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PROPRIETARY NAME® / GENERIC DRUG NAME: Xeljanz® / Tofacitinib

PROTOCOL NO.: A3921111

PROTOCOL TITLE: A Phase 3, Multi-Site, Randomized, Mixed-Blind, Parallel-Group Treatment Withdrawal and Re-Treatment Study of the Efficacy and Safety of 2 Oral Doses of CP-690,550 in Subjects With Moderate to Severe Chronic Plaque Psoriasis

Study Centers: A total of 65 centers in 12 countries took part in the study and randomized subjects; 2 in Argentina; 3 in Australia; 2 in Brazil; 5 in Bulgaria; 8 in Canada; 3 in Denmark; 1 in Finland; 3 in Greece; 1 in the Netherlands; 2 in Slovakia; 3 in the United Kingdom; and 32 in the United States.

Study Initiation and Final Completion Dates: 09 September 2010 to 31 January 2013

Phase of Development: Phase 3

Study Objectives:

Primary Objectives:

- To compare the efficacy responses of tofacitinib (5 mg twice a day [BID] and 10 mg BID) versus placebo following 24 weeks of tofacitinib treatment and subsequent withdrawal of active treatment at various timepoints during the 16-week double-blind active or placebo treatment period in subjects with moderate to severe chronic plaque psoriasis who were candidates for systemic therapy or phototherapy.

- To evaluate the regaining of efficacy responses of tofacitinib (5 mg BID and 10 mg BID) following 4-16 weeks of tofacitinib treatment withdrawal and subsequent re-treatment in subjects with moderate to severe chronic plaque psoriasis who were candidates for systemic therapy or phototherapy.

- To evaluate the safety and tolerability of tofacitinib (5 mg BID and 10 mg BID) in subjects with moderate to severe chronic plaque psoriasis who were candidates for systemic therapy or phototherapy.

Secondary Objectives:

- To evaluate the efficacy of tofacitinib (5 mg BID and 10 mg BID) for the reduction in severity of plaque psoriasis at various timepoints during 56 weeks of treatment in

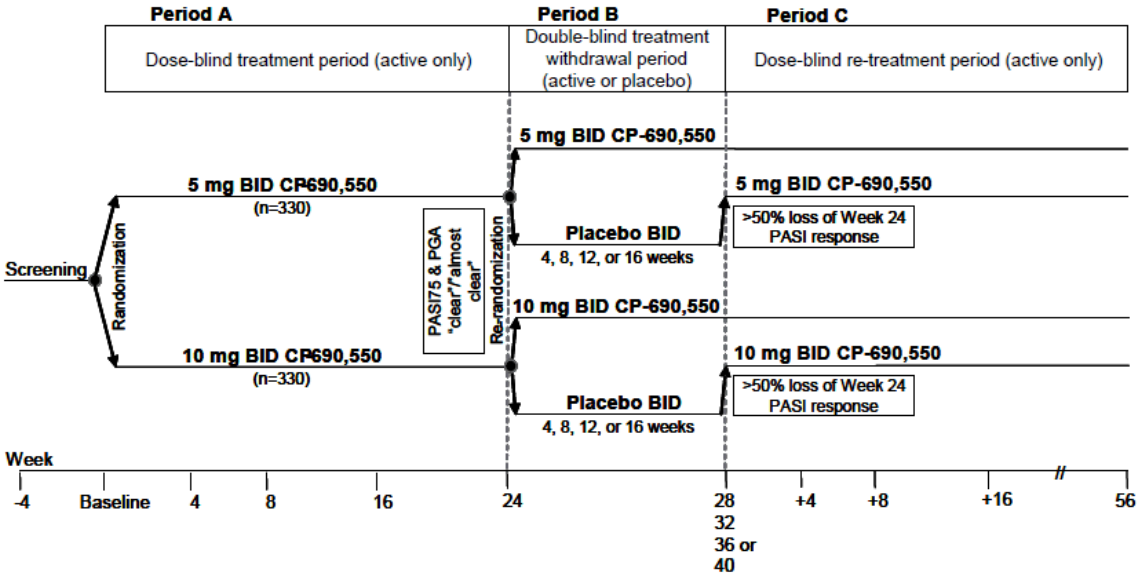
subjects with moderate to severe chronic plaque psoriasis who were candidates for systemic therapy or phototherapy.

- To evaluate the effects of tofacitinib (5 mg BID and 10 mg BID) on patient reported outcome (PRO) measures at various timepoints during 56 weeks of treatment in subjects with moderate to severe chronic plaque psoriasis who were candidates for systemic therapy or phototherapy.

METHODS

Study Design: This 56-week study of the efficacy and safety of 2 oral doses of tofacitinib (5 mg BID and 10 mg BID) was divided into 3 treatment periods: an initial dose-blind active treatment period (Period A) of 24 weeks duration, followed by a double-blind active or placebo treatment period (Period B) of variable duration (4 to 16 weeks), and concluding with a 16-week dose-blind active treatment period (Period C). The study design is presented in Figure 1 and in Table 1 and Table 2.

Figure 1 Study Design



BID = twice daily; CP-690,550 = tofacitinib; n = number of subjects; PASI = Psoriasis Area and Severity Index; PGA = Physician Global Assessment.

Table 1. Schedule of Activities (Screening, Period A, and Period B)

Study Activity[a] - Screening - Period A - Period B	Screening[a]			Dose-Blind Treatment Period A					Double-Blind Treatment Period B		
				Visit A0	Visit A1	Visit A2	Visit A3	Visit A4	Visit B1	Visit B2	Visit B3
	If >4 Wk Wash-out Required	Within 4 Wks of D1	4-2 Wks Prior to D1	Baseline (D1)	Wk 4 (D29)	Wk 8 (D57)	Wk 16 (D113)	Wk 24 (D169)	Wk 28 (D197)	Wk 32 (D225)	Wk 36 (D253)
Informed consent[b]	X	X									
Register for subject identification number[b]	X	X									
Psoriasis diagnosis, medical history[c]	X	X									
Current/prior medications[d,h]	X	X									
Complete physical examination[e]	X	X		X				X			
Targeted physical examination[e]					X	X	X		X	X	X
Vital signs, temperature	X	X		X	X	X	X	X	X	X	X
Weight, waist and hips circumference		X		X				X			
Height		X									
12-lead electrocardiogram (ECG)	X	X		X				X			
QuantiFERON-TB Gold (or Mantoux/PPD skin test)[f]	X	X									
Chest radiographs[f]	X	X									
Laboratory testing											
Hematology[g]	X	X		X	X	X	X	X	X	X	X
Serum chemistry (fasting)[h,i]	X	X		X	X	X	X	X	X	X	X
Lipid panel (fasting)[h,j]	X	X		X	X	X	X	X	X	X	X
Lipoproteins (fasting)[h,k]				X				X	X	X	X
Urinalysis, urine pregnancy test (β-hCG)[l]	X	X		X	X	X	X	X	X	X	X
C-reactive protein (hsCRP)		X		X				X			
HBsAg, HCV Ab, HIV serology	X	X									
Molecular profiling sampling[m]				X	X		X	X	X	X	X
Pharmacokinetic (PK) sampling[n]						X					
Clinical evaluation of psoriasis											
Psoriasis Area and Severity Index (PASI) & ody surface area (BSA)			X	X[o]	X	X	X	X[o]	X[o]	X[o]	X[o]
Physician Global Assessment (PGA)			X	X	X	X	X	X[o]	X	X	X
Patient reported outcomes											
Itch severity item (ISI)		X		X	X	X	X	X	X	X	X
Dermatology life quality index (DLQI)				X	X	X	X	X	X	X	X

