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U.S. FDA Approves Pfizer's XELJANZ® (tofacitinib) for the Treatment of Active Ankylosing Spondylitis

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NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) for XELJANZ® / XELJANZ® XR (tofacitinib) for the treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.

"We are proud to offer XELJANZ, a treatment option for ankylosing spondylitis that does not require an injection or an infusion, to treat this debilitating and chronic immuno-inflammatory disease," said Mike Gladstone, Global President, Inflammation & Immunology, Pfizer. "This regulatory approval affirms the clinical value and versatility of XELJANZ, the first and only Janus kinase (JAK) inhibitor approved for five indications in the United States for the treatment of patients with certain immuno-inflammatory conditions."

The approval of XELJANZ for AS is based on data from a Phase 3, multicenter, randomized, double-blind, placebo-controlled study that evaluated the efficacy and safety of tofacitinib 5 mg twice daily versus placebo in 269 adult patients living with active AS. The study met its primary endpoint showing that at week 16, the percentage of patients achieving an Assessment in SpondyloArthritis international Society (ASAS)20 response was significantly greater with tofacitinib (56.4%, n= 75) versus placebo (29.4%, n=40) ($p<0.0001$). In addition, the percentage of patients achieving an ASAS40 response was significantly greater with tofacitinib (40.6%, n=54) versus placebo (12.5%, n=17) ($p<0.0001$), a key secondary endpoint of the study.[1] ASAS20/40 are used for defining improvement or response to treatment.[2] The safety profile observed in patients with AS treated with XELJANZ was consistent with the safety profile observed in rheumatoid arthritis (RA) and psoriatic arthritis (PsA) patients.

"Ankylosing spondylitis, a type of arthritis that causes inflammation in certain parts of the spine, affects more than 350,000 people in the U.S.[3] This disease often occurs in early adulthood and causes pain, swelling and possibly restricted mobility,"[4] said Steven Taylor, Executive Vice President, Mission and Strategic Initiatives of the Arthritis Foundation. "With this approval, physicians and patients now have an additional oral treatment option that can help address this chronic and often progressive disease."

About XELJANZ® (tofacitinib)

XELJANZ is the first and only oral JAK inhibitor approved in the United States in five indications. XELJANZ is indicated in patients who have had an inadequate response or intolerance to one or more TNF blockers: in adults with active AS, adults with moderately to severely active RA, active PsA, moderately to severe active ulcerative colitis (UC) and in children two and older with active polyarticular course juvenile idiopathic arthritis (pcJIA).

XELJANZ has been studied in more than 50 clinical trials worldwide, including more than 20 trials in RA patients, and prescribed to over 300,000 adult patients (the majority of whom were RA patients) worldwide since

2012.[5,6,7] As the developer of XELJANZ, Pfizer is committed to advancing the science of JAK inhibition and enhancing understanding of this medicine through robust clinical development programs in the treatment of immuno-inflammatory conditions.

Earlier this month, the FDA updated the prescribing information for XELJANZ and included a new boxed warning for major adverse cardiovascular events and updated boxed warnings regarding mortality, malignancies and thrombosis (with corresponding updates to applicable warnings and precautions). In addition, indications for the treatment of adults with moderately to severely active RA or active PsA, and patients who are two years of age and older with active pcJIA were revised to require inadequate response or intolerance to one or more TNF blockers.

About Ankylosing Spondylitis

Ankylosing Spondylitis is a chronic, inflammatory disease that affects men and women in early adulthood. The onset of symptoms usually occurs before the age of 30 and seldom occur after the age of 45. Symptoms of AS include chronic pain and stiffness in the back and hips for those living with the disease and can negatively impact health-related quality of life. Over time, some patients may experience fusion of the vertebrae in the spinal column.[8] According to studies, more than 350,000 people live with AS in the United States.[3]

INDICATIONS

Rheumatoid Arthritis

- XELJANZ/XELJANZ XR (tofacitinib) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more TNF blockers.
- Limitations of Use: Use of XELJANZ/XELJANZ XR in combination with biologic disease-modifying antirheumatic drugs (DMARDs) or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Psoriatic Arthritis

- XELJANZ/XELJANZ XR is indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers.
- Limitations of Use: Use of XELJANZ/XELJANZ XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Ankylosing Spondylitis

- XELJANZ/XELJANZ XR is indicated for the treatment of adult patients with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers.
- Limitations of Use: Use of XELJANZ/XELJANZ XR in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Ulcerative Colitis

- XELJANZ/XELJANZ XR is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have had an inadequate response or intolerance to one or more TNF blockers.

