SUPPLEMENTAL MATERIAL

Complete inclusion and exclusion criteria

Patients who enrolled in this study must have met all of the following inclusion criteria:

- Have evidence of a personally signed and dated informed consent document indicating that the patient (or a legally acceptable representative) has been informed of all pertinent aspects of the study
- Be willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures
- Female patients of childbearing potential and at risk for pregnancy must have agreed to use a highly effective method of contraception throughout the study and for at least 28 days after the last dose of assigned treatment
- Female patients of non-childbearing potential must meet ≥1 of the following criteria:
    - Have undergone a documented hysterectomy and/or bilateral oophorectomy
    - Have medically confirmed ovarian failure
    - Achieved post-menopausal status, defined as cessation of regular menses for ≥12 consecutive months with no alternative pathological or physiological cause; status may be confirmed by having a serum follicle-stimulating hormone level within the laboratory's reference range for post-menopausal females

(All other female patients, including female patients with tubal ligations, were considered to be of childbearing potential)

- Have signs and symptoms consistent with the diagnosis of psoriatic arthritis (PsA) for ≥6 months and fulfilled Classification Criteria for Psoriatic Arthritis (CASPAR)[1] criteria at screening and had evidence of active arthritis based upon number of tender/painful and swollen joints

    - To meet the CASPAR criteria, patients must have inflammatory articular disease (joint, spine, or entheseal) with three points from the following five categories:

        i. Have evidence of current psoriasis, a personal history of psoriasis or a family history of psoriasis. Current psoriasis is defined as psoriatic skin or scalp disease present today as judged by a rheumatologist or dermatologist. A personal history of psoriasis is defined as a history of psoriasis that may be obtained from a patient, family physician, dermatologist, rheumatologist or other qualified healthcare provider. A family history of psoriasis is defined as a history of psoriasis in a first- or second-degree relative according to patient report

            - Current psoriasis is assigned a score of 2; all other features are assigned a score of 1

        ii. Have typical psoriatic nail dystrophy including onycholysis, pitting and hyperkeratosis observed on current physical examination

        iii. Have a negative test result for the presence of rheumatoid factor by any method except latex, but preferably by enzyme-linked immunosorbent assay or nephelometry, according to the local laboratory reference range

iv. Have either current dactylitis, defined as swelling of an entire digit, or a history of dactylitis recorded by a rheumatologist

v. Have radiographic evidence of juxta-articular new bone formation, appearing as ill-defined ossification near joint margins (but excluding osteophyte formation) on plain radiographs of the hand or foot

- Patients must have active arthritis at both screening and baseline, as defined by having both:
  - ≥3 tender/painful joints on motion (out of 68 joints assessed) and
  - ≥3 swollen joints (out of 66 joints assessed).
- Patients must have active plaque psoriasis at screening that has been diagnosed or confirmed by a dermatologist or a Sponsor-approved rheumatologist

- Have ongoing treatment with a stable dose of a conventional synthetic disease-modifying antirheumatic drug (csDMARD; e.g. methotrexate or sulfasalazine)
  - All local standard-of-care practices for the administration of permitted background DMARD therapy, including laboratory testing, contraceptive requirements, follow-up care and contraindications should be performed according to local standards of care throughout the study
  - Patients must receive permitted background csDMARDs and should remain on a stable dose of one csDMARD throughout the course of the study

  - *Methotrexate*: maximum dose of 20 mg/week; minimum duration of therapy is 4 months, and dose must be stable for 4 weeks prior to the first dose of the study drug. Patients on methotrexate should be on an adequate and stable dose of folate supplementation (not less than 5 mg weekly based on folic acid unless such doses would violate the local label guidelines or standard of care) for ≥4 weeks prior to the first dose of the study drug. Patients must not have had previous serious toxicity while on methotrexate and must not be expected to require evaluation for possible methotrexate toxicity (e.g. require a liver biopsy for methotrexate toxicity) during the study

  - *Sulfasalazine*: maximum dose of 3 g/day; minimum duration of therapy is 3 months, and dose must be stable for 4 weeks prior to the first dose of the study drug

- Have had a documented inadequate response to ≥1 csDMARDs due to lack of efficacy or toxicity/lack of toleration

- May have received a tumour necrosis factor inhibitor (TNFi)

- Must be a Chinese adult ≥18 years of age at the screening visit

- Have no evidence of active, latent, or inadequately treated infection with *Mycobacterium tuberculosis* (TB) as defined by all of the following:

  - A negative QuantiFERON-TB Gold (QFT-G) in-tube test performed at or within 3 months prior to a given screening visit. A negative purified protein derivative (PPD) test could be substituted for the QFT-G in-tube test only if the central laboratory was unable to perform the test or could not determine

the results to be positive or negative, and the Pfizer Study Clinician approved it, on a case-by-case basis. Patients with a history of Bacille Calmette–Guérin (BCG) vaccination would be tested with the QFT-G test

- No local QFT-G testing is accepted for meeting the inclusion criterion
- A chest radiograph taken at or within the 3 months prior to screening without changes suggestive of active TB infection as determined (and documented) by a qualified radiologist or pulmonologist as per local standard of care
- Have no history of either untreated or inadequately treated latent or active TB infection
- If a patient has previously received an adequate course of therapy for either latent (9 months of isoniazid or an acceptable alternative regimen) or active (acceptable multi-drug regimen) TB infection per local practice, neither a PPD test nor a QFT-G in-tube test need be obtained, but a chest radiograph must be obtained if they have not done so within the prior 3 months. A patient who is currently being treated for either latent or active TB infection must only be enrolled with exclusion of close contacts of multi-drug resistant TB, documentation of an adequate treatment regimen and prior approval of the Sponsor

- Have discontinued all disallowed concomitant medications for the required time prior to the first dose of study medication and are taking only those concomitant medications in doses and frequency allowed by the protocol
- If receiving any investigational or marketed treatment for PsA or psoriasis not mentioned elsewhere, must have had that treatment discontinued for 4 weeks or

