March 19, 2024

Announcement of Publication in The Lancet Neurology from the Clinical Study of Investigational ND0612 for Parkinson's Disease

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Akihiro Tsujimura; hereinafter, “MTPC”), a member of the Mitsubishi Chemical Group, announced that results from the phase 3 clinical study of investigational ND0612 in people with Parkinson's disease (PD) experiencing motor fluctuations were published in The Lancet Neurology on March 15 (U.K. time). The clinical study has been conducted by MTPC’s wholly-owned subsidiary, NeuroDerm Ltd. (Head Office: Rehovot, Israel; CEO: Kengo Isshiki).

Title: Safety and efficacy of continuous subcutaneous levodopa-carbidopa infusion (ND0612) for Parkinson’s disease with motor fluctuations (BouNDless):a phase 3, randomized, double-blind, double-dummy, multicentre trial
DOI: https://doi.org/10.1016/S1474-4422(24)00052-8

The data published in The Lancet Neurology includes the results of a phase 3 trial evaluating the efficacy, safety and tolerability in a group of patients receiving investigational ND0612 - a continuous, 24 hours/day subcutaneous (SC) infusion of liquid levodopa/carbidopa (LD/CD) - in comparison to a group of patients receiving oral immediate-release LD/CD in people with PD experiencing motor fluctuations. Key study findings include:

- Treatment with ND0612 demonstrated favorable efficacy with a statistically significant addition ($p<0.0001$) of 1.72 hours in “ON” time without troublesome dyskinesia over oral IR-LD/CD, thus meeting the trial’s primary endpoint.
- The trial also demonstrated positive and clinically meaningful results for the first four secondary endpoints, including the key secondary endpoint with an additional 1.40-hour reduction in daily “OFF” time ($p<0.0001$) with ND0612 vs. oral IR-LD/CD.
- The remaining secondary endpoints that reached statistical significance were the Movement Disorders Society-Unified Parkinson’s Disease Rating Scale (MDS-UPDRS) Part II scores (-3.05 [-4.28, -1.81], $p<0.0001$), the Patients Global Impression of Change (Odds Ratio [OR]: 5.31 [2.67, 10.58], $p<0.0001$) and Clinician Global Impression of Improvement (OR: 7.23 [3.57, 14.64], $p<0.0001$).
- The systemic safety profile of ND0612 was consistent with the well-established safety profile of oral standard of care LD/CD. Infusion site reactions (ISRs) were the most reported treatment emergent adverse events (TEAEs) in any group during the DBDD period (57% for ND0612 vs. 43% for IR-LD/CD).
- Some infusion site reactions (infusion site nodule, infusion site bruising, infusion site infection, infusion site erythema, infusion site pain, infusion site eschar and infusion site swelling) were more frequent in the ND0612 group compared to placebo and oral LD/CD groups. Additionally, only 6% of study participants discontinued the trial during the DBDD

period due to any reason – including 5% due to AEs – compared to discontinuation rates of 6% and 3%, respectively, of study participants in the oral LD/CD groups.

MTPC Group is focusing on R&D related to the central nervous system disease area and is further continuing to create new treatment options for all facing neurodegenerative diseases. MTPC group believes that the publication of positive clinical results support ND0612 – a continuous, 24 hours/day SC infusion of liquid LD/CD, as a potential treatment option for people with PD experiencing motor fluctuations.

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■ About ND0612

ND0612 is an investigational drug-device combination therapy – a 24 hours/day, continuous subcutaneous (SC) infusion of liquid levodopa/carbidopa (LD/CD) for the treatment of motor fluctuations in people with Parkinson's disease (PD). Development of investigational ND0612 is being led by NeuroDerm Ltd., a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC). The safety and efficacy of ND0612 in PD is under review by the U.S. Food and Drug Administration (FDA), who has assigned a Prescription Drug User Fee Act (PDUFA) target action date for the second quarter of CY (calendar year) 2024. If approved, Mitsubishi Tanabe Pharma America, Inc. (MTPA), an MTPC wholly-owned subsidiary (Head Office: Jersey City, NJ, USA; President: Yasutoshi Kawakami), intends to commercialize the therapy in the U.S.

■ About NeuroDerm Ltd.

NeuroDerm Ltd. is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC), based in Israel, inspired to reduce disease burden and improve the quality of life of patients and their families through innovative drug-device combination therapies and technologies. NeuroDerm is an integrated pharmaceutical and medical technology company developing central nervous system (CNS) product candidates. For additional information, please visit NeuroDerm's website at www.neuroderm.com or follow the Company on LinkedIn.

■ 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 (MTPC). It was established by MTPC in 2015 to develop and advance our pipeline as well as commercialize approved pharmaceutical products in North America. For more information, please visit www.mt-pharma-america.com