



August 28th, 2019

**The Start of a Phase 3 Clinical Trial of Continuous Subcutaneous Liquid  
levodopa/carbidopa Administration (ND0612)  
for patients with fluctuating Parkinson's disease**

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; President & Representative Director: Masayuki Mitsuka) announced today that its subsidiary, NeuroDerm Ltd. (Head Office: Rehovot, Israel; Chief Executive Officer and Director: Oded S. Lieberman), has started a pivotal phase 3 clinical trial (BouNDless) of continuous subcutaneous liquid levodopa/carbidopa administration (ND0612) in the U.S.

In the treatment of Parkinson's disease (PD), as the disease progresses, it is important to appropriately control plasma levels of levodopa, a standard of therapy for PD.

ND0612 is the first liquid formulation of levodopa and carbidopa developed by NeuroDerm. ND0612 can be continuously and subcutaneously administered, both day and night, using a small belt pump, thereby providing stable control of the plasma levels of levodopa. This administration is expected to significantly reduce motor complications, i.e. reduction of impaired motor and non-motor functions and troublesome dyskinesia, in patients with PD, whose symptoms are no longer controlled by conventional treatments who have only limited remaining treatment options that require highly invasive surgery associated with serious side effects. ND0612 was shown in previous phase 1 and phase 2 studies to be safe, tolerable and effective.

The BouNDless is aimed to establish efficacy, safety, and tolerability data evidence of continuous subcutaneous ND0612 infusion in comparison with oral levodopa/carbidopa in patients with PD experiencing motor fluctuations. Since levodopa and carbidopa are approved drugs, NeuroDerm plans to submit a 505(b)(2) NDA to the FDA, relying, in part, on the FDA's previous findings from the data that were not developed by NeuroDerm or published literature.

Many diseases in the world pose issues that cannot be overcome with existing treatments. Mitsubishi Tanabe Pharma will make continued efforts to deliver pharmaceuticals to patients fighting against diseases.

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### **About Parkinson's disease**

Parkinson's disease affects approximately 5 million patients worldwide. It is caused by decreasing dopamine signaling in the brain as dopaminergic brain cells die off. Levodopa is the "Gold Standard" therapy for Parkinson's disease and virtually all patients receive it, together with a levodopa degradation inhibitor (usually carbidopa). When administered through the oral route, however, levodopa plasma concentrations undergo sharp fluctuations reaching high peaks and low troughs that contribute to the clinical and motor complications in Parkinson's patients. In advanced Parkinson's disease patients, oral levodopa therapy becomes ineffective, leaving patients with limited treatment options that are highly invasive and/or burdensome such as deep brain stimulation or intra-duodenal levodopa/ carbidopa gel infusion.

### **About ND0612**

ND0612 is the first liquid formulations of levodopa and carbidopa to be administered subcutaneously to conveniently achieve steady state levodopa plasma levels. Levodopa and carbidopa are nearly always administered orally and suffer from an unfavorable pharmacokinetic profile associated with this administration route. ND0612 is a novel approach designed to improve the drugs' pharmacokinetic profile and maintain stable, therapeutic levodopa plasma concentrations, thereby significantly ameliorating motor fluctuations and non-motor complications in Parkinson's disease.