

Online supplementary table 1 Events in the open-label phase due to the COVID-19 pandemic: protocol deviations, discontinuation of study drug and withdrawal from study

Patients with events, n (%)	Tofacitinib 5 mg BID (N=133)	Placebo→ tofacitinib 5 mg BID (N=136)
Protocol deviations	21 (15.8)	22 (16.2)
Did not remain on stable dose of permitted concomitant medication as specified per protocol	0	2 (1.5)
Revised/updated ICD not signed at the first patient visit after the revised/approved ICD was available at site	0	1 (0.7)
Dosing/administration error: patient temporarily stopped study drug administration for a longer duration than allowed after Week 16 visit	0	2 (1.5)
Lab performed out of visit window	2 (1.5)	0
Lab samples after Week 16 visit were not collected for a study visit	12 (9.0)	14 (10.3)
Patient was a woman of childbearing potential, and pregnancy testing or FSH testing was not performed, or negative test result was not documented prior to dosing	1 (0.8)	0
ECGs not performed at protocol-required time points or out of acceptable time window or not submitted to central vendor	7 (5.3)	9 (6.6)
Efficacy assessments/procedures not performed at appropriate visits	11 (8.3)	14 (10.3)
Patient-reported outcome questionnaires not performed at appropriate visits	0	1 (0.7)
Procedure/test not performed as specified in the protocol	15 (11.3)	16 (11.8)
Missing or incomplete visits or visits occurring outside of allowable visit windows	14 (10.5)	13 (9.6)
Discontinued study drug	0	3 (2.2)
Withdrawal from study by patient	0	2 (1.5)

Data are from the Week 48 final analysis.

All patients had completed the double-blind phase in December 2019. As such, there were no events due to COVID-19 in the double-blind phase. Throughout the study (double-blind and open-label phases), there were no cases of COVID-19.

BID, twice daily; COVID-19, coronavirus disease 2019; ECG, electrocardiogram; FSH, follicle-stimulating hormone; ICD, informed consent document; N, number of patients in safety analysis set; n, number of patients with event.