Appendix E: Journal Information Piece for Family Practitioners, General Practitioners, and Internal Medicine Specialists

Important Drug Warning for Family Practitioners, General Practitioners, and Internal Medicine Specialists about Risks and Potential Risks with XELJANZ

XELJANZ® (tofacitinib citrate) is an inhibitor of Janus kinases (JAKs) approved by the Food and Drug Administration (FDA) for adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). The recommended dose of XELJANZ is 5 mg twice daily.

The safety and efficacy of XELJANZ® for conditions other than RA have not yet been established.

Limitations of Use
XELJANZ is not recommended to be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

Serious Risks of XELJANZ® (tofacitinib)
Serious Infections: Patients treated with XELJANZ are at increased risk for developing serious infections leading to hospitalization or death, including active tuberculosis (TB), invasive fungal infections, bacterial, viral and other infections due to opportunistic pathogens. The risk of herpes zoster is increased in patients treated with XELJANZ and appears to be higher in patients treated with XELJANZ in Japan. Avoid use of XELJANZ in patients with an active infection, including localized infections. If a serious infection develops, XELJANZ should be interrupted until the infection is controlled.

Malignancies and Lymphoproliferative Disorders: Consider the risks and benefits of XELJANZ treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing XELJANZ in patients who develop a malignancy. Lymphoma, solid cancers, and NMSC have been reported in patients treated with XELJANZ. NMSC has been identified as an adverse drug reaction.

Laboratory Abnormalities: Lymphocytes, neutrophils, hemoglobin, and lipids should be monitored, as abnormalities in these parameters were associated with XELJANZ treatment in Phase 3 clinical trials. Please see the full Prescribing Information for more information.

Reporting Adverse Events
To report any adverse events with the use of XELJANZ, contact:
- Pfizer Safety at 1-800-438-1985
- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at www.fda.gov/medwatch/report.htm
This is not a comprehensive representation of the potential risks associated with use of XELJANZ. For a complete description of these potential risks, please visit the XELJANZ REMS web site (www.XELJANZREMS.com) for Prescribing Information and Medication Guide.