Dainippon Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Masayo Tada) launches “TRERIEF® tablet 25 mg” (generic name: zonisamide), a Parkinson’s disease drug, in Japan as of March 13.

Zonisamide is a chemical compound that was created by the Company. This product was put on the market as an antiepileptic agent under the product name of EXCEGRAN® in 1989. Since then it has been extensively used under approvals by 36 countries in the world. When this product was administered to a Japanese patient with Parkinson’s disease for the specific purpose of treating convulsion attacks which occurred to this particular patient, the convulsion attacks disappeared and simultaneously the symptoms of Parkinson’s disease were alleviated. Based on this finding, since 2001 the Company has pursued a program to develop this drug as an agent to cure Parkinson’s disease.

Parkinson’s disease has a higher morbidity next to Alzheimer’s disease among neurodegenerative diseases. Its major symptoms are such movement disorders as tremor at rest, muscle rigidity, akinesia, and impairment of postural reflexes. Parkinson’s disease occurs from lack of dopamine at nerve terminals, and its standard therapies are medication to correct the deficiency in function of dopamine.

In clinical trials of TRERIEF®, such beneficial effects as improvement in movement ability and betterment in activities of daily living have been found in those patients with advanced Parkinson’s disease who are not sufficiently cured by any of the above-mentioned standard therapies.

The Company anticipates further contribution to better therapies of Parkinson’s disease through early penetration of TRERIEF® into the market.
Profile of “TRERIEF®” for Parkinson’s disease

[Brand Name] TRERIEF®

[Generic Name] zonisamide

[Content / Description] Pale yellow film-coated oval tablets, containing 25mg of zonisamide per tablet

[Indication] Parkinson’s disease (to be administered in case sufficient effects are not obtained even though any of other Parkinson’s disease drugs is administered besides a levodopa-containing agent)

[Dosage and Administration] TRERIEF® (zonisamide) should be administered in association with levodopa agent
The dose of TRERIEF® (zonisamide) for adults is usually 25mg once daily.

2) Improved the total score of UPDRS* Part III (motor examination) and Part II (activities of daily living)
3) Once-daily dosing
4) Enhanced and elongated the action of L-dopa in rat models of Parkinson’s disease
5) Augmented the effect of L-dopa to increase extracellular dopamine levels in the rat striatum

[Manufacturer and Distributor] Dainippon Sumitomo Pharma Co., Ltd.

[Date of Approval] January 21, 2009

[Date of NHI Price Listing] March 13, 2009

[NHI Drug Price Standard] 25 mg Tablet: ¥1084.9

[Packaging] [PTP] 100 tablets (10 x 10)
[PTP] 500 tablets (10 x 50)

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