



## **NEURODERM AND MITSUBISHI TANABE PHARMA ANNOUNCE PRESENTATION OF LONG -TERM SAFETY OF LEVODOPA/CARBIDOPA INFUSION WITH ND0612 AT INTERNATIONAL CONGRESS OF PARKINSON'S DISEASE AND MOVEMENT DISORDERS**

**REHOVOT, September 14, 2020 /** — NeuroDerm Ltd., a clinical stage pharmaceutical company, and wholly-owned subsidiary of Mitsubishi Tanabe Pharmaceutical Company, developing drugs for central nervous system (CNS) diseases, today announced the presentation of long-term safety data from a Phase 2b trial for ND0612, a potential treatment for Parkinson's disease (PD) that continuously delivers carbidopa/levodopa (CD/LD) by subcutaneous infusion without surgery. In the trial, which included patients from 46 sites in 8 countries, ND0612 infusion was found to be safe with generally mild to moderate local AEs which were reversible and manageable and no unexpected TEAEs for systemic levodopa treatment over 12-months. Long-term data will continue to be collected in patients enrolled in the study extension, some of whom are now in their 4th year of treatment. These findings were presented at the 24th International Congress of Parkinson's Disease and Movement Disorders (MDS) being held virtually September 12-15, 2020.

These data mark a major milestone for NeuroDerm and ND0612 as the results from this study will establish the foundation of the safety profile data required by regulatory agencies in the US, Canada and Europe.

ND0612 is a proprietary liquid levodopa/carbidopa (LD/CD) drug-device combination delivering a continuous subcutaneous infusion. The BeyoND study is a multi -center, international, open-label, Phase 2b safety study to assess the long-term safety (systemic and local) and tolerability of continuous subcutaneous infusion of ND0612. In the BeyoND study, all patients receive open-label treatment with high dose ND0612 infusion for 12 months. After month 12, patients are allowed to continue with study treatment for an extension period. At the time of this press release, over 100 patients have completed the primary 12-month period, and numerous patients continue in the extension, some of whom are in their 5<sup>th</sup> consecutive year of ND0612 treatment.

“This presentation of robust, long-term safety of ND0612 is pivotal to our mission of developing ND0612 as an effective, safe and more convenient treatment option for patients with Parkinson's disease experiencing motor fluctuations,” said Ayelet Altman, NeuroDerm's Chief Executive Officer. “The fact that we have patients in their 4<sup>th</sup>



consecutive year with ND0612 speaks to the value of this therapy to manage patients' PD symptoms over the long term, while we continue to gain more data on the efficacy of ND0612, through our ongoing phase 3, BouNDless study, which is now actively enrolling in 17 countries.”

ND0612 is designed to significantly reduce motor complications in Parkinson's disease by maintaining steady, therapeutic levodopa plasma levels in a convenient self-use manner. ND0612 is intended to replace current treatments for patients experiencing motor fluctuations that would otherwise require highly invasive surgery associated with serious side effects.

ND0612 was shown in previous phase I and phase II studies to be safe and tolerable, reaching steady state, clinically meaningful levodopa blood concentrations.

More information on the trial can be found at <https://clinicaltrials.gov/ct2/show/NCT02726386>

### **About Parkinson's Disease**

Parkinson's disease affects approximately 10 million patients worldwide. 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. For patients experiencing motor complications, there are limited treatment options which are highly invasive and/or burdensome such as deep brain stimulation or intra-duodenal LD/CD gel infusion. Subcutaneous infusion of levodopa has the potential to provide a better tolerated and more convenient route of continuous levodopa delivery thereby preventing or delaying the need for surgical intervention in patients with Parkinson's disease.

### **About ND0612**

ND0612 is the first liquid formulation of levodopa and carbidopa to be administered subcutaneously to conveniently achieve steady state levodopa plasma levels. Levodopa and carbidopa are nearly always administered orally and suffer from an unfavorable pharmacokinetic profile associated with this administration route. NeuroDerm's proprietary technology for continuous subcutaneous delivery of liquid levodopa and carbidopa is a novel approach designed to improve the drugs' 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 a clinical-stage pharmaceutical company, and wholly-owned subsidiary of Mitsubishi Tanabe 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. In Parkinson's disease, the company has two product candidates in development which offer a solution for Parkinson's disease patient from the moderate to the very severe stage of the disease. NeuroDerm is headquartered in the Weizmann Science Park, Rehovot, Israel.

### **Overview of Mitsubishi Tanabe Pharma Corporation (MTPC)**

Mitsubishi Tanabe Pharma, which was founded in 1678, has its headquarters in Doshomachi, Osaka, which is the birthplace of Japan's pharmaceutical industry. With business centered on ethical pharmaceuticals, Mitsubishi Tanabe Pharma is a well-established company and has the longest history of any listed company in Japan. In accordance with the corporate philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," the Company formulated the key concept of Open Up the Future under the Medium-Term Management Plan 2016-2020. Through the discovery of drugs that address unmet medical needs, centered on its priority disease areas — autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world. For more information, go to <http://www.mt-pharma.co.jp/>.

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