Mitsubishi Tanabe Pharma America Press Release

MITSUBISHI TANABE PHARMA CORPORATION GROUP ANNOUNCES PRESENTATION OF PATIENT- REPORTED RESULTS FROM PHASE 2 ND0612 STUDY AT INTERNATIONAL CONGRESS OF PARKINSON'S DISEASE AND MOVEMENT DISORDERS

Investigational Treatment with ND0612 Showed Improved Patient Ratings for Activities of Daily Living, Quality of Life and Overall Clinical Status in the Phase 2 Study

Phase 3 ND0612 BouNDless Study Actively Enrolling Patients

JERSEY CITY, N.J., September 23, 2019 – Mitsubishi Tanabe Pharma Corporation Group announced today the presentation of an analysis of secondary, patient-reported outcomes from a Phase 2 trial for ND0612, an investigational treatment for Parkinson's disease (PD) designed to continuously deliver carbidopa/levodopa (CD/LD) by subcutaneous infusion without surgery. In the trial, an improvement in measures for activities of daily living (ADL) and quality of life were reported among people receiving continuous 24-hour ND0612 treatment for 28 days, with over 70 percent of patients reporting an improvement in overall clinical status as early as day three. These findings were presented at the 23rd International Congress of Parkinson's Disease and Movement Disorders® in Nice, France, being held September 22-26, 2019.

"Many people with Parkinson's disease take multiple doses of oral CD/LD as their disease progresses, which can cause additional motor fluctuations that may be debilitating and contribute to poor quality of life," said Atsushi Fujimoto, President, MTPA. "The data presented at MDS add to the body of research on ND0612, which is being studied as the first non-surgical option designed to provide continuous delivery of CD/LD for Parkinson's disease patients experiencing motor fluctuations. We look forward to gaining additional insights on this investigational treatment through the Phase 3 study, which is now enrolling."

The 28-day randomized, parallel-group, open label, blinded-rater Phase 2 study enrolled 38 patients (1:1) to two dosing regimens of ND0612. Supplemental oral CD/LD was used as needed. Patient-reported outcomes were measured using the Unified Parkinson Disease Rating Scale (UPDRS) Part II (ADL) at day 28 and the Parkinson's disease Questionnaire (PDQ-39) at day 27. In addition, patients self-rated their impression of improvement at days three and 28.

Patients in the continuous 24-hour ND0612 treatment group reported a statistically significant change in UPDRS ADL score compared to baseline (-2.9; p=0.02). Quality of life improved in the 24-hour ND0612 treatment group (-7.5 mean change in PDQ-39 vs. baseline; p=0.02). Patients reported improvement in six out of eight PDQ-39 quality of life domains, including bodily discomfort, activities of daily living, emotional wellbeing, mobility, communication and stigma.

“We are encouraged by the patient-reported outcomes with ND0612, which show the potential impact of stabilizing CD/LD levels with continuous treatment on a variety of clinical, daily living and quality of life measures,” said Sheila Oren, M.D., MBA, Chief Medical Officer, NeuroDerm, Ltd. “We are proud of the research behind ND0612 to date and committed to learning more about this investigational treatment for people with fluctuating Parkinson’s disease through the recently initiated Phase 3 study.”

The study design for the Phase 3 BouNDless trial was also presented at the MDS meeting. The trial, investigating the efficacy, safety and tolerability of ND0612 compared to oral immediate-release CD/LD, is currently recruiting people with PD who are experiencing motor fluctuations.

In August 2019, the first of approximately 300 participants was enrolled in the BouNDless study. To be eligible, patients’ symptoms must be no longer controlled by conventional treatments (an average of at least 2.5 hours of motor fluctuations daily, with a minimum of 2 hours every day in the “OFF” state during waking hours). The primary objective of the study, which will be conducted at approximately 120 sites globally, 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. Further details are available at https://www.clinicaltrials.gov (NCT04006210).

About Motor Fluctuations

Motor fluctuations are alterations between periods of being "ON," during which a person with Parkinson’s disease 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.[1,2]

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/.

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

[2] Kadastik-Eerme 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.