Tofacitinib Efficacy in Patients with Rheumatoid Arthritis and Probable Depression/Anxiety: Post-Hoc Analysis of Phase 3 and 3b/4 Randomized Controlled Trials

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ELECTRONIC SUPPLEMENTARY MATERIAL

Table S1 Summary of phase 3 and phase 3b/4 RCTs included in the post-hoc analysis

ClinicalTrials.gov identifier	Protocol number	Patients initially receiving tofacitinib, *n*	Patient population	Tofacitinib doses	Control arm	Study duration
Phase 3						
NCT00960440[a]	ORAL Step, A3921032	267	Moderate to severe RA with inadequate response to TNFi	5 or 10 mg BID with background MTX	Placebo (advanced to tofacitinib at month 3)	6 months
NCT00847613[b]	ORAL Scan, A3921044	637	Active RA with inadequate response to MTX	5 or 10 mg BID with background MTX	Placebo (advanced to tofacitinib at month 3 [non-responders] or 6 [remaining patients])	24 months
NCT00814307[c]	ORAL Solo, A3921045	488	Active RA with inadequate response to ≥ 1 DMARD	5 or 10 mg BID monotherapy	Placebo (advanced to tofacitinib at month 3)	6 months
NCT00856544[d]	ORAL Sync, A3921046	633	Active RA with inadequate response to ≥ 1 DMARD	5 or 10 mg BID with background non-biologic DMARD	Placebo (advanced to tofacitinib at month 3 [non-responders] or 6 [remaining patients])	12 months
NCT00853385[e]	ORAL Standard, A3921064	405	Active RA with incomplete response to MTX	5 or 10 mg BID with background MTX	Adalimumab 40 mg SC Q2W; placebo (patients receiving placebo were advanced to tofacitinib at month 3 [non-responders] or 6 [remaining patients])	12 months
Phase 3b/4						
NCT02187055[f]	ORAL Strategy, A3921187	760	Active RA with incomplete response to MTX	5 mg BID monotherapy or with background MTX	Adalimumab 40 mg SC Q2W with background MTX	12 months

[a]Burmester GR, et al. Lancet. 2013;381:451–60. [b]van der Heijde D, et al. Arthritis Rheum. 2013;65:559–70. [c]Fleischmann R, et al. N Engl J Med. 2012;367:495–507. [d]Kremer J, et al. Ann Intern Med. 2013;159:253–61. [e]van Vollenhoven RF, et al. N Engl J Med. 2012;367:508–19. [f]Fleischmann R, et al. Lancet. 2017;390:457–68.
BID twice daily, *DMARD* disease-modifying antirheumatic drug, *MTX* methotrexate, *Q2W* every 2 weeks, *RA* rheumatoid arthritis, *RCT* randomized controlled trial, *SC* subcutaneous, *TNFi* tumor necrosis factor inhibitor