



FOR IMMEDIATE RELEASE

April 16, 2010

Pfizer Japan
Eisai Co., Ltd

Lyrica[®] has been approved for treatment of postherpetic neuralgia

Tokyo, Japan, April 16, 2010—Pfizer Japan Inc. (Head Office: Tokyo; President: Ichiro Umeda) announced that Lyrica[®] Capsules (generic name: pregabalin) has been approved today in Japan for the treatment of postherpetic neuralgia.

This product will be jointly promoted in Japan by Pfizer Japan Inc. and Eisai Co., Ltd. (Headquarters: Tokyo; President and CEO: Haruo Naito).

Lyrica was developed by Pfizer Inc. (USA) and is currently approved in over 105 countries worldwide. Its major mode of action is thought to express its analgesic effects by suppressing the output of various neurotransmitters from overexcited nerves. The efficacy and safety of Lyrica have already been proven in a number of clinical trials. Lyrica is also listed as a first-line drug in the treatment guidelines/algorithm for neuropathic pain (including postherpetic neuralgia) in the United States and Europe.

Postherpetic neuralgia (PHN) is a disorder representative of peripheral neuropathic pain caused by nerve damage. Herpes zoster appears when viral resistance is lowered due to latent neuromuscular infection by varicella / herpes zoster viruses following first infection with chicken pox. PHN is considered an intractable pain, and symptoms include continued burning or electric shock-like pain after skin symptoms of herpes zoster have healed.

Lyrica has an entirely new mode of action from existing analgesic treatments, and domestic phase 3 trials have confirmed the efficacy and safety of its analgesic effects. It is also under review for indication approval for peripheral neuropathy, and development is underway to secure indication for fibromyalgia.

With this approval, Pfizer Japan Inc. and Eisai Co., Ltd. will contribute to the QOL improvement for patients with PHN by providing Lyrica Capsules as a new treatment.

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Outline of Lyrica®

Product name: Lyrica® Capsules (25mg, 75mg, 150 mg)
Generic name: Pregabalin
Approval date: April 16, 2010
Manufacture/sold by: Pfizer Japan Inc.
Co-promotion with: Eisai Co., Ltd.
Effect/efficacy: Postherpetic neuralgia
Administration/dosage: Normally, adults are orally administered an initial dosage of 150mg pregabalin in two divided doses per day. Then, daily dosage is titrated to 300mg over one week. The amount of dosage varies depending on age and symptoms. However, daily dosage should never exceed 600mg and should be orally administered in two divided doses per day.

Property:

1. Abundant evidence

Approved in 105 countries and regions around the world (as of April 2010)
Recommended by the International Association for the Study of Pain and various other overseas academic societies as a first-line drug in the treatment of postherpetic neuralgia.

2. New action mechanism

Unlike existing analgesic treatments, Lyrica® has a new action mechanism where it binds to calcium ion channel $\alpha_2\delta$ sub-units which are distributed in the nervous system

3. Superior analgesic effect

Takes effect from the first week of administration
Effect maintained even for long-term administration

4. Safety profile

In a domestic dose-response trial, a domestic long-term administration trial, a foreign late phase 2 trial, a foreign phase 3 trial and a foreign long-term administration trial, adverse events (including abnormal clinical laboratory test results) were found to have occurred in 1,084 cases (64.5%) out of 1,680 cases. The most common adverse events were floating dizziness (393 cases, 23.4%), somnolence (267 cases, 15.9%), and edema (179 cases, 10.7%) (based on the total of investigation data collected prior to approval) Severe adverse events reported were heart failure, lung edema, loss of consciousness, rhabdomyolysis, renal failure, and blood vessel edema.

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