5 half-lives, whichever was longer. All biological agents not otherwise mentioned must be discontinued for a minimum of 6 months prior to the first dose of the study drug

- Must not be receiving TNFi; patients on TNFi must discontinue according to the following criteria:
    - *Etanercept and its biosimilar biological products (Enbrel®, Yisaipu®, Qiangke®, Anbainuo®)*: discontinue ≥4 weeks prior to the first dose of the study drug
    - *Adalimumab (Humira®)*: discontinue ≥10 weeks prior to the first dose of the study drug
    - *Infliximab (Remicade®)*: discontinue ≥8 weeks prior to the first dose of the study drug
    - *Golimumab (Simponi®)*: discontinue ≥10 weeks prior to the first dose of the study drug
    - *Certolizumab (Cimzia®)*: discontinue ≥10 weeks prior to the first dose of the study drug
    - Other biosimilar biological products could follow the requirements of their reference product after confirming they have the same half-lives
- Patients who have already been taking oral corticosteroids (but not injectable) may participate in the study:

- *Oral corticosteroids*: patients who have already been receiving oral corticosteroids must remain on a stable dose of ≤10 mg/day of prednisone or equivalent for 4 weeks prior to the first dose of the study drug
- *Injected (e.g. intra-articular, intramuscular or intravenous) corticosteroids*: discontinue 4 weeks prior to the first dose of the study drug

- Patients who have already been taking NSAIDs/cyclooxygenase-2 (COX-2) inhibitors may participate in the study provided that the dose is stable for 1 week prior to the first dose of the study drug

- Patients are to discontinue active psoriasis treatments prior to enrolling in the study
  - *Biologics*: all biological agents, which includes investigational and marketed agents, that were not otherwise mentioned must be discontinued for a minimum of 6 months prior to the first dose of the study drug
  - *Topical treatments that could affect psoriasis (e.g. corticosteroids, tars, keratolytics, anthralin, vitamin D analogues and retinoids)*: must be discontinued ≥2 weeks prior to the first dose of the study drug. Exceptions: the following topical treatments are allowed: non-medicated emollients for use over the whole body; topical steroids including hydrocortisone and hydrocortisone acetate ≤1% for the palms, soles, face and intertriginous areas only; tar and salicylic acid preparations for the scalp only; and shampoos free of corticosteroid for the scalp only
  - *Ultraviolet B (UVB) (narrowband or broadband) phototherapy*: must be discontinued ≥2 weeks prior to the first dose of the study drug

- *Psoralens + UVA phototherapy (PUVA)*: must be discontinued ≥4 weeks prior to the first dose of the study drug

Patients with any of the following characteristics/conditions will not be included in the study:

- Currently have non-plaque forms of psoriasis (e.g. erythrodermic, guttate or pustular psoriasis), with the exception of nail psoriasis (which is allowed)
- Investigator site staff members directly involved in the conduct of the study and their family members, site staff members otherwise supervised by the investigator or patients who were Pfizer employees, including their family members, directly involved in the conduct of the study
- Have participated in other interventional studies involving investigational drug(s) (phases 1–4) within 4 weeks before the current study begins and/or during study participation. Participation in any observational studies during study participation is permitted
- Pregnant female patients, breastfeeding female patients and female patients of childbearing potential who are unwilling or unable to use a highly effective method of contraception as outlined in this protocol for the duration of the study and for at least one ovulatory cycle after last dose of investigational product. Women of childbearing potential must have tested negative for pregnancy prior to enrolment in this study
- Have had blood dyscrasias within 3 months prior to the first dose of the study drug including confirmed:
  - Haemoglobin <10 g/dL (<100 g/L)

- White blood cell count $<3.0 \times 10^9$/L (<3000 mm^3)
- Absolute neutrophil count $<1.5 \times 10^9$/L (<1500 mm^3)
- Absolute lymphocyte count $<1.0 \times 10^9$/L (<1000/mm^3)
- Platelet count $<100 \times 10^9$/L ($<100,000$/mm^3)

- Have estimated creatinine clearance <40 mL/min based on Cockcroft–Gault equation
- Have total bilirubin, aspartate aminotransferase (AST), or alanine aminotransferase (ALT) more than 1.5 times the upper limit of normal (ULN) at screening visit
- Have current or recent history of a severe, progressive, or uncontrolled renal, hepatic, haematological, gastrointestinal, metabolic (including hypercholesterolemia), endocrine, pulmonary, cardiovascular or neurologic disease
- Have history of any autoimmune rheumatic disease other than PsA (including systemic lupus erythematosus, mixed connective tissue disease, scleroderma and polymyositis) or known diagnosis of fibromyalgia, without approval by Sponsor. Also excluded are patients with prior history of, or current, rheumatic inflammatory disease other than PsA (e.g. gout, reactive arthritis and chronic Lyme disease) without approval by Sponsor
- Patients with known immunodeficiency disorder or a first-degree relative with a hereditary immunodeficiency
- Patients in Functional Class IV as defined by the American College of Rheumatology (ACR) classification of functional status for rheumatoid arthritis (RA; i.e., limited in ability to perform usual self-care, vocational and avocational activities)[2]

- Have history of an infected joint prosthesis at any time, with the prosthesis still *in situ*
- Have history of any lymphoproliferative disorder, such as Epstein–Barr virus (EBV) related lymphoproliferative disorder, history of lymphoma, leukaemia or signs and symptoms suggestive of current lymphatic disease
- Have history of recurrent (more than one episode) herpes zoster or disseminated (a single episode) herpes zoster or disseminated (a single episode) herpes simplex
- Have history of active infection (including localised infection):
    - Requiring hospitalisation, parenteral antimicrobial therapy or as otherwise judged clinically significant by the investigator, within the 6 months prior to the first dose of study medication
    - Requiring oral antimicrobial therapy within 2 weeks prior to the first dose of study medication
- Have any prior treatment with non-B-cell-specific lymphocyte-depleting agents/therapies (e.g. alemtuzumab [Campath®] or efalizumab ([Raptiva®]), alkylating agents (e.g. cyclophosphamide or chlorambucil) or total lymphoid irradiation. Patients who have received rituximab or other selective B-lymphocyte-depleting agents (including experimental agents) are eligible if they have not received such therapy for ≥1 year prior to the first dose of the study drug and have normal CD19/20+ counts by fluorescence-activated cell sorter analysis
- Patients who have been vaccinated with live or attenuated vaccines within the 6 weeks prior to the first dose of study medication or are to be vaccinated with these

vaccines at any time during treatment or within 6 weeks following the discontinuation of study medication

