Sumitomo Dainippon Pharma

News Release

April 6, 2017

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Positive Topline Results from a Phase 3 Study of TRERIEF®, a therapeutic agent for Parkinson's disease, in the Treatment of Patients with Parkinsonism in Dementia with Lewy Bodies (DLB)

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Masayo Tada) announced today positive topline results from a Phase 3 study evaluating its therapeutic agent for Parkinson's disease ("PD") TRERIEF® (generic name: zonisamide, "TRERIEF") in patients with Parkinsonism in Dementia with Lewy Bodies (DLB) met the primary endpoint. The study is conducted for obtaining approval for the new indication of the TRERIEF in Japan.

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, were 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 incidences of TEAEs in 25 mg/day, 50 mg/day and placebo groups were 48.7%, 54.5% and 47.1%, respectively and 50 mg/day group was slightly higher than placebo group. There were no apparent differences in incidences of serious TEAEs among treatment groups.

According to the study's results, Sumitomo Dainippon Pharma intends to submit a supplemental New Drug Application (sNDA) in Japan for Parkinsonism accompanying DLB in FY2017.

*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.

<Reference information>

About a phase 3 study in patients with Parkinsonism accompanying DLB

The study was a multi-center, placebo-controlled, randomized, double blind study to evaluate the efficacy and safety of 12-week administration of TRERIEF 25 mg/day and 50 mg/day in comparison with placebo with patients in Japan diagnosed with Parkinsonism accompanying DLB. A total of 351 patients were grouped into TRERIEF 25 mg/day (n=117), 50 mg/day (n=114) and placebo (n=120). The primary endpoint was change from the baseline of the UPDRS Part III total score after 12 weeks of administration. An open-label, long-term extension study is underway to further evaluate the safety and efficacy of TRERIEF through a 40-week administration of TRERIEF 25 mg/day or TRERIEF 50 mg/day in patients with Parkinsonism accompanying DLB.

About TRERIEF

TRERIEF is an agent for the treatment of PD, created originally by Sumitomo Dainippon Pharma, and was launched in Japan in March 2009, with PD (to be administered in case sufficient effects are not obtained even though any of other PD drugs is administered besides a levodopa-containing agent) as the indications. 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 treatment option for PD.

About DLB

DLB is a form of dementia that has the following three principal symptoms:

(1) Progressive and variable decrease in cognitive function.
(2) Visual hallucinations with detailed and specific content.
(3) Parkinsonism

There have been reports that DLB accounts for 4%, or 10 to 15%, of all cases of dementia. It is the second most frequent type of degenerative dementia after Alzheimer's disease.

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