NON-INTERVENTIONAL/LOW-INTERVENTIONAL STUDY TYPE 1 STUDY REPORT ABSTRACT

Study Title: Non-Interventional Study to Review the Changes of Depression After First Year of Tofacitinib Treatment in Rheumatoid Arthritis (Xeljanz®)

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Keywords: tofacitinib, depression, rheumatoid arthritis (RA), anxiety, safety

Rationale and background: The occurrence of depression, pain, anxiety, and sleep disturbances can be connected to RA. As expected, these comorbidities lead to the prescription of the analgesics (opioid, non-opioid, adjuvants), anxiolytics, antidepressants and/or hypnotics. Whether the use of JAK inhibitor (tofacitinib) in the treatment of the primary disease is associated with change in the prevalence or severity of these comorbidities is not well known.

Research question and objectives: The primary objective was to describe and evaluate the changes of depression level within 12 months from the start of tofacitinib therapy in patients with RA and at least minimal level of depression. The secondary objectives were to describe and evaluate the level and changes of impact on patient´s life, anxiety and insomnia in patients with RA and at least minimal level of depression. Additionally, this study aimed to help in description of safety and effectiveness of tofacitinib for the treatment of RA.

Study design: single arm, prospective, multi-center non-interventional study

Setting: This non-interventional study followed the population of patients with moderate to severe rheumatoid arthritis, who were currently prescribed tofacitinib treatment for the first time and who scored at least 11 points on CUDOS scale (equivalent of minimal depression). Patients were followed for the period of 12 months and had a total of 3 visits per patient as per common medical care.

Subjects and study size, including dropouts: A total of 73 patients were enrolled in the study (signed an informed consent form). Data analysis included 70 patients at Visit 1, 66 patients at Visit 2 and 62 patients at Visit 3. The originally planned sample size (123 patients without drop-out) was not reached.

Variables and data sources: The data were obtained from medical records and patient questionnaires (CUDOS, CUXOS, JSEQ), this study did not impose any changes to the routine management of patients.

Results: The mean CUDOS score decreased from 21.97 points to 9.29 points after 12 months of tofacitinib treatment. The mean CUXOS decreased from 20.45 points to 8.21 points. The mean JSEQ score decreased from 9.40 points to 5.48 points.

Discussion: In Patient with rheumatoid arthritis, after 12 months of tofacitinib treatment in this study reduction in depression of more than 10% was observed. In addition, to that the level of anxiety, insomnia and impact of the disease on patient´s life decreased as well. These are descriptive results that do not support any further conclusions. Additional exploration is needed to control for confounders and permit analysis of causality. The safety evaluations confirm the risk-profile of tofacitinib treatment as a medication with a low frequency of adverse events.

Marketing Authorization Holder(s):

[redacted]

Names and affiliations of principal investigators:

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