Online supplementary figure S1 Efficacy of tofacitinib 5 mg BID vs placebo at Week 16: (A) ASAS20 response^a and (B) ASAS40 response,^a stratified by bDMARD treatment history.^b



Data are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. ^aNormal approximation was used. Missing response was considered as non-response. ^bbDMARD treatment history was derived from the clinical database. ASAS, Assessment of SpondyloArthritis international Society; bDMARD, biologic disease-modifying antirheumatic drug; BID, twice daily; IR, inadequate response or intolerance; N, number of patients in full analysis set; N1, number of patients in full analysis set, stratified by bDMARD treatment history; SE, standard error; TNFi, tumour necrosis factor inhibitor.

Online supplementary figure S2 Efficacy of tofacitinib 5 mg BID vs placebo \rightarrow tofacitinib 5 mg BID^a for ASAS components over time up to Week 48: (A) Δ PtGA,^b (B) Δ total back pain,^b (C) Δ BASFI^b and (D) Δ morning stiffness (inflammation; mean of questions 5 and 6 of the BASDAI).^b



Lata up to veek 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. **p<0.01, ***p<0.001 for comparing tofacitinib 5 mg BID vs placebo. *p≤0.05 for comparing tofacitinib 5 mg BID vs placebo, according to the pre-specified step-down testing procedure for type I error-control of ASAS components. *Patients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line). *Mixed model for repeated measures included fixed effects of treatment group, visit, treatment-group-by-visit interaction, stratification factor (bDMARD treatment history: bDMARD-naïve vs TNFi-IR or prior bDMARD use without IR) derived from the clinical database, stratification-factor-by-visit interaction, baseline value and baseline-value-by-visit interaction. The model used a common unstructured variance-covariance matrix, without imputation for missing values. Two separate models were used. In the analyses of results through the first 16 weeks, the data cut-off of 19 December 2019 was used; the results through Week 16 are from this model. In the analyses of the results through Week 48 (including all post-baseline data through Week 48, the Week 48 final data were used; the results from Week 24 through Week 48 are from this model. A, change from baseline; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; bDMARD, biologic disease-modifying antirheumatic drug; BID, twice daily; IR, inadequate response or intolerance; LSM, least squares mean; N, number of patients in full analysis set; N1, number of patients with observation at visit; PtGA, Patient Global Assessment of Disease Activity; SE, standard error; TNFi, tumour necrosis factor inhibitor. **Online supplementary figure S3** Efficacy of tofacitinib 5 mg BID vs placebo→tofacitinib 5 mg BID^a over time up to Week 48: (A) ASAS partial remission^b and (B) ASAS 5/6 response.^b



Data up to Week 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. *p<0.05, ***p<0.001 for comparing tofacitinib 5 mg BID vs placebo. *Patients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line). *Normal approximation adjusting for the stratification factor (bDMARD treatment history: bDMARD-naïve vs TNFi-IR or prior bDMARD use without IR) derived from the clinical database via the Cochran–Mantel–Haenszel approach was used. Missing response was considered as non-response. ASAS, Assessment of SpondyloArthritis international Society; bDMARD, biologic disease-modifying antirheumatic drug; BID, twice daily; IR, inadequate response or intolerance; N, number of patients in full analysis set; SE, standard error; TNFi, tumour necrosis factor inhibitor.

Online supplementary figure S4 Efficacy of tofacitinib 5 mg BID vs placebo→tofacitinib 5 mg BID^a over time up to Week 48: (A) ASDAS clinically important improvement,^{b,c} (B) ASDAS major improvement,^{b,d} (C) ASDAS LDA^{b,e} and (D) ASDAS inactive disease.^{b,f}



Data up to Week 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. * $p \le 0.05$, **p < 0.01, ***p < 0.001 for comparing tofacitinib 5 mg BID vs placebo. *Patients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line). *Normal approximation adjusting for the stratification factor (bDMARD treatment history: bDMARD-naïve vs TNFi-IR or prior bDMARD use without IR) derived from the clinical database via the Cochran–Mantel–Haenszel approach was used. Missing response was considered as non-response. *Analysed in patients with baseline ASDAS ≥ 1.736 : tofacitinib 5 mg BID, N1=132; placebo \rightarrow tofacitinib 5 mg BID, N1=136. *Analysed in patients with baseline ASDAS ≥ 2.636 : tofacitinib 5 mg BID, N1=123; placebo \rightarrow tofacitinib 5 mg BID, N1=129. *Analysed in patients with baseline ASDAS ≥ 2.636 : tofacitinib 5 mg BID, N1=136. *Analysed in patients with baseline ASDAS ≥ 2.1 : tofacitinib 5 mg BID, N1=131; placebo \rightarrow tofacitinib 5 mg BID, N1=136. *Analysed in patients with baseline ASDAS ≥ 1.33 : tofacitinib 5 mg BID, N1=133; placebo \rightarrow tofacitinib 5 mg BID, N1=136. ASDAS, Ankylosing Spondylitis Disease Activity Score using high-sensitivity C-reactive protein; bDMARD, biologic disease-modifying antirheumatic drug; BID, twice daily; IR, inadequate response or intolerance; LDA, low disease activity; N, number of patients in full analysis set; N1, number of patients who met the baseline ASDAS inclusion criterion for the analysis; SE, standard error; TNFi, tumour necrosis factor inhibitor.

