

NeuroDerm Achieves Primary Endpoint in ND0612H Phase II Trial for Advanced Parkinson's Disease; Seeks Broader EU Label Based on iNDiGO Trial Following EMA Meeting

- Trial 006 demonstrated a statistically significant and clinically meaningful reduction in OFF-time and increase in proportion of patients "ON" by 8:00 am (primary and key secondary endpoints) -
- The trial also showed statistically significant reduction in troublesome dyskinesia and a complete reduction of OFF-time to zero hours in 66% of responders (post hoc sub-groups analyses) -
- Company to host conference call and webcast today at 8:30 a.m. ET-

REHOVOT, Israel, March 1, 2017 – NeuroDerm Ltd. (Nasdaq: NDRM), a clinical stage pharmaceutical company developing drug-device combinations for central nervous system (CNS) disorders, today announced that a preliminary analysis of trial 006 demonstrated that the trial successfully met its primary, key secondary and additional secondary endpoints. 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.

NeuroDerm also announced that it has modified its EU clinical and regulatory development strategy following a meeting with the European Medicines Agency (EMA). The modified strategy will be based on NeuroDerm's restarted and amended iNDiGO phase III efficacy study (trial 007), rather than on bioequivalent pharmacokinetic (PK) studies. Based on discussions with the EMA, NeuroDerm believes that this strategy should allow it to pursue a broader EU label, with no effect on its clinical and regulatory timelines.

"The very prominent responder effect, as well as the significant reductions in OFF-time and troublesome dyskinesia observed in trial 006, are extremely encouraging and demonstrate the substantial potential for ND0612 to make a meaningful difference in the lives of patients living with Parkinson's disease," said Oded S. Lieberman, PhD, CEO of NeuroDerm. "We believe that restarting and amending the iNDiGO trial, incorporating both an ND0612H arm and new endpoints that reflect these very positive preliminary results from trial 006, should support a broader label in the EU and increase the clinical and commercial potential of ND0612 while not affecting our clinical timelines. We are committed to improving the lives of Parkinson's patients by achieving our clinical and regulatory objectives as quickly as possible and providing Parkinson's disease patients with a safer and more effective alternative to current treatment options."

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 Design

Trial 006 was a 28-day multicenter, international (US, 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.

Trial 006 Preliminary Results

The 38 enrolled subjects had typical characteristics for patients with advanced Parkinson's disease including: an average age of 63.5 years, 11.5 years since diagnosis and an average baseline OFF-time of 5.3 hours per day.

OFF-time (primary endpoint):

The primary endpoint was met in R1. From 5.5 hours at baseline, the OFF-time was reduced by 2.8 hours (p equals 0.004). There was a smaller, non-statistically significant reduction of 1.3 hours in OFF-time in R2.

“ON” by 8:00am and 9:00am (key secondary endpoint):

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 equals 0.020), and, by 9:00am, from 26% at baseline to 75% (p equals 0.004). In R2, dosing began in the morning and there was therefore no improvement from baseline at either timepoint.

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

In R1, 42% of patients had a complete reduction in OFF-time to zero hours (in R2, 11% experienced complete resolution of OFF-time). Patients who experienced reduction in OFF-time (greater than 0 hours change) during the trial were defined as “Responders” and constituted 68% of all patients (12 patients in R1 and 14 patients in R2). Eight (66%) of the Responders in R1 (and two (14%) of the Responders in R2) experienced a complete reduction of their OFF-time to zero hours; all Responders in R1 experienced a reduction of more than 50% in their OFF-time.

“Good” ON (secondary endpoint):

Good ON (defined as “ON” with no or mild dyskinesia, as assessed by the blinded rater) increased in R1 from 9.2 hours by 3.7 hours (p less than 0.001), and in R2 from 8.5 hours by 2.8 hours (p equals 0.003).

Unified Parkinson's Disease Rating Scale (UPDRS) III by 8:00am (post-hoc analysis):

UPDRS III score by 8:00am decreased in R1 from 37.4 at baseline by 19.1 points (p less than 0.001) and from 37.3 at baseline by 10.7 points in R2 (p equals 0.001).

Troublesome Dyskinesia (post hoc analysis):

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

Oral LD Dosing and Frequency (post hoc analysis):

Average dosing frequency of oral levodopa decreased in all patients from 6.6 times at baseline to 2.3 times per day by day 28. The average dose of oral LD decreased from approximately 1100mg at baseline to approximately 330mg.



Safety and Tolerability:

33 subjects (87%) out of 38 completed the study with 5 who did not complete the study, two of which were due to adverse events: one due to an infection at the infusion site and the other due to worsening of symptoms. Infusion site reactions (nodules, bruising and erythema) 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.

