Sumitomo Dainippon Pharma

News Release

July 2, 2018

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Obtains Approval in Japan for TRERIEF®, a therapeutic agent for Parkinson's disease, for an Additional Indication of Parkinsonism in Dementia with Lewy Bodies

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Hiroshi Nomura) announced today that it received approval in Japan for TRERIEF® OD Tablets 25 mg and TRERIEF® Tablets 25 mg (generic name: zonisamide), a therapeutic agent for Parkinson's disease ("PD"), for an additional indication of parkinsonism in dementia with Lewy bodies ("DLB").

TRERIEF®, created originally by Sumitomo Dainippon Pharma, was launched in Japan in March 2009, with PD (to be administered in case sufficient effects are not obtained for patients using levodopa, potentially with other PD drugs) as the indication. Subsequently, in August 2013, approval for an additional dosage and administration for the treatment of wearing-off was obtained.

Pathologically, DLB is classified as part of the Lewy body disease spectrum, which also includes PD. The symptoms of parkinsonism in DLB are nearly the same as the symptoms of motor dysfunction in PD. Such being the case, Sumitomo Dainippon Pharma has been working on the clinical development of TRERIEF®, under the assumption that its action on motor dysfunction in PD will also have an effect on parkinsonism in DLB.

By obtaining the approval, TRERIEF® has become the world's first drug to be indicated for parkinsonism in DLB. Sumitomo Dainippon Pharma believes that TRERIEF® will become a new therapeutic option for parkinsonism in DLB, contributing to the treatment of patients with such symptoms.

<Reference information>

Approval of additional indications, dosage and administration of TRERIEF® OD Tablets 25 mg and TRERIEF® Tablets 25 mg

	New (additions are underlined)	Previous
Indications	1. Parkinson's disease (to be administered in case sufficient effects are not obtained for patients using levodopa, potentially with other PD drugs) 2. Parkinsonism in dementia with Lewy bodies	Parkinson's disease (to be administered in case sufficient effects are not obtained for patients using levodopa, potentially with other PD drugs)

	(to be administered in case parkinsonism persists in patients using levodopa)	
Dosage and Administration	This drug is to be administered in combination with levodopa. 1. Parkinson's disease Usually, doses of 25 mg are administered orally to adults as zonisamide once daily. To reduce wearing-off in treating Parkinson's disease, doses of 50 mg are administered orally once daily. 2. Parkinsonism in dementia with Lewy bodies Usually, doses of 25 mg are administered orally to adults as zonisamide once daily.	This drug is to be administered in combination with levodopa. Usually, doses of 25 mg are administered orally to adults as zonisamide once daily. To reduce wearing-off in treating Parkinson's disease, doses of 50 mg are administered orally once daily

Note: TRERIEF® is available in the three formulations of "TRERIEF® OD Tablets 25 mg," "TRERIEF® Tablets 25 mg," and "TRERIEF® OD Tablets 50 mg." The "indication" and "dosage and administration" of "TRERIEF® OD Tablets 50 mg" remain unchanged.

About dementia with Lewy bodies (DLB)

DLB is a form of dementia, and it has progressive cognitive impairment as essential symptom and the following four core features :

(1) Fluctuating cognition.
(2) Recurrent visual hallucinations.
(3) REM sleep behavior disorder.
(4) Parkinsonism

While there are several reports on epidemiological studies of DLB, the Ministry of Health, Labour and Welfare of Japan reported in its 2014 Patient Survey that there are 144,000 patients in Japan suffering from "vascular dementia and unspecified dementia," which includes DLB.

Contact:
Public & Investor Relations Group, Corporate Governance
Sumitomo Dainippon Pharma Co., Ltd.
TEL: +81-6-6203-1407 (Osaka); +81-3-5159-3300 (Tokyo)