Table 1. Schedule of Activities (Screening, Period A, and Period B)

Study Activity[a] - Screening - Period A - Period B	Screening[a]			Dose-Blind Treatment Period A					Double-Blind Treatment Period B		
				Visit A0	Visit A1	Visit A2	Visit A3	Visit A4	Visit B1	Visit B2	Visit B3
	If >4 Wk Wash-out Required	Within 4 Wks of D1	4-2 Wks Prior to D1	Baseline (D1)	Wk 4 (D29)	Wk 8 (D57)	Wk 16 (D113)	Wk 24 (D169)	Wk 28 (D197)	Wk 32 (D225)	Wk 36 (D253)
Short form-36 (version 2, acute) (SF-36)				X				X			
Patient Global Assessment (PtGA)				X	X	X	X	X	X	X	X
EuroQol 5 dimensions (EQ-5D)				X				X			
Psoriasis Life Stress Inventory (PLSI)				X		X		X			
Randomization[p]				X				X			
Review of concomitant medications				X	X	X	X	X	X	X	X
Adverse event (AE) reporting				X	X	X	X	X	X	X	X
Endpoint assessment of adverse events[q]				X	X	X	X	X	X	X	X
Study drug dispensing				X		X	X	X		X	
Regimen adherence review/drug accountability					X	X	X	X	X	X	X
Dispense topical emollient, as needed	X	X	X	X	X	X	X	X	X	X	X

Period A was a dose-blind treatment period. All subjects were randomized to treatment with tofacitinib (5 mg BID or 10 mg BID) through Visit A4/Week 24. At Visit A4/Week 24, the subject registration/randomization/study drug management system (IVRS/IWRS) determined subject eligibility for Period B based on the efficacy response:

- Responders: All subjects who achieved ≥PASI75 (at least a 75% reduction in the Psoriasis Area and Severity Index relative to baseline) and PGA response of "clear" or "almost clear" were considered responders and progressed to Period B. Visit A4/Week 24 was the last visit in Period A and was also the start of the treatment withdrawal period (Period B).
- Non-responders: All subjects, as described below, were considered non-responders and discontinued from the study; Visit A4/Week 24 was designated and conducted as the Early Termination (ET) visit (Visit C4/Week 56). These subjects had the opportunity to transfer to the long-term, open-label safety study (a Phase 3, multi-site, open-label study of the long term safety and tolerability of 2 oral doses of tofacitinib in subjects with moderate to severe chronic plaque psoriasis [NCT01163253]) if eligible and if the study site was participating in this open-label safety study .
  - Subjects had not achieved ≥PASI75;
  - Subjects had achieved PGA response of "clear" or "almost clear;"
  - Subjects had achieved only one response criterion (achieved ≥PASI75 or PGA response of "clear" or "almost clear", but not both).

Period B was a double-blind treatment withdrawal period. Subjects who entered Period B were re-randomized at Visit A4/Week 24 and received either tofacitinib (5 mg BID or 10 mg BID) or matching placebo BID. This period started once Visit A4/Week 24 was completed. The duration of and the number of visits attended in Period B were variable based on each subject's efficacy response. At the beginning of each visit in Period B, the IVRS/IWRS determined the subject's eligibility for Period C based on the efficacy response. The designation of each visit during Period B as a Period B or a Period C visit depended on each subject's efficacy response as follows:

- Week 28:
  - Subjects who achieved a >50% loss of the Visit A4/Week 24 PASI response (demonstrated a loss of adequate efficacy response) immediately progressed to Period C and Week 28 and was designated and conducted as the Visit C0.
  - Subjects who did not achieve a >50% loss of the Visit A4/Week 24 PASI response (demonsted at least a partial efficacy response or greater) continued in Period B and Week 28 and were designated and conducted as Visit B1. Subjects who continued in Period B then attended the Week 32 Visit.

Table 1. Schedule of Activities (Screening, Period A, and Period B)

Study Activity[a] - Screening - Period A - Period B	Screening[a]			Dose-Blind Treatment Period A					Double-Blind Treatment Period B		
				Visit A0	Visit A1	Visit A2	Visit A3	Visit A4	Visit B1	Visit B2	Visit B3
	If >4 Wk Wash-out Required	Within 4 Wks of D1	4-2 Wks Prior to D1	Baseline (D1)	Wk 4 (D29)	Wk 8 (D57)	Wk 16 (D113)	Wk 24 (D169)	Wk 28 (D197)	Wk 32 (D225)	Wk 36 (D253)

- Week 32:
  - Subjects who achieved a >50% loss of the Visit A4/Week 24 PASI response (demonstrated a loss of adequate efficacy response) immediately progressed to Period C and Week 32 and were designated and conducted as the Visit C0.
  - Subjects who did not acheve a >50% loss of the Visit A4/Week 24 PASI response (demonstrated at least a partial efficacy response or greater) continued in Period B and Week 32 and was designated and conducted as Visit B2. Subjects who continued in Period B then attended the Week 36 Visit.

Week 36:

- Subjects who achieved a >50% loss of the Visit A4/Week 24 PASI response (demonstrated a loss of adequate efficacy response) immediately progressed to Period C and Week 36 and were designated and conducted as the Visit C0.
- Subjects who did not achieve a >50% loss of the Visit A4/Week 24 PASI response (demonstratedeast partial efficacy response or greater) continued in Period B and Week 36 and were designated and conducted as Visit B3. Subjects who continued in Period B then attended the Week 40 Visit. For these subjects, Week 40 was the last visit of treatment withdrawal (Period B) and the first visit of re-treatment (Period C, Visit C0).