- Patients with any condition possibly affecting oral drug absorption (e.g. gastrectomy, clinically significant diabetic gastroenteropathy or certain types of bariatric surgery such as gastric bypass); procedures such as gastric banding that simply divide the stomach into separate chambers are NOT exclusionary

- Have history of alcohol or drug abuse unless in full remission for longer than 6 months prior to first dose of study medication

- Patients with a screening 12-lead electrocardiogram (ECG) that has demonstrated clinically relevant abnormalities (as determined by a qualified cardiologist) that may affect patient safety (e.g. pattern of acute myocardial infarction, acute ischemia or serious arrhythmia) or interpretation of study results (e.g. continuously paced ventricular rhythm or complete left bundle branch block)

- Patients with a malignancy or with a history of malignancy, with the exception of adequately treated or excised non-metastatic basal cell or squamous cell cancer of the skin or cervical carcinoma *in situ*

- Those with significant trauma or surgery procedure within 1 month prior to the first dose of study medication or any planned elective surgery during the study period

- Patients requiring prohibited concomitant medications

- Patients known to be infected with human immunodeficiency virus, hepatitis B virus or hepatitis C virus (HCV) or any chronic infection

- Hepatitis B surface antigen (HBsAg) positivity is exclusionary; patients who are HBsAg negative but hepatitis B core antibody (HBcAb) positive must have undergone further testing and be hepatitis B surface antibody (HBsAb) positive to be considered for enrolment

- Patients who are HCV antibody positive must have undergone further testing for HCV RNA and are allowed to enrol if negative

- Patients with evidence of skin conditions (e.g. eczema) at the time of the screening or baseline visit that would interfere with the evaluation of psoriasis

- Patients who are considered to be at increased risk for gastrointestinal perforation (e.g. a patient with diverticulitis) by the investigator or Sponsor

- Patients who have any factors or clinical characteristics potentially related to the risk of venous thromboembolism that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgement of the investigator, would make the patient inappropriate for entry into this study

- Patients with other acute, chronic medical or psychiatric conditions including recent (within the past year) or active suicidal ideation or behaviour or with laboratory abnormalities that may increase the risk associated with study participation or investigational product administration or that may interfere with the interpretation of study results and, in the judgement of the investigator, would make the patient inappropriate for entry into this study

- Patients who have previously participated in any study of tofacitinib or have any previous clinical experience of tofacitinib
- Patients who, in the opinion of the investigator or Pfizer (or designee), would be uncooperative or unable to comply with study procedures.

Details on primary efficacy endpoints

The ACR defines improvement in RA (ACR50) as a ≥50% reduction from baseline in the number of tender or painful joints (of 68 joints assessed) and swollen joints (of 66 joints assessed) and a ≥50% improvement in ≥3 of the following remaining ACR measures: patient's assessment of arthritis pain (on a Visual Analogue Scale [VAS]; ranging from 0 to 100 mm; 0=no pain and 100=most severe pain); Patient's Global Assessment of arthritis (PtGA VAS; ranging from 0 to 100 mm; 0=very well and 100=very poorly); Physician Global Assessment of arthritis (PGA VAS; ranging from 0 to 100 mm; 0=very good and 100=very poor); C-reactive protein (CRP) level; and Health Assessment Questionnaire-Disability Index (HAQ-DI; ranging from 0 to 3, with higher scores indicating greater disability).[3]

Study outcomes

The following secondary efficacy endpoints up to month 6 were assessed:

- ACR50 response rates at remaining time points
- ACR20/70 response rates calculated similarly to ACR50 with the respective percent improvement
- Change from baseline in ACR response components including change from baseline in the numbers of tender/painful joints and swollen joints, patient's assessment of arthritis pain VAS, PtGA VAS, PGA VAS, CRP level and HAQ-DI
- HAQ-DI scores were based on eight domains assessing patient difficulty with daily living activities over the past week and ranging from 0 to 3, with 0=no difficulty, 1=some difficulty, 2=much difficulty and 3=unable to do.[4] The HAQ-DI score is computed as the average of the domain scores (scores range from 0 to 3, with higher scores indicating greater disability). Response was defined as a decrease from baseline ≥0.30 for patients with baseline HAQ-DI ≥0.30 at all time points or a decrease from baseline ≥0.35 for patients with baseline HAQ-DI ≥0.35 at all time points
- Psoriatic Arthritis Response Criteria (PsARC) response rate calculated based on four measurements: tender joint count (out of 68 joints assessed), swollen joint count (out of 66 joints assessed), PGA VAS and PtGA VAS. A 'PsARC responder' was defined as improvement in two of the following four criteria, one of which must be joint pain or swelling, without worsening in any measure: (1) ≥20% improvement in PGA (VAS); (2) ≥20% improvement in PtGA (VAS); (3) ≥30% improvement in tender joint count (68); and (4) ≥30% improvement in swollen joint count (66)[5]

- Change from baseline in Physician's Global Assessment of Psoriasis (PGA-PsO) and PGA-PsO response rates in patients with baseline PGA-PsO >0. PGA-PsO assessed erythema, induration and scaling across all psoriatic lesions across all psoriatic lesions on a 5-point scale, with higher scores indicating greater severity. The severity scores of each domain were summed, averaged, and rounded to the nearest whole number. Response was defined as PGA-PsO score of 0 or 1 and decrease from baseline ≥2 in patients with baseline PGA-PsO ≥2

