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To whom it may concern

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Notice Regarding Receiving Manufacturing and Marketing Approval for Additional Formulation, Madopar® L50 Combination Tablets for the Treatment of Parkinsonism

1. Circumstances Leading to Receiving Manufacturing and Marketing Approval

TAIYO HOLDINGS CO., LTD. (hereinafter "Taiyo holdings") hereby announces that its consolidated subsidiary Taiyo Pharma Co., Ltd. (hereinafter "Taiyo Pharma") has received approval for manufacturing and marketing for Parkinsonism treatment Madopar® Combination tablet (generic name: levodopa・benserazide hydrochloride) today.

Madopar® is a combination of levodopa 100 mg and benserazide hydrochloride 28.5 mg, a peripheral dopa decarboxylase inhibitor, and have been marketed in Japan since 1980 for the indication of Parkinson's disease and Parkinson's syndrome.

Parkinson's disease is a neurodegenerative disorder that is caused by relatively selective damage to dopamine neurons in the substantia nigra and is foregrounded by motor symptoms, mainly motor lability, tremor, and muscle rigidity. There are an estimated 289,000 patients in Japan[1)]. In Parkinson's disease, while motor complications are better maintained when levodopa is administered in sufficient doses, the incidence of motor complications increases steadily depending on the dose and duration of levodopa administration, making it important to keep the levodopa dose at an appropriate level. [2)]

Against this background, the Japan Neurological Society and Movement Disorder Society of Japan requested Taiyo Pharma to develop an additional half-dose formulation of Madopar® (levodopa 100 mg and benserazide hydrochloride 14.25 mg) in order to improve motor complications such as dyskinesia and weight bearing-off caused by levodopa dosage adjustment in Parkinson's disease patients and to reduce the burden on healthcare professionals. In response to a request for the development of an additional dosage form, Taiyo Pharma developed the dosage form and received approval for manufacturing and marketing. Taiyo Pharma will launch Madopar® L50 immediately after it is listed on the National Healthcare Insurance Drug Price Standard.

To contribute to patients and healthcare professionals, Taiyo Pharma will continuously develop pharmaceuticals that meet the medical community's needs.

1) Patients Survey (Ministry of Health, Labour and Welfare, 2020)
2) Parkinson's Disease Clinical Practice Guidelines (Japan Neurological Society, 2018)

2. Future Outlook

The impact of this matter, including that on the consolidated business results of Taiyo Holdings for the fiscal year ending March 31, 2024, will be minute. However, Taiyo Holdings will promptly provide notification of any matters that merit disclosure should they arise.

Product Overview

Since this translation of the product overview is prepared in February 2024 based on the current Japanese text at that time, the translation may not reflect the latest information due to continuous revision of package inserts. The latest Japanese text is available on PMDA (and MAH) website.

Bland name	Madopar® L50
Generic name	Levodopa・Benserazide Hydrochloride
Active ingredients of medicine	1 tablet contains 50mg levodopa and 14.25mg Benserazide Hydrochloride (12.5 mg as Benserazide)
Indications	Parkinson's disease and Parkinson's syndrome
Dosage and administration	For patients who have not been treated with levodopa so far: The usual adult initial daily dosage is 2 to 6 tablets divided into 1 to 3 times, orally administered after meals. Subsequently, gradually increase the daily dose by 2 to 4 tablets every 2 or 3 days, and the maintenance dose is 6 to 12 tablets per day. For patients who are currently being treated with levodopa: The usual adult initial daily dosage is changed to the levodopa dose equivalent to about 1/5 of the current daily dose (2 tablets of this tablets contain 100 mg levodopa) divided into 1 to 3 times, orally administered after meals. Subsequently, gradually increase or decrease the daily maintenance dose of 6 to 12 tablets per day. The dose may be increased or decreased depending on the age or symptoms as appropriate.