AE = adverse event; ALT = alanine aminotransferase; AST = aspartate aminotransferase; β-hCG = beta-human chorionic gonadotropin; BID = twice daily; BSA = body surface area; CHD = coronary heart disease; CO2 = carbon dioxide; CRF = case report form; CV-SEAC = cardiovascular safety endpoint adjudication; CK = creatinine kinase; D = day; DLQI = dermatology life quality index; ECG = electrocardiogram; EQ-5D = EuroQol 5 dimensions; EOS = end of study; ET = early termination; GGT = gamma glutamyl-transferase; HbA1c = glycated hemoglobin; HBsAg = hepatitis B surface antigen; HCV Ab = Hepatitis C antibody; HDL-C = high density lipoprotein cholesterol; HEENT = head, eyes, ears, nose and throat; HIV = human immunodeficiency virus; hsCRP = high sensitivity C-reactive protein; ISI = Itch Severity Item; IVRS/IWRS = interactive voice response system/interactive web-based response system; LDH = lactate dehydrogenase; LDL-C = low density lipoprotein cholesterol; LPD = lymphoproliferative disorder; PASI = Psoriasis Area and Severity Index; PGA = Physician's Global Assessment; PK = pharmacokinetic; PPD = purified protein derivative; PtGA = Patient Global Assessment; QFT-G = QuantiFERON-TB Gold; RBC = red blood cell; SF-36 = short form-36; TB = tuberculosis; WBC = white blood cell; Wk = week.

a. Screening procedures were to be performed/confirmed within 4 weeks prior to the Baseline/Day 1 visit, and were performed over >1 visit.
For subjects who required a washout >4 weeks in duration, a first screening visit was conducted to determine if the subject was initially eligible for the study and therefore appropriate to be washed out of the treatment regimen. These subjects should have returned for a subsequent screening visit within 4 weeks prior to Baseline/Day 1, at which time all screening procedures were repeated.
The clinical evaluations of psoriasis at Screening (PASI, BSA, PGA) had an additional requirement to be performed no later than 2 weeks prior to the Baseline/Day 1 visit; ie, between 4 to 2 weeks prior to the Baseline/Day 1 Visit.
There was a fasting requirement (9 hours) at Screening (for the fasting lipid panel and fasting glucose).
All visits: Sites were to attempt to schedule each subject's visits to occur in the morning (prior to the subject's morning dose) and at the same time of the day for that subject.
Visit windows: Screening = +3 day window; Visit A0 (Baseline/Day 1) = no window; all other post-baseline visits = ±3 day window. Visit A0 (Baseline/Day 1) wasthe reference date that subsequent visits in Period A and Period B were scheduled. Visit C0 (first visit in Period C/re-treatment) became the reference date that subsequent visits in Period C were scheduled.
Early termination (ET) visit: If a subject discontinued from the study early, final study procedures were completed as described for Visit C4/Week 56.
End of study (EOS) visit:
- If a subject transferred to the long-term, open-label safety study, the EOS Visit for Study A3921111 was Visit C4/Week 56.

Table 1. Schedule of Activities (Screening, Period A, and Period B)

Study Activity[a] - Screening - Period A - Period B	Screening[a]			Dose-Blind Treatment Period A					Double-Blind Treatment Period B		
				Visit A0	Visit A1	Visit A2	Visit A3	Visit A4	Visit B1	Visit B2	Visit B3
	If >4 Wk Wash-out Required	Within 4 Wks of D1	4-2 Wks Prior to D1	Baseline (D1)	Wk 4 (D29)	Wk 8 (D57)	Wk 16 (D113)	Wk 24 (D169)	Wk 28 (D197)	Wk 32 (D225)	Wk 36 (D253)

- If a subject did not transfer to the long-term, open-label safety study and study drug was taken within the 2 weeks prior to Visit C4/Week 56/ET, an off-treatment Follow-up/EOS visit was to be conducted at the Follow-up Visit/Week 58-60/EOS (2-4 weeks after Visit C4/Week 56).
- If a subject did not transfer to the long-term, open-label safety study and study drug was not taken within the 2 weeks prior to Visit C4/Week 56/ET, an additional off-treatment Follow-up/EOS visit was to be conducted at the discretion of the Investigator, ie, at the Follow-up Visit/Week 58-60/EOS (2-4 weeks after Visit C4/Week 56).

b. Subjects may have been taking prohibited medications that required a wash-out period that extended beyond the screening period duration. For these subjects, a first screening visit occurred to obtain written informed consent prior to initiation of the wash-out period. In such cases, informed consent and registration for subject identification number did not need to be repeated at the subsequent screening visit.

c. Medical history included targeted collection of details on plaque psoriasis, nail psoriasis, any prior rheumatologist confirmed diagnosis of psoriatic arthritis or rheumatoid arthritis, plaque psoriasis co-morbidities, cardiovascular risk factors, and any history of liver biopsy. Smoking status that included passive smoking, average weekly alcohol consumption, and family history of premature coronary heart disease (CHD) was also collected.

d. The Case report form (CRF) categorized collection of current/prior medications that included details on use of (a) previous therapies for psoriasis and response outcome, (b) antihypertensive medications, (c) antidiabetic medications, and (d) lipid-lowering medications.

e. Complete physical examination included general appearance; skin; head, eyes, ears, nose and throat (HEENT); heart; lungs; abdomen; lower extremities (peripheral edema); neurologic; and lymph nodes. Targeted physical examination consisted of skin, heart, lungs, abdomen, lower extremities (peripheral edema), and lymph nodes.

f. QuantiFERON-TB Gold (QFT-G) (or Mantoux/purified protein derivative [PPD] tuberculin skin test) and chest radiographs were performed unless previously done within 3 months of the screening visit and the results were documented prior to randomization. QFT-G did not have to be performed if a subject had previously received a documented adequate course of therapy for either latent or active tuberculosis (TB) infection. Mantoux/PPD tuberculin skin testing, if needed, required an additional visit to the clinic to read test results. Chest radiographs, if needed, may have required a non-study visit to a different location.

g. Hematology included white blood cell (WBC) count/differential; hemoglobin; hematocrit; red blood cell (RBC) count and morphology; and reticulocyte and platelet counts. Hemoglobin A1c (HbA1c) was measured at Baseline/Day 1 only. All hematology tests were performed by a central laboratory.

h. There was a fasting requirement (9 hours) for serum chemistry (fasting glucose), lipid panel, and lipoproteins. The blood draws for laboratories requiring a fasting state may have been taken up to 48 hours prior to the Baseline/Day 1 visit and up to 48 hours prior to or following all other visits, as necessary to ensure samples were collected in a fasting state. It was essential that these samples were collected in a fasting state.
Subjects should have taken prescribed permitted oral concomitant medication, as needed, prior to study visits, if it could have been administered with water only. Prescribed permitted oral concomitant medication that must have been taken with food or after meals should not have been taken until after the fasting visit procedures (laboratory test sample collection, vital signs and weight measurement, and ECG recording) had been completed.
The time of day for study visits should have been considered in the context of specific underlying medical conditions (eg, diabetes mellitus) and other requirements (eg, fasting, administration of prescribed permitted concomitant medication). Subjects who had specific underlying medical conditions (eg, diabetes mellitus) may have needed additional instructions regarding the fasting requirement and the timing of concomitant medication administration (eg, insulin) on study visit days.

i. Serum chemistry (fasting) included urea nitrogen, creatinine, glucose (fasting), calcium, sodium, potassium, bicarbonate or total CO_2, chloride, total protein, total bilirubin, direct bilirubin, indirect bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, gamma-glutamyl transferase (GGT), albumin, lactate dehydrogenase (LDH) and creatine kinase (CK). All serum chemistry tests were performed by a central laboratory.

