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FDA NEWS RELEASE

FOR IMMEDIATE RELEASE

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FDA Approves First Drug for Treating Fibromyalgia

The U.S. Food and Drug Administration today approved Lyrica (pregabalin), the first drug to treat fibromyalgia, a disorder characterized by pain, fatigue and sleep problems.

Lyrica reduces pain and improves daily functions for some patients with fibromyalgia.

"Today's new approval marks an important advance, and provides a reason for optimism for the many patients who will receive pain relief with Lyrica," said Steven Galson, M.D., M.P.H., director of FDA's Center for Drug Evaluation and Research. "However, consumers should understand that some patients did not experience benefit in clinical trials. We still have more progress to make for treatment of this disorder."

Persons with fibromyalgia typically experience long-lasting or chronic pain, as well as muscle stiffness and tenderness. Fibromyalgia affects about 3 million to 6 million people in the United States each year. The disorder mostly affects women and typically develops in early-to-middle adulthood.

There is no test for the diagnosis of fibromyalgia. Doctors make a diagnosis by conducting physical examinations, evaluating symptoms, and ruling out other conditions.

Individuals with fibromyalgia have been shown to experience pain differently from other people. Studies have shown that such patients have decreased pain after taking Lyrica, but, the mechanism by which Lyrica produces such an effect is unknown.

Two double-blind, controlled clinical trials, involving about 1,800 patients, support approval for use in treating fibromyalgia with doses of 300 milligrams or 450 milligrams per day.

The most common side effects of Lyrica include mild-to-moderate dizziness and sleepiness. Blurred vision, weight gain, dry mouth, and swelling of the hands and feet also were reported in clinical trials. The side effects appeared to be dose-related. Lyrica can impair motor function and cause problems with concentration and attention. FDA advises that patients talk to their doctor or other health care professional about whether use of Lyrica may impair their ability to drive.

Lyrica already is approved for treating partial seizures, pain following the rash of shingles and pain associated with diabetes nerve damage (diabetic neuropathy).

Lyrica is manufactured by New York-based Pfizer Inc. Pfizer has agreed to perform a study of the drug in children with fibromyalgia and a study in breastfeeding women.

To see a consumer article called *Living with Fibromyalgia, First Drug Approved*, visit www.fda.gov/consumer/updates/fibromyalgia062107.html

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