

August 30, 2017

Sumitomo Dainippon Pharma Co., Ltd.

**Sumitomo Dainippon Pharma Submits an Application 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: Masayo Tada) announced today that it has submitted an application in Japan for TRERIEF® (generic name: zonisamide, "TRERIEF"), 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 dose and dosage for the treatment of wearing-off was obtained. TRERIEF is currently accepted as one of the treatment options for PD in Japan.

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.

If this application is approved, TRERIEF will be 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.

This application includes data from a phase 3 study of TRERIEF in patients with parkinsonism accompanying DLB. The topline results of phase 3 study were disclosed on April 6, 2017.

<Reference information>

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.

About a phase 3 study in patients with parkinsonism accompanying DLB

The study was a multi-center, placebo-controlled, randomized, double blind 12-week study intended to evaluate the efficacy and safety of TRERIEF, involving 351 patients with parkinsonism accompanying DLB, randomized to receive TRERIEF 25 mg/day (n=117) or 50 mg/day (n=114), or placebo (n=120). The UPDRS* Part III (motor examination) total score at 12 weeks, the primary endpoint of the study, statistically significantly improved in modified ITT population in both 25 mg/day and 50 mg/day groups, compared with placebo group. [Differences vs placebo group in the changes: 25 mg/day group -2.7 (adjusted p=0.005) and 50 mg/day group -2.6 (adjusted p=0.005)] The common TEAEs observed in the study were already reported in previous studies.

*The Unified Parkinson's Disease Rating Scale (UPDRS) is the most widely used rating scale for disability and impairment in PD, and also is the primary outcome measure in most clinical trials of PD therapeutics.

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