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Changes in Continuous Subcutaneous Liquid levodopa/carbidopa Administration (ND0612) for patients with fluctuating Parkinson's disease Development Plan and an Impairment Loss (Non-recurring Items)

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; President & Representative Director: Hiroaki Ueno) announced today that its subsidiary, NeuroDerm Ltd. (Head Office: Rehovot, Israel; Chief Executive Officer and Director: Ayelet Altman), has changed the global phase 3 clinical trial plan of continuous subcutaneous liquid levodopa/carbidopa administration (ND0612) in the U.S. and Europe. Following this change, MTPC recorded an impairment loss for a part of intangible assets in the first-half of FY2020

In the global development of ND0612, due to the overlap between the expansion of COVID-19 and the important start-up period of phase 3 study; opening clinical trial sites and patient enrollment, MTPC decided to extend the development period for about 1.5 years from the plan at the time of review of "Medium-Term Management Plan 16 -20" announced in November 2018. Under the revised ND0612 development plan, NDA/MAA are to be filed in the U.S. and Europe simultaneously in FY2023.

Based on the above changes in the development plan, profitability is expected to decline due to delayed clinical studies and the competitors' development status. As a result of reviewing the business plan based on the results of recent market research, MTPC recorded an impairment loss (non-recurring items) of 84.5 billion Japanese yen for intangible assets related to NeuroDerm projects in the first-half of FY2020.

ND0612, a combination of medicines and devices, is expected to be an innovative medicine that meets unmet medical needs. Mitsubishi Tanabe Pharma Group is continuing to work to bring new treatment options 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.