Table 1. Schedule of Activities (Screening, Period A, and Period B)

Study Activity[a] - Screening - Period A - Period B	Screening[a]			Dose-Blind Treatment Period A					Double-Blind Treatment Period B		
				Visit A0	Visit A1	Visit A2	Visit A3	Visit A4	Visit B1	Visit B2	Visit B3
	If >4 Wk Wash-out Required	Within 4 Wks of D1	4-2 Wks Prior to D1	Baseline (D1)	Wk 4 (D29)	Wk 8 (D57)	Wk 16 (D113)	Wk 24 (D169)	Wk 28 (D197)	Wk 32 (D225)	Wk 36 (D253)

j. Lipid panel (fasting) included total cholesterol, low density lipoprotein cholesterol (LDL-C; if triglycerides were >400 mg/dL, LDL-C was determined by direct measurement), high density lipoprotein cholesterol (HDL-C), and triglycerides. All lipid panel tests were performed by a central laboratory.

k. Lipoproteins (fasting) includd apolipoproteins A1 and B as well as measurements of other lipoproteins, particle number, and particle size. Lipoprotein analyses were held and conducted in batches at a later time to reduce inter-assay variability.

l. Urinalysis included specific gravity, pH, protein, glucose, ketones, nitrites, blood, and leukocyte esterase/WBC. If the urinalysis was positive for blood, nitrites, leukocyte esterase/WBC, and/or protein, a microscopic analysis was performed. If the urinalysis was positive for nitrites and/or leukocyte esterase/WBC or if clinically indicated, a urine culture was performed. All urinalysis were performed by a central laboratory.

m. Molecular profiling (pharmacogenomic) research component was optional and conducted only at participating sites; refer to the "Molecular Profiling Supplement" for further details.

n. On study visit days, subjects were to be instructed to refrain from dosing at home and were to take the morning dose in the clinic. Post-dose PK samples (2 hours post-in-clinic dose) was collected at Visit A2 (Week 8) and Visit C2 (C0+8 weeks).

o. Clinical evaluations of psoriasis (PASI with or without PGA, as required) were entered in the IVRS/IWRS at selected visits. The system calculated the efficacy response and determined subject eligibility for Period B and subject progression during Period B (current visit name/designator to inform the study site which study activities were to be conducted).

p. Subjects were randomized at Baseline/Day 1 and were be re-randomized at Visit A4/Week 24 if eligible to enter Period B.

q. Specific cardiovascular events were submitted to the Cardiovascular Safety Endpoint Adjudication Committee (CV-SEAC) for adjudication. Biopsies collected for potential malignancy events were submitted to the central laboratory for pathologist over-read.

Table 2 Schedule of Activities (Period C and Follow-up)

Study Activity[a] - Period C - Follow-up	Dose-Blind Re-Treatment Period C						Follow-Up (EOS)[a]
	Visits Completed in Period B	Visit C0	Visit C1 (Visit C0 + 4 wks)	Visit C2 (Visit C0 + 8 wks)	Visit C3 (Visit C0 + 16 wks)	Visit C4 (ET / EOS)[l]	
	None	Week 28 (D197)	Week 32 (D225)	Week 36 (D253)	Week 44 (D309)	Week 56 (D393)	Week 58-60 (D407-421)
	Visit B1	Week 32 (D225)	Week 36 (D253)	Week 40 (D281)	Week 48 (D337)		
	Visit B1 & B2	Week 36 (D253)	Week 40 (D281)	Week 44 (D309)	Week 52 (D365)		
	Visit B1, B2, & B3	Week 40 (D281)	Week 44 (D309)	Week 48 (D337)	Skip to Visit C4		
Informed consent[b]							
Register for subject identification number							
Psoriasis diagnosis, medical history[c]							
Current/prior medications[d,h]							
Complete physical examination[e]						X	X
Targeted physical examination[e]		X	X	X	X		
Vital signs, temperature		X	X	X	X	X	X
Weight, waist and hips circumference		X				X	
Height							
12-Lead electrocardiogram (ECG)						X	
QuantiFERON®-TB Gold (or Mantoux/PPD skin test[f]							
Chest radiographs[f]							
Laboratory Testing							
Hematology[g]		X	X	X	X	X	X
Serum chemistry (fasting)[h,i]		X	X	X	X	X	X
Lipid panel (fasting)[h,j]		X	X	X	X	X	X
Lipoproteins (fasting)[h,k]		X				X	
Urinalysis, urine pregnancy test (β-hCG)[l]		X	X	X	X	X	X
C-reactive protein (hsCRP)		X				X	
HBsAg, HCV Ab, HIV serology							
Molecular profiling sampling[m]		X	X		X	X	X
Pharmacokinetic sampling[n]				X			
Clinical Evaluation of Psoriasis							
Psoriasis Area and Severity Index (PASI) & body surface area (BSA)		X[o]	X	X	X	X	X
Physician Global Assessment (PGA)		X	X	X	X	X	X
Patient Reported Outcomes							

Table 2 Schedule of Activities (Period C and Follow-up)

Study Activity[a] - Period C - Follow-up	Dose-Blind Re-Treatment Period C						Follow-Up (EOS)[a]
	Visits Completed in Period B	Visit C0	Visit C1 (Visit C0 + 4 wks)	Visit C2 (Visit C0 + 8 wks)	Visit C3 (Visit C0 + 16 wks)	Visit C4 (ET / EOS)[l]	
	None	Week 28 (D197)	Week 32 (D225)	Week 36 (D253)	Week 44 (D309)	Week 56 (D393)	Week 58-60 (D407-421)
	Visit B1	Week 32 (D225)	Week 36 (D253)	Week 40 (D281)	Week 48 (D337)		
	Visit B1 & B2	Week 36 (D253)	Week 40 (D281)	Week 44 (D309)	Week 52 (D365)		
	Visit B1, B2, & B3	Week 40 (D281)	Week 44 (D309)	Week 48 (D337)	Skip to Visit C4		
Itch severity item (ISI)		X	X	X	X	X	X
Dermatology life quality index (DLQI)		X	X	X	X	X	
Short form-36 (version 2, acute) (SF-36)		X				X	
Patient Global Assessment (PtGA)		X	X	X	X	X	
EuroQol 5 dimensions (EQ-5D)		X				X	
Psoriasis Life Stress Inventory (PLSI)		X		X		X	
Randomization[p]							
Review of concomitant medications		X	X	X	X	X	X
Adverse event reporting		X	X	X	X	X	X
Endpoint assessment of adverse events[q]		X	X	X	X	X	X
Study drug dispensing		X		X	X		
Regimen adherence review drug accountability		X	X	X	X	X	
Dispense topical emollient, as needed		X	X	X	X	X	

Period C was a dose-blind re-treatment period. At the start of Period C (Visit C0), subjects who had treatment withdrawn, ie, placebo treatment in Period B, were re-started at the same dose of tofacitinib (5 mg BID or 10 mg BID) that they were randomized to in Period A through Week 56. Subjects who did not have treatment withdrawn, ie, remained on the same dose of tofacitinib (5 mg BID or 10 mg BID) in Period B as in Period A, and continued on that same dose in Period C through Week 56. All subjects (both those who had study drug withdrawn as well as those who did not have study drug withdrawn in Period B) attended scheduled visits in Period C regardless of the Period B PASI response.

