For immediate release

February 22, 2012
Shionogi & Co., Ltd.
Eli Lilly Japan K.K.

Serotonin/Noradrenalin Reuptake Inhibitor Cymbalta® Capsule 20 mg, 30mg Approval of Additional Indication for Diabetic Neuropathic Pain

Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President: Isao Teshirogi; hereinafter called "Shionogi") and Eli Lilly Japan K.K. (Head Office Kobe, Japan; President and General Manager: Alfonso G. Zulueta; hereinafter called "Lilly Japan") today announced that it has received an approval for an additional indication of a serotonin/noradrenalin reuptake inhibitor, Cymbalta® Capsule 20 mg and Cymbalta® Capsule 30 mg (generic name: duloxetine hydrochloride) for diabetic neuropathic pain (DNP) in Japan.

Cymbalta® was created by Eli Lilly and Company of the United States. Since its US launch in 2004, it has been approved as an antidepressant for the treatment of major depressive disorder in 101 countries and for DNP in 98 countries in the world and international pain medication guidelines recommend it as the first-line treatment for DNP (as of October 2011).[1]

Because DNP is caused by the functional abnormality in the peripheral or spinal nerves, it often lasts for 3 months or more and becomes intractable, chronic pain. Its symptoms are characterized by left-right symmetry that causes pain to the same site in the both hands or both legs. The pain often increases during rest at night, causing sleep disorder some times. The cause or mechanism of DNP has not been understood yet, while its symptoms are supposed to develop in association with several factors including metabolic disorder, blood sugar disorder and nerve regeneration disorder. According to an investigation by a surveillance study group of the Japan Physicians Association carried out in 2000, it is reported that neuropathy is a symptom developed in approximately 40 percent of diabetic patients and the most common symptom in 3 major diabetic complications.[2]

According to a report based on results of a 2007 questionnaire survey[3] conducted among pain treatment specialists, physician satisfaction related to DNP treatment is 30 percent and contribution of drug treatment is slightly below 50 percent. These degrees are considered to be by no means high.

The approval this time of the additional indication makes it possible for Cymbalta®, as a new treatment option for DNP, to contribute to improving patient Quality of Life (QOL). Shionogi and Lilly Japan are committed to making a contribution to treatment through our all-out effort to deliver and gather information necessary for ensuring adequate usage of Cymbalta® and high-quality information services.

1 Cymbalta is recommended as the first-line treatment for DNP in world's major medication guidelines for neuropathic pain including those of International Association for the Study of Pain, National Institute for Clinical Excellence (NICE) of the UK, and European Federation of Neurological Societies (EFNS). In Japan, too, similarly to overseas guidelines, EBM-based information supports a guideline proposed by Japan Society of Pain Clinicians. The guideline takes Japanese medical environment into consideration and recommends Cymbalta as the first-line treatment for DNP.

2 A surveillance study group of the Japan Physicians Association: Journal of Japan Physicians Association, 2001, 16 (4), 353

3 Japan Health Science Foundation: Domestic Infrastructure Technology Survey Report、2008, 22

Product outline of Cymbalta®

- Product name: Cymbalta® Capsule 20mg, 30mg
- Generic name: Duloxetine hydrochloride
- Effect/efficacy: Depression/depressive condition, diabetic neuropathic pain (Additional indication approved on February 22, 2012)
- Administration/dosage: Normally for an adult, Cymbalta® (40 mg as duloxetine) should orally be administered once daily after breakfast. Administration should start with 20 mg a day. After an interval of a week or more, daily dosage can be increased with an increment of 20 mg. In case the drug shows insufficient effect, its dosage can be increased to 60 mg a day.
- Approval date: January 20, 2010
- NHI pricing date: April 16, 2010
- Price: Cymbalta® Capsule 20mg: 169.30 yen per capsule
  Cymbalta® Capsule 30mg: 230.50 yen per capsule

About Shionogi & Co., Ltd.

Shionogi, as a research-driven pharmaceutical company, dedicates to deliver pharmaceuticals that offer the greatest possible level of satisfaction to patients, their families, and healthcare providers and that improve QOL for patients and their families worldwide based on the Company policy, “Shionogi strives constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve.” To achieve the above goal, the Company is constantly engaged in research, development, manufacturing and marketing activities with a primary focus on prescription drugs, OTC drugs and diagnostics. Shionogi will strive to achieve The 3rd medium-term business plan for 5 years from April 2010 through March 2015 under the slogan,”SONG for the Real Growth”, to pursue further growth globally. For more details, please visit www.shionogi.co.jp

About Eli Lilly Japan K.K.

Eli Lilly Japan K.K. is an affiliate of Eli Lilly and Company and makes a contribution to Japanese healthcare through import, development, manufacture and marketing of innovative drugs. Lilly Japan provides therapies in the areas of neuroscience, cancer, diabetes, growth disorder and musculoskeletal, including schizophrenia, depression, bipolar disorder, attention-deficit hyperactivity disorder (AD/HD), cancer (non-small-cell lung cancer, pancreatic cancer, biliary tract cancer, malignant pleural mesothelioma, urothelium cancer, breast cancer and ovarian cancer), diabetes, growth disorder and osteoporosis. For more information, visit our website at http://www.lilly.co.jp

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