Mitsubishi Tanabe Pharma

May 29, 2025

U.S. FDA Accepts Resubmission for ND0612, an Investigational Treatment for Motor Fluctuations in Parkinson's Disease

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; President, Representative Director: Akihiro Tsujimura; hereinafter, "MTPC") today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) resubmission for investigational ND0612, which is being developed by MTPC's wholly-owned subsidiary, NeuroDerm Ltd. (Head Office: Rehovot, Israel; CEO: Kengo Isshiki), for the treatment of motor fluctuations in people living with Parkinson's disease (PD). The FDA assigned a Prescription Drug User Fee Act (PDUFA) target action date in the third quarter of FY2025.

Regarding the development of ND0612 in the United States, the NDA was initially submitted to the FDA in 2023; however, MTPC announced the receipt of a complete response letter[*1] (CRL) in June 2024. Since then, MTPC Group has been working on the resubmission of the NDA in consultation with the FDA.

This resubmission primarily focused on providing additional information regarding the safety of carbidopa, one of the components of ND0612, as pointed out in the CRL, as well as additional information on product quality, device, and manufacturing site inspections.

PD is a progressive chronic neurological disorder affecting over ten million people worldwide, including approximately one million people in the United States[*2]. In addition to the resubmission in the United States, MTPC Group submitted a marketing authorization application (MAA) for ND0612 in Europe, which was accepted and is currently under review. MTPC Group is focusing on research related to diseases of the central nervous system and continues to create new treatment options for all facing neurodegenerative diseases.

[*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] Who Has Parkinson's? Parkinson's Foundation.
https://www.parkinson.org/understanding-parkinsons/statistics#:~:text=More%20than%2010%20million%20people
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■ About ND0612

ND0612 is an investigational drug-device combination therapy – a 24-hours, 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, 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.