ALT = alanine aminotransferase; AST = aspartate aminotransferase; β-hCG = beta-human chorionic gonadotropin; BID = twice daily; BSA = body surface area; CHD = coronary heart disease; CK = creatinine kinase; CO2 = carbon dioxide; CRF = case report form; CV-SEAC = cardiovascular safety endpoint; adjudication committees; D = day; DLQI = dermatology life quality index; ECG = electrocardiogram; EOS = end of study; EQ-5D = EuroQol 5 dimensions; ET = early termination; GGT = gamma glutamyl-transferase; HBsAg = hepatitis B surface antigen; HbA1c = glycated hemoglobin; HCV Ab = hepatitis C antibody; HDL-C = high density lipoprotein cholesterol; HEENT = head, eyes, ears, nose and throat; HIV = human immunodeficiency virus; hsCRP = high sensitivity C-reactive protein; ISI = itch severity item; IVRS/IWRS = interactive voice response system/interactive web-based response system; LDH = lactate dehydrogenase; LDL-C = low density lipoprotein cholesterol; PASI = Psoriasis Area and Severity Index; PGA = Physician's Global Assessment; PK = pharmacokinetic; PPD = purified protein derivative; PtGA = Patient Global Assessment; QFT-G = QuantiFERON®-TB Gold; RBC = red blood cell; SF-36 = short form-36; TB = tuberculosis; WBC = white blood cell.

a. Screening procedures were to be performed/confirmed within 4 weeks prior to the Baseline/Day 1 visit, and were performed over more than 1 visit. For subjects who required a washout >4 weeks in duration, a first screening visit was conducted to determine if the subject was initially eligible for the study and therefore appropriate to be washed out of the treatment regimen. These subjects should have returned for a subsequent screening visit within 4 weeks prior to Baseline/Day 1, at which time all screening procedures were repeated.

Table 2 Schedule of Activities (Period C and Follow-up)

Study Activity[a] - Period C - Follow-up	Dose-Blind Re-Treatment Period C						Follow-Up (EOS)[a]
	Visits Completed in Period B	Visit C0	Visit C1 (Visit C0 + 4 wks)	Visit C2 (Visit C0 + 8 wks)	Visit C3 (Visit C0 + 16 wks)	Visit C4 (ET / EOS)[1]	
	None	Week 28 (D197)	Week 32 (D225)	Week 36 (D253)	Week 44 (D309)	Week 56 (D393)	Week 58-60 (D407-421)
	Visit B1	Week 32 (D225)	Week 36 (D253)	Week 40 (D281)	Week 48 (D337)		
	Visit B1 & B2	Week 36 (D253)	Week 40 (D281)	Week 44 (D309)	Week 52 (D365)		
	Visit B1, B2, & B3	Week 40 (D281)	Week 44 (D309)	Week 48 (D337)	Skip to Visit C4		

The clinical evaluations of psoriasis at Screening (PASI, BSA, PGA) had an additional requirement to be performed no later than 2 weeks prior to the Baseline/Day 1 visit; ie, between 4 to 2 weeks prior to the Baseline/Day 1 visit.
There was a fasting requirement (9 hours) at Screening (for the fasting lipid panel and fasting glucose).
All visits: Sites were to attempt to schedule each subject's visits to occur in the morning (prior to the subject's morning dose) and at the same time of the day for that subject.
Visit windows: Screening = +3 day window; Visit A0 (Baseline/Day 1) = no window; all other post-baseline visits = ±3 day window. Visit A0 (Baseline/Day 1) was the reference date that subsequent visits in Period A and Period B were scheduled. Visit C0 (first visit in Period C/re-treatment) became the reference date that subsequent visits in Period C were scheduled.
ET Visit: If a subject discontinued from the study early, final study procedures were completed as described for Visit C4/Week 56.
EOS Visit:

- If a subject transferred to the long-term, open-label safety study, the EOS Visit for this study was Visit C4/Week 56.
- If a subject did not transfer to the long-term, open-label safety study and study drug was taken within the 2 weeks prior to Visit C4/Week 56/ET, an off-treatment Follow-up/EOS visit was to be conducted at the Follow-up Visit/Week 58-60/EOS (2-4 weeks after Visit C4/Week 56).
- If a subject did not transfer to the long-term, open-label safety study and study drug was not taken within the 2 weeks prior to Visit C4/Week 56/ET, an additional off-treatment Follow-up/EOS visit was to be conducted at the discretion of the Investigator, ie, at the Follow-up Visit/Week 58-60/EOS (2-4 weeks after Visit C4/Week 56).

b. Subjects may have been taking prohibited medications that required a washout period that extended beyond the screening period duration. For these subjects, a first screening visit occurred to obtain written informed consent prior to initiation of the washout period. In such cases, informed consent and registration for subject identification number did not need to be repeated at the subsequent screening visit.

c. Medical history included targeted collection of details on plaque psoriasis, nail psoriasis, any prior rheumatologist confirmed diagnosis of psoriatic arthritis or rheumatoid arthritis, plaque psoriasis co-morbidities, cardiovascular risk factors, and any history of liver biopsy. Smoking status that included passive smoking, average weekly alcohol consumption, and family history of premature coronary heart disease (CHD) was also collected.

d. The case report form (CRF) categorized collection of current/prior medications that included details on use of (a) previous therapies for psoriasis and response outcome, (b) antihypertensive medications, (c) antidiabetic medications, and (d) lipid-lowering medications.

e. Complete physical examination included general appearance; skin; head, eyes, ears, nose, and throat (HEENT); heart; lungs; abdomen; lower extremities (peripheral edema); neurologic and lymph nodes. Targeted physical examination consisted of skin, heart, lungs, abdomen, lower extremities (peripheral edema), and lymph nodes.

f. QuantiFERON®-TB Gold (QFT-G) (or mantoux/ purified protein derivative [PPD] tuberculin skin test) and chest radiographs were performed unless previously done within 3 months of the screening visit and the results were documented prior to randomization. QFT-G need did not have to be performed if a subject had previously received a documented adequate course of therapy for either latent or active tuberculosis (TB) infection. Mantoux/PPD tuberculin skin testing, if needed, required an

Table 2 Schedule of Activities (Period C and Follow-up)

