following IRs were observed in the current all-bari-RA: gastrointestinal (GI) perforation (0.04), and tuberculosis (TB) (0.14). Fewer than 1% of pts discontinued due to abnormal lab results.

Conclusions: In this updated integrated analysis of patients with moderately to severely active RA, including patients exposed for up to 6 years, baricitinib maintained a safety profile that was similar to that previously reported (1,2) acceptable in the context of demonstrated efficacy (3,4).

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FREQUENCY AND DURATION OF EARLY NON-SERIOUS ADVERSE EVENTS IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH TOFACITINIB 5 MG TWICE DAILY AS MONOTHERAPY AND COMBINATION THERAPY

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Objectives: Tolerability remains ill-defined in clinical trials and most commonly refers to non-serious adverse events (AEs) that may impact patient satisfaction and treatment adherence. Tofacitinib is an oral Janus kinase inhibitor for the treatment of RA. This update to a previously reported post hoc analysis[1] describes the frequency and duration of the most commonly reported non-serious AEs related to tolerability in patients with RA receiving tofacitinib 5 mg twice daily (BID) as monotherapy or in combination with conventional synthetic (cs) DMARDs in Phase (P)3 and P3b/4 studies.

Methods: Data were pooled from the following studies of tofacitnib in patients with moderate to severe RA: ORAL Step (NCT00960440); ORAL Solo (NCT00814307); ORAL Scan (NCT00847613); ORAL Sync (NCT00856544); ORAL Standard (NCT00853385); and ORAL Strategy (NCT02187055). This analysis included data from patients receiving tofacitinib 5 mg BID monotherapy (ORAL Solo, ORAL Strategy), placebo (PBO; ORAL Solo), or tofacitinib 5 mg BID or PBO with csDMARDs (all studies except ORAL Solo). Non-serious AEs (defined as AEs affecting patients' day-to-day experience and ability to tolerate treatment) with an incidence rate (IR, patients with events per 100 patient-years [PY]) ≥5 were evaluated up to Month 3. Infections, laboratory test abnormalities, general disorders, or events not reported directly by patients, and musculoskeletal events likely due to underlying RA, were excluded, to focus on AEs that could impact treatment adherence.

Results: Of the 2657 patients included in the analysis; 1976 received tofacitinib 5 mg BID (monotherapy: N=627; combination: N=1349); 681 received PBO (monotherapy: N=122; combination: N=559). Up to Month 3, the most frequently reported non-serious AEs which met the search criteria were headache, diarrhea, nausea, vomiting, dyspepsia, and abdominal pain upper; IRs ≥10 were observed for headache and diarrhea (tofacitinib 5 mg BID monotherapy, combination therapy and PBO monotherapy), and nausea (PBO monotherapy and combination therapy). Duration of AEs was ≤4 weeks for the majority of patients experiencing headache, diarrhea, or gastric discomfort (defined as any gastrointestinal pain, dyspepsia, epigastric discomfort, or abdominal discomfort or pain). Overall, in patients receiving tofacitinib 5 mg BID and PBO, respectively, 43.2% and 64.7% experienced headache; 66.1% and 81.3% experienced diarrhea; and 36.2% and 58.6% experienced gastric discomfort, for ≤2 weeks. The majority of AEs were mild or moderate.

Conclusions: Overall, non-serious, non-infectious AEs were mild or moderate and self-limiting. The frequency of non-serious AEs was comparable for patients receiving tofacitinib as monotherapy, or in combination with csDMARDs, and was generally similar for patients receiving tofacitinib compared with patients receiving PBO.

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TOFACITINIB IN RHEUMATOID ARTHRITIS: AN UPDATED ANALYSIS OF REAL-WORLD DATA IN LATIN AMERICA

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Objectives: Tofacitinib is an oral Janus kinase inhibitor for the treatment of rheumatoid arthritis (RA). It is administered as monotherapy or in combination with conventional synthetic disease-modifying antirheumatic drugs (csDMARDs). A previous analysis characterized patients with RA who initiated tofacitinib and assessed the safety of tofacitinib in a real-world Latin American (LA) setting.[1]Here, we provide an updated analysis involving a larger patient population across more LA countries.

Methods: All adult patients with RA who initiated tofacitinib from 29 private/public centers in 10 countries (Argentina, Brazil, Chile, Colombia, Dominican Republic, Ecuador, Guatemala, Mexico, Panama, Peru) were considered for inclusion in this observational analysis. Data were obtained via a standardized format focusing on demographics, drug history, adverse events (AEs), AEs of special interest, latent tuberculosis (TB) screening (positive purified protein derivative or QuantiFERON-TB Gold), selected confirmed laboratory abnormalities (defined in terms of increases above upper limit of normal [ULN], or cell counts <500 cells/mm^3), and discontinuation rates.

Results: In 582 patients (90.9% female), mean age was 51.8 years, mean disease duration was 10.5 years, and mean tofacitinib exposure was 13.6 months (659.6 total patient-years). Tofacitinib treatment was post-csDMARD in 51.5% of patients, post-1 biologic DMARD (bDMARD) in 21.6%, and post-≥2 bDMARDs in 26.8%; 39.3% of patients received tofacitinib monotherapy and 60.7% of patients received tofacitinib with csDMARDs. Of the 42/548 patients (7.7%) vaccinated against herpes zoster (HZ) before starting tofacitinib, none developed HZ. Of 40/548 patients (7.3%) with latent TB, none developed TB infections. 90 AEs, 9 serious infections, 18 HZ AEs (none multidermatomal, serious or severe), 1 malignancy (thyroid cancer), and 1 opportunistic infection (TB) occurred. Elevations >3 × ULN of liver enzymes, increases of creatine phosphokinase >ULN, and cytopenias (<500 cells/mm^3) were infrequent (≤1%). Tofacitinib was withdrawn in 86 (14.8%) patients due to lack of efficacy (n=43; 7.4%), AEs (n=27; 4.6%), or other reasons (n=16; 2.7%).

Conclusions: In this analysis of real-world LA data, almost 40% of patients starting tofacitinib received monotherapy and around half were using tofacitinib as second-line treatment post-csDMARD failure. Safety appeared consistent with that of approved bDMARDs; [2] there were no new safety concerns versus clinical trials of tofacitinib in LA patients with RA.[3] However, the analysis is limited by the small sample size and limited exposure follow-up.

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EXPERIENCE OF THE USE OF BIOLOGICAL THERAPIES IN A URUGUAYAN CENTER OF RHEUMATOLOGY: DATA FROM THE BIOBADAGUAY REGISTRY

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