Preliminary Results:

Preliminary trial 006 results demonstrate that the R1 dosing regimen provides a significant reduction in OFF-time and a significant increase in ON-time with no or mild dyskinesia. A substantial percentage of subjects experienced complete resolution of OFF-time. The treatment was associated with some nodules, consistent with prior trials, but otherwise did not raise new safety or tolerability concerns. Benefits were also seen with the R2 regimen in spite of the study design whereby patients started levodopa therapy later in the morning. ND0612H devices were generally found to be reliable with only few minor, correctable malfunctions reported. No inconvenience related to the wearing of the device was reported for either day or night administration.

Detailed trial results will be presented at a future medical meeting.

ND0612 EU Clinical and Regulatory Development

NeuroDerm recently received minutes from a meeting held in January 2017 with the EMA's Scientific Advice Working Party. Based on this meeting and on the preliminary results of trial 006, NeuroDerm has modified its EU clinical and regulatory development path. Upon completion of its ongoing trials, NeuroDerm plans to submit a marketing application based on the results of an amended iNDiGO phase III efficacy study and the ongoing BeyoND (trial 012) long-term safety trial, seeking to obtain a broader label for ND0612 than the label that could have been granted under a PK regulatory route in the EU. The previously planned PK trial (trial 009) will not be carried out. Anticipated timelines for submission of the EU marketing application remain unchanged. NeuroDerm's U.S. clinical and regulatory development timelines also remain unchanged.

iNDiGO Trial

NeuroDerm's iNDiGO phase III efficacy study (trial 007) will be restarted and amended to support a broad label claim in the EU for ND0612. The trial will be expanded from 150 to 240 patients by adding a third treatment arm of ND0612H to the current ND0612L and control arms. Furthermore, new endpoints that reflect the recent trial 006 results, including a responder analysis, will be incorporated into this trial. NeuroDerm believes that these should enable the company to seek approval for both the low- and high-dose versions of ND0612 in the EU. It is anticipated that iNDiGO will be completed in 2018, in parallel to the ongoing long term BeyoND safety trial (Trial 012).

Conference Call Details

NeuroDerm will host a conference call at 8:30 a.m. ET today. Individuals can access the webcast in the Events and Presentations section of the Company's website, [by clicking here](#), or by dialing 844-452-2810 (U.S.) or 574-990-9831 (outside of the U.S.). The passcode is 79280228. A webcast will be archived on the website.

About ND0612

ND0612 is designed to significantly reduce motor complications in Parkinson's disease patients through continuous, subcutaneous delivery of LD/CD solution. Previously completed Phase II trials demonstrated that the low dose ND0612L maintained steady, therapeutic levodopa plasma concentrations that were associated with major changes in several clinical parameters including "OFF" time reductions when added to optimal oral standard of care. The high dose ND0612H, intended for severe Parkinson's disease patients, was shown to reach even higher



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levodopa steady plasma levels, indicating that it may provide an effective therapy alternative to current treatments requiring surgery such as deep brain stimulation and LD/CD Intestinal Gel.

About Parkinson's disease

Parkinson's disease is a progressive neurodegenerative illness characterized by reduced dopamine in the brain, resulting in a debilitating decrease in the patient's motor and non-motor functions. Its symptoms, such as trembling in the extremities and face, slowness of movement and impaired balance and coordination, worsen over time and gravely impact the patient's quality of life. Levodopa is the most effective treatment for Parkinson's disease. However, chronic oral levodopa treatment is associated with fluctuations in motor response as result of which, despite the benefits of the drug, patients can experience periods of impaired motor and non-motor functions, also referred to as "OFF" time. In addition, mainly as a result of excessive/intermittent oral doses of levodopa aimed at treating the "OFF" time, some patients experience involuntary movements, or dyskinesia. The "OFF" time and dyskinesia affect the majority of levodopa-treated Parkinson's disease patients and can interfere with day-to-day functions, causing patients to become severely disabled. Current evidence suggests that intermittent dosing with standard oral formulations of levodopa contributes to the development of these motor complications. By contrast, it has been shown that continuous administration of levodopa can effectively treat motor fluctuations in Parkinson's disease patients without increasing troublesome dyskinesia; however, a convenient route for continuous administration has not been introduced to date.

About NeuroDerm

NeuroDerm is a clinical-stage pharmaceutical company developing drug-device combinations for central nervous system (CNS) disorders that are designed to overcome major deficiencies of current treatments and achieve enhanced clinical efficacy through continuous, controlled administration. NeuroDerm has three product candidates in different stages of development which offer a solution for almost every Parkinson's disease patient from the moderate to the very severe stage of the disease. NeuroDerm has developed a line of levodopa and carbidopa (LD/CD) product candidates administered through small belt pumps that deliver a continuous, controlled dose of LD/CD. The LD/CD product candidates are ND0612L and ND0612H, which are used for treatment of moderate and advanced Parkinson's disease patients, respectively, and which are delivered subcutaneously. 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, 2015 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



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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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