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Pfizer Statement on Lyrica (Pregabalin) Patent Infringement in Japan

Monday, August 17, 2020 - 06:40am

Tokyo, Japan/New York, NY. August 17, 2020: Upjohn, a division of Pfizer, today announced that it has filed patent infringement suits against multiple generic companies alleging patent infringement related to Lyrica (pregabalin) as well as requesting a preliminary injunction. Pfizer has taken this action as a result of the decision by the Japan Ministry of Health, Labor and Welfare(MHLW)to approve generic applications referencing Pfizer's product LYRICA. We believe the amended valid patent claims recently confirmed by the Japan Patent Office on July 14, 2020 cover the LYRICA approved indications of neuropathic and fibromyalgia pain, and thus approval and subsequent commercialization of any generic version of LYRICA would constitute patent infringement. Following approval, generic versions of LYRICA would be able to enter the market following pricing decisions due to be issued in December 2020, pending the outcome of Pfizer's patent infringement lawsuit.

"Pfizer is disappointed with today's decision, which we believe violates our patent rights for Lyrica, and we have taken the appropriate legal and regulatory steps to vigorously defend our intellectual property," said Akihisa Harada, President of Pfizer Japan. "The discovery that Lyrica is effective at relieving the symptoms of enhanced sensitivity to pain (hyperalgesia) and pain from stimuli that aren't normally painful (tactile allodynia), the main symptoms of neuropathic and fibromyalgia pain, is part of the innovation of Lyrica, and that innovation continues to benefit millions of patients. We support a stable and reliable system of innovation and patent protection that is balanced with timely and lawful generic entry to protect the rights of all stakeholders."

Global Burden of Chronic Neuropathic Pain

Living with chronic pain deeply impacts many patients around the world. General population studies using validated screening methods have found that 8% of adults worldwide currently suffer from neuropathic pain and it is one of the leading causes of disability. The complex and subjective nature of pain makes it difficult to assess both in terms of intensity and response to treatment. As a result, innovation in chronic pain treatment is challenging, with few new agents approved over the past decade.

"Ten years ago, the pain treatment was focused on the administration of NSAIDs and combined with nerve block and surgical therapy. Under such circumstances, the launch of Lyrica, which has a new mechanism of action that directly affects nerves, reduced pain in many patients and improved their QOL," said Toshihiko Taguchi, M.D., Ph.D., Department of Orthopedic Surgery at Yamaguchi Rosai Hospital and former President of the Japanese Society for Spinal Surgery. "Lyrica is an innovative drug that has contributed to raise awareness of a new concept of pain called "neuropathic pain"."

Lyrica: A "Breakthrough" Treatment for Patients

The introduction of Lyrica in 2004 revolutionized the “science of pain” and significantly enhanced knowledge, treatment and understanding of neuropathic pain conditions. Prior to the advent of Lyrica, neuropathic pain was not a well understood or effectively managed condition with limited treatment options. In 2007, Lyrica received priority review by the U.S. Food and Drug Administration and was designated as a “breakthrough” treatment for fibromyalgia, a debilitating condition affecting millions of patients and for which no treatment existed.

Lyrica in Japan

Pfizer is committed to ensuring that patients benefit from important and clinically effective medicines long after the expiry of patents. Lyrica was first launched in Japan as a treatment for postherpetic neuralgia in June 2010; the agent was then 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. In 2013, Pfizer received approval in Japan to replace the indication of peripheral neuropathic pain for Lyrica with the new and broader indication of neuropathic pain. In Japan, Lyrica is co-promoted with Eisai. Please click here for the full prescribing information and Medication Guide for LYRICA or visit http://www.lyrica.com/.

Pfizer Disclosure Notice: The information contained in this statement is as of August 17, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this statement as the result of new information or future events or developments. This release contains forward-looking information about Upjohn’s filing of patent infringement suits against multiple generic companies alleging patent infringement [related to LYRICA] as well as requesting a preliminary injunction, 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, our ability to protect our patents and other intellectual property, both domestically and internationally, including against claims of invalidity that could result in loss of exclusivity, such as claims related to our LYRICA patents in Japan, and in response to any pressure, or legal or regulatory action by, various stakeholders or governments that could potentially result in us not seeking intellectual property protection for or agreeing not to enforce intellectual property related to our medicines; uncertainties regarding the impact of COVID-19 on our business, operations and financial results; other business effects, including the effects of industry, market, economic, political or regulatory conditions; 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, 2019 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 http://www.sec.gov/ and www.pfizer.com. Media Contact: Steve Danehy (212) 733-1538 Steven.Danehy@Pfizer.com Investor Contact: Ryan Crowe (212) 733-8160 Ryan.Crowe@Pfizer.com