NON-INTERVENTIONAL STUDY REPORT ABSTRACT

Title: AN EVALUATION OF EARLY USE PATTERNS TO ASSESS THE EFFECTIVENESS OF XELJANZ® (TOFACITINIB CITRATE) IN RHEUMATOID ARTHRITIS: A RETROSPECTIVE NON-INTERVENTIONAL DATABASE STUDY OF PROSPECTIVELY COLLECTED OBSERVATIONAL DATA EMBEDDED WITHIN OPAL-QUMI

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Keywords: Tofacitinib, treatment patterns, effectiveness, adherence, real-world data

Rationale and background: Tofacitinib, a selective inhibitor of the Janus kinase (JAK) family of kinases and a targeted synthetic Disease-Modifying Anti-Rheumatic Drug (tsDMARD) is indicated for the treatment of rheumatoid arthritis (RA). Limited data exist to describe the characteristics and outcomes of patients who receive tofacitinib in a real-world setting.

Research question and objectives: To understand treatment patterns, adherence, clinical effectiveness, and PROs among Australian patients with RA treated with tofacitinib.

Study design: This is a retrospective, non-interventional cohort study for new users of tofacitinib or biologic DMARDs. Patients were propensity score matched based on age, sex, and selected baseline treatment combinations. Treatment effectiveness, persistence and percentage of patients receiving monotherapy or combination therapy were evaluated.

Setting: Data will be extracted from the Australian Optimizing Patient outcomes in Australian RheumatoLogy (OPAL) dataset that collects information from individual clinicians' routine clinical consultations.

Subjects and study size, including dropouts: To be eligible for the study patients must be: diagnosed with RA, ≥18 years of age, received ≥1 prescription for tofacitinib or a bDMARD and ≥1 year of follow-up since prescription of tofacitinib or a bDMARD.

Patients diagnosis with autoimmune rheumatic disease or inflammatory bowel disease except for RA will be excluded from the study.

Data for 652 and 2158 patients administered tofacitinib and bDMARDs respectively were extracted.

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Variables and data sources: The primary exposure of interest is an initial prescription for tofacitinib or a bDMARD during the sample selection window. The date of the first prescription after the start of the sample selection window will serve as the study index date and the beginning of the post-index period.

Results: Data from 2810 patients were extracted and 1950 patients were included in the matched population (1300 bDMARD and 650 tofacitinib). Patients were predominantly aged 55 to 74 years (57.8%) and female (81.2%). After 18 months of treatment, 52.4% and 57.8% of patients had achieved disease activity score (DAS) remission in the bDMARD and tofacitinib groups, respectively. The median treatment persistence for tofacitinib was similar to bDMARDs: 34.2 months and 33.8 months, respectively. In the overall population, more patients were prescribed tofacitinib as monotherapy (43.4%) compared with bDMARD monotherapy (33.4%).

Discussion: Results from this study suggest that tofacitinib is an effective and enduring intervention in RA with persistence and effectiveness comparable to bDMARDs with an overall trend for more use of tofacitinib as monotherapy than bDMARDs.

Marketing Authorization Holder(s): Pfizer Limited

Names and affiliations of principal investigators:

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