- Proportion of patients achieving ≥75% improvement from baseline in Psoriasis Area and Severity Index (PASI75) in patients with baseline psoriatic body surface area (BSA) ≥3% and baseline PASI >0 measured over three domains (erythema, induration and scaling). Each domain was scored ranging from 0 to 4, with 4 indicating more severe symptoms. PASI examines four body regions, each scored from 0 to 6 according to the percentage psoriatic BSA affected. Each region is also weighted according to its approximate percentage of the whole body.[6] PASI can vary in increments of 0.1 units from 0.0 to 72.0, with higher scores representing increasing severity of psoriasis

- Change from baseline in Dactylitis Severity Score (DSS) in patients with baseline DSS >0 and resolution of dactylitis (defined as DSS=0). Dactylitis severity was assessed for each of the 20 digits in hands and feet based upon digit tenderness, using a scale of 0–3, where 0=no tenderness and 3=extreme tenderness. The DSS was the sum of the severity scores across the 20 digits (range: 0 to 60, with a higher score indicating more severe dactylitis)

- Change from baseline in Leeds Enthesitis Index (LEI) in patients with baseline LEI >0 and resolution of enthesitis (defined as LEI=0); LEI was calculated based on

the number of sites with enthesitis in the following six sites (right and left): lateral epicondyle humerus, medial femoral condyle and Achilles tendon insertion. Scores ranged from 0 to 6, with higher scores indicating a greater number of affected sites.[7]

Other efficacy endpoints assessed up to month 6 included:

- Change from baseline in Nail Psoriasis Severity Index (NAPSI) in patients with baseline NAPSI >0. Score was based on the assessment of a single target fingernail, which was the worst-case fingernail at baseline and was evaluated consistently through the entire study. The target fingernail was evaluated for nail matrix psoriasis (including any of the following parameters: pitting, leukonychia, red spots in lunula nail plate crumbling) and nail bed psoriasis (including any of the following parameters: onycholysis, splinter haemorrhages, oil drop [salmon patch] discoloration and nail bed hyperkeratosis). Scores ranged from 0 to 8, with higher scores indicating greater severity[8] and

- Change from baseline in Disease Activity Score in 28 joints with CRP (DAS28-3[CRP]), which was composed of three domains: tender/painful joint count (28 joints), swollen joint count (28 joints) and CRP (mg/L). Scores ranged from 0 to 9.4 (with plausible values of CRP) with higher scores being indicative of worse disease activity.[9]

Patient-reported outcomes included the Short Form-36 Health Survey (version 2, acute) Mental Component Summary and Physical Component Summary scores, which are based on a 36-item health status measure across eight general health domains. These were scaled to be centred at 50, with a standard deviation of 10; higher scores were indicative of better health-related quality of life.[10]

Post hoc analysis included the proportion of patients meeting criteria for minimal disease activity, which was defined as meeting ≥5 out of seven items: ≤1 tender joint, ≤1 swollen joint, a PASI score of ≤1 or a BSA covered by psoriasis of ≤3%, pain VAS ≤15 mm, PtGA VAS ≤20 mm, HAQ-DI ≤0.5 and ≤1 tender enthesitis site (based on LEI).[11]

Safety assessments included the incidence of adverse events (AEs) from months 0 to 3 and months 0 to 6, classified according to Medical Dictionary for Regulatory Activities (MedDRA) version 24.0, including serious AEs and AEs leading to discontinuation. AEs of special interest included serious infections, herpes zoster infection (serious and non-serious), opportunistic infections, malignancies excluding non-melanoma skin cancer (NMSC), NMSC, major adverse cardiovascular events, thromboembolisms (including deep vein thrombosis [DVT], pulmonary embolism [PE], arterial thromboembolism [ATE]), hepatic events and gastrointestinal perforations. Cardiovascular events, opportunistic infections, malignancies, some thromboembolic events (DVT and PE) and hepatic events were reviewed and adjudicated by external expert committees, blinded to treatment allocation.

Physical examinations, vital signs and clinical laboratory tests were evaluated up to month 6.

Laboratory values and clinical laboratory abnormalities

The proportions of patients who had a single haemoglobin drop of >2 g/dL below baseline and creatine kinase >5× the ULN, which were criteria for monitoring, were generally similar across treatment groups up to month 6 (online supplemental table S1). No patients in the tofacitinib 5 mg BID group had laboratory values meeting the protocol criteria for discontinuation, compared with one patient in the placebo→tofacitinib 5 mg BID group (online supplemental table 1).

Up to month 6, the proportions of patients with bilirubin >1× ULN, aspartate aminotransferase >1×, ≥2× and ≥3× ULN and alanine aminotransferase >1× and ≥2× ULN were higher with tofacitinib 5 mg BID than with placebo→tofacitinib 5 mg BID (online supplemental table 2).

Supplemental Table 1 Laboratory values meeting protocol defined criteria for monitoring, up to month 6 (safety analysis set*)†

	Month 0–3		Month 0–6	
	Tofacitinib 5 mg BID (N=136)	**Placebo (N=68)**	**Tofacitinib 5 mg BID (N=136)**	**Placebo→ tofacitinib 5 mg BID (N=68)**
Laboratory values meeting criteria for monitoring, n (%)‡				
Any single haemoglobin drops >2 g/dL below baseline	3 (2.2)	2 (2.9)	3 (2.2)	3 (4.4)
Platelet count <100 × 10^9 /L	1 (0.7)	0	1 (0.7)	0
Serum creatinine increase >50% or increase >0.5 mg/dL over the average of screening and baseline values	0	1 (1.5)	0	1 (1.5)
Any creatine kinase >5× ULN	2 (1.5)	1 (1.5)	2 (1.5)	1 (1.5)

* All patients who received ≥1 dose of study medication.

† Notably, no patients met the following protocol criteria for discontinuation: two sequential ANC <1.0 × 10^9/L, ALC <500/mm^3; two sequential haemoglobin <8.0 g/dL or decrease of >30% from baseline value; two sequential platelet counts <75 × 10^9/L; two sequential AST or ALT

elevations ≥3× ULN with at least one total bilirubin ≥2× ULN; two sequential AST or ALT elevations ≥3× ULN, accompanied by hepatic injury (e.g. new-onset elevated PT/INR); two sequential AST or ALT elevations >5× ULN, regardless of total bilirubin or accompanying signs or symptoms; serum creatinine increase >50% or increase >0.5 mg/dL over the average of screening and baseline values; two sequential creatine kinase elevations >10× ULN; or a confirmed positive urine pregnancy test in a woman of childbearing potential.

