Pfizer Highlights Leadership in Rheumatology and Inflammation with Data to be Presented at the ACR/ARHP 2014 Annual Meeting

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21 Abstracts, Including Additional Clinical Trial Data and Real-World Analyses, Add to the Body of Evidence for XELJANZ® (Tofacitinib Citrate) as a Treatment Option for Adults with Moderate to Severe Rheumatoid Arthritis - - - Efficacy Results from a Phase 2 Study of Anti-IL-6 in Patients with Systemic Lupus Erythematosus - - - Phase 1 Abstracts for Two Pfizer Biosimilars in Development; Both Assets Move into Phase 3 Comparability Trials

Pfizer Inc. announced today that it will present data for several of its marketed and investigational medicines for inflammatory and immunological conditions at the American College of Rheumatology (ACR) / Association of Rheumatology Health Professionals (ARHP) 2014 Annual Meeting (November 14-19, Boston, Massachusetts). Twenty-one abstracts for XELJANZ® (tofacitinib citrate) will be presented, including the six-year safety and efficacy analyses from long-term extension (LTE) studies and a summary of real-world patient experience, additional post-hoc analyses from the clinical development program, and health and economics outcomes research, adding to the substantial body of evidence for XELJANZ as an oral treatment option for moderate to severe rheumatoid arthritis (RA). Data will also be presented for several additional Pfizer assets, including PF-04236921, an investigational anti-IL-6 biologic in Phase 2 development for Systemic Lupus Erythematosus (SLE), LYRICA® (pregabalin) capsules CV in fibromyalgia, and two biosimilars [PF-05280586, a potential biosimilar to Rituxan®/MabThera1 (rituximab) and PF-06438179, a potential biosimilar to Remicade®2 (infliximab)].

“Inflammation is one of the core research areas for Pfizer; our robust inflammation program has spanned over 60 years and includes more than 10 assets under

investigation at various stages of development," said Steve Romano, MD, senior vice president and Head, Global Medicines Development for the Pfizer Global Innovative Pharmaceutical business. "Through our research, Pfizer is focused on addressing unmet needs for people living with inflammatory diseases that are often chronic and debilitating, such as rheumatoid arthritis and lupus. Pfizer is pleased to share new data from this growing portfolio during the ACR annual meeting as it demonstrates our continued commitment to researching and sharing scientific evidence for inflammatory conditions."

XELJANZ Data to be Presented

Highlights from the XELJANZ abstracts include post-hoc analyses from the ORAL Start study comparing the relationship between clinical measures of efficacy and patient-reported outcomes (PROs) in RA patients treated with XELJANZ monotherapy compared to methotrexate (MTX)(presentation 2488), a podium presentation of efficacy and safety observations up to six years from two open-label long-term extension studies evaluating 4,858 patients treated for a total exposure of 12,359 patient-years (presentation 849), and an analysis of post-marketing spontaneous adverse event reports over 18 months since the launch of XELJANZ in 2012 (presentation 465). Five abstracts using health economics and outcomes research on the current RA treatment paradigm from real-world data sources, including XELJANZ, will also be presented.

In the United States, XELJANZ is indicated for the treatment of adults with moderate to severe RA who have had an inadequate response or intolerance to MTX. XELJANZ may be used alone or in combination with MTX or other non-biologic, disease-modifying antirheumatic drugs (DMARDs). Use of XELJANZ in combination with biologic DMARDs or potent immunosuppressants, such as azathioprine and cyclosporine, is not recommended. The approved dose is a 5 mg pill taken twice daily. XELJANZ is not indicated in MTX-naïve patients.

Additional Data from the Pfizer Inflammation Portfolio

Pfizer will also present abstracts on an anti-IL-6 compound in subjects with SLE and on LYRICA (pregabalin) capsules CV in fibromyalgia.

Phase 1 data will be presented at the conference for two Pfizer biosimilars in development: PF-05280586, a potential biosimilar to Rituxan®/MabThera1 (rituximab) and PF-06438179, a potential biosimilar to Remicade®2 (infliximab).

