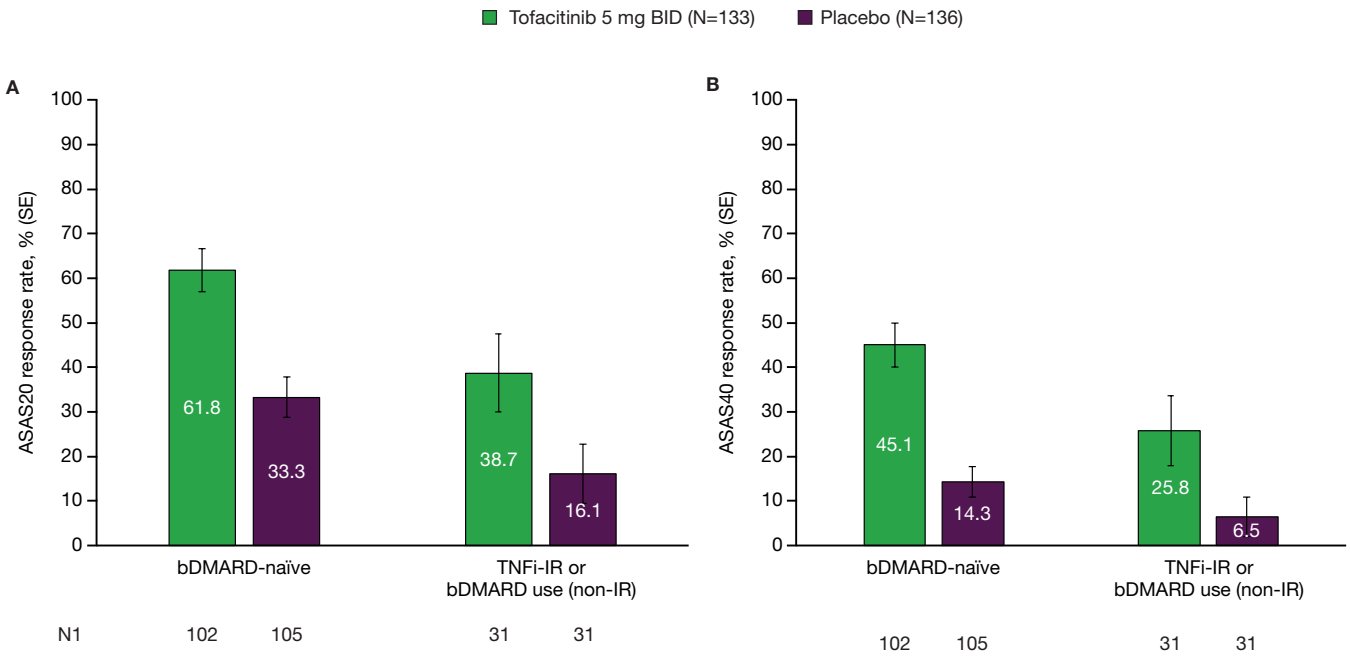
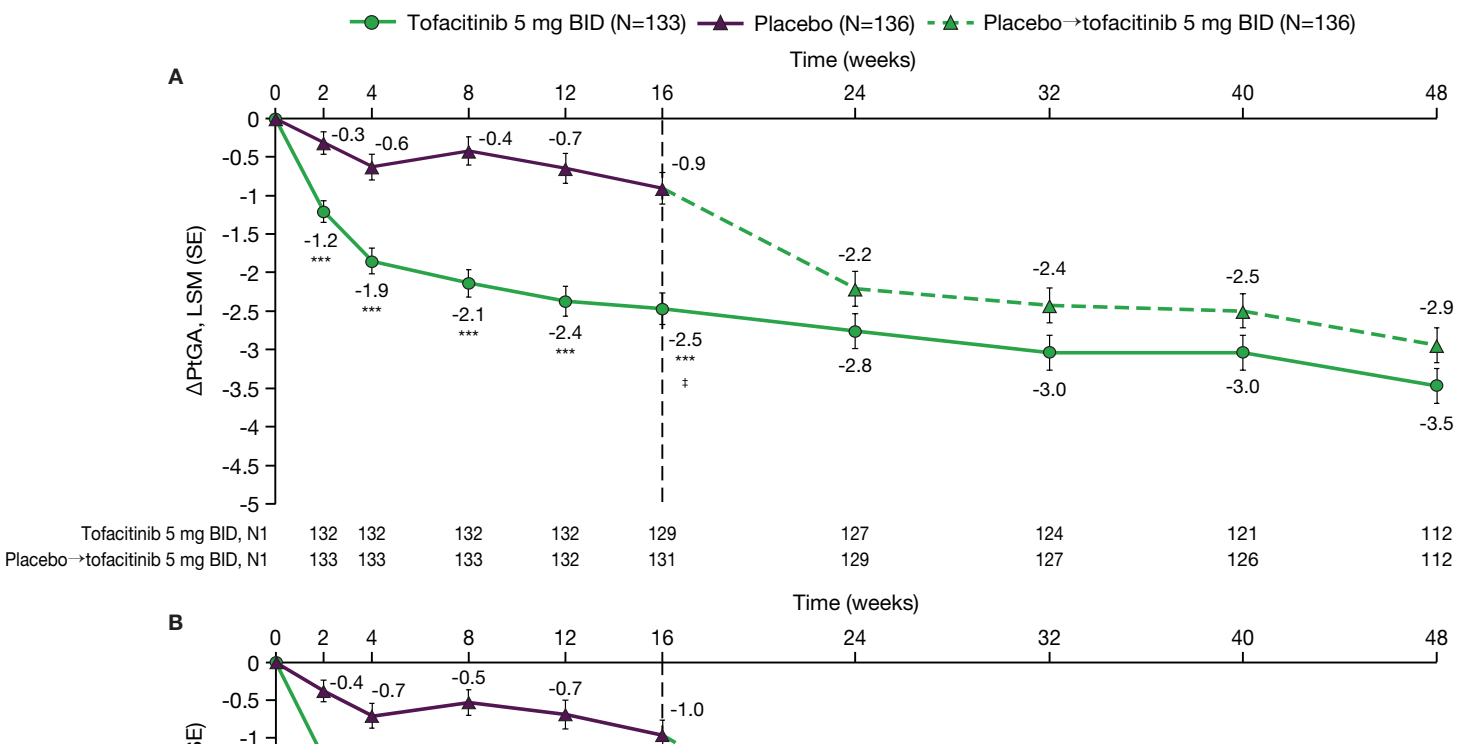
Online supplementary figure S1 Efficacy of tofacitinib 5 mg BID vs placebo at Week 16: (A) ASAS20 response[a] and (B) ASAS40 response,[a] stratified by bDMARD treatment history.[b]



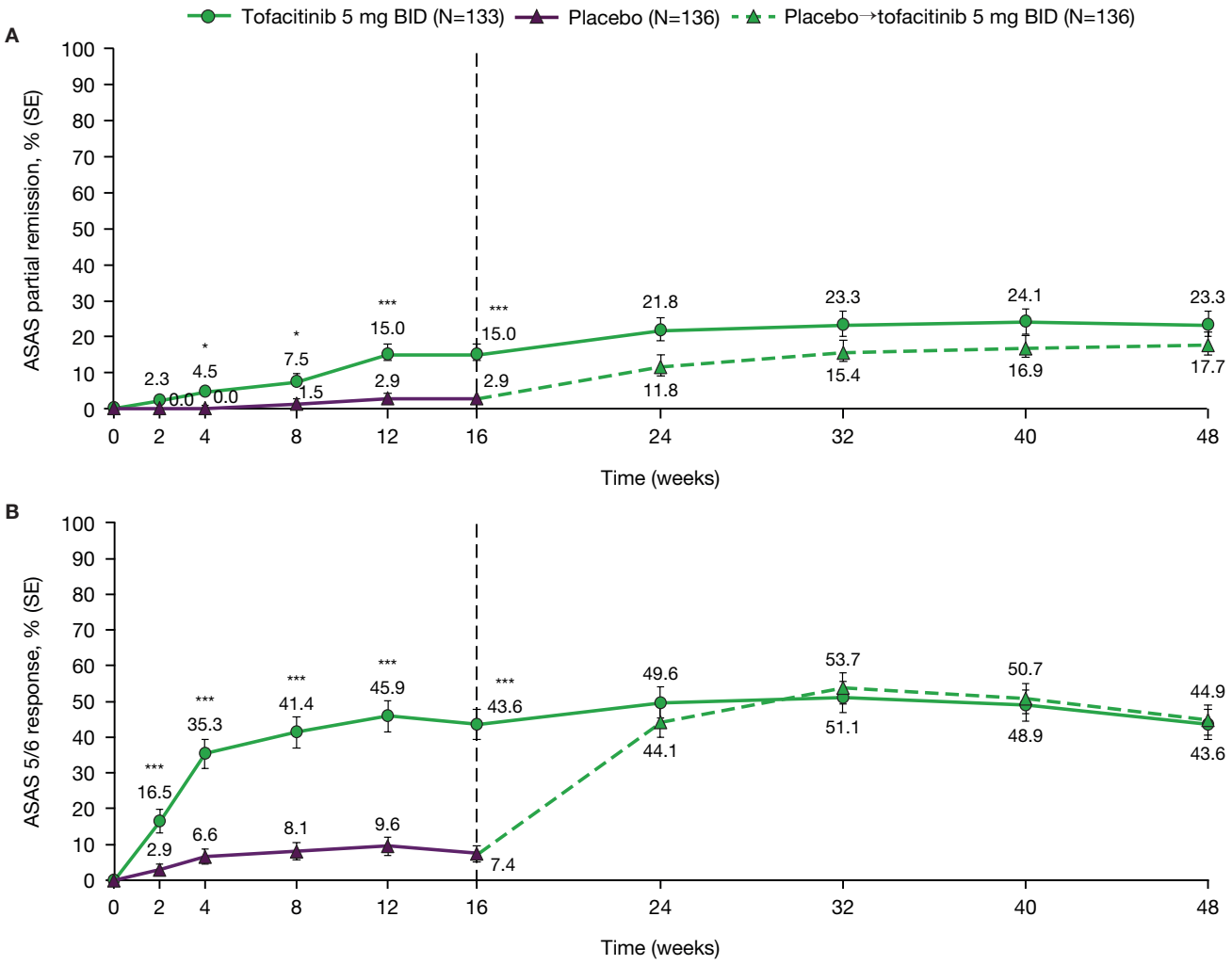
Data are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. [a]Normal approximation was