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To whom it may concern

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## Notice Regarding Launch of “MADOPAR<sup>®</sup> Combination Tablets L50” for a Treatment of Parkinsonism

TAIYO HOLDINGS CO., LTD. (hereinafter, “Taiyo Holdings”) hereby announces that today, TAIYO Pharma Co., Ltd. (hereinafter, “Taiyo Pharma”), a consolidated subsidiary of Taiyo Holdings, newly launched “MADOPAR<sup>®</sup> Combination Tablets L50” (generic name: levodopa • benserazide hydrochloride), a therapeutic agent for Parkinsonism treatment.

### 1. Circumstances Leading to the Launch of the New Product

Madopar<sup>®\*</sup> 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<sup>1)</sup>. 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. <sup>2)</sup>

Against this backdrop, at the request of Japanese Society of Neurology and Movement Disorder Society of Japan to develop a half-dose formulation of Madopar<sup>®</sup> (levodopa 50 mg, 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, Taiyo Pharma developed a half-dose formulation and acquired approval for manufacturing and marketing on February 15, 2024.

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

\* In line with the launch of “MADOPAR<sup>®</sup> Combination Tablets L50,” Taiyo Pharma will continue selling Madopar<sup>®</sup> after changing its name to “MADOPAR<sup>®</sup> Combination Tablets L100.”

## 2. Product Overview

Since this translation of the product overview is prepared in June 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.

Brand name	Madopar <sup>®</sup> 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	<p>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.</p> <p>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.</p>

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

## 3. Future Outlook

The impact of this matter, including that on the consolidated business results of Taiyo Holdings for the fiscal year ending March 31, 2025, will be minute. However, Taiyo Holdings will promptly provide notification of any matters that merit disclosure should they arise.