"Based on the completion of these studies, we have initiated Phase 3 comparability trials for these assets," said Dr. Salomon Azoulay, global clinical and medical affairs head,

Pfizer Global Established Pharma. “We now have three biosimilars, including PF-05280014, a potential biosimilar to Herceptin®3(trastuzumab), in Phase 3 trials.”

LIST OF SELECTED ABSTRACTS OF INTEREST FROM THE INFLAMMATION PORTFOLIO

Abstracts can be accessed on the ACR 2014 annual meeting website at the following link: http://www.acrannualmeeting.org/abstracts/

XELJANZ (tofacitinib citrate)

Primary and Long-Term Extension Study Data

“Tofacitinib, an oral Janus kinase inhibitor, in the treatment of rheumatoid arthritis: safety and efficacy in open-label, long-term extension up to 6 years.” Wollenhaupt J, Silverfield J, Lee EB, et. al. [Oral Presentation 849; November 16, 2014 3:45 p.m.] “Evaluation of the effect of tofacitinib on measured glomerular filtration rate in patients with active rheumatoid arthritis.” Kremer J, Kivitz AJ, Simon-Campos JA, et. al. [Presentation 459; November 16, 2014 8:30 a.m. – 4:00 p.m.] “Effects of tofacitinib on bone marrow edema, synovitis and joint erosions in methotrexate-naïve patients with early active rheumatoid arthritis (duration ≤2 years): results of an exploratory Phase 2 MRI study.” Conaghan P, Østergaard M, Wu C, et. al. [Presentation 1181; November 17, 2014 8:30 a.m. – 4:00 p.m.] “Pharmacokinetics, bioavailability and safety of a modified-release once-daily formulation of tofacitinib in healthy volunteers.” Lamba M, Wang R, Fletcher T, et. al. [Presentation 1478; November 17, 2014 8:30 a.m. – 4:00 p.m.]
Post-hoc Analyses and Integrated Summaries

“Relationship between different clinical measurements and patient-reported outcomes: results for ORAL Start.” Fleischmann R, Strand V, Wilkinson B, et. al. [Presentation 2488; November 18, 2014 8:30 a.m. – 4:00 p.m.] “Efficacy and safety of tofacitinib following inadequate response to nonbiologic DMARD or biologic DMARD.” Charles-Schoeman C, Burmester G, Nash P, et. al. [Presentation 493; November 16, 2014 8:30 a.m. – 4:00 p.m.] “Comprehensive summary of the efficacy and safety of tofacitinib at 5 mg twice-daily in patients with rheumatoid arthritis and an inadequate response to disease-modifying antirheumatic drugs.” Bird P, Bensen W, El-Zorkany B, et. al. [Presentation 461; November 16, 2014 8:30 a.m. – 4:00 p.m.]
Safety Analyses

“Assessment of lipid changes in patients with early rheumatoid arthritis treated with tofacitinib or methotrexate over 24 months.” Charles-Schoeman C, Dikranian A, Taylor J, et. al. [Presentation 487; November 16, 2014 8:30 a.m. – 4:00 p.m.] “Analysis of non-melanoma skin cancer across the tofacitinib rheumatoid arthritis clinical program.” Curtis

JR, Lee EB, Martin G, et. al. [Presentation 460; November 16, 2014 8:30 a.m. – 4:00 p.m.] “Analysis of early neutropenia, clinical response, and serious infection events in patients receiving tofacitinib for rheumatoid arthritis.” Strand V, Dikranian A, Beal J, et. al.[Presentation 2489; November 18, 2014 8:30 a.m. – 4:00 p.m.] “Relationship between NK cell count and important safety events in rheumatoid arthritis patients treated with tofacitinib.” Van Vollenhoven R, Tanaka Y, Riese R, et. al. [Presentation 508; November 16, 2014 8:30 a.m. – 4:00 p.m.] “18-month worldwide post-marketing surveillance experience of tofacitinib.” Cohen S, Curtis JR, Fleischmann R and Chen Y. [Presentation 465; November 16, 2014 8:30 a.m. – 4:00 p.m.] “Meta-analysis of serious infections with tofacitinib and biological treatment in rheumatoid arthritis clinical trials.” Strand V, Ahadieh S, French J, et. al. [Presentation 458; November 16, 2014 8:30 a.m. – 4:00 p.m.] “Pregnancy outcomes in the tofacitinib RA safety database through April 2014.” Marren A, Chen Y, Frazier D and Geier J. [Oral Presentation 1908; November 17 4:30 p.m.]

