April 4, 2022

Long-Term Safety Profile from Phase 2b Clinical Trials of Parkinson's Disease Drug Candidate (ND0612) Presents at 2022 American Academy of Neurology Annual Meeting

Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Hiroaki Ueno; hereinafter, “MTPC”), a member of the Mitsubishi Chemical Holdings Group, announced today that the positive long-term safety data from the phase 2b clinical trials (BeyoND stutdy; hereinafter, “this study”）of the Parkinson's disease drug candidate (ND0612) which is being conducted by its wholly owned subsidiary, NeuroDerm Ltd. (Head Office: Rehovot, Israel; CEO: Ayelet Altman) will be presented at 2022 American Academy of Neurology Annual Meeting (hereinafter, "AAN") on April 5 local time.

Cumulative safety data from 114 participants enrolled in the long-term extension period of this study (beyond one year) with Parkinson’s disease experiencing motor fluctuations will be presented in AAN. 95% of participants who completed one year of treatment enrolled in the extension period (some patients continuing in their sixth year of treatment) and this is the first time that safety data beyond one year have been obtained from continuous levodopa/carbidopa treatment. Treatment-emergent adverse events (TEAEs) were generally mild to moderate. Over more than four years, 17.5% of participants discontinued treatment due to an adverse event after their first year of enrollment, including four (3.5%) patients who withdrew due to infusion site reactions. Infusion site reactions were the most frequent TEAEs, such as nodules, hematoma, infection, pain, and eschar[*1]. Nausea was the drug-related systemic TEAE with incidence over 5% (7.0%).

New treatments are awaited especially by patients with advanced Parkinson’s disease to improve their quality of life as most of them experience motor fluctuations and difficult to adequately control it by oral medications along with the progress of the disease. ND0612, a drug-device combination product with a subcutaneous delivery system continuous infusion of liquid levodopa/carbidopa, is a therapeutic agent candidate for Parkinson's disease that can potentially offer a more reliable, sustained relief of motor fluctuations. This study confirms that ND0612 can be the new option that meets the unmet medical needs of Parkinson's disease treatment that remains safe and well tolerated over the long-term.

Global phase 3 clinical study of ND0612 is currently ongoing and expected launch in the U.S. and globally in fiscal 2024. MTPC is focusing on the R&D of central nervous system disease area and further continuing to create new options for all facing Parkinson’s disease.

*1 Dry and hard dead tissue

Mitsubishi Chemical Holdings Group
Corporate Communications Div.
Osaka Corporate Communications Dept.
Media contacts: [+81] (0)6-6205-5119

■About Parkinson’ s Disease

Parkinson’s disease affects more than five million patients worldwide.[1] It is caused by decreasing dopamine signaling in the brain as dopaminergic brain cells die off.[2] Levodopa is the “Gold Standard” therapy for Parkinson’s disease and nearly all patients receive it, together with a levodopa degradation inhibitor (usually carbidopa).[3] When administered orally, levodopa plasma concentrations undergo sharp fluctuations reaching high peaks and low troughs that contribute to the clinical and motor complications in patients with Parkinson’s disease.[4] With disease progression, oral levodopa therapy may become less effective while increasing the frequency of motor complications, leaving patients with limited treatment options that are highly invasive and/or burdensome.[4]

■About ND0612

ND0612 is the combination product candidate of levodopa and carbidopa combined with a continuous subcutaneous administration system. ND0612 is a novel approach designed to reduce motor fluctuations in Parkinson's disease patients by improving the drugs’ pharmacokinetic profile and maintain stable, therapeutic levodopa plasma concentrations.

■About NeuroDerm, Ltd.

NeuroDerm, Ltd. is a pharmaceutical company based in Israel with significant capabilities in new formulation research and technology development for combining pharmaceuticals with medical devices for the treatment of central nervous system diseases. Mitsubishi Tanabe Pharma wholly owned NeuroDerm in October 2017 to expand its pipeline in the key R&D disease area, central nervous system. www.neuroderm.com

References

1. Global, regional, and national burden of Parkinson’s disease, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. GBD 2016 Parkinson’s Disease Collaborators. Lancet Neurol 2018; 17: 939-953.
2. Parkinson’s 101. The Michael J. Fox Foundation. Available at: https://www.michaeljfox.org/parkinsons-101#q2. Accessed March 15, 2022.
3. S Fahn. Levodopa in the treatment of Parkinson’s disease. J Neural Transm Suppl.2006;(71):1-15. doi: 10.1007/978-3-211-33328-0_1.
4. C D Marsden. Problems with long-term levodopa therapy for Parkinson’s disease. Clin Neuropharmacol. 1994;17 Suppl 2:S32-44.