

## **NeuroDerm Presents Six Posters at the 21st International Congress of Parkinson's Disease and Movement Disorders**

- Includes demographic data from the ND0612 trial 006 and complete data from a Phase 1 pharmacokinetic study of ND0701 -

**REHOVOT, Israel – June 8, 2017** – NeuroDerm Ltd. (Nasdaq: NDRM), a clinical stage pharmaceutical company developing drug-device combinations for central nervous system (CNS) disorders, today announced that it will present six posters related to its clinical pipeline in a poster session today from 1:15 p.m. to 2:45 p.m. PT 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.

Tami Rachmilewitz, MD, Medical Director at NeuroDerm will present complete demographic 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).

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. Final safety and efficacy results from this trial were presented Monday in a late-breaking poster session (Abstract LBA41).

Baseline characteristics of the 38 patients enrolled in trial 006 were:

- Mean age of 63.5 years
- 68.4% male
- Majority of patients with a modified Hoehn and Yahr Stage of 2 (bilateral involvement without balance impairment, 63.2%) or 2.5 (mild bilateral disease with recover on pull test, 23.7%)
- Mean of 11.5 years since diagnosis of Parkinson's disease, 5.6 years since onset of motor fluctuations and 3.7 years since the onset of dyskinesia
- Mean daily OFF-time of 5.3 hours and daily time with moderate or severe dyskinesia of 1.9 hours
- Mean Unified Parkinson's Disease Rating Scale (UPDRS) III of 37.3
- Mean LD dose of 1094.9 mg and mean frequency of LD dosing of 6.9 times a day

Baseline characteristics were similar between the R1 (24-hour administration of ND0612, n=19) and R2 (14-hour administration of ND0612, n = 19) dose cohorts.

"Patients participating in trial 006 had baseline characteristics typical of advanced Parkinson's disease that was already negatively impacting their motor function," said Oded S. Lieberman, PhD, CEO of NeuroDerm. "That the trial met its primary, key secondary and additional secondary endpoints even in patients with advanced disease is highly encouraging and supports the growing body of data that suggests ND0612 may have potential as a transformative therapy for Parkinson's disease."

During today's poster session, Cecile Durlach, Medical Director Europe at NeuroDerm will present final results from a Phase 1 pharmacokinetic (PK) study (trial 101) of ND0701 in a poster titled "ND0701: A new concentrated formulation of Apomorphine for continuous

subcutaneous administration – human PK data” (Abstract 1391). NeuroDerm reported top-line results from this trial in December 2016.

### **Trial 101 Design**

Trial 101 was a Phase-1, randomized, open-label, two-sequence, partial cross-over, pilot study comparing the PK of ND0701 with that of commercial apomorphine (APO-go®) in 18 healthy volunteers. The primary objective was to evaluate the PK and relative bioavailability of ND0701 subcutaneous (SC) infusion and commercial apomorphine. The secondary objective was to assess the safety and tolerability of ND0701 and commercial apomorphine administered by SC infusion over 12 hours.

All subjects received an initial 1 mg/h dose of ND0701 on Day 1, followed by 2 mg/h ND0701 and 2 mg/h commercial apomorphine on subsequent dosing days in a randomized, partial cross-over manner, based on the recommendation of titrating commercial apomorphine for better tolerability. Subjects were randomized into 2 sequences to receive 3 consecutive doses.

PK blood samples were collected pre-dose and at predetermined time points up to 24 hours after start of infusion for determination of apomorphine plasma concentrations. Safety and tolerability assessments were done at specified time points until completion of the follow-up visit. Evaluation of safety parameters included analysis of adverse events (AEs), laboratory variables, vital signs, electrocardiograms (ECGs), infusion site reactions, and physical examination findings.

### **Trial 101 Final Results**

All 18 subjects were included in the safety and PK populations. PK analysis datasets were defined for formal statistical analysis and comprised 16 subjects, as two subjects withdrew from the study.

#### PK Results

Following 12 hours of SC infusion with the three regimens, the bioavailability of apomorphine from ND0701 (24.00 mg [2 mg/h]) was comparable to that of commercial apomorphine (24.28 mg [2 mg/h]). Statistical analysis confirmed that peak and total exposures were similar for ND0701 and commercial apomorphine, as were peak and total exposures for dose-corrected parameters of the two dosing regimens of ND0701 ( $C_{max}$ ,  $AUC_{0-last}$  and  $AUC_{0-inf}$ ), indicating close to dose-proportional increase.

#### Safety Results

Both ND0701 and commercial apomorphine appeared to be well tolerated under the conditions of the study and no severe or serious treatment-emergent AEs (TEAEs) were reported for any subject. The lowest incidence was following ND0701 2 mg/h (50%). TEAEs were reported in 64.7% of subjects receiving 2 mg/h of commercial apomorphine. The incidence of TEAEs was highest following the initial 1 mg/h dose of ND0701 (83.3%), which is expected on the first day of titration.

ND0701 TEAEs were most frequently reported in the gastrointestinal and nervous system disorders system organ classes. The most frequently reported events within these categories were nausea, vomiting, dizziness, and somnolence; the lowest incidence was observed following ND0701 2 mg/h. The majority of TEAEs were mild in severity, none were severe. Only one TEAE was reported as local site reaction for a severe nodule (44 mm × 8 mm in size) following 2 mg/h commercial apomorphine ApoGo infusion. All post-dose physical examinations were normal, except for a muscle spasm associated with a pre-dose AE. There were no clinically significant findings in any vital signs, laboratory assessments and ECGs.

Erythema, swelling, and pain were noted at infusion sites for a few subjects across regimens, with no notable difference in incidence or severity between the ND0701 2 mg/h sites and the

commercial apomorphine 2 mg/h sites; all incidents resolved by the 28-day follow-up visit. Infusion site nodules were reported more frequently and their incidence and severity were higher at sites administered commercial apomorphine 2 mg/h (10 small, 1 medium, and 1 severe nodule) compared with sites administered ND0701 2 mg/h (6 small nodules). More nodules were still evident at the 28-day follow-up visit following administration of commercial apomorphine 2 mg/h (n=4) compared with ND0701 2 mg/h (n=1).

“The results of trial 101 align with findings from previous preclinical studies that demonstrated expected good local safety and tolerability of ND0701 with comparable PK to commercial apomorphine,” noted Dr. Lieberman. “These findings support the continued development of ND0701, and we remain on track to meet with EU regulatory authorities to discuss the ND0701 clinical development plan in the first half of 2017 and to initiate a follow-on PK study by the end of the year.”

The following abstracts will also be presented during the poster session today from 1:15 p.m. to 2:45 p.m. by Tami Rachmilewitz, MD and Liat Adar, PhD, Director of Clinical pharmacology:

- “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)
- “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.*

**NeuroDerm Contact:**

Oded S. Lieberman, PhD, CEO  
oded@neuroderm.com  
Tel.: +972-8-946 2729  
Cell: +1-617-517 6077

**U.S. Investor Contact:**

David Carey  
Lazar Partners Ltd.  
dcarey@lazarpartners.com  
+212-867-1768