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Eisai Co., Ltd.

EISAI TO LAUNCH BOTULINUM TOXIN TYPE B NEUROMUSCULAR-BLOCKING AGENT NERBLOC® INTRAMUSCULAR INJECTION 2500 UNITS IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it will launch NerBloc® Intramuscular Injection 2500 Units (botulinum toxin type B, "NerBloc"), a neuromuscular-blocking agent, in Japan on March 27 as a treatment for cervical dystonia.

Botulinum toxin type B is a protein produced by the anaerobic bacterium *Clostridium botulinum* type B. By acting specifically on motor nerve terminals at the neuromuscular junction, it inhibits the release of acetylcholine from the cholinergic nerve endings and exhibits muscle relaxant effects. Eisai acquired the exclusive rights to develop and market NerBloc in Japan from U.S.-based Elan Pharmaceuticals, Inc. and Ireland-based Elan Pharma International Ltd. (collectively, "Elan") in September 2000 and was approved as the marketing authorization holder following product development. NerBloc was then listed on the National Health Insurance (NHI) drug price list on February 22, 2013.

In a double-blind, placebo-controlled trial (Study 131) conducted by Eisai in Japan in patients with cervical dystonia, NerBloc showed statistically significant improvement in TWSTRS (Toronto Western Spasmodic Torticollis Rating Scale) total score from baseline to week four versus placebo. No serious side effects were reported, with the most common adverse events being difficulty in swallowing, dry mouth and thirst.

Cervical dystonia causes symptoms such as cephalic displacement, tremor, scoliosis, and cervical pain as a result of abnormal cervical muscle contraction. Symptoms normally appear during adolescence or adulthood, progressing for anywhere between several months and several years before they eventually reach a plateau. Cervical dystonia can be treated with botulinum toxin therapy, oral medications such as anticholinergic agents and muscle relaxants, or surgery. Most notably, botulinum toxin is listed in overseas treatment guidelines as a safe and effective modality for the treatment of cervical dystonia and is recommended as a first-line treatment option for the condition.

Eisai obtained exclusive European marketing rights for the drug from U.S.-based Solstice Neurosciences, LLC (a wholly owned subsidiary of US WorldMeds, LLC) who had previously assumed the rights to the drug from Elan, and currently markets the drug in Europe under the brand name NeuroBloc®. By providing NerBloc as a new treatment option for cervical dystonia in Japan, Eisai aims to make further contributions to patients. In accordance with approval conditions, Eisai will conduct a post-marketing use results survey (all-case surveillance) in all patients who are administered NerBloc until the predetermined number of patients has been reached, in order to promote the effective and safe use of the drug.

[Please refer to the following notes for a product outline and photograph as well as further information on Study 131.]

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[Notes to editors]

1. NerBloc® Product Outline

1) Product Name:	NerBloc® Intramuscular Injection 2500 Units
2) Generic Name:	Botulinum toxin type B
3) Indications and Usage:	Cervical dystonia
4) Dosage and Administration:	Adults should be administered botulinum toxin type B in accordance with the following dosages by intramuscular injection into the tonic muscle.* If multiple muscles are affected, dosage should be divided among affected muscles. ・The recommended total initial dose of NerBloc is 2500 units or 5000 units ・If effects are insufficient or symptoms reoccur, patients may be administered a maximum subsequent dose of 10000 units. However, subsequent dosing should not take place within two months of initial dose. *Main tonic muscle: sternocleidomastoid, scalene, trapezius, levator scapulae, splenius capitis, semispinalis capitis
5) Listed Price:	NerBloc® Intramuscular Injection 2500 Units 28,902 yen per vial containing 2500 units
6) Packaging:	NerBloc® Intramuscular Injection 2500 Units 1 vial containing 2500 units

2. About Study 131

Study Design:	Multicenter, randomized, double-blind, placebo-controlled, parallel, dose-response trial
Eligibility:	Patients with cervical dystonia (between 20 and 74 years old, inclusive), 130 subjects
Primary Objective:	Evaluation of safety and efficacy of botulinum toxin type B
Study Arms:	Botulinum toxin type B 2500, 5000 and 10000 units, placebo
Duration:	Single-dose administration
Primary Endpoint:	Change in TWSTRS* total score from baseline to week 4.

*TWSTRS (Toronto Western Spasmodic Torticollis Rating Scale) is comprised of three subscales (Torticollis Severity Scale: measures degree of cephalic displacement; Disability Scale: measures work, activities of daily living, etc.; Pain Scale: measures cervical pain) and is used as an assessment tool in the treatment of cervical dystonia.

[Product Photograph]