

October 23, 2025

Receipt of Complete Response Letter from U.S. FDA for investigational ND0612

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director, CEO: Akihisa Harada; hereinafter, "MTPC") today announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter* for the New Drug Application (NDA) of investigational ND0612 for the treatment of motor fluctuations in people with Parkinson's disease, which is being developed by its wholly-owned subsidiary, NeuroDerm Ltd. (Head Office: Rehovot, Israel).

The FDA has issued observations regarding the manufacturing site and the nonclinical information for ND0612. In response, MTPC Group will continue to work closely with the FDA on the resubmission 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.

*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.

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■ About ND0612

ND0612 is a therapy that provides 24-hour continuous, subcutaneous infusion delivery of liquid carbidopa/levodopa through a non-surgical pump system to patients. There is an ongoing unmet need for oral levodopa/carbidopa, which is difficult to achieve a stable clinical response due to fluctuations in levodopa blood levels. ND0612 has the potential to reduce motor fluctuations in Parkinson's disease patients by maintaining stable levodopa blood levels and improving its pharmacokinetic profile compared to conventional oral therapy.

■ About NeuroDerm

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](#).