Tanabe Pharma
Creating hope for all facing illness.

Press Release

April 30, 2026

European Commission Grants Marketing Authorization for Onerji® for the Treatment of Parkinson's Disease

Tanabe Pharma Corporation (Head Office: Osaka, Japan; Representative Director, CEO: Akihisa Harada; hereinafter "Tanabe Pharma") announced that Onerji® (project code: ND0612), a continuous subcutaneous infusion of liquid levodopa/carbidopa (LD/CD), received marketing authorization from the European Commission on April 27 (local time) in the European Union (EU) for the treatment of motor fluctuations in patients with advanced Parkinson's disease (PD) which are not sufficiently controlled by oral anti-Parkinson medicinal products. Onerji® is being developed by Tanabe Pharma's wholly-owned subsidiary, NeuroDerm, Ltd. (Head Office: Rehovot, Israel).

Onerji® is a therapy that provides 24-hour continuous, subcutaneous infusion of liquid LD/CD using a portable infusion pump system (the YURWAY® Delivery System or the Crono Twin ND pump) and is expected to improve the pharmacokinetic profile by maintaining stable and continuous LD plasma concentrations.

In the global Phase 3 clinical study (BouNDless trial) conducted in people with PD experiencing motor fluctuations, Onerji® was administered with supplemental oral LD/CD and demonstrated a statistically significant increase in ON time without troublesome dyskinesia and a statistically significant reduction in OFF time compared with immediate-release oral LD/CD. In addition, favorable results were observed in a late Phase 2 long-term safety study (BeyoND study) evaluating the long-term safety and tolerability of Onerji®.

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■ About ND0612

ND0612 (product name within EU: Onerji®) is a 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 advanced 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 pharmacokinetic profile to maintain a stable clinical response. ND0612 reduces motor fluctuations in patients with PD by improving the drugs' pharmacokinetic profile and maintaining stable and continuous therapeutic LD plasma concentrations through continuous subcutaneous infusion of liquid LD/CD.

■ About Parkinson's disease

Parkinson's disease (PD) is a progressive chronic neurological disorder that affects more than ten million patients worldwide.[1] It is characterized by decreasing dopamine signaling in the brain as dopaminergic brain cells die off[2] leading to slowness and reduced movement (akinesia or bradykinesia), tremor, muscle rigidity, and postural instability.[3] PD is also associated with non-motor symptoms that may affect sleep, mental/cognitive/behavioral tasks, and autonomic nervous system function.[3] Levodopa, which shows antiparkinsonian effect by compensating for decreased dopamine, orally administered together with a levodopa degradation inhibitor (usually carbidopa) is the most commonly used therapy for PD. Oral levodopa intake leads to fluctuating plasma concentrations, with high peaks and low troughs that contribute to the progressive emergence of disabling motor fluctuations in many people with PD.[5]

■ About NeuroDerm Ltd.

NeuroDerm is a wholly-owned subsidiary of 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.

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