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To whom it may concern

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Notice regarding Application for Manufacturing and Marketing Approval for Half-dose formulation of Madopar® combination tablets for the treatment of Parkinsonism

1. Circumstances leading to Application for 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 developed a half-dose formulation of the Parkinsonism treatment Madopa® (generic name: levodopa・benserazide hydrochloride), and today submitted an application to the Ministry of Health, Labour and Welfare for manufacturing and marketing approval for additional dosage form.

Madopar® combination tablets is a combination of levodopa 100 mg and benserazide hydrochloride 28.5 mg, a peripheral dopa decarboxylase inhibitor, and has 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.[1)] There are an estimated 289,000 patients in Japan. 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® combination tablets (levodopa 100 mg and benserazide hydrochloride 14.28 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 submitted an application for manufacturing and marketing approval.

To contribute patients and healthcare professionals, Taiyo Pharma will continuously develop pharmaceuticals that meet needs of the medical community as the development of an additional half-dose formulation of Madopar® combination tablets that respond to the voices of the medical community.

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, 2023, will be minute. However, Taiyo Holdings will promptly provide notification of any matters that merit disclosure should they arise.

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