used. Missing response was considered as non-response. [b]bDMARD treatment history was derived from the clinical database. ASAS, Assessment of SpondyloArthritis international 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[a] for ASAS components over time up to Week 48: (A) ΔPtGA,[b] (B) Δtotal back pain,[b] (C) ΔBASFI[b] and (D) Δmorning stiffness (inflammation; mean of questions 5 and 6 of the BASDAI).[b]



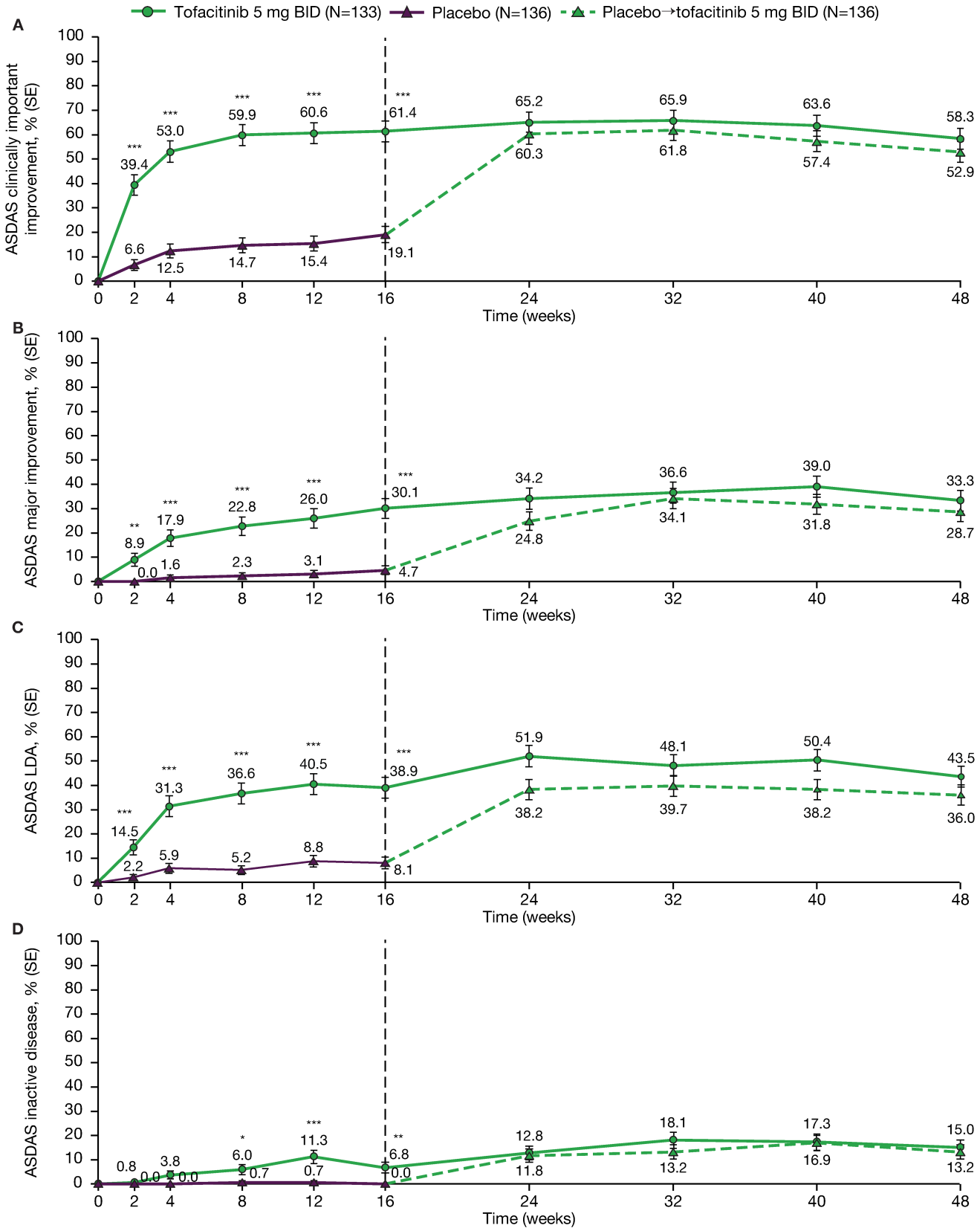
Data up to Week 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. **p<0.01, ***p<0.001 for comparing tofacitinib 5 mg BID vs placebo. ‡p≤0.05 for comparing tofacitinib 5 mg BID vs placebo, according to the pre-specified step-down testing procedure for type I error-control of ASAS components. [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. Δ, 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]