‡ Notably, no patients met the following protocol criteria for monitoring: ANC $<1.2 \times 10^9$/L and ALC $<0.5 \times 10^9$/L.

ALC, absolute lymphocyte count; ALT, alanine aminotransferase; ANC, absolute neutrophil count; AST, aspartate aminotransferase; BID, twice daily; INR, international normalised ratio; M, month; n, number of patients who met the criteria; N, number of evaluable patients;

PT, prothrombin time; ULN, upper limit of normal.

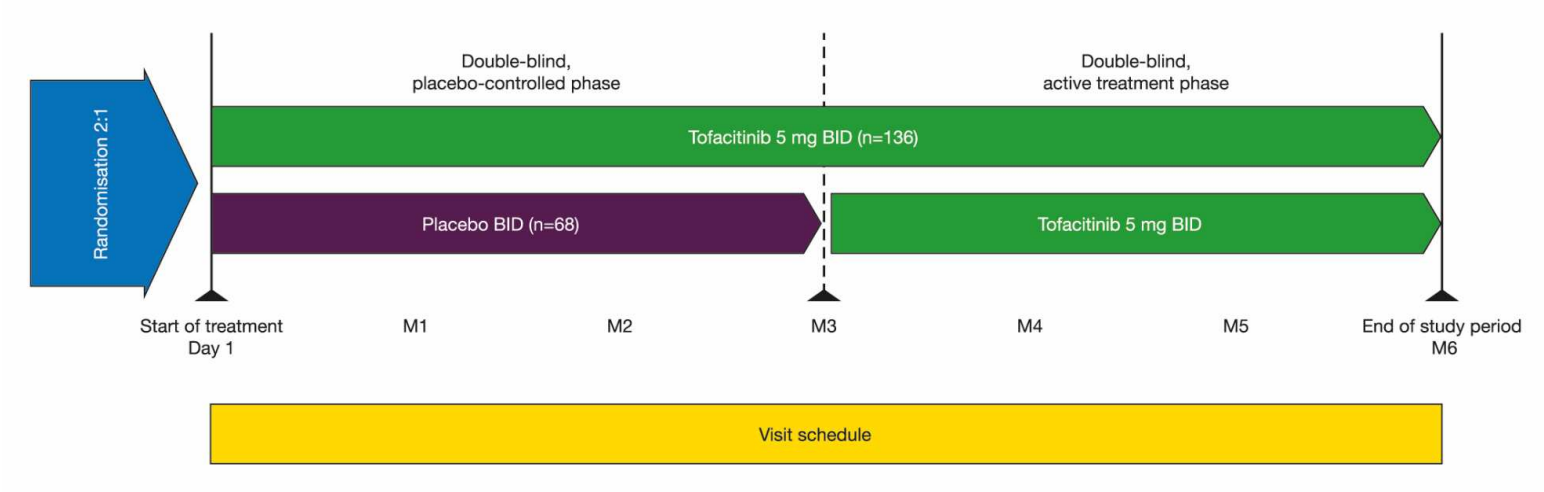
Supplemental Table 2 Elevation of bilirubin and transaminase levels, up to month 6 (safety analysis set*,†)

	Month 0–3		**Month 0–6**	
	Tofacitinib 5 mg BID (N=136)	**Placebo (N=68)**	**Tofacitinib 5 mg BID (N=136)**	**Placebo→ tofacitinib 5 mg BID (N=68)**
	N1=135	N1=67	N1=135	N1=67
Bilirubin (mg/dL), n (%)				
>1× ULN	6 (4.4)	2 (3.0)	11 (8.1)	5 (7.5)
≥2× ULN	0	0	0	0
≥3× ULN	0	0	0	0
AST (U/L), n (%)				
>1× ULN	26 (19.3)	6 (9.0)	33 (24.4)	12 (17.9)
≥2× ULN	4 (3.0)	1 (1.5)	6 (4.4)	2 (3.0)
≥3× ULN	1 (0.7)	0	1 (0.7)	0
≥5× ULN	0	0	0	0
ALT (U/L), n (%)				
>1× ULN	37 (27.4)	10 (14.9)	52 (38.5)	16 (23.9)
≥2× ULN	7 (5.2)	0	12 (8.9)	3 (4.5)
≥3× ULN	3 (2.2)	0	4 (3.0)	2 (3.0)
≥5× ULN	0	0	0	0

* All patients who received ≥1 dose of study medication.

† All patients with normal and abnormal baseline results are included.