Placebo

Online supplementary figure S5 Efficacy of tofacitinib 5 mg BID vs placebo \rightarrow tofacitinib 5 mg BID^a over time up to Week 48: (A) Δ BASDAI^b and (B) BASDAI50 response.^c



Data up to Week 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. *p<0.05, ***p<0.001 for comparing tofacitinib 5 mg BID vs placebo. ^aPatients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line). ^bMixed model for repeated measures included fixed effects of treatment group, visit, treatment-group-by-visit interaction, stratification factor (bDMARD treatment history: bDMARD-naïve vs TNFi-IR or prior bDMARD use without IR) derived from the clinical database, stratification-factor-by-visit interaction, baseline value and baseline-value-by-visit interaction. The model used a common unstructured variance-covariance matrix, without imputation for missing values. Two separate models were used. In the analyses of results through the first 16 weeks, the data cut-off of 19 December 2019 was used; the results through Week 16 are from this model. In the analyses of the results through Week 48 (including all post-baseline data through Week 48), the Week 48 final data were used; the results from Week 24 through Week 48 are from this model. "Normal approximation adjusting for the stratification factor derived from the clinical database via the Cochran–Mantel–Haenszel approach was used. Missing response was considered as non-response. Δ, change from baseline; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; bDMARD, biologic disease-modifying antirheumatic drug; BID, twice daily; IR, inadequate response or intolerance; LSM, least squares mean; N, number of patients in full analysis set; N1, number of patients with observation at visit; SE, standard error; TNFi, tumour necrosis factor inhibitor.





Data up to Week 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. *p<0.05, **p<0.01 for comparing tofacitinib 5 mg BID vs placebo. ^aPatients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line). ^bMixed model for repeated measures included fixed effects of treatment group, visit, treatment-group-by-visit interaction, stratification factor (bDMARD treatment history: bDMARD-naïve vs TNFi-IR or prior bDMARD use without IR) derived from the clinical database, stratification-factor-by-visit interaction, baseline value and baseline-value-by-visit interaction. The model used a common unstructured variance-covariance matrix, without imputation for missing values. Two separate models were used. In the analyses of results through the first 16 weeks, the data cut-off of 19 December 2019 was used; the results through Week 16 are from this model. In the analyses of the results through Week 48 (including all post-baseline data through Week 48, the Week 48 final data were used; the results from Week 24 through Week 48 are from this model. ^cAnalysed in patients with baseline MASES >0. ^dAnalysed in patients with baseline; bDMARD, biologic disease-modifying antirheumatic drug; BID, twice daily; IR, inadequate response or intolerance; LSM, least squares mean; MASES, Maastricht Ankylosing Spondylitis Enthesitis Score; N, number of patients in full analysis set; N1, number of patients with observation at visit; SE, standard error; SJC(44), swollen joint count in 44 joints; TNFi, tumour necrosis factor inhibitor.



1.7

Tofacitinib 5 mg BID, N1 33 33 33

Placebo→tofacitinib 5 mg BID, N1 38 37 37

Online supplementary figure S7 Efficacy of tofacitinib 5 mg BID vs placebo + tofacitinib 5 mg BID vs placebo + tofacitinib 5 mg BID^a over time up to Week 48: descriptive analyses of mean (A) ASDAS, (B) hsCRP (mg/dL), (C) BASMI, (D) FACIT-F total score, (E) PtGA, (F) total back pain, (G) BASFI, (H) morning stiffness (inflammation), (I) BASDAI, (J) MASES, (K) SJC(44).

0.9

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Tofacitinib 5 mg BID, N1 71

Placebo→tofacitinib 5 mg BID, N1 81

0.5

0 2

Time (weeks)

- Tofacitinib 5 mg BID (N=133) → Placebo (N=136) - ▲ - Placebo→tofacitinib 5 mg BID (N=136)



Data up to Week 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. *Patients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line). *Analysed in patients with baseline SJC(44) >0. ASDAS, Ankylosing Spondylitis Disease Activity Score using hsCRP; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; BASFI, Bath Ankylosing Spondylitis Enthesitis Score; N, number of patients with observation at visit; PtGA, Patient Global Assessment of Chronic Illness Therapy-Fatigue; hsCRP, high-sensitivity; SE, standard error; SJC(44), swollen joint count in 44 joints.

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Online supplementary figure S8 Mean laboratory values over time in patients receiving tofacitinib 5 mg BID or placebo tofacitinib 5 mg BID ar placebo tofaci



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