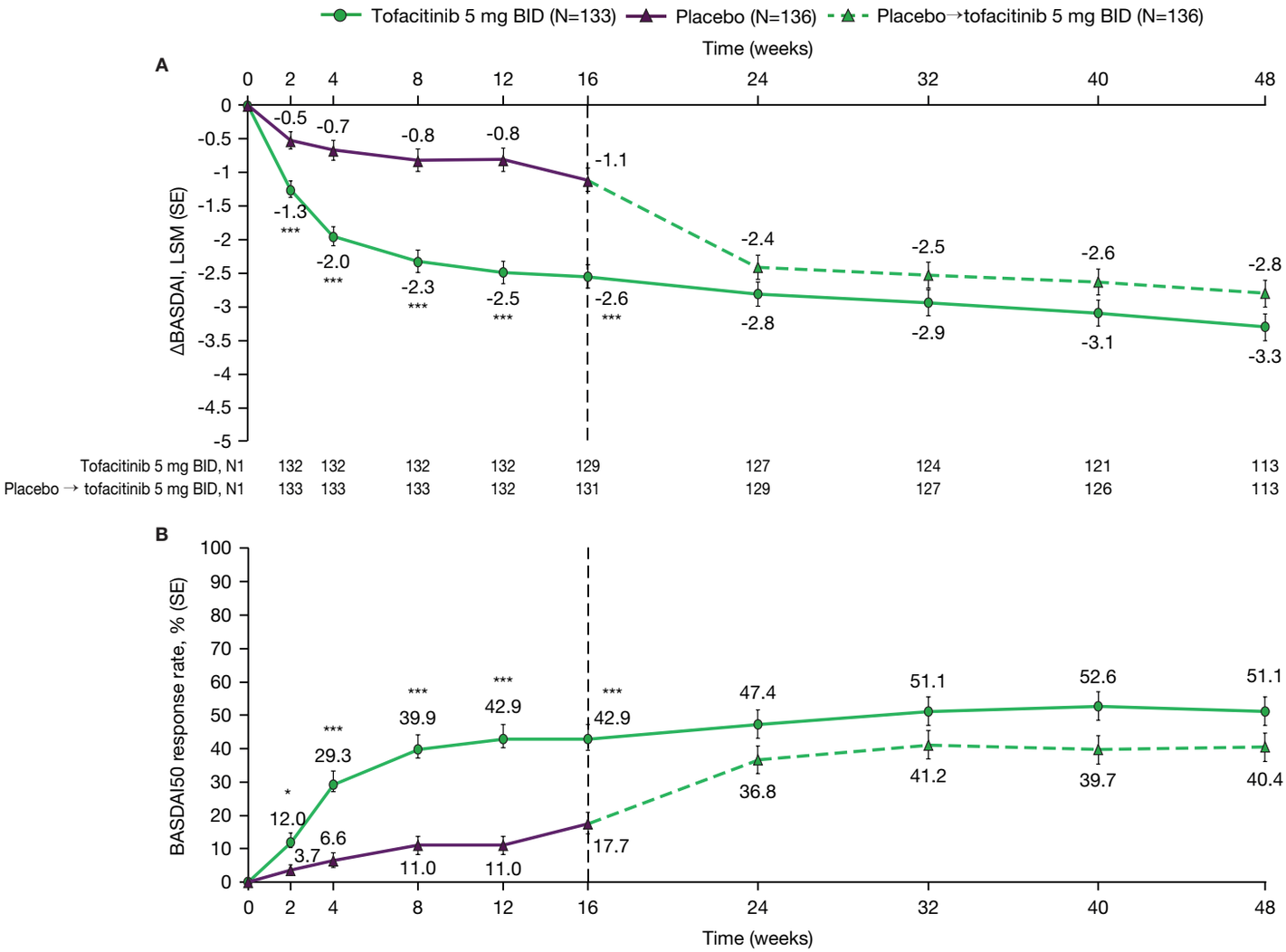
Data up to Week 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. *p≤0.05, ***p<0.001 for comparing tofacitinib 5 mg BID vs placebo. [a]Patients receiving placebo advanced to tofacitinib 5 mg BID at 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[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]



