

June 11, 2024

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

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Akihiro Tsujimura; hereinafter, "MTPC"), a member of the Mitsubishi Chemical Group, today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (hereinafter "CRL") 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; CEO: Kengo Isshiki).

MTPC Group is currently reviewing the CRL and will work closely with the FDA to address its comments to consider the future direction.

\*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](http://www.neuroderm.com) or follow the Company on LinkedIn.