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

Data are from the Week 16 analysis; data cut-off 19 December 2019; data snapshot 29 January 2020. *Normal approximation was used. Missing response was considered as non-response. bDMARD 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 - tofacitinib 5 mg BID for ASAS components over time up to Week 48: (A) ΔPtGA,"n (B) Δtotal back pain,"n (C) ΔBASFI" and (D) Δmorning stiffness (inflammation; mean of questions 5 and 6 of the BASDAI)."p

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<0.01, ***p<0.001 for comparing tofacitinib 5 mg BID vs placebo. p/H11088 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. a 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. ∆, 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 over time up to Week 48: (A) ASAS partial remission a 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.

a Patients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line).

b 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\* over time up to Week 48: (A) ASDAS clinically important improvement,\(^\text{3,4}\) (B) ASDAS major improvement,\(^\text{3,4}\) (C) ASDAS LDA\(^\text{3,4}\) and (D) ASDAS inactive disease.\(^\text{3,4}\)

\*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.  
\(^\text{3}\) Analysed in patients with baseline ASDAS $\geq1.736$: tofacitinib 5 mg BID, N=132; placebo - tofacitinib 5 mg BID, N=136.  
\(^\text{4}\) Analysed in patients with baseline ASDAS $\geq2.638$: tofacitinib 5 mg BID, N=123; placebo - tofacitinib 5 mg BID, N=129.  
\(^\text{5}\) Analysed in patients with baseline ASDAS $\geq2.1$: tofacitinib 5 mg BID, N=131; placebo - tofacitinib 5 mg BID, N=136.  
\(^\text{6}\) Analysed in patients with baseline ASDAS $\geq1.3$: tofacitinib 5 mg BID, N=133; placebo - tofacitinib 5 mg BID, N=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.
Online supplementary figure S5  Efficacy of tofacitinib 5 mg BID vs placebo → tofacitinib 5 mg BID over time up to Week 48:
(A) ∆BASDAIa and (B) BASDAI50 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. a Patients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line). b 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. c 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. ∆, 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.

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Online supplementary figure S6  Efficacy of tofacitinib 5 mg BID vs placebo →tofacitinib 5 mg BID* over time up to Week 48: (A) ∆MASESb,c and (B) ∆SJC(44)d.

(A) ∆MASES, LSM (SE)

(B) ∆SJC(44), LSM (SE)

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. a Patients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line). b,c Analysed in patients with baseline MASES >0. d Analysed in patients with baseline SJC(44) >0. ∆, change from 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.
Online supplementary figure S4  Mean laboratory values over time in patients receiving tofacitinib 5 mg BID or placebo — tofacitinib 5 mg BID up to Week 48: (A) haemoglobin, (B) lymphocytes, (C) neutrophils, (D) AST, (E) ALT, (F) creatine kinase, (G) cholesterol, (H) HDL cholesterol, and (I) LDL cholesterol.

Placebo
Placebo
Placebo
→
→
→
Tofacitinib 5 mg BID, N1
Tofacitinib 5 mg BID, N1
Tofacitinib 5 mg BID, N1

a

Patients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line).

Mean laboratory values over time in patients receiving tofacitinib 5 mg BID or placebo — assessed in fasting state. ALT, alanine aminotransferase; AST, aspartate aminotransferase; BID, twice daily; HDL, high-density lipoprotein; LDL, low-density lipoprotein; N, number of patients in safety analysis set; N1, number of patients with observation at visit; SE, standard error.

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