Study Activity[a] - Period C - Follow-up	Dose-Blind Re-Treatment Period C						Follow-Up (EOS)[a]
	Visits Completed in Period B	Visit C0	Visit C1 (Visit C0 + 4 wks)	Visit C2 (Visit C0 + 8 wks)	Visit C3 (Visit C0 + 16 wks)	Visit C4 (ET / EOS)[1]	
	None	Week 28 (D197)	Week 32 (D225)	Week 36 (D253)	Week 44 (D309)	Week 56 (D393)	Week 58-60 (D407-421)
	Visit B1	Week 32 (D225)	Week 36 (D253)	Week 40 (D281)	Week 48 (D337)		
	Visit B1 & B2	Week 36 (D253)	Week 40 (D281)	Week 44 (D309)	Week 52 (D365)		
	Visit B1, B2, & B3	Week 40 (D281)	Week 44 (D309)	Week 48 (D337)	Skip to Visit C4		

additional visit to the clinic to read test results. Chest radiographs, if needed, may have required a non-study visit to a different location.

g. Hematology included white blood cell (WBC) count/differential; hemoglobin; hematocrit; red blood cell (RBC) count and morphology; and reticulocyte and platelet counts. Hemoglobin A1c (HbA1c) was be measured at Baseline/Day 1 only. All hematology tests were be performed by a central laboratory.

h. There was a fasting requirement (9 hours) for serum chemistry (fasting glucose), lipid panel, and lipoproteins. The blood draws for labs requiring a fasting state may have been taken up to 48 hours prior to the Baseline/Day 1 Visit and up to 48 hours prior to or following all other visits, as necessary to ensure samples were collected in a fasting state. It was essential that these samples were collected in a fasting state.
Subjects should have taken prescribed permitted oral concomitant medication, as needed, prior to study visits, if it could have been administered with water only. Prescribed permitted oral concomitant medication that must have been taken with food or after meals should not have been taken until after the fasting visit procedures (laboratory test sample collection, vital signs and weight measurement, and ECG recording) had been completed.
The time of day for study visits should have been considered in the context of specific underlying medical conditions (eg, diabetes mellitus) and other requirements (eg, fasting, administration of prescribed permitted concomitant medication). Subjects who had specific underlying medical conditions (eg, diabetes mellitus) may have needed additional instructions regarding the fasting requirement and the timing of concomitant medication administration (eg, insulin) on study visit days.

i. Serum chemistry (fasting) included urea nitrogen, creatinine, glucose (fasting), calcium, sodium, potassium, bicarbonate or total CO_2, chloride, total protein, total bilirubin, direct bilirubin, indirect bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, gamma-glutamyl transferase (GGT), albumin, lactate dehydrogenase (LDH) and creatine kinase (CK). All serum chemistry tests were performed by a central laboratory.

j. Lipid panel (fasting) includes total cholesterol, low density lipoprotein cholesterol (LDL-C; if triglycerides were >400 mg/dL, LDL-C was determined by direct measurement), high density lipoprotein cholesterol (HDL-C), and triglycerides. All lipid panel tests were performed by a central laboratory.

k. Lipoproteins (fasting) included apolipoproteins A1 and B as well as measurements of other lipoproteins, particle number, and particle size. Lipoprotein analyses were held and conducted in batches at a later time to reduce inter-assay variability.

l. Urinalysis included specific gravity, pH, protein, glucose, ketones, nitrites, blood, and leukocyte esterase/WBC. If the urinalysis was positive for blood, nitrites, leukocyte esterase/WBC, and/or protein, a microscopic analysis was performed. If the urinalysis was positive for nitrites and/or leukocyte esterase/WBC or if clinically indicated, a urine culture was performed. All urinalysis were performed by a central laboratory.

m. Molecular profiling (pharmacogenomic) research component was optional and conducted only at participating sites; refer to the "Molecular Profiling Supplement" for further details.

n. On study visit days, subjects were to be instructed to refrain from dosing at home and were to take the morning dose in the clinic. Post-dose PK samples (2 hours post-in-clinic dose) was collected at Visit A2 (Week 8) and Visit C2 (C0 + 8 weeks).

o. Clinical evaluations of psoriasis (PASI with or without PGA, as required) were entered in the IVRS/IWRS at selected visits. The system calculated the efficacy response and determined subject eligibility for Period B and subject progression during Period B (current visit name/designator to inform the study site which study activities were to be conducted)

Table 2 Schedule of Activities (Period C and Follow-up)

Study Activity[a] - Period C - Follow-up	Dose-Blind Re-Treatment Period C						Follow-Up (EOS)[a]
	Visits Completed in Period B	Visit C0	Visit C1 (Visit C0 + 4 wks)	Visit C2 (Visit C0 + 8 wks)	Visit C3 (Visit C0 + 16 wks)	Visit C4 (ET / EOS)[1]	
	None	Week 28 (D197)	Week 32 (D225)	Week 36 (D253)	Week 44 (D309)	Week 56 (D393)	Week 58-60 (D407-421)
	Visit B1	Week 32 (D225)	Week 36 (D253)	Week 40 (D281)	Week 48 (D337)		
	Visit B1 & B2	Week 36 (D253)	Week 40 (D281)	Week 44 (D309)	Week 52 (D365)		
	Visit B1, B2, & B3	Week 40 (D281)	Week 44 (D309)	Week 48 (D337)	Skip to Visit C4		

p. Subjects were randomized at Baseline/Day 1 and were re-randomized at Visit A4/Week 24 if eligible to enter Period B.

q. Specific cardiovascular events were submitted to the Cardiovascular Safety Endpoint Adjudication Committee (CV-SEAC) for adjudication. Biopsies collected for potential malignancy events were submitted to the central laboratory for pathologist over-read.

Number of Subjects (Planned and Analyzed): A total of 1090 subjects screened for entry into the study, 674 subjects were randomized to treatment in Period A: 336 in the tofacitinib 5 mg BID group and 338 subjects in the tofacitinib 10 mg BID group. The study enrolled 674 subjects: 20 in Argentina, 24 in Australia, 12 in Brazil, 27 in Bulgaria, 129 in Canada, 18 in Denmark, 4 in Finland, 5 in Greece, 5 in Netherlands, 9 in Slovakia, 16 in the United Kingdom, 405 in United States.

Diagnosis and Main Criteria for Inclusion: Eligible subjects were males or females aged at least 18 years, had chronic (≥12 months) plaque-type psoriasis involving at least 10% of total body surface area (BSA) and a Psoriasis Area and Severity Index (PASI) score of ≥12 and a Physician's Global Assessment (PGA) score of 3 or 4 at Baseline. Eligible subjects showed no evidence of active, latent, or inadequately treated infection with tuberculosis or other serious infections. The subjects excluded with non-plaque or drug induced forms of psoriasis. Subjects who cannot discontinue current oral, injectable or topical therapy for psoriasis or cannot discontinue phototherapy (Psoralen Ultraviolet A; Ultraviolet B) were excluded. The subjects excluded with any uncontrolled significant medical condition.

Study Treatment: Tofacitinib tablet (5 mg BID and 10 mg BID) or placebo was taken orally BID (approximately every 12 hours) for up to 56 weeks. Following the 56-week treatment period, subjects either enrolled in the long-term, open-label safety study, if eligible, or remained in this study to complete the off-treatment follow-up/end of study (EOS) Visit (Follow-up Visit/Week 58-60/EOS) conducted 2-4 weeks after the final study drug dosing.