- Limitations of Use: Use of XELJANZ in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Polyarticular Course Juvenile Idiopathic Arthritis

- XELJANZ/XELJANZ Oral Solution is indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.
- Limitations of Use: Use of XELJANZ/XELJANZ Oral Solution in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS
Patients treated with XELJANZ* are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

If a serious infection develops, interrupt XELJANZ until the infection is controlled.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before XELJANZ use and during therapy. Treatment for latent infection should be initiated prior to XELJANZ use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

The most common serious infections reported with XELJANZ included pneumonia, cellulitis, herpes zoster, urinary tract infection, diverticulitis, and appendicitis. Avoid use of XELJANZ in patients with an active, serious infection, including localized infections.

In the UC population, XELJANZ 10 mg twice daily was associated with greater risk of serious infections compared to 5 mg twice daily. Opportunistic herpes zoster infections (including meningoencephalitis, ophthalmologic, and disseminated cutaneous) were seen in patients who were treated with XELJANZ 10 mg twice daily.

The risks and benefits of treatment with XELJANZ should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection, or those who have lived or traveled in areas of endemic TB or mycoses. Viral reactivation including herpes virus and hepatitis B reactivation have been reported. Screening for viral hepatitis should be performed in accordance with clinical guidelines before starting therapy.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with XELJANZ, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Caution is also recommended in patients with a history of chronic lung disease, or in those who develop interstitial lung disease, as they may be more prone to infection.

MORTALITY

In a large, randomized, post marketing safety study in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor comparing XELJANZ 5 mg twice a day or XELJANZ 10 mg twice a day to tumor necrosis factor (TNF) blockers, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with XELJANZ 5 mg twice a day or XELJANZ 10 mg twice a day. A XELJANZ/XELJANZ Oral Solution 10 mg twice daily (or a XELJANZ XR 22 mg once daily) dosage is not recommended for the treatment of RA or PsA. For UC, use XELJANZ at the lowest effective dose and for the shortest duration needed to achieve/maintain therapeutic response.

MALIGNANCIES

Malignancies, including lymphomas and solid tumors, have occurred in patients treated with XELJANZ and other Janus kinase inhibitors used to treat inflammatory conditions. In RA patients, a higher rate of malignancies (excluding NMSC) was observed in patients treated with XELJANZ 5 mg twice a day or XELJANZ 10 mg twice a day compared with TNF blockers.

Lymphomas and lung cancers were observed at a higher rate in patients treated with XELJANZ 5 mg twice a day or XELJANZ 10 mg twice a day in RA patients compared to those treated with TNF blockers. Patients who are current or past smokers are at additional increased risk.

Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed at an increased rate in renal transplant patients treated with XELJANZ and concomitant immunosuppressive medications.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with XELJANZ particularly in patients with a known malignancy (other than a successfully treated (NMSC), patients who develop a malignancy while on treatment, and patients who are current or past smokers. A XELJANZ 10 mg twice daily (or a XELJANZ XR 22 mg once daily) dosage is not recommended for the treatment of RA or PsA.

Other malignancies were observed in clinical studies and the postmarketing setting including, but not limited to, lung cancer, breast cancer, melanoma, prostate cancer, and pancreatic cancer. NMSCs have been reported in patients treated with XELJANZ. Periodic skin examination is recommended for patients who are at increased risk for skin cancer. In the UC population, treatment with XELJANZ 10 mg twice daily was associated with greater risk of NMSC.

MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE)

RA patients 50 years of age and older with at least one cardiovascular risk factor, treated with XELJANZ 5 mg twice daily or XELJANZ 10 mg twice daily, had a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction and stroke), compared with those treated with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue XELJANZ/XELJANZ XR/XELJANZ Oral Solution in patients that have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with XELJANZ, particularly in patients who are current or past smokers and patients with other CV risk factors. Inform patients about the symptoms of serious CV events. A XELJANZ 10 mg twice a day (or a XELJANZ XR 22 mg once daily) dosage is not recommended for the treatment of RA or PsA.

THROMBOSIS

Thrombosis, including pulmonary embolism, deep venous thrombosis, and arterial thrombosis have occurred in patients treated with XELJANZ and other Janus kinase inhibitors used to treat inflammatory

conditions. Many of these events were serious and some resulted in death. RA patients 50 years of age and older with at least one cardiovascular risk factor treated with XELJANZ 5 mg twice daily or XELJANZ 10 mg twice daily compared to TNF blockers had an observed increase in incidence of these events. Avoid XELJANZ/XELJANZ XR/XELJANZ Oral Solution in patients at risk. Discontinue XELJANZ/XELJANZ XR/XELJANZ Oral Solution and promptly evaluate patients with symptoms of thrombosis.

