U.S. Food and Drug Administration Approval of XELJANZ® (tofacitinib citrate) and Invitation to Media Briefing from Pfizer

Tuesday, November 06, 2012 - 06:55am

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) has received approval from the U.S. Food and Drug Administration (FDA) for XELJANZ® (tofacitinib citrate) 5 mg twice daily for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. XELJANZ may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs). XELJANZ should not be used in combination with biologic DMARDs or with potent immunosuppressives, such as azathioprine and cyclosporine.

XELJANZ (ZEL'jans') is the first approved RA treatment in a new class of medicines known as Janus kinase (JAK) inhibitors and the first new oral DMARD approved for RA in more than 10 years.

On November 6, at 6:00 P.M. ET, Pfizer will convene a panel, including Pfizer leadership and a prominent RA expert, to discuss the implications of having an additional treatment option for RA patients and rheumatologists. These panelists will be available for a Q&A session following opening remarks.

Geno Germano, President and General Manager, Specialty Care and Oncology, Pfizer – Pfizer’s business approach to RA drug development Yvonne Greenstreet, MD, Senior Vice President and Head of Medicines Development, Specialty Care Business Unit, Pfizer – XELJANZ data and clinical development program; a new approach to treating RA Mark Flanagan, Senior Principal Scientist, Pfizer – Research perspective on the development of XELJANZ Vibeke Strand, MD, Adjunct Clinical Professor, Division of Immunology and

Rheumatology, Stanford University School of Medicine – Clinical perspective on XELJANZ and what this new treatment option means for patients Liz Barrett, President, North America, Specialty Care Business Unit, Pfizer – Commitment to patients, details on patient access program

Please join the teleconference by dialing either (866) 246-2545 in the United States and Canada or (706) 634-2365 outside of the United States and Canada. The passcode is “Pfizer Approval.”

To view the press release, please visit www.pfizer.com.

For full prescribing information, including boxed warning and Medication Guide, please visit www.XELJANZ.com.

About XELJANZ

XELJANZ is a prescription medicine called a Janus kinase (JAK) inhibitor. XELJANZ is used to treat adults with moderately to severely active rheumatoid arthritis in whom methotrexate did not work well.

It is not known if XELJANZ is safe and effective in people with hepatitis B or C. XELJANZ is not for people with severe liver problems. It is not known if XELJANZ is safe and effective in children.
Important Safety Information

XELJANZ can lower the ability of the immune system to fight infections. Some people have serious infections while taking XELJANZ, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections. Healthcare providers should test patients for TB before starting XELJANZ, and monitor them closely for signs and symptoms of TB and other infections during treatment. XELJANZ may increase the risk of certain cancers by changing the way the immune system works. Lymphoma and other cancer can happen in patients taking XELJANZ. Some people taking XELJANZ get tears in their stomach or intestines. Patients should tell their healthcare providers right away if they have fever and stomach-area pain that does not go away or a change in bowel habits. XELJANZ can cause changes in certain lab test results including low blood cell counts, increases in certain liver tests and increases in cholesterol levels. Normal cholesterol levels are important to good heart health. Healthcare providers may stop XELJANZ treatment because of changes in blood cell counts or liver test results. Patients should tell their healthcare providers if they plan to become pregnant or are pregnant. It is not known if XELJANZ will harm an unborn baby. To monitor the outcomes of pregnant women

exposed to XELJANZ, a pregnancy registry has been established. Physicians are encouraged to register patients and pregnant women are encouraged to register themselves by calling 1-877-311-8972.

Patients should tell their healthcare providers if they plan to breastfeed or are breastfeeding. Patients and their healthcare providers should decide if they will take XELJANZ or breastfeed. They should not do both.

In carriers of the hepatitis B or C virus (viruses that affect the liver), the virus may become active while using XELJANZ. Healthcare providers may do blood tests for hepatitis before and during treatment with XELJANZ. Common side effects include upper respiratory tract infections (common cold, sinus infections), headache, diarrhea, nasal congestion, sore throat and runny nose (nasopharyngitis).
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At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global healthcare portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer 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 the world's leading biopharmaceutical company, we also collaborate with healthcare providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

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