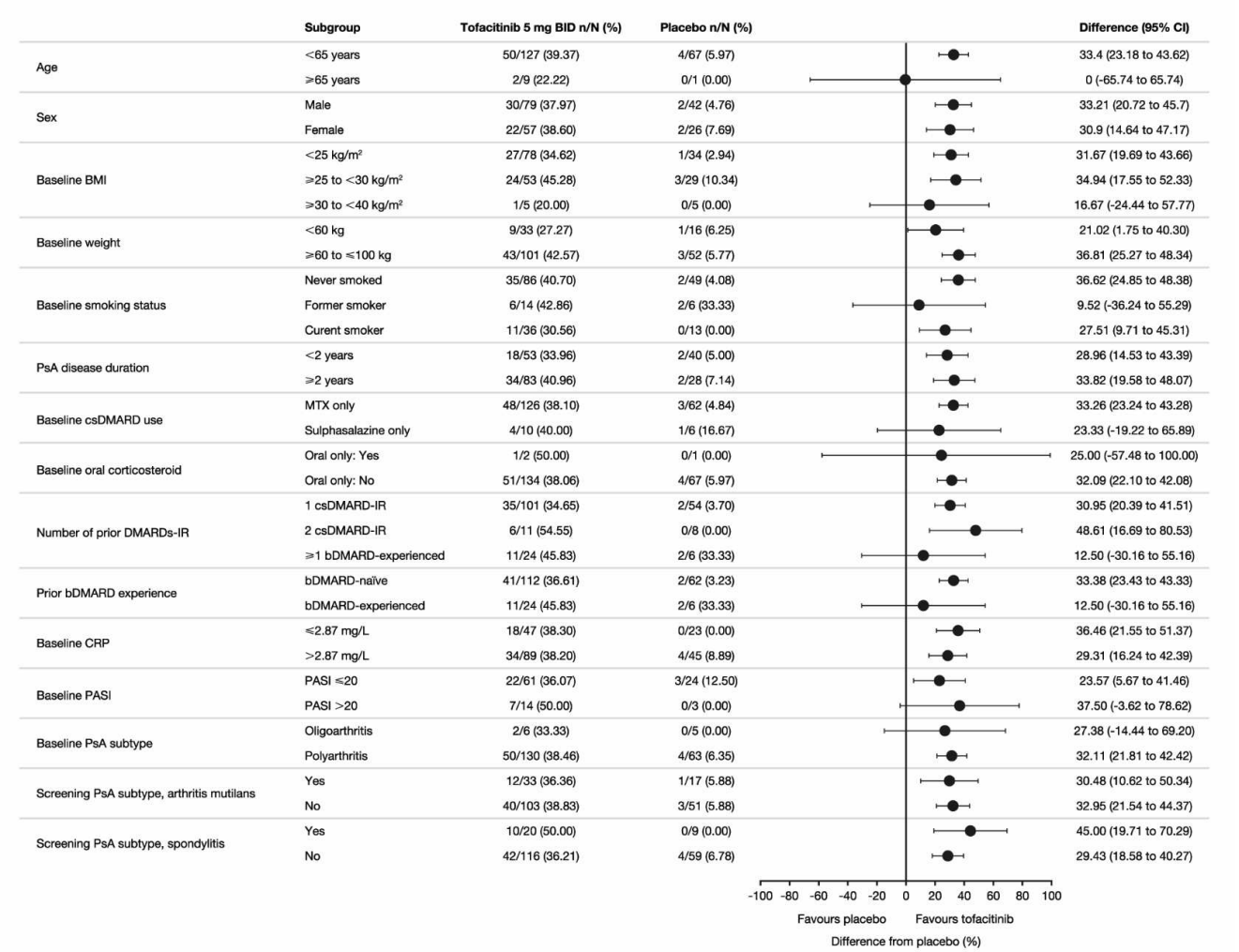
ALT, alanine aminotransferase; AST, aspartate aminotransferase; BID, twice daily; n, number of patients who met the criteria; N, number of patients in safety analysis set; N1, number of evaluable patients; ULN, upper limit of normal.



Supplemental Figure 1 Trial design.

For patients randomised to the placebo group, treatment was switched to tofacitinib 5 mg BID at month 3 in a blinded manner. Blinding regarding the treatment regimen was maintained throughout the trial.

BID, twice daily; M, month; n, number of eligible patients.



	Subgroup	Tofacitinib 5 mg BID n/N (%)	Placebo n/N (%)	Difference (95% CI)
Age	<65 years	50/127 (39.37)	4/67 (5.97)	33.4 (23.18 to 43.62)
	⩾65 years	2/9 (22.22)	0/1 (0.00)	0 (-65.74 to 65.74)
Sex	Male	30/79 (37.97)	2/42 (4.76)	33.21 (20.72 to 45.7)
	Female	22/57 (38.60)	2/26 (7.69)	30.9 (14.64 to 47.17)
Baseline BMI	<25 kg/m²	27/78 (34.62)	1/34 (2.94)	31.67 (19.69 to 43.66)
	⩾25 to <30 kg/m²	24/53 (45.28)	3/29 (10.34)	34.94 (17.55 to 52.33)
	⩾30 to <40 kg/m²	1/5 (20.00)	0/5 (0.00)	16.67 (-24.44 to 57.77)
Baseline weight	<60 kg	9/33 (27.27)	1/16 (6.25)	21.02 (1.75 to 40.30)
	⩾60 to ⩽100 kg	43/101 (42.57)	3/52 (5.77)	36.81 (25.27 to 48.34)
Baseline smoking status	Never smoked	35/86 (40.70)	2/49 (4.08)	36.62 (24.85 to 48.38)
	Former smoker	6/14 (42.86)	2/6 (33.33)	9.52 (-36.24 to 55.29)
	Curent smoker	11/36 (30.56)	0/13 (0.00)	27.51 (9.71 to 45.31)
PsA disease duration	<2 years	18/53 (33.96)	2/40 (5.00)	28.96 (14.53 to 43.39)
	⩾2 years	34/83 (40.96)	2/28 (7.14)	33.82 (19.58 to 48.07)
Baseline csDMARD use	MTX only	48/126 (38.10)	3/62 (4.84)	33.26 (23.24 to 43.28)
	Sulphasalazine only	4/10 (40.00)	1/6 (16.67)	23.33 (-19.22 to 65.89)
Baseline oral corticosteroid	Oral only: Yes	1/2 (50.00)	0/1 (0.00)	25.00 (-57.48 to 100.00)
	Oral only: No	51/134 (38.06)	4/67 (5.97)	32.09 (22.10 to 42.08)
Number of prior DMARDs-IR	1 csDMARD-IR	35/101 (34.65)	2/54 (3.70)	30.95 (20.39 to 41.51)
	2 csDMARD-IR	6/11 (54.55)	0/8 (0.00)	48.61 (16.69 to 80.53)
	⩾1 bDMARD-experienced	11/24 (45.83)	2/6 (33.33)	12.50 (-30.16 to 55.16)
Prior bDMARD experience	bDMARD-naïve	41/112 (36.61)	2/62 (3.23)	33.38 (23.43 to 43.33)
	bDMARD-experienced	11/24 (45.83)	2/6 (33.33)	12.50 (-30.16 to 55.16)
Baseline CRP	⩽2.87 mg/L	18/47 (38.30)	0/23 (0.00)	36.46 (21.55 to 51.37)
	>2.87 mg/L	34/89 (38.20)	4/45 (8.89)	29.31 (16.24 to 42.39)
Baseline PASI	PASI ⩽20	22/61 (36.07)	3/24 (12.50)	23.57 (5.67 to 41.46)
	PASI >20	7/14 (50.00)	0/3 (0.00)	37.50 (-3.62 to 78.62)
Baseline PsA subtype	Oligoarthritis	2/6 (33.33)	0/5 (0.00)	27.38 (-14.44 to 69.20)
	Polyarthritis	50/130 (38.46)	4/63 (6.35)	32.11 (21.81 to 42.42)
Screening PsA subtype, arthritis mutilans	Yes	12/33 (36.36)	1/17 (5.88)	30.48 (10.62 to 50.34)
	No	40/103 (38.83)	3/51 (5.88)	32.95 (21.54 to 44.37)
Screening PsA subtype, spondylitis	Yes	10/20 (50.00)	0/9 (0.00)	45.00 (19.71 to 70.29)
	No	42/116 (36.21)	4/59 (6.78)	29.43 (18.58 to 40.27)

