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Update on U.S. Development Plan of Investigational ND0612 for the Treatment of Motor Fluctuations in People with 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, today announced an update to the regulatory development plan in the United States (hereinafter, "U.S.") for investigational ND0612 for the treatment of motor fluctuations in people with Parkinson's Disease and is targeting resubmission of a new drug application (hereinafter, "NDA") for mid-2025. ND0612 is being developed by MTPC's wholly-owned subsidiary, NeuroDerm Ltd. (Head Office: Rehovot, Israel; CEO: Kengo Isshiki).

NeuroDerm filed the NDA to the U.S. Food and Drug Administration (hereinafter, "FDA") in 2023 and MTPC Group announced the receipt of a complete response letter[*1] (hereinafter, "CRL") in June 2024. MTPC Group has updated the development plan of ND0612 following a Type A meeting[*2] that was recently held with the FDA to discuss the contents of the CRL including additional safety information on the carbidopa ingredient of ND0612, as well as additional information on product quality, device, and manufacturing site inspections and next steps. The FDA did not identify any issues related to the efficacy of ND0612.

MTPC Group will continue to work closely with the FDA on the resubmission process and remains committed to bringing new treatment options for people living with neurodegenerative diseases in the central nervous system, one of the key areas of focus for R&D.

[*1] A complete response letter is issued by the FDA upon completion of the review for the new drug application when the application is not approved under the current conditions.

[*2] Type A meetings are reserved for discussions necessary for an otherwise stalled product development program to proceed or to address an important safety issue.

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■ About ND0612

ND0612 is an investigative drug-device combination therapy – a 24 hours/day, continuous subcutaneous infusion of liquid levodopa/carbidopa (LD/CD) for the treatment of motor fluctuations in people with Parkinson's Disease (PD). There is an ongoing unmet need for treatment innovation for people with PD, as oral LD/CD treatments yield a variable and unfavorable pharmacokinetic profile to maintain a stable clinical response. ND0612 is designed to reduce motor fluctuations in patients with PD by improving the drugs' pharmacokinetic and maintain stable and continuous therapeutic levodopa plasma concentrations through continuous subcutaneous infusion of liquid LD/CD.

■ About NeuroDerm Ltd.

NeuroDerm 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 Ltd. 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.