



**FOR IMMEDIATE RELEASE**  
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Pfizer Japan Inc.  
Eisai Co., Ltd.

## **NEW INDICATION APPROVED IN JAPAN FOR LYRICA® CAPSULES**

Pfizer Japan Inc. (Headquarters: Tokyo, President: Ichiro Umeda, "Pfizer") announced today that it has received approval in Japan to replace the current indication of peripheral neuropathic pain for pain treatment Lyrica® Capsules (pregabalin, "Lyrica") with the new and broader indication of neuropathic pain.

The drug is co-promoted in Japan by Pfizer and Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai"), with both companies working to provide information on its proper use.

Lyrica is a therapeutic agent for the treatment of pain that was originally developed by Pfizer Inc. (United States). It is currently approved in 120 countries and regions worldwide (as of July 2012) and is recommended as a first-line treatment for neuropathic pain and fibromyalgia by leading academic societies, including the International Association for the Study of Pain. As its major mechanism of action, Lyrica is thought to express its analgesic effect by inhibiting the release of various neurotransmitters in an overexcited nervous system. Lyrica was first launched in Japan as a treatment for postherpetic neuralgia in June 2010; the agent was approved in October 2010 for the broader indication of peripheral neuropathic pain, which includes postherpetic neuralgia, and again in June 2012 for the additional indication of pain associated with fibromyalgia. This latest approval for the indication of neuropathic pain, which includes peripheral neuropathic pain, is a partial label change to the current indications for Lyrica and is based on confirmation of the drug's efficacy in treating pain associated with spinal cord injury, which is a representative central neuropathic pain disorder.

Neuropathic pain is pain that occurs as a result of nerve damage or a functional anomaly accompanying such damage, and it indicates a variety of pain types accompanied by disturbance of perception. It can be categorized as peripheral or central according to the site of the nerve lesion. The pathologies and pathogeneses of neuropathic pain are complex and varied, so it is considered to be a form of intractable pain for which NSAIDs (non-steroidal anti-inflammatory drugs) and other analgesics cannot be expected to have much effect.

With the approval of this latest indication for Lyrica, a drug with a unique mechanism of action unprecedented in approved pain treatments to date, Pfizer and Eisai will continue to contribute to improvement of quality of life in patients suffering from neuropathic pain.

**[Please refer to the following notes for a Lyrica product outline.]**

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**<Notes to editors>**

**Lyrica® Capsules Product Outline**

(Underlined parts indicate newly approved indications and usage / dosage and administration.)

Product Name: Lyrica® Capsules 25 mg, 75 mg, 150 mg

Generic Name: pregabalin

Date of Approval: April 16, 2010

Date of NHI Drug Price Listing: June 11, 2010

Date of Launch: June 22, 2010

Manufactured and Marketed by: Pfizer Japan Inc.

Co-promoted by: Eisai Co., Ltd.

Indications and Usage: Neuropathic pain,  
Pain associated with fibromyalgia

Dosage and Administration: Neuropathic pain  
The usual adult dosage for oral use begins at 150 mg/day of pregabalin twice daily, and should be gradually increased to 300 mg/day over 1 week or more. Dosage should be adjusted, depending on age or symptoms. However, the daily maximum dose should not be beyond 600 mg, and should be orally administered twice daily.

Pain associated with fibromyalgia  
The usual adult dosage for oral use begins at 150 mg/day of pregabalin twice daily, and should be gradually increased to 300 mg/day over 1 week or more and then maintained at 300-450 mg/day as needed. Dosage should be adjusted, depending on age or symptoms. However, the daily maximum dose should not be beyond 450 mg, and should be orally administered twice daily.