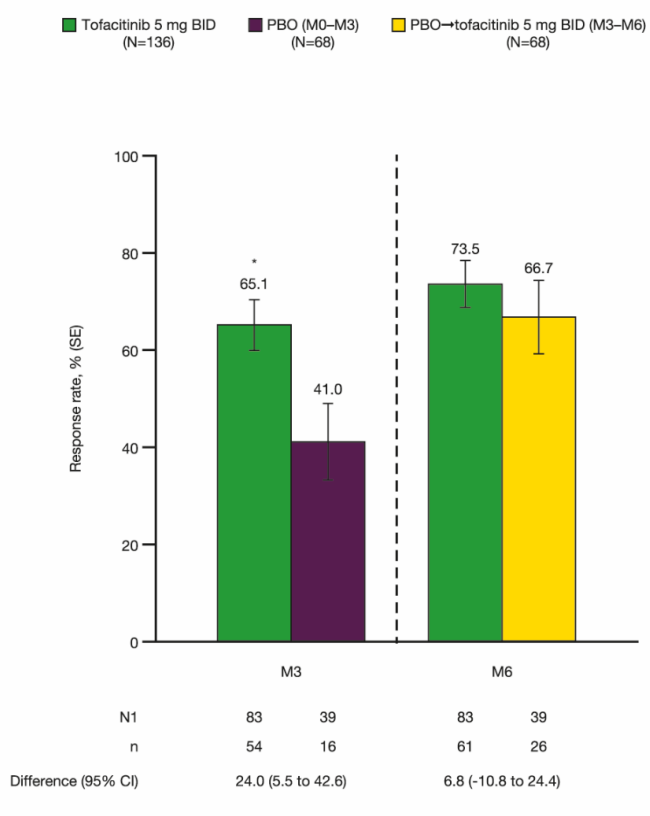
Supplemental Figure 2 Forest plot of differences in ACR50 response rates between tofacitinib 5 mg BID and placebo at month 3 by baseline subgroups (full analysis set*,†).

If there was no response or 100% response in any one of the two treatment groups (e.g. subgroups of age ≥65 years), when calculating proportions, 0.5 was added to the numerator, and 1.0 was added to the denominator in both treatment groups for calculation of the treatment difference, standard error and 95% CIs. Estimated response rates were reported without adjustment.

* All randomised patients who received ≥1 dose of study medication.

† Missing values were considered as non-response.

ACR, American College of Rheumatology; ACR50, ≥50% improvement in ACR response criteria; bDMARD, biological DMARD; BID, twice daily; BMI, body mass index; BSA, body surface area; CI, confidence interval; CRP, C-reactive protein; csDMARD, conventional synthetic DMARD; DMARD, disease-modifying antirheumatic drug; IR, inadequate response; MTX, methotrexate; n, number of patients meeting response criteria; N, number of patients; PASI, Psoriasis Area and Severity Index; PsA, psoriatic arthritis.

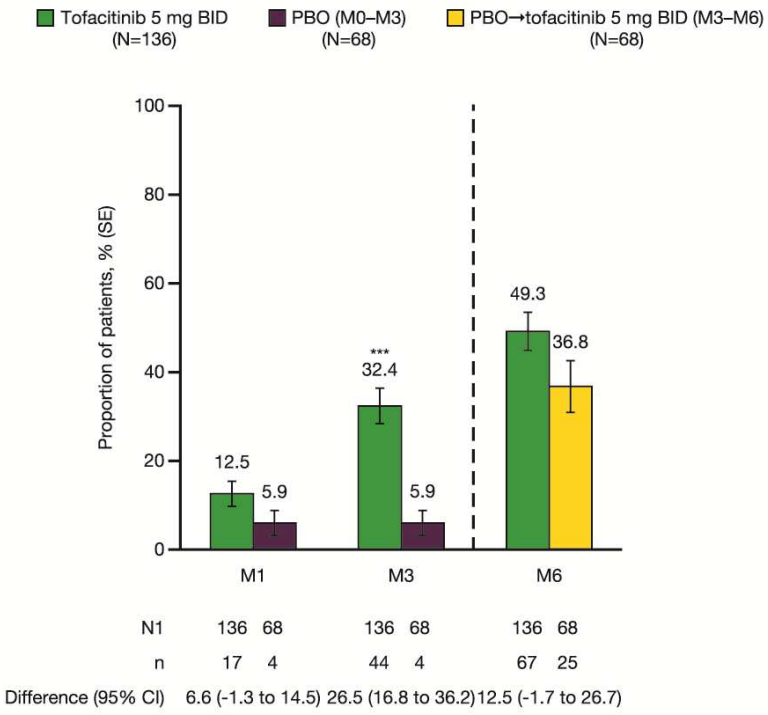


Supplemental Figure 3 HAQ-DI response† at months 3 and 6 (full analysis set).‡,§

The dotted line after month 3 indicates that patients in the placebo group were switched to tofacitinib 5 mg BID from month 3 for the remainder of the study.