Non-clinical

“An analysis of in-vitro cytokine inhibition profiles of tofacitinib and other Janus kinase inhibitors at clinically-meaningful concentrations.” Dowty ME, Lin TS, Wang L, et. al. [Presentation 1514; November 17, 2014 8:30 a.m. – 4:00 p.m.]
Health and Economics Outcomes Research Including Real-World Data

“Clinical characteristics of RA patients newly prescribed tofacitinib citrate (tofacitinib) in the United States after Food and Drug Administration approval: Results from the CORRONA US rheumatoid arthritis registry.” Kavanaugh A. [Presentation 1537; November 17, 2014 8:30 a.m. – 4:00 p.m.] “Effects of tofacitinib on health care resource utilization and work productivity in US patients with rheumatoid arthritis.” Strand V, Riese R, Gerber R, et. al. [Presentation 2487; November 18, 2014 8:30 a.m. – 4:00 p.m.] “Understanding patient preferences associated with the use of therapies for rheumatoid arthritis: results of conjoint analysis.” Saverno K, Louder A, Singh A, et. al. [Presentation 2395; November 18, 2014 8:30 a.m. – 4:00 p.m.] “Primary non-adherence, associated clinical outcomes and healthcare resource utilization among rheumatoid arthritis patients prescribed injectable biologics.” Harnett J, Wiederkehr D, Gerber R, et. al. [Presentation 2406; November 18, 2014 8:30 a.m. – 4:00 p.m.] “Evaluation of real world experience with non-biologic DMARDs in the treatment of RA in an electronic health record database.” Wiederkehr D, Harnett J, Gerber R, et. al.” [Presentation 100; November 16, 2014 8:30 a.m. 4:00 p.m.] “Evaluation of biologic treatment patterns, clinical outcomes, and healthcare resource utilization post-tumor necrosis factor inhibitor discontinuation in rheumatoid arthritis.” Harnett J, Wiederkehr D, Gerber R, et. al. [Presentation 1145; November 17, 2014 8:30 a.m. – 4:00 p.m.]

ANTI-IL-6

"Improvement of disease activity and reduction of severe flares following subcutaneous administration of an IL-6 monoclonal antibody (mAb) in subjects with active generalized systemic lupus erythematosus (SLE)." Wallace DJ, Popa S, Spindler AJ, et. al. [Presentation L3; November 18, 2014 5:00 p.m. - 5:15 p.m.]
BIOSIMILARS

"Immunogenicity assessment of PF-06438179, a potential biosimilar to infliximab, in healthy volunteers." Udata C, Donghua Y, Cai C, et. al. [Presentation 1501; November 17, 2014 8:30 a.m. – 4:00 p.m.] "A phase I trial comparing PF-05280586 (a potential biosimilar) and rituximab in subjects with active rheumatoid arthritis." Becker J, Donghua Y, Melia L, et. al. [Presentation 1502; November 17, 2014 8:30 a.m. – 4:00 p.m.]
LYRICA or Fibromyalgia

“Predictive modeling of a fibromyalgia diagnosis: increasing the accuracy using real world data.” Emir B, Mardekian J, Masters E, et. al. [Presentation 2076; November 17, 2014 8:30 a.m. – 4:00 p.m.] “Examination of patients newly diagnosed with fibromyalgia: use of guideline-recommended therapies and opioids in clinical practice.” Shah S, Halpern R, Cappelleri J, et. al. [Presentation 1882; November 17, 2014 4:30 p.m. – 6:00 p.m.] “Work productivity and healthcare utilization in patients with fibromyalgia and comorbid depression taking antidepressant medication.” Landen J, Burbridge C, Masters E, et. al. [Presentation 1094; November 17, 2014 8:30 a.m. – 4:00 p.m.] “Carryover effects in crossover design studies in fibromyalgia and other pain conditions.” Emir B, Whalen E, Pauer L, et. al. [Presentation 2080; November 17, 2014 8:30 a.m. – 4:00 p.m.] “The efficacy of pregabalin for treating fibromyalgia patients with moderate or severe baseline widespread pain.” Clair A and Emir B. [Presentation 1879; November 17, 2014 4:30 p.m. – 6:00 p.m.] “Understanding baseline clinical characteristics may be of use in considering the response to pregabalin in fm patients with comorbid depression.” Pauer L, Landen J, Brown P, et. al. [Presentation 1108; November 17, 2014 8:30 a.m. – 4:00 p.m.]

