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Pfizer announces results from XeljanzÃ?Â® Xr oral shift study

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Results to be Presented During a Late-Breaking Oral Session at the Annual European Congress of Rheumatology (EULAR 2019)

Pfizer Inc. has announced positive results from ORAL Shift, a Phase 3b/4 study in adult patients with moderately to severely active rheumatoid arthritis (RA). Patients who achieved low disease activity (LDA) with XELJANZ® (tofacitinib) extended release (XR) 11 mg once daily (QD) plus methotrexate (MTX) after a 24-week open-label run-in period, were randomized to evaluate the efficacy and safety of XELJANZ XR 11 mg QD as monotherapy after MTX withdrawal compared with XELJANZ XR with continued MTX.

The study demonstrated non-inferiority of MTX withdrawal with XELJANZ XR 11 mg QD compared to XELJANZ XR 11 mg QD plus MTX at week 48 as measured by the primary endpoint, the change in the Disease Activity Score (DAS28-4[ESR]) from randomization at week 24 to the end of the double-blind MTX withdrawal phase at week 48. The study results will be presented during a late-breaking oral session at the Annual European Congress of Rheumatology (EULAR 2019) in Madrid, Spain (15 June).

“The results of ORAL Shift provide important information on the use of XELJANZ XR as monotherapy after methotrexate withdrawal, which is significant as some people living with rheumatoid arthritis are unable or unwilling to use methotrexate,” said Stanley Cohen, MD, Metroplex Clinical Research Center, Dallas, TX. “From a clinical perspective, these results give physicians data to help inform the decision to take appropriate patients off methotrexate.”

XELJANZ® (tofacitinib) is approved in the U.S. for adult patients in three indications: moderately to severely active rheumatoid arthritis (RA), active psoriatic arthritis (PsA) and moderately to severely active ulcerative colitis (UC). Globally, XELJANZ is approved in more than 130 countries for the treatment of moderately to severely active RA and has been prescribed to an estimated 205,000 patients.

As the developer of tofacitinib, Pfizer is committed to advancing the science of JAK inhibition and enhancing understanding of tofacitinib through robust clinical development programs in the treatment of immune-mediated inflammatory conditions.