No.11-05

January 21, 2011
Eisai Co., Ltd.

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

Eisai Co., Ltd. (Headquarters: Eisai, President & CEO: Haruo Naito) announced today that it has received approval to market the botulinum toxin type B neuromuscular-blocking agent NerBloc® Intramuscular Injection 2500 Units (generic name: botulinum toxin type B, "NerBloc") in Japan for the treatment of cervical dystonia in adults.

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.

In a double-blind placebo-controlled trial (Study 131) conducted in Japan in patients with cervical dystonia, NerBloc® demonstrated a statistically significant improvement in TWSTRS (Toronto Western Spasmodic Torticollis Rating Scale) total score from baseline to week four compared with placebo. Furthermore, the study also showed that efficacy and safety profiles were consistent with studies conducted overseas.

Eisai acquired the exclusive rights to develop and market botulinum toxin type B in Japan through an agreement it concluded with U.S. based Elan Pharmaceuticals, Inc. and Ireland-based Elan Pharma International Ltd. (collectively referred to as "Elan") in September 2000. In May 2007, the company subsequently obtained exclusive European marketing rights from Solstice Neurosciences Inc. (Headquarters: United States, "Solstice"), who had assumed the rights to the agent from Elan, and currently markets it in Europe under the brand name NeuroBloc®. In the United States, the agent is marketed by Solstice Neurosciences LLC, a wholly-owned subsidiary of US WorldMeds LLC, under the brand name MYOBLOC® Injection.

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. In Japan, cervical dystonia is reported to affect approximately 2.8 individuals per 100,000 population. Cervical dystonia can be treated with botulinum toxin therapy, anticholinergic agents, oral medications such as 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 in developed countries.

With the approval of NerBloc®, Eisai will enhance its line-up of neurology products and make further contributions to addressing the diversified needs of and increasing the benefits provided to patients.

[Please refer to the following notes for a product outline and further details on Study 131]

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

1. NerBloc® Product Outline

Product Name:

NerBloc® Intramuscular Injection 2500 Units

Generic Name:

Botulinum Toxin Type B

Indications and Usage:

Cervical Dystonia

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 2,500 Units or 5,000 Units
- If effects are insufficient or symptoms reoccur, patients may be administered a maximum subsequent dose of 10,000 Units. However, subsequent dosing should not take place within two months of initial dose.

*Tonic Muscle: sternocleidomastoid, scalene, trapezius, levator scapulae, splenius capitis, semispinalis capitis

2. About Study 131

Study Design:

Multi-center, open-label, double-blind, placebo-controlled, parallel, dose response trial

Eligibility:

Patients with cervical dystonia (between 21 and 73 years old) 130 subjects

Primary Objective:

Evaluation of safety and efficacy of botulinum toxin type B

Study Arms:

Botulinum toxin type B 2,500, 5,000, 10,000 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.