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Pfizer Receives Six Months Pediatric Exclusivity for LYRICA® (pregabalin)

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Pfizer Inc. (NYSE: PFE) today announced that the U.S. Food and Drug Administration (FDA) has granted pediatric exclusivity for LYRICA®. This grant extends the period of U.S. market exclusivity for LYRICA by an additional six months, to June 30, 2019.

LYRICA is currently approved in the U.S. for fibromyalgia, diabetic nerve pain, spinal cord injury nerve pain and pain after shingles in adults. LYRICA is also approved as adjunctive therapy for the treatment of partial onset seizures in patients four years of age and older.

The pediatric exclusivity determination is based on data from the LYRICA Pediatric Epilepsy Program, which were submitted in response to the FDA's Written Request to Pfizer to evaluate the use of LYRICA as adjunctive therapy for partial onset seizures in pediatric epilepsy patients. These were also required post-marketing studies.

Important Safety Information

LYRICA is not for everyone. LYRICA may cause serious, even life threatening, allergic reactions. Stop taking LYRICA and call your doctor right away if you have any signs of a serious allergic reaction. Some signs are swelling of your face, mouth, lips, gums, tongue, throat or neck or if you have any trouble breathing, or have a rash, hives or blisters.

Drugs used to treat seizures increase the risk of suicidal thoughts or behavior. LYRICA may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Patients, family members or caregivers should call the doctor right away if they notice suicidal thoughts or actions, thoughts of self harm, or any unusual changes in mood or behavior. These changes may include new or worsening depression, anxiety, restlessness, trouble sleeping, panic attacks, anger, irritability, agitation, aggression, dangerous impulses or violence, or extreme increases in activity or talking. If you have suicidal thoughts or actions, do not stop LYRICA without first talking to your doctor.

LYRICA may cause swelling of your hands, legs and feet, which can be serious for people with heart problems. LYRICA may cause dizziness and sleepiness. You should not drive or work with machines until you know how LYRICA affects you. Also, tell your doctor right away about muscle pain or problems along with feeling sick and feverish, or any changes in your eyesight including blurry vision or if you have any kidney problems or get dialysis.

Some of the most common side effects of LYRICA are dizziness, blurry vision, weight gain, sleepiness, trouble concentrating, swelling of your hands and feet, dry mouth, and feeling "high." If you have diabetes, tell your doctor about any skin sores.

You may have a higher chance for swelling and hives if you are also taking angiotensin-converting enzyme (ACE) inhibitors so tell your doctor if you are taking these medications. You may have a higher chance of swelling of your hands or feet or gaining weight if you are also taking certain diabetes medicines. Do not drink alcohol while on LYRICA. You may have a higher chance for dizziness and sleepiness if you take LYRICA with alcohol, narcotic pain medicines, or medicines for anxiety.

Before you start LYRICA, tell your doctor if you are planning to father a child, or if you are pregnant, or plan to become pregnant. Breastfeeding is not recommended while taking LYRICA. If you have had a drug or alcohol problem, you may be more likely to misuse LYRICA.

In studies, a specific type of blood vessel tumor was seen in mice, but not in rats. The meaning of these findings in humans is not known.

Do not stop taking LYRICA without talking to your doctor. If you stop suddenly you may have headaches, nausea, diarrhea, trouble sleeping, increased sweating, or you may feel anxious. If you have epilepsy, you may have seizures more often.

Please click here for the full prescribing information and Medication Guide for LYRICA or visit http://www.lyrica.com/.

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of November 27, 2018. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about LYRICA (pregabalin), including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development; uncertainties regarding the ability to protect and enforce intellectual property and other proprietary rights; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of LYRICA; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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