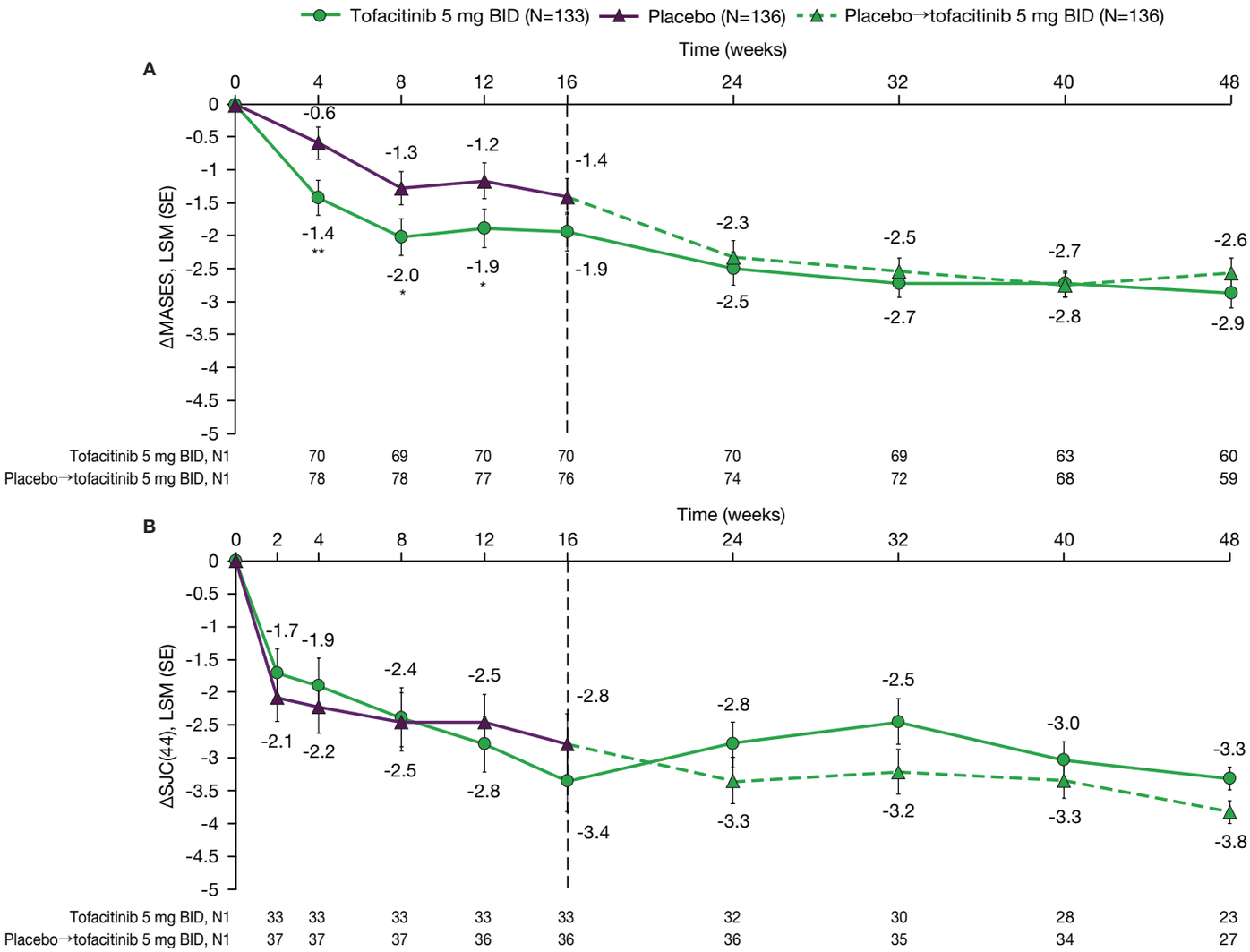
Data up to Week 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. *p≤0.05, **p<0.01, ***p<0.001 for comparing tofacitinib 5 mg BID vs placebo. [a]Patients receiving placebo advanced to tofacitinib 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. [c]Analysed in patients with baseline ASDAS ⩾1.736: tofacitinib 5 mg BID, N1=132; placebo→tofacitinib 5 mg BID, N1=136. [d]Analysed in patients with baseline ASDAS ⩾2.636: tofacitinib 5 mg BID, N1=123; placebo→tofacitinib 5 mg BID, N1=129. [e]Analysed in patients with baseline ASDAS ⩾2.1: tofacitinib 5 mg BID, N1=131; placebo→tofacitinib 5 mg BID, N1=136. [f]Analysed in patients with baseline ASDAS ⩾1.3: tofacitinib 5 mg BID, N1=133; placebo→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.