A XELJANZ 10 mg twice daily (or XELJANZ XR 22 mg once daily) dosage is not recommended for the treatment of RA or PsA. In a long-term extension study in UC, five cases of pulmonary embolism were reported in patients taking XELJANZ 10 mg twice daily, including one death in a patient with advanced cancer. For UC, use XELJANZ at the lowest effective dose and for the shortest duration needed to achieve/maintain therapeutic response.

GASTROINTESTINAL PERFORATIONS
Gastrointestinal perforations have been reported in XELJANZ clinical trials, although the role of JAK inhibition is not known. In these studies, many patients with rheumatoid arthritis were receiving background therapy with Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). There was no discernible difference in frequency of gastrointestinal perforation between the placebo and the XELJANZ arms in clinical trials of patients with UC, and many of them were receiving background corticosteroids. XELJANZ should be used with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis or taking NSAIDs).

HYPERSENSITIVITY
Angioedema and urticaria that may reflect drug hypersensitivity have been observed in patients receiving XELJANZ and some events were serious. If a serious hypersensitivity reaction occurs, promptly discontinue tofacitinib while evaluating the potential cause or causes of the reaction.

LABORATORY ABNORMALITIES
Lymphocyte Abnormalities: Treatment with XELJANZ was associated with initial lymphocytosis at one month of exposure followed by a gradual decrease in mean lymphocyte counts. Avoid initiation of XELJANZ treatment in patients with a count less than 500 cells/mm^3. In patients who develop a confirmed absolute lymphocyte count less than 500 cells/mm^3, treatment with XELJANZ is not recommended. Risk of infection may be higher with increasing degrees of lymphopenia and consideration should be given to lymphocyte counts when assessing individual patient risk of infection. Monitor lymphocyte counts at baseline and every 3 months thereafter.

Neutropenia: Treatment with XELJANZ was associated with an increased incidence of neutropenia (less than 2000 cells/mm^3) compared to placebo. Avoid initiation of XELJANZ treatment in patients with an ANC less than 1000 cells/mm^3. For patients who develop a persistent ANC of 500-1000 cells/mm^3, interrupt XELJANZ dosing until ANC is greater than or equal to 1000 cells/mm^3. In patients who develop an ANC less than 500 cells/mm^3, treatment with XELJANZ is not recommended. Monitor neutrophil counts at baseline and after 4-8 weeks of treatment and every 3 months thereafter.

Anemia: Avoid initiation of XELJANZ treatment in patients with a hemoglobin level less than 9 g/dL. Treatment with XELJANZ should be interrupted in patients who develop hemoglobin levels less than 8 g/dL or whose hemoglobin level drops greater than 2 g/dL on treatment. Monitor hemoglobin at baseline and after 4-8 weeks of treatment and every 3 months thereafter.

Liver Enzyme Elevations: Treatment with XELJANZ was associated with an increased incidence of liver enzyme elevation compared to placebo. Most of these abnormalities occurred in studies with background

DMARD (primarily methotrexate) therapy. If drug-induced liver injury is suspected, the administration of XELJANZ should be interrupted until this diagnosis has been excluded. Routine monitoring of liver tests and prompt investigation of the causes of liver enzyme elevations is recommended to identify potential cases of drug-induced liver injury.

Lipid Elevations: Treatment with XELJANZ was associated with dose-dependent increases in lipid parameters, including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. Maximum effects were generally observed within 6 weeks. There were no clinically relevant changes in LDL/HDL cholesterol ratios. Manage patients with hyperlipidemia according to clinical guidelines. Assessment of lipid parameters should be performed approximately 4-8 weeks following initiation of XELJANZ therapy.

VACCINATIONS
Avoid use of live vaccines concurrently with XELJANZ. The interval between live vaccinations and initiation of tofacitinib therapy should be in accordance with current vaccination guidelines regarding immunosuppressive agents. Update immunizations in agreement with current immunization guidelines prior to initiating XELJANZ therapy.

PATIENTS WITH GASTROINTESTINAL NARROWING
Caution should be used when administering XELJANZ XR to patients with pre-existing severe gastrointestinal narrowing. There have been rare reports of obstructive symptoms in patients with known strictures in association with the ingestion of other drugs utilizing a non-deformable extended-release formulation.

