



**PHASE 3 CLINICAL TRIAL EVALUATING CONTINUOUS SUBCUTANEOUS
CARBIDOPA/LEVODOPA (ND0612) INITIATED IN THE UNITED STATES
FOR PARKINSON'S DISEASE WITH MOTOR FLUCTUATIONS**

JERSEY CITY, N.J., August 28, 2019 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced the initiation of the Phase 3 BouNDless study investigating the efficacy, safety and tolerability of ND0612, a potential non-surgical, subcutaneous continuous treatment, compared to oral immediate-release carbidopa/levodopa (CD/LD) in people with Parkinson's disease (PD) experiencing motor fluctuations.

"While oral CD/LD is the established standard for treating motor symptoms in Parkinson's disease, many patients experience a decline in benefit as their disease advances requiring them to take multiple doses throughout the day in an effort to control symptoms, often with unpredictable results," said Atsushi Fujimoto, President, MTPA. "We look forward to researching the potential efficacy and safety of continuous subcutaneous treatment with ND0612 on managing motor fluctuations and other complications of Parkinson's disease, through the BouNDless study."

Motor fluctuations are alterations between periods of being "ON," during which a person with PD experiences a response to medication and symptoms are controlled, and being "OFF," which often is a debilitating reemergence of motor symptoms such as tremor, rigidity, slowness of movement, as well as impaired balance and falls. Instead of the relative control of symptoms people may experience with oral CD/LD treatment early on in their disease, symptoms return before the next dose is scheduled, or are only partially controlled by a given dose.^{1,2}

"Given the limitations of current therapeutic options for Parkinson's disease, we recognized the importance of developing a potential non-surgical continuous treatment that may stabilize CD/LD plasma levels and alleviate the disabling motor fluctuations that are often exacerbated with disease progression," said Sheila Oren, M.D., MBA, Chief Medical Officer, NeuroDerm, Ltd. "We are excited that the Phase 3 study of ND0612 is underway, and we may be one step closer to potentially bringing a much-needed treatment option to patients."

Clinical development of ND0612 is being led by NeuroDerm. If regulatory approval is obtained, MTPA intends to commercialize the therapy in the U.S. Both MTPA and NeuroDerm are wholly owned subsidiaries of Mitsubishi Tanabe Pharma Corporation (MTPC).

The multicenter, randomized, active-controlled, double-blind, double-dummy, parallel group clinical trial will enroll a total of approximately 300 people with PD experiencing motor fluctuations, whose symptoms are no longer controlled by conventional treatments (average of at least 2.5 hours motor

fluctuations daily, with a minimum of 2 hours every day in the “OFF” state during waking hours), at approximately 120 sites globally. The primary objective of the study is to determine the effect of ND0612 on daily “GOOD ON” time (defined as the sum of “ON” time without dyskinesia and “ON” time with non-troublesome dyskinesia), as measured by a self-reported patient diary assessing motor function.

The BouNDless study design will be presented at the International Congress of Parkinson’s Disease and Movement Disorders in Nice, France, being held September 22-26, 2019.

Further details are available at www.clinicaltrials.gov (NCT04006210).

About Mitsubishi Tanabe Pharma America, Inc.

Based in Jersey City, N.J., Mitsubishi Tanabe Pharma America, Inc. (MTPA) is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation’s (MTPC) 100 percent owned U.S. holding company, Mitsubishi Tanabe Pharma Holdings America, Inc. MTPA is dedicated to delivering innovative products that address the unmet medical needs of patients in North America. It was established by MTPC to commercialize approved pharmaceutical products in North America with plans to expand its product line through collaborations with partners. For more information, please visit www.mt-pharma-america.com or follow us on [Twitter](#) and [Facebook](#).

About NeuroDerm, Ltd.

Based in Israel, NeuroDerm, Ltd. is a clinical-stage pharmaceutical company developing central nervous system (CNS) product candidates that are designed to address major deficiencies of current treatments and achieve clinical efficacy through continuous, controlled administration. NeuroDerm’s technology enables new routes of administration for existing drugs that address their current deficiencies and achieve clinical efficacy. NeuroDerm is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC). For additional information, please visit NeuroDerm’s corporate website at www.neuroderm.com.

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.³ 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. MTPC is the parent company of MTPA and the license holder of RADICAVA. For more information, go to <http://www.mt-pharma.co.jp/>.

Media inquiries:

Mitsubishi Tanabe Pharma America

Debbie Etchison

908-340-8578

[Media MTPA@mt-pharma-us.com](mailto:MTPA@mt-pharma-us.com)

¹ Clark CE (2007). Parkinson's Disease. *British Medical Journal*. 335, 441-445. <https://doi.org/10.1136/bmj.39289.437454.AD>.

² Kadastik-Eerne L, Taba N, Asser T, et al (2017). Factors associated with motor complications in Parkinson's disease. *Brain and Behavior*, 7:e00837. <https://doi.org/10.1002/brb3.837>.

³ Research by TOKYO SHOKO RESEARCH, LTD.