Online supplementary figure S5 Efficacy of tofacitinib 5 mg BID vs placebo→tofacitinib 5 mg BID[a] over time up to Week 48: (A) ΔBASDAI[b] and (B) BASDAI50 response.[c]



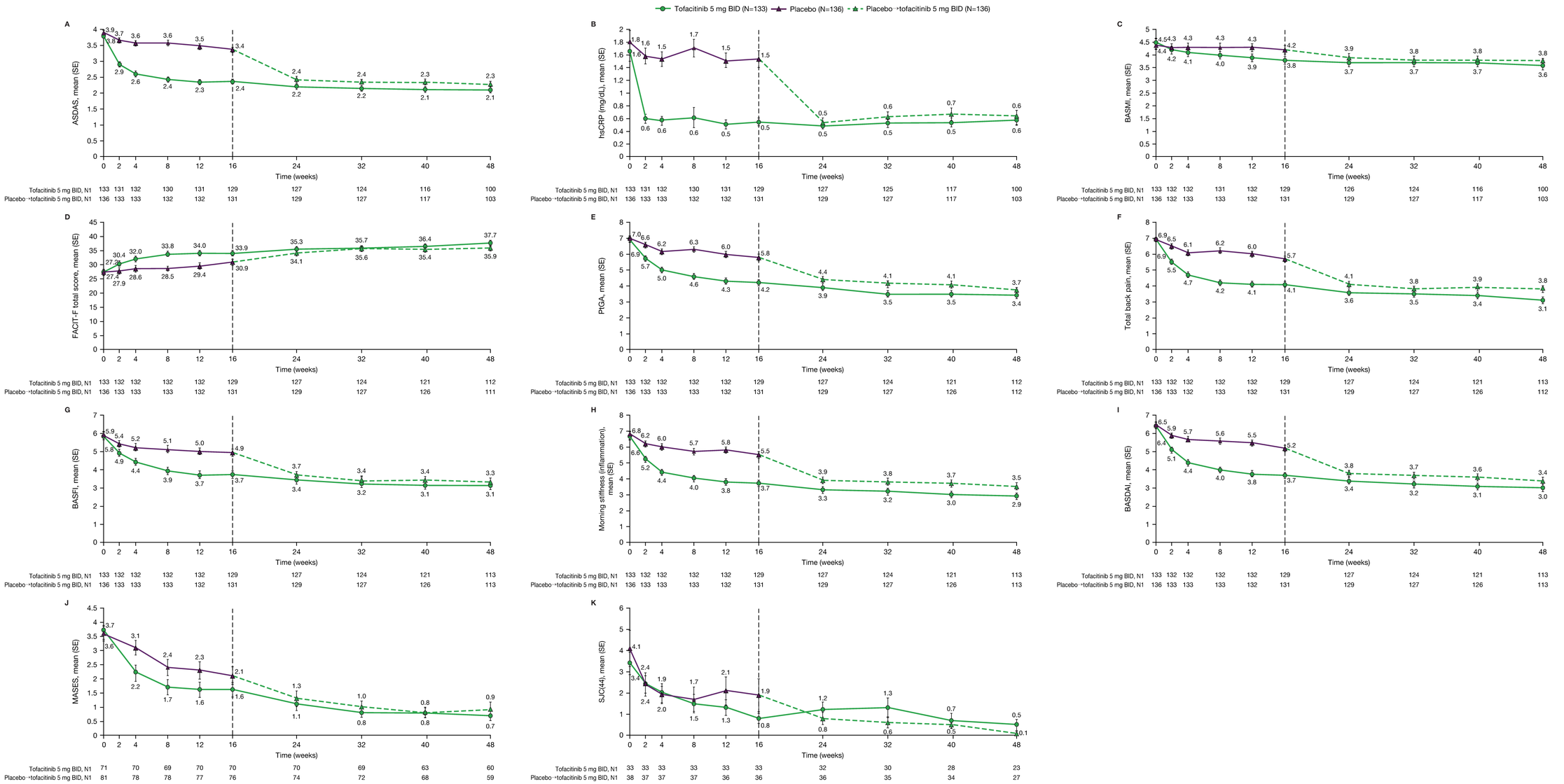
Data up to Week 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. *p⩽0.05, ***p<0.001 for comparing tofacitinib 5 mg BID vs placebo. [a]Patients receiving placebo advanced to tofacitinib 5 mg BID at 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. 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.

Online supplementary figure S6 Efficacy of tofacitinib 5 mg BID vs placebo→tofacitinib 5 mg BID[a] over time up to Week 48: (A) ΔMASES[b,c] and (B) ΔSJC(44).[b,d]



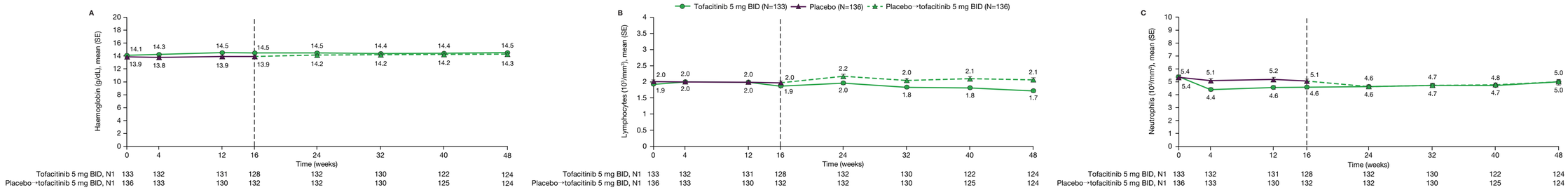
Data up to Week 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. *p≤0.05, **p<0.01 for comparing tofacitinib 5 mg BID vs placebo. [a]Patients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line). [b]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]Analysed in patients with baseline MASES >0. [d]Analysed in patients with baseline SJC(44) >0. Δ, 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.