1. Rituxan® is a registered U.S. trademark of Biogen Idec Inc.; MabThera is a trademark of F. Hoffman-La Roche AG.

2. Remicade® is a registered U.S. trademark of Janssen Biotech, Inc.

3. Herceptin® is a registered U.S. trademark of Genentech, Inc.

XELJANZ U.S. Label Information

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 which methotrexate did not work well. XELJANZ may be used as a single agent or in combination with MTX or other non-biologic disease-modifying antirheumatic drugs (DMARDs). Use of XELJANZ in combination with biologic DMARDs or potent immunosuppressants, such as azathioprine and cyclosporine is not recommended. The recommended dose is 5 mg twice-daily (BID).

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. People should not start taking XELJANZ if they have any kind of infection unless their healthcare provider tells them it is okay. XELJANZ may increase the risk of certain cancers by changing the way the immune system works. Malignancies were observed in clinical studies of XELJANZ. The risks and benefits of treatment should be considered prior to initiating XELJANZ in patients with chronic or recurrent infection; who have been exposed to tuberculosis; with a history of a serious or an opportunistic infection; who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or with underlying conditions that may predispose them to infection. Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), was observed in clinical studies with XELJANZ. Use of live vaccines should be avoided concurrently with XELJANZ. Update immunizations in agreement with current immunization guidelines prior to initiating XELJANZ therapy. Some people who have taken XELJANZ with certain other medicines to prevent kidney transplant rejection have had a problem with certain white blood cells growing out of control (Epstein Barr virus-associated post-transplant lymphoproliferative disorder). Some people taking XELJANZ get tears in their stomach or intestines. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. Patients should tell their healthcare provider right away if they have fever and stomach-area pain that does not go away, or a change in bowel habits. 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). XELJANZ can cause changes in certain lab test results

including low blood cell counts, increases in certain liver tests, and increases in cholesterol levels. Healthcare providers should do blood tests before starting patients on XELJANZ and while they are taking XELJANZ, to check for these side effects. 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. Use of XELJANZ in patients with severe hepatic impairment is not recommended. 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 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 provider 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 before and during treatment with XELJANZ. Common side effects include upper respiratory tract infections (common cold, sinus infections), headache, diarrhea, and nasal congestion, sore throat, and runny nose (nasopharyngitis).
Please click the direct link to the full prescribing information for XELJANZ, including boxed warning and Medication Guide:http://labeling.pfizer.com/ShowLabeling.aspx?id=959.

About LYRICA

LYRICA is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy, management of post herpetic neuralgia, as adjunctive therapy for adult patients with partial onset seizures, management of fibromyalgia and management of neuropathic pain associated with spinal cord injury.

Important Safety Information

LYRICA is contraindicated in patients with known hypersensitivity to pregabalin or any of its other components. Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy.

There have been postmarketing reports of hypersensitivity in patients shortly after initiation of treatment with LYRICA. Adverse reactions included skin redness, blisters, hives, rash, dyspnea, and wheezing. Discontinue LYRICA immediately in patients with

these symptoms.

There have been postmarketing reports of angioedema in patients during initial and chronic treatment with LYRICA. Specific symptoms included swelling of the face, mouth (tongue, lips, and gums), and neck (throat and larynx). There were reports of life-threatening angioedema with respiratory compromise requiring emergency treatment. Discontinue LYRICA immediately in patients with these symptoms.

