:15 p.m. to 2:45 p.m. PT.

Trial 006 Endpoints

The primary endpoint of this study was to assess the change from baseline to day 28 in daily OFF-time (normalized to 16 waking hours) as assessed by a blinded rater. A key secondary endpoint was to assess the

percentage of subjects who were "ON" by 8:00am and 9:00am. Additional secondary endpoints were also evaluated as well as safety and tolerability.

Trial 006 Study Efficacy and Safety Results

Five subjects did not complete the study. Reasons for discontinuation were: adverse events (n = 2), lack of efficacy (n = 2), and withdrawal of consent (n = 1).

Primary endpoint (OFF-time) and key secondary endpoint ("ON" by 8:00am and 9:00am) achieved in R1:

The primary endpoint was met in R1. The OFF-time was reduced by 2.8 hours (p = 0.004), from 5.6 hours at baseline. There was a smaller, non-statistically significant reduction of 1.3 hours in OFF-time in R2.

In R1, the proportion of patients who achieved the first "ON" by 8:00am (as reported by the patient) increased from 11% at baseline to 50% by day 28 (p = 0.02), and, by 9:00am, from 32% at baseline to 75% (p = 0.007).

Good ON (secondary endpoint):

Good ON (defined as no or mild dyskinesia, as assessed by the blinded rater) increased in R1 by 3.7 hours (p < 0.001), from 9.2 hours. Although the R2 regimen was not designed to provide optimal ND0612H dosing, significant improvements in Good ON were also observed in this cohort, increasing by 2.8 hours (p = 0.003), from 8.5 hours.

Complete reduction of OFF-time (post-hoc analysis):

In R1, 42% of patients had a complete reduction in OFF-time to zero hours (11% in R2).

Troublesome Dyskinesia (post hoc analysis):

Troublesome dyskinesia (defined as "ON" with moderate or severe dyskinesia as assessed by the blinded rater) decreased by 3.5 hours (p = 0.011), from 5.1 hours at baseline, in the subgroup of all patients who had at least 1 hour of troublesome dyskinesia at baseline (n = 14, R1 and R2 combined).

Reduction in Unified Parkinson's Disease Rating Scale (UPDRS) III (post-hoc analysis):

UPDRS III score at 8:00am decreased in R1 by 17.1 points, from 37.4 at baseline to 20.3. Reductions in UPDRS scores in R1 were maintained throughout the day and also observed at 12:00pm (6.9 points) and 4:00pm (6.5 points)

Safety and Tolerability:

Both regimens were well tolerated. Of the 38 subjects, four reported six serious adverse events, including one subject with subcutaneous abscess and orthostatic hypotension, and another with worsening PD symptoms. These two patients did not complete the study. Additionally, one subject fell and fractured his nose, and there was one case of suspected panniculitis that was eventually ruled out. Infusion site reactions (nodules, bruising, erythema and hemorrhage) were common, yet generally well tolerated. These results corroborate the safety and tolerability data obtained in previous studies and did not raise new safety or tolerability concerns.

Additionally, the ND0612H infusion pump systems were reliable with only few minor, correctable malfunctions reported. No major inconvenience related to the wearing of the device was reported for either day or night administration.

The following abstracts featuring NeuroDerm clinical data will also be presented during the poster session on Thursday, June 8 from 1:15 p.m. to 2:45 p.m.:

- "Pharmacokinetic profile of continuous levodopa/carbidopa delivery when administered subcutaneously (ND0612) versus duodenal infusion" (Abstract 1337)
- "Patient perspectives using the ND0612 mini-pump" (Abstract 1384)
- "ND0612 (levodopa/carbidopa for subcutaneous infusion) achieves stable levodopa plasma levels when administered in low and high doses in patients with PD" (Abstract 1386)
- "ND0701: A new concentrated formulation of Apomorphine for continuous subcutaneous administration – human PK data" (Abstract 1391)
- "Identification of the optimal carbidopa concentration in subcutaneously administered ND0612" (Abstract 1393)

About NeuroDerm

NeuroDerm is a clinical-stage pharmaceutical company developing central nervous system (CNS) product candidates that are designed to overcome major deficiencies of current treatments and achieve enhanced clinical efficacy through continuous, controlled administration. NeuroDerm's main focus is in Parkinson's disease, where it has three clinical stage product candidates in development which offer a solution for almost every Parkinson's disease patient, from moderate to the very severe stage of the disease. The primary product candidates are a line of levodopa and carbidopa (LD/CD) products administered through small belt pumps that deliver a continuous, controlled dose of LD/CD. The LD/CD product candidates, ND0612L and ND0612H, are aimed at the treatment of moderate and advanced Parkinson's disease patients, respectively, and are delivered

subcutaneously. NeuroDerm is also designing a patch pump for future use. In addition, NeuroDerm is developing ND0701, a novel subcutaneously delivered apomorphine formulation for patients who suffer from moderate to severe Parkinson's disease and who do not respond well to LD/CD. NeuroDerm is headquartered in the Weizmann Science Park in Rehovot, Israel.

Forward-Looking Statements

This press release contains forward-looking statements, within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended that involve risks and uncertainties. Such forward-looking statements may include projections regarding our future performance and may be identified by words like "anticipate," "assume," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "future," "will," "seek" and similar terms or phrases. The forward-looking statements contained in this press release are based on management's current expectations and projections about future events. There are important factors that could cause our actual results, levels of activity, performance or achievements to differ materially from the results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. In particular, you should consider the risks provided under "Risk Factors" in our annual report on Form 20-F for the year ended December 31, 2016 filed with the Securities and Exchange Commission. Any forward-looking statement made by us in this press release speaks only as of the date hereof. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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