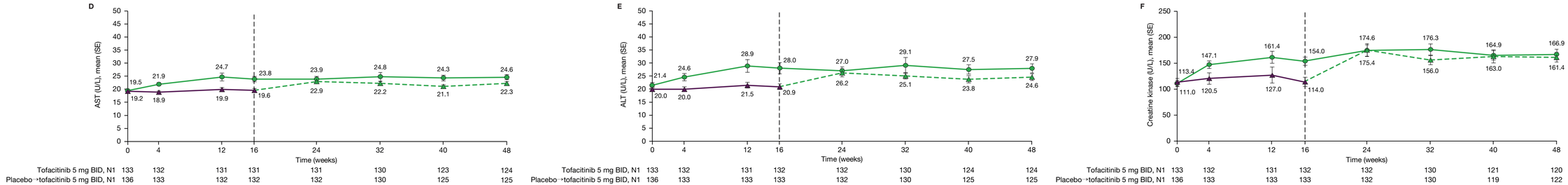
Online supplementary figure S7 Efficacy of tofacitinib 5 mg BID vs placebo→tofacitinib 5 mg BID[a] over time up to Week 48: descriptive analyses of mean (A) ASDAS, (B) hsCRP (mg/dL), (C) BASMI, (D) FACIT-F total score, (E) PtGA, (F) total back pain, (G) BASFI, (H) morning stiffness (inflammation), (I)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

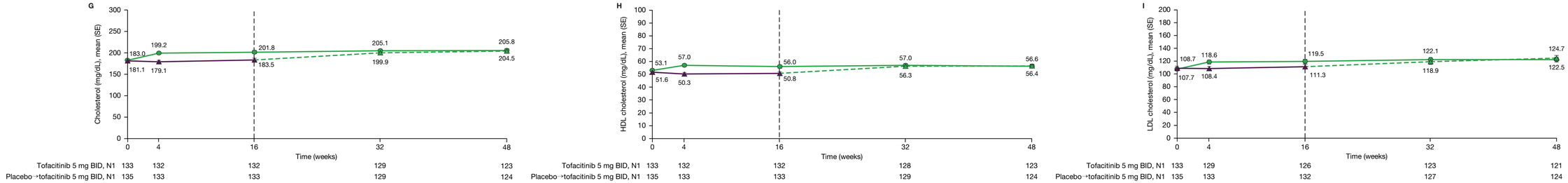


Data up to Week 16 are from the Week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Data for Weeks 24-48 are from the Week 48 final analysis. [a]Patients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line). [b]Analysed in patients with baseline MASES >0. [c]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; BASMI, Bath Ankylosing Spondylitis Metrology Index; BID, twice daily; FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; hsCRP, high-sensitivity C-reactive protein; MASES, Maastricht Ankylosing Spondylitis Enthesitis Score; 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; SJC(44), swollen joint count in 44 joints.

Online supplementary figure S8 Mean laboratory values over time in patients receiving tofacitinib 5 mg BID or placebo→tofacitinib 5 mg BID[a] up to Week 48: (A) haemoglobin, (B) lymphocytes, (C) neutrophils, (D) AST, (E) ALT, (F) creatine kinase, (G) cholesterol,[b] (H) HDL cholesterol[b] and (I) LDL cholesterol.[b]







Data are from the Week 48 final analysis. [a]Patients receiving placebo advanced to tofacitinib 5 mg BID at Week 16 (dashed line). [b]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.