February 21, 2025

EMA Accepts Marketing Authorization Application for ND0612, an Investigational Treatment for Motor Fluctuations in 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 the European Medicines Agency (EMA) has accepted for review the marketing authorization application (MAA) for ND0612, an investigational treatment for motor fluctuations in Parkinson's disease (PD) on February 20 (local time). ND0612 is being developed by MTPC's wholly-owned subsidiary, NeuroDerm, Ltd. (Head Office: Rehovot, Israel; CEO: Kengo Isshiki). The MAA was submitted to the EMA by Mitsubishi Tanabe Pharma GmbH (Headquarters: Düsseldorf, Germany) under the centralized procedure, which applies to all member states of the European Union (EU), Iceland, Norway and Liechtenstein.

The MAA is supported by efficacy, safety and tolerability data from the global Phase 3 BouNDless trial of ND0612 compared to oral immediate-release levodopa/carbidopa (LD/CD), as well as long-term safety and tolerability data from the ongoing Phase 2b BeyoND trial of ND0612 beyond one year in people with PD.

PD is a progressive, chronic neurological disorder that affects more than 10 million patients worldwide. * The most commonly used therapy for PD involves oral administration of LD, which shows antiparkinsonian effect by compensating for decreased dopamine, together with a LD degradation inhibitor (usually CD) to supplement the dopamine deficiency. However, oral LD intake may chronically lead to motor fluctuations such as involuntary movements (dyskinesia) caused by excessive effect of the drug and wearing off in which the drug no longer works as effectively as it used to. As PD progresses, adjustments in oral therapy become less effective in managing the symptoms of the disease, in addition to increasing the risk for motor fluctuations. ND0612, a 24-hours/day, continuous subcutaneous infusion of LD/CD, aims to stabilize blood levels of LD, improving pharmacokinetic profiles, extending ON time without troublesome dyskinesia and reducing the off time in adults with PD.

In addition to the European application, MTPC Group is also in the process of resubmitting its new drug application (NDA) for ND0612 to the United States Food and Drug Administration (FDA). MTPC Group is focusing on R&D related to diseases of the central nervous system and continues to create new treatment options for all facing neurodegenerative diseases.

*Who Has Parkinson's? Parkinson's Foundation.
https://www.parkinson.org/understanding-parkinsons/statistics#:~:text=More%20than%2010%20million%20people
Accessed February 18, 2025.

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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, 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.

■ About Mitsubishi Tanabe Pharma GmbH

Mitsubishi Tanabe Pharma GmbH, a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation, was established in Düsseldorf, Germany in 2003 as a sales subsidiary of Mitsubishi Tanabe Pharma Europe (London, UK). Since its establishment, Mitsubishi Tanabe Pharma GmbH has been marketing pharmaceuticals as a marketing authorization holder in various European countries and now focuses on marketing of RADICAVA® Oral Suspension (generic name: edaravone), an ALS treatment, at its sales base in Lenzburg, Switzerland.