Abstract #: 5

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Title: **Effectiveness and safety of tofacitinib in Canadian patients with rheumatoid arthritis: primary results from a multicentre, observational study**

Objective(s): To describe primary and key secondary effectiveness and safety endpoints in the first, ongoing, large-scale, national, observational study (CANTORAL) assessing effectiveness/safety of a Janus kinase inhibitor (tofacitinib) in Canadian patients with rheumatoid arthritis (RA).

Method(s): Patients with moderate-to-severe RA initiating tofacitinib between November 2017–July 2020 were enrolled across 45 Canadian sites and managed per clinical standard of care. Effectiveness (to Month [M]12) was assessed in enrolled patients (full analysis set), and safety (to M36) was evaluated in patients with ≥1 post-baseline visit (safety analysis set) as of February 26, 2021. Co-primary endpoints: proportions of patients achieving CDAI low disease activity (LDA; <10) and remission (<2.8) at M6. Secondary endpoints: proportions of patients achieving CDAI LDA and remission, DAS28-4(ESR) LDA (<3.2) and remission (<2.6), and DAS28-4(CRP) <3.2 and <2.6, over time; proportions of patients achieving improvements in HAQ-DI ≥minimum clinically important difference (MCID; ≥0.22), HAQ-DI normative values (≤0.25), and ≥50% Pain (VAS) improvement at M3. Safety outcomes: treatment-emergent adverse events (TEAEs), serious AEs (SAEs), deaths, and AEs of special interest.

Result(s): 504 patients were included (female: 77.8%, white: 82.9%, mean age: 59.3 years, mean disease duration: 10.2 years, bDMARD-naïve: 66.5%, receiving baseline background csDMARDs: 62.5%). At M6, 61.1% and 17.8% of patients achieved CDAI LDA and remission, respectively. A similar pattern was observed at M3 for DAS28-4(CRP) <3.2 and <2.6 (61.6% and 38.1%, respectively) and LDA and remission, measured by CDAI (47.6% and 13.4%, respectively) and DAS28-4(ESR) (49.8% and 26.9%, respectively); results were maintained to M12. At M3, HAQ-DI MCID, normative values, and ≥50% Pain improvement were achieved by 53.7%, 19.9%, and 42.9% of patients, respectively. Of 495 patients, 64.8% (IR [events per 100 patient-years]: 126.6) and 10.5% (IR: 11.1) of patients experienced TEAEs and SAEs, respectively; deaths occurred in 3 (IR: 0.7) patients. Serious infections, MACE, herpes zoster (non-serious/serious), malignancies excluding NMSC, NMSC, and thrombosis (arterial or venous thrombosis) were reported in 3.8% (IR: 4.6), 0.6% (IR: 0.4), 1.6% (IR: 1.4), 1.6% (IR: 1.4), 0.8% (IR: 0.8), and 0.2% (IR: 0.2) of patients, respectively.

Conclusion(s): CANTORAL results are consistent with tofacitinib efficacy/safety in the RA clinical program and Canadian observational studies of advanced therapies approved for RA. Limitations included the small sample size and limited duration of follow-up.

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