* p<0.05 vs placebo (to month 3). † Defined as a decrease in HAQ-DI from baseline ≥0.30 in patients with baseline HAQ-DI ≥0.30. ‡ All randomised patients who received ≥1 dose of study medication. §Missing values were considered as non-response.

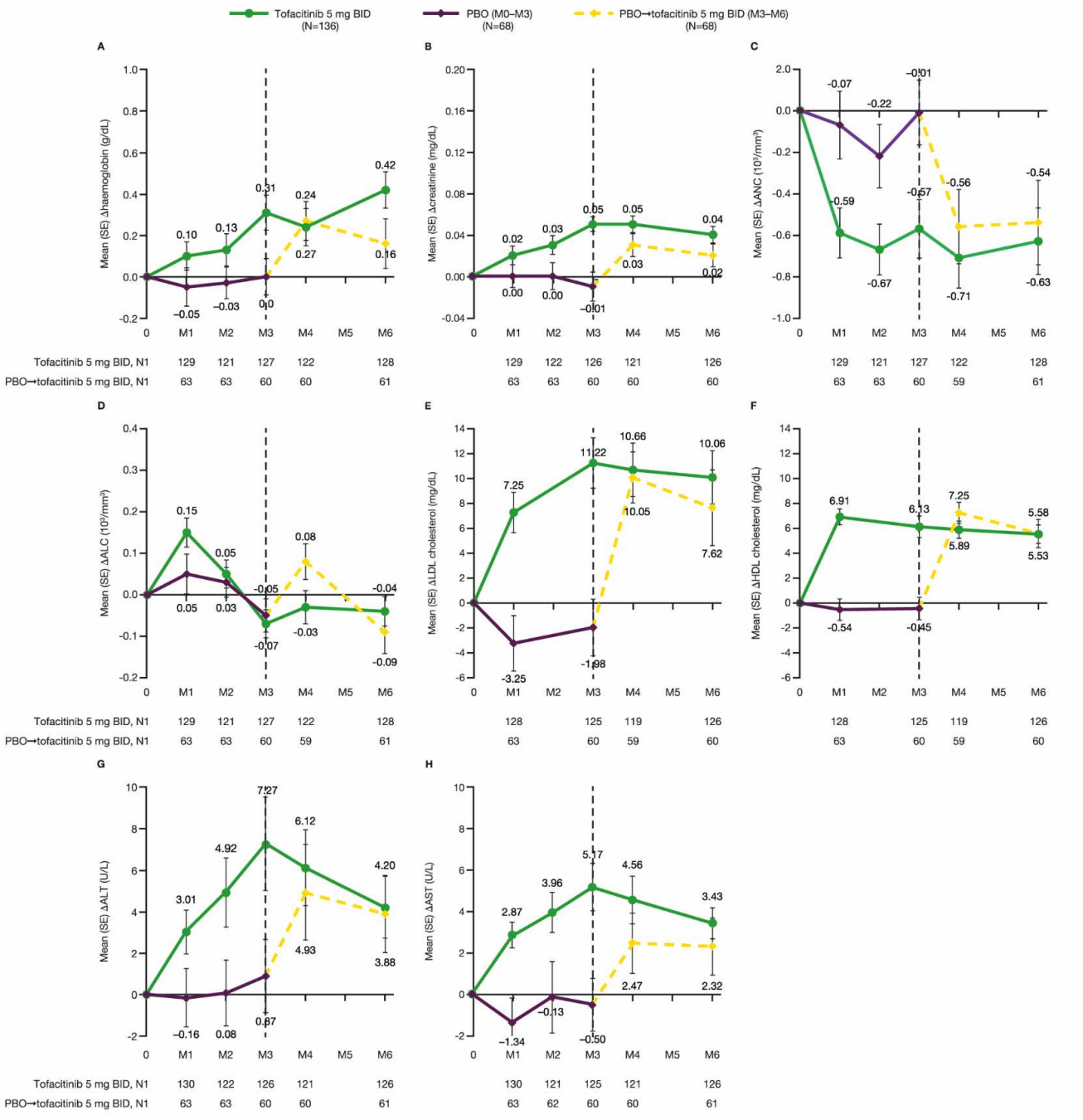
BID, twice daily; HAQ-DI, Health Assessment Questionnaire-Disability Index; M, month; n, number of patients meeting response criteria; N, number of patients in full analysis set; N1, number of patients with baseline HAQ-DI ≥0.30; PBO, placebo; SE, standard error.



Supplemental Figure 4 Proportion of patients achieving minimal disease activity (full analysis set†,‡).

This analysis was performed post hoc. The dotted line after month 3 indicates that patients in the placebo group were switched to tofacitinib 5 mg BID from month 3 for the remainder of the study. * $p<0.0001$ vs placebo (to month 3). † All randomised patients who received ≥1 dose of study medication. ‡ Missing values were considered as non-response.

BID, twice daily; CI, confidence interval; M, month; N, number of patients in full analysis set; n, number of patients meeting response criteria; N1, number of patients assessed; PBO, placebo; SE, standard error.



Supplemental Figure 5 Mean (SE) change from baseline in (A) haemoglobin, (B) creatinine*, (C) absolute neutrophil count, (D) absolute lymphocyte count, (E) LDL cholesterol, (F) HDL cholesterol, (G) ALT and (H) AST up to month 6 (safety analysis set†).

The dotted line at month 3 indicates that patients in the placebo group were switched to tofacitinib 5 mg BID from month 3 for the remainder of the study.

* Post hoc analysis; observations with data-entry issues were excluded.

† All patients who received ≥1 dose of study medication.

Δ, change from baseline; ALC, absolute lymphocyte count; ALT, alanine aminotransferase; ANC, absolute neutrophil count; AST, aspartate aminotransferase; BID, twice daily; HDL, high-density lipoprotein; LDL, low-density lipoprotein; M, month; N, number of patients in full analysis set; N1, number of patients assessed; SE, standard error.

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