

Eisai botulinum toxin injection to help relax muscles

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Singapore: Eisai launched NerBloc Intramuscular Injection 2500 Units (botulinum toxin type B, "NerBloc"), a neuromuscular-blocking agent, in Japan 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 US-based Elan Pharmaceuticals, and Ireland-based Elan Pharma International 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 total score as per Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) 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 US-based Solstice Neurosciences 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.