NON-INTERVENTIONAL STUDY REPORT ABSTRACT

Title: A Retrospective Database Study to Evaluate Rates of Influenza and Related Diagnoses between Patients Treated with Tofacitinib and Other Systemic Therapies within Cohorts of RA, PsA, and UC Patients: A Post-Authorization Safety Study of Tofacitinib

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Name and affiliation of the main author: Redacted

Keywords: tofacitinib, influenza, rheumatoid arthritis, psoriatic arthritis, ulcerative colitis

Rationale and background: Little is known about the association between treatment with immunosuppressive drugs and the incidence of influenza and influenza-related complications in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ulcerative colitis (UC). Further, guidelines on management of patients with immune-mediated disease in the context of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and coronavirus disease 2019 (COVID-19) indicate uncertainty in the rheumatology and gastroenterology communities on the safety of JAK inhibitors (JAKi), including tofacitinib, in this setting. The overall goal of this retrospective observational study was to help inform prescribers and patients of the overall safety of tofacitinib and other treatments for RA, PsA and UC with respect to the development of influenza, influenza-like illness (ILI) and associated clinical outcomes.

Research question and objectives:
What is the occurrence of influenza, influenza-like illness, and related clinical outcomes among persons prescribed Xeljanz or other systemic therapies among patients with RA, PsA and UC?

The objectives for this study were to:

- To describe demographics and clinical characteristics of RA, PsA, and UC patient cohorts.
- To describe the occurrence of influenza, influenza-like illness, and related clinical outcomes in RA, PsA and UC patients stratified by tofacitinib and other systemic therapy exposures, overall and during each influenza season.

Study design: This is a retrospective cohort study of RA, PsA, and UC patients aged ≥ 18 years from the Redacted database in the US. The study period is 01 June 2014 through 31 May 2019.

Setting: Redacted, which is derived from 150,000 healthcare providers and more than 2,000 hospitals and 7,000 clinics in the US and includes more than 103 million patients receiving care as of January 2020. Clinical, claims and other medical administrative data is obtained from both inpatient and ambulatory EHRs, practice management systems, and numerous other internal systems.

Subjects and study size, including dropouts: 199,697 patients aged ≥ 18 years were enrolled into the study: 137,910 with RA, 19,179 with PsA, and 42,608 with UC.

Variables and data sources: The variables assessed were RA, PsA, and UC diagnoses, demographics, drug class exposures, baseline comorbidities, influenza and influenza-like illness diagnoses, influenza vaccinations, influenza complication diagnoses, and hospitalizations.

Results: In RA patients, the tofacitinib-JAKi treatment group (mostly tofacitinib users) had the highest rates of influenza and influenza-like illness compared with the other treatment groups. In PsA patients, the non-TNFi treatment group had the highest rates of influenza and influenza-like illness. In UC patients, the non-TNFi group had the highest rate of influenza and the TNFi group had the highest rate of influenza-like illness. Tofacitinib-JAKi influenza counts were <3 in both PsA and UC patient groups and did not contribute meaningfully to these results.

Discussion: The study's results are descriptive only, with no adjustment for potential confounding, including patient channeling, and no distinction between monotherapy and combination therapy. Accordingly, causal attributions to a particular drug class are not warranted.

Marketing Authorization Holder(s): Pfizer Limited

Names and affiliations of principal investigators: RedactedRedacted RedactedRedactedRedactedRedacted