Efficacy and Pharmacokinetic Endpoints, and Patient Reported Outcomes:

Primary Endpoints:

- Proportion of subjects maintaining a PASI75 response (at least a 75% reduction in PASI relative to Baseline/Day 1) during the 16-week double-blind active or placebo treatment period (tofacitinib treatment withdrawal; Period B).

- Proportion of subjects maintaining a PGA response (PGA of "clear" or "almost clear") during the 16-week double-blind active or placebo treatment period (tofacitinib treatment withdrawal; Period B).

- Among subjects who had a >50% reduction of the Visit A4/Week 24 PASI response during tofacitinib treatment withdrawal, the proportion of subjects achieving a PASI75 response during tofacitinib re-treatment (Period C).

- Among subjects who had a PGA of "mild," "moderate," or "severe" during tofacitinib withdrawal, the proportion of subjects achieving a PGA response (PGA of "clear" or "almost clear") during tofacitinib re-treatment (Period C).

Secondary Endpoints:

- Time to PASI75 response during initial tofacitinib treatment (Period A)

- Time to PGA response during initial tofacitinib treatment (Period A).

- Time to loss of adequate response, defined as >50% reduction of the Visit A4/Week 24 PASI response during the 16-week double-blind active or placebo treatment period (tofacitinib treatment withdrawal; Period B).

- Proportion of subjects achieving a PASI50-75 response (at least 50 but >75) with Dermatology Life Quality Index (DLQI) ≤5 per visit during the initial tofacitinib treatment (Period A).

- Proportion of subjects with rebound (defined as worsening of psoriasis over Baseline [Day 1, Visit A0] value [PASI ≥125% of Baseline] or new type of psoriasis [pustular, erythrodermic, as reported on AE forms]) during the period between Week 24 (Visit A4) and Week 32 (Visit B2).

- Proportion of subjects with worsening of psoriasis over Baseline (Day 1, Visit A0) value (PASI ≥125% of Baseline) or new type of psoriasis (pustular, erythrodermic, as reported on AE forms) during the 16-week double-blind active or placebo treatment period (tofacitinib treatment withdrawal; Period B).

- Time to loss of >50% of the Visit A4/Week 24 PASI response and loss of PGA response (PGA of "clear" or "almost clear") during the 16-week double-blind active or placebo treatment period (tofacitinib treatment withdrawal; Period B).

- Time to PASI75 response and time to PGA response during tofacitinib re-treatment (Period C).

- Time to regain PASI75 and PGA response (PGA of "clear" or "almost clear") during tofacitinib re-treatment (Period C) among the subjects who lost both PASI75 response and PGA response ("clear" or "almost clear") at the beginning of Period C.

- The proportion of subjects regaining PASI75 and PGA response (PGA of "clear" or "almost clear") during tofacitinib re-treatment (Period C) among the subjects who lost both PASI75 response and PGA response ("clear" or "almost clear") at the beginning of Period C.

- PASI75 response at various timepoints through Week 56

- PGA response at various timepoints through Week 56.

- Actual and change from Baseline in PASI and PASI component scores at various timepoints through Week 56.

- Proportion of subjects achieving at least a 50%, 90%, and 100% reduction in PASI relative to Baseline (PASI50, PASI90 and PASI100, respectively) during Period A and Period C.

- Proportion of subjects with a PASI score ≥125% of the Baseline PASI score at various timepoints through Week 56.

- Actual, change and percent change from Baseline in total psoriatic BSA and psoriatic BSA by body region at various timepoints through Week 56.

- Proportion of subjects in each PGA category at various timepoints through Week 56.

- Actual and change from Baseline in the Itch Severity Item (ISI) score at various timepoints through Week 56.

- Actual and change from baseline on the Dermatology Life Quality Index (DLQI) score at various timepoints through Week 56.

- Proportion of subjects achieving an ISI score of '0', an ISI score of '0' or '1', and at least 2 points reduction from Baseline in ISI score at various timepoints through Week 56.

- Time to ISI success (ISI score ≤1) and time to ISI reduction (a 2-point decrease in ISI score) during Period A and Period C.

Pharmacokinetic Endpoint:

- PK of tofacitinib (5 mg BID and 10 mg BID) at Visit A2 (Week 8) and Visit C2 (C0 + 8 weeks).

Concentration-time data for tofacitinib were summarized by descriptive statistics, and graphical presentation for Periods A and C.

Patient Reported Outcome Measures:

- Other patient reported outcome (PRO) measures to be assessed at various timepoints through Week 56.
    - Short Form-36 (Version 2, Acute) (SF-36).
    - Patient Global Assessment of Psoriasis (PtGA).
    - EuroQol 5 Dimensions (EQ-5D).

Safety Evaluations:

Safety was assessed by physical examinations, vital signs, ECGs, clinical laboratory results, and the spontaneous reporting of AEs in all subjects who received at least 1 dose of study drug.

Statistical Methods:

This study included 3 treatment periods: A, B, and C. The primary statistical hypotheses were based on data solely from Period B. Analyses of endpoints during Periods A and C, including 2 primary endpoints in Period C, were intended to be descriptive in nature.

A logrank test was used to analyze the 2 primary endpoints in Period B. A fixed sequence approach was applied. Specifically, there were 2 independent sequences for comparison of the active doses (tofacitinib 5 mg BID and 100 mg BID) versus corresponding placebo for each endpoint: one sequence for the PASI75 response and the other sequence for the PGA response. With each endpoint, the low-dose group was compared with placebo prior to comparison of the high-dose group versus placebo. Statistical significance could be claimed for a given endpoint in the sequence only if the prior step met the requirements for significance. Comparisons were made at the 0.025 (2-sided) level to control the overall type 1 error rate at the 0.05 level.

Due to the nature of this study design, there were 4 Full Analysis Sets (FAS): 3 for each of the 3 study periods (A, B, and C) and 1 for the overall study.

Period A - Full Analysis Set (FAS-A):

The Period A - Full Analysis Set (FAS-A) included all subjects who were randomized at Baseline and received at least 1 dose of the randomized investigational drug (tofacitinib 5mg BID or 10 mg BID) during Period A.

Period B - Full Analysis Set (FAS-B):

The Period B - Full Analysis Set (FAS-B) included all subjects who were re-randomized at the end of period A and received at least 1 dose of investigational drug (tofacitinib 5 mg BID or 10 mg BID) or placebo at the beginning of Period B. The primary statistical hypotheses for this study were tested on this analysis population.

Period C - Full Analysis Set (FAS-C):

The Period C - Full Analysis Set (FAS-C) included all FAS-B subjects who were advanced to the re-treatment period (Period C) during the 16 weeks of Period B and received at least 1 dose of investigational drug (tofacitinib 5 mg BID, or 10 mg BID) during Period C.