HEPATIC and RENAL IMPAIRMENT
Use of XELJANZ in patients with severe hepatic impairment is not recommended. For patients with moderate hepatic impairment or with moderate or severe renal impairment taking XELJANZ 5 mg twice daily or XELJANZ XR 11 mg once daily, reduce to XELJANZ 5 mg once daily. For UC patients with moderate hepatic impairment or with moderate or severe renal impairment taking XELJANZ 10 mg twice daily, reduce to XELJANZ 5 mg twice daily. If taking XELJANZ XR 22 mg once daily, reduce to XELJANZ XR 11 mg once daily.

ADVERSE REACTIONS
The most common serious adverse reactions were serious infections. The most commonly reported adverse reactions during the first 3 months in controlled clinical trials in patients with RA with XELJANZ 5 mg twice daily and placebo, respectively (occurring in greater than or equal to 2% of patients treated with XELJANZ with or without DMARDs) were upper respiratory tract infection, nasopharyngitis, diarrhea, headache, and hypertension. The safety profile observed in patients with active PsA treated with XELJANZ was consistent with the safety profile observed in RA patients.

Adverse reactions reported in ?5% of patients treated with either 5 mg or 10 mg twice daily of XELJANZ and ? 1% greater than reported in patients receiving placebo in either the induction or maintenance clinical trials for UC were: nasopharyngitis, elevated cholesterol levels, headache, upper respiratory tract infection, increased blood creatine phosphokinase, rash, diarrhea, and herpes zoster.

USE IN PREGNANCY
Available data with XELJANZ use in pregnant women are insufficient to establish a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. There are risks to the mother and the fetus associated with rheumatoid arthritis and UC in pregnancy. In animal studies, tofacitinib at 6.3 times the maximum recommended dose of 10 mg twice daily demonstrated adverse embryo-fetal findings. The relevance of these findings to women of childbearing potential is uncertain. Consider pregnancy planning and prevention

for females of reproductive potential.

* Unless otherwise stated, “XELJANZ” in the Important Safety Information refers to XELJANZ, XELJANZ XR, and XELJANZ Oral Solution.

Please see full Prescribing Information, including BOXED WARNING for XELJANZ available at: www.xeljanzpi.com.

About Pfizer Inflammation & Immunology

At Pfizer Inflammation & Immunology, we strive to deliver breakthroughs that enable freedom from day-to-day suffering for people living with autoimmune and chronic inflammatory diseases, which can be debilitating, disfiguring and distressing, dramatically affecting what they can do. With a focus on Rheumatology, Gastroenterology and Medical Dermatology, our current portfolio of approved medicines and investigational molecules spans multiple action and delivery mechanisms, from topicals to small molecules, biologics and biosimilars. Our differentiated R&D approach resulted in one of the broadest pipelines in the industry, where we purposefully match molecules to diseases where we believe they can make the biggest difference. Building on our decades-long commitment and pioneering science, we continue to advance the standard of care for patients with these debilitating diseases and are working hand-in-hand with patients, caregivers and the broader healthcare community on healthcare solutions for the many challenges of managing chronic inflammatory diseases, allowing patients to live their best lives.

To learn more, visit www.pfizer.com/science/immunology-inflammation.

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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, including innovative medicines and vaccines. 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 170 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 December 14, 2021. 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 XELJANZ / XELJANZ XR / XELJANZ Oral Solution (tofacitinib) and a new indication for XELJANZ / XELJANZ XR in the U.S. for the treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers, including their 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, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of

unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; uncertainties regarding the commercial success of XELJANZ, XELJANZ XR and XELJANZ Oral Solution; whether and when applications for XELJANZ, XELJANZ XR or XELJANZ Oral Solution for AS or any other indications may be filed in any jurisdictions; whether and when any applications that may be pending or filed for any potential indications for XELJANZ, XELJANZ XR or XELJANZ Oral Solution in any jurisdictions may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy, and, if approved, whether they will be commercially successful; uncertainties regarding the commercial or other impact of the results of clinical trial A3921133 (ORAL Surveillance) or any other Janus kinase (JAK) inhibitor studies and data, the updated prescribing information or any other potential actions by regulatory authorities based on analysis of such studies and data, including on other JAK inhibitors in our portfolio, which will depend, in part, on benefit-risk assessments and labeling determinations; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of XELJANZ, XELJANZ XR and XELJANZ Oral Solution; uncertainties regarding the impact of COVID-19 on our business, operations and financial results; 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, 2020 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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