



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

## **Lyrica<sup>®</sup> Capsules Approved in Japan for Additional Indication of Pain Associated with Fibromyalgia**

Pfizer Japan Inc. (Headquarters: Tokyo, President: Ichiro Umeda, "Pfizer") announced today that it has received approval to market Lyrica<sup>®</sup> Capsules (pregabalin, "Lyrica") in Japan for the additional indication of pain associated with fibromyalgia.

Lyrica 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 proper use of the drug.

Fibromyalgia is a condition characterized by chronic widespread pain that is often accompanied by various symptoms such as fatigue, trouble sleeping and anxiety, all of which lead to a significant reduction in patients' quality of life. Although fibromyalgia is estimated to affect some two million people in Japan, there is still a lack of awareness about the condition itself, which has resulted in delays in patients seeking both diagnosis and treatment. Up until now, there have been no drugs approved in Japan for the treatment of fibromyalgia, and the medical community has long anticipated the introduction of a medicine that can be used to treat the condition efficaciously and safely based on solid evidence.

Lyrica is currently approved for various indications in 120 countries and regions worldwide (as of February 2012) and is recommended as a first-line treatment for neuropathic pain or fibromyalgia by leading academic societies both in Japan and overseas, including the International Association for the Study of Pain. Lyrica was first approved in Japan as a treatment for postherpetic neuralgia in June 2010, with the agent being approved in October of the same year for the new broader indication of peripheral neuropathic pain, which includes postherpetic neuralgia. This latest approval of Lyrica for additional indication of pain associated with fibromyalgia was based on efficacy and safety confirmed in a Phase III, double blind, comparative study and a long-term study conducted in Japan.

With the approval of this latest indication, Pfizer and Eisai expect to be able to offer Lyrica as a new treatment option to patients suffering from fibromyalgia 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:	Peripheral neuropathic pain, <u>Pain associated with fibromyalgia</u>
Dosage and Administration:	Peripheral 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.  <u>Pain associated with fibromyalgia</u> <u>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.</u>