Antiepileptic drugs (AEDs) including LYRICA increase the risk of suicidal thoughts or behavior in patients taking AEDs for any indication. Monitor patients treated with any AED for any indication for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Pooled analyses showed clinical trial patients taking an AED had approximately twice the risk of suicidal thoughts or behavior than placebo treated patients. The estimated incidence rate of suicidal behavior or ideation among 27,863 AED-treated patients was 0.43 percent, compared to 0.24 percent among 16,029 placebo-treated patients, representing an increase of approximately one patient for every 530 patients treated with an AED.

The most common adverse reactions across all LYRICA clinical trials are dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, constipation, euphoric mood, balance disorder, increased appetite, and thinking abnormal (primarily difficulty with concentration/attention).

Inform patients taking LYRICA that dizziness and somnolence may impair their ability to perform potentially hazardous tasks such as driving or operating complex machinery until they have sufficient experience with LYRICA to determine its effect on cognitive and motor function.

In controlled studies, a higher proportion of patients treated with LYRICA reported blurred vision (7 percent) than did patients treated with placebo (2 percent), which resolved in a majority of cases with continued dosing. Consider more frequent assessment for patients who are already routinely monitored for ocular conditions.

Higher frequency of weight gain and edema was observed in patients taking both LYRICA and thiazolidinedione antidiabetic drugs. Exercise caution when coadministering these drugs. Patients who are taking other drugs associated with angioedema such as angiotensin converting enzyme inhibitors (ACE- inhibitors) may be at increased risk of developing angioedema. Exercise caution when using LYRICA in patients who have had a previous episode of angioedema.

LYRICA may exacerbate the effects of oxycodone, lorazepam, or ethanol on cognitive and gross motor functioning.

Patients with a history of drug or alcohol abuse may have a higher chance of misuse or abuse of LYRICA.

Withdraw LYRICA gradually over a minimum of 1 week. Discontinue LYRICA immediately in patients with symptoms of hypersensitivity or angioedema.

Patients with a creatinine clearance of 30 to 60 mL/min had a greater incidence of discontinuation due to adverse reactions than patients with normal creatinine clearance. Adjust the daily dose of LYRICA for patients with reduced renal function (creatinine clearance ≤60 mL/min) and in those undergoing hemodialysis. Administer a supplemental dose of LYRICA immediately following every 4-hour hemodialysis treatment.

In standard, preclinical in vivo lifetime carcinogenicity studies of LYRICA, an unexpectedly high incidence of hemangiosarcoma was identified in 2 different strains of mice. The clinical significance of this finding is unknown. In clinical studies across various patient populations comprising 6396 patient-years of exposure in patients >12 years of age, new or worsening preexisting tumors were reported in 57 patients.

Please see full LYRICA prescribing information at www.LYRICA.com.

About Pfizer Biosimilars

Pfizer is leveraging its breadth of therapeutic area expertise, advanced R&D capabilities, technology, manufacturing capability and commercial scale to build a broad portfolio of medicines, including biosimilar and innovative medicines, to meet the needs of our patients and the broader healthcare community by offering a wide array of therapeutic choices. Pfizer’s dedication to creating quality biosimilar medicines reflects our commitment to address the evolving needs of patients, payers, and physicians throughout the world. Pfizer’s clinical stage pipeline in biosimilars includes five monoclonal antibodies (mAb) ranging from Phase 1 through Phase 3 clinical development. For more information, please visitwww.Pfizer.com.

Pfizer Inc.: Working together for a healthier world®

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, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of November 12, 2014. 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 statements about XELJANZ, LYRICA, and certain product candidates (PF-05280586, PF-06438179 and PF-04236921) that involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Forward-looking statements include statements regarding the potential benefits of such products and product candidates, as well as clinical trial data relating to such products and product candidates and the potential implications of such data. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data, and the need for additional clinical studies to confirm certain results discussed in this release; whether and when new drug applications or supplemental drug applications may be filed or re-filed in any jurisdictions for the products and product candidates; whether and when regulatory authorities in jurisdictions in which such applications are pending, will be submitted or will be re-filed will approve such applications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such products and product candidates; 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, 2013 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

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