

Supplementary Table 1. Phase III and LTE studies included in this analysis (1)

Study name	ClinicalTrials.gov identifier	Patients receiving tofacitinib, n	Patient population	Tofacitinib dose	Control group	Study duration
Phase III						
ORAL Step, A3921032 (2)	NCT00960440	267	Patients with moderate to severe RA with inadequate response to TNFi	5 or 10 mg BID with background MTX	Placebo	6 months
ORAL Solo, A3921045 (3)	NCT00814307	610	Patients with active RA with inadequate response to ≥ 1 DMARD	5 or 10 mg BID monotherapy	Placebo (advanced to tofacitinib at month 3)	6 months
ORAL Sync, A3921046 (4)	NCT00856544	792	Patients with active RA with inadequate	5 or 10 mg BID with background csDMARD	Placebo (non-responders advanced to	12 months

			response to ≥1 DMARD		tofacitinib at month 3; all remaining placebo patients advanced to placebo at month 6)	
ORAL Start, A3921069 (5)	NCT01039688	770	MTX-naïve patients with active RA	5 or 10 mg BID monotherapy	MTX	24 months
ORAL Scan, A3921044 (6)	NCT00847613	797	Patients with active RA with inadequate response to MTX	5 or 10 mg BID with background MTX	Placebo (non-responders advanced to tofacitinib at month 3; all remaining placebo patients advanced to placebo at month 6)	24 months

ORAL Standard, A3921064 (7)	NCT00853385	513	Patients with active RA with incomplete response to MTX	5 or 10 mg BID with background MTX	Adalimumab 40 mg SC Q2W; placebo (non-responders advanced to tofacitinib at month 3; all remaining placebo patients advanced to placebo at month 6)	12 months
LTE						
ORAL Sequel, A3921024 (8, 9)	NCT00413699	2,308 (as of March 31, 2015)	Patients with active RA who participated in phase I, II, or III index studies	5 or 10 mg BID, concomitant DMARDs permitted	None	Ongoing

A3921041 (8-10)	NCT00661661	486	Japanese patients with active RA who participated in phase II studies A3921039 and A3921040 or phase III ORAL Scan	5 or 10 mg BID, concomitant DMARDs permitted	None	72 months
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BID = twice daily; csDMARD = conventional synthetic DMARD; DMARD = disease-modifying antirheumatic drug; LTE = long-term

extension; MTX = methotrexate; Q2W = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous; TNFi = tumor necrosis factor inhibitor

References

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