The efficacy results in Period C were evaluated on FAS-C or the different subsets of the FAS-C population. For example, the FAS-C for the proportion of subjects regaining a PASI75 response among subjects who lost >50% Visit A4/Week 24 PASI responses during Period B included all subjects who advanced to Period C due to a >50% reduction of the Visit A4/Week 24 PASI response during the tofacitinib treatment withdrawal (Period B), ie, subjects who were advanced to Period C without loss of a >50% of the Visit A4/Week 24 PASI response during Period B were excluded. The FAS-C for the proportion of subjects who regained a PGA response among subjects who lost the PGA response during Period B included all subjects who advanced to Period C and had a PGA of “mild,” “moderate,” or “severe,” during tofacitinib withdrawal during Period B, i.e., subjects who were advanced to Period C and had not had a PGA of “mild,” “moderate,” or “severe” during Period B were excluded.

Overall Study Period - Full Analysis Set (FAS)

The overall study period – Full Analysis Set (FAS) was the same as FAS-A.

Per Protocol Analysis Set: The 'Per Protocol' (PP) Analysis Set was a subset of subjects from FAS-B. Subjects who had a protocol deviation thought to affect the efficacy analysis was excluded from the PP efficacy analysis. The Per Protocol Analysis Set was defined for Period B only. Note that the protocol deviation may have occurred during Period A. Protocol deviations were assessed by the project team prior to the unblinding of the study. This list of subjects along with exclusions from the PP analyses were put into the trial master file.

Safety Analyses Sets:

There were 4 Safety Analysis Sets: 3 for the 3 study periods (A, B, and C) and 1 for the overall study period.

Period A - Safety Analysis Set (Safety-A):

The Period A - Safety Analysis Set (Safety-A) will include all subjects who received at least 1 dose of the investigational drug (tofacitinib 5mg BID or 10 mg BID) during Period A.

Period B - Safety Analysis Set (Safety-B):

The Period B - Safety Analysis Set (Safety-B) included all subjects who received at least 1 dose of investigational drug (tofacitinib 5 mg BID or 10 mg BID) or placebo during Period B.

Period C – Safety Analysis Set (Safety-C):

The Period C - Safety Analysis Set (Safety-C) included all subjects who were advanced to the re-treatment period (Period C) during the 16 weeks of Period B and received at least 1 dose of investigational drug (tofacitinib 5 mg BID, or 10 mg BID) during Period C.

Overall Study Period - Safety Analysis Set (Safety)

The overall study period – the Safety Analysis Set (Safety) consists of all subjects who received at least 1 dose of the investigational drug (tofacitinib or placebo) during any study Period.

RESULTS

Subject Disposition and Demography: The dispositions of the subjects are summarized in Table 3, Table 4, and Table 5.

Table 3. Subject Evaluation During the Initial Tofacitinib Treatment (Safety-A)

	Tofacitinib 5 mg BID n (%)	Tofacitinib 10 mg BID n (%)	Total N (%)
Screened			1090
Randomized[a]	336	338	674
Safety analysis set[b]	331 (100)	335	666 (100)
Full analysis set (FAS)[c]	331 (100)	335 (100)	666 (100)
Completed	297 (89.7)	297 (88.7)	594 (89.2)
Number of subjects with inadequate response, intolerant, or contraindicated to protocol-specified systemic therapies			
<3	314 (94.9)	315 (94.0)	629 (94.4)
≥3	17 (5.1)	20 (6.0)	37 (5.6)
Not eligible for Period B and not entered into Period B	181 (54.7)	114 (34.0)	295 (44.3)
Not eligible but entered into Period B	6 (1.8)	7 (2.1)	13 (2.0)
Eligible and entered into Period B (treatment withdrawal)	108 (32.6)	172 (51.3)	280 (42.0)
Eligible but not entered into Period B (treatment withdrawal)	2 (0.6)	4 (1.2)	6 (0.9)
Discontinued[d]	34 (10.3)	38 (11.3)	72 (10.8)
Primary reason for discontinuation:			
Death	1 (0.3)	0 (0.0)	1 (0.2)
Adverse event(s)	7 (2.1)	9 (2.7)	16 (2.4)
Related to study drug	5 (1.5)	6 (1.8)	11 (1.7)
Not related to study drug	2 (0.6)	3 (0.9)	5 (0.8)
Insufficient clinical response (assessed by Investigator)	6 (1.8)	7 (2.1)	13 (2.0)
Lost to follow-up	6 (1.8)	7 (2.1)	13 (2.0)
No longer willing to participate in the study	12 (3.6)	7 (2.1)	19 (2.9)
Other[e]	2 (0.6)	8 (2.4)	10 (1.5)

Insufficient clinical response for study specified threshold at Visit A4/Week 24 if subjects did not achieve both PASI75 response and PGA response of "clear" or "almost clear."

BID = twice daily, FAS = Functional Analysis Set, N = number of subjects, n = number of subjects in pre-specified criteria.

a. Eight subjects were randomized but never received study drug during Period A.
b. Safety Analysis Set - all subjects who received at least one dose of study drug during Period A.
c. Full Analysis Set-A (FAS-A) - all subjects who were randomized and received at least 1 dose of the randomized study drug during Period A.
d. Subjects were defined as discontinued if they did not complete the Week 24 visit and did not enter Period B.
e. "Other" included all reasons not specified above.

Table 4. Subject Evaluation During Treatment Withdrawal (Safety-B)

	Tofacitinib 5 mg BID	Placebo-for Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Placebo-for Tofacitinib 10 mg BID	Total
	n (%)	n (%)	n (%)	n (%)	N (%)
Re-randomized (from Period A)	31	83	45	134	293
Safety Analysis Set[a]	31 (100)	82 (100)	45 (100)	133 (100)	291 (100)
Full Analysis Set B (FAS-B)[b]	31 (100)	82 (100)	45 (100)	133 (100)	291 (100)
PP Analysis Set[c]	30 (96.8)	80 (97.6)	43 (95.6)	131 (98.5)	284 (97.6)
Completed	28 (90.3)	76 (92.7)	42 (93.3)	120 (90.2)	266 (91.4)
Discontinued[d]	3 (9.7)	6 (7.3)	3 (6.7)	13 (9.8)	25 (8.6)
Primary reason for discontinuation:					
Death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Adverse event(s)	1 (3.2)	0 (0.0)	1 (2.2)	3 (2.3)	5 (1.7)
Related to study drug	0 (0.0)	0 (0.0)	1 (2.2)	2 (1.5)	3 (1.0)
Not related to study drug	1 (3.2)	0 (0.0)	0 (0.0)	1 (0.8)	2 (0.7)
Insufficient clinical response (assessed by Investigator)	0 (0.0)	1 (1.2)	0 (0.0)	2 (1.5)	3 (1.0)
Lost to follow-up	1 (3.2)	0 (0.0)	0 (0.0)	3 (2.3)	4 (1.4)
No longer willing to participate in study	1 (3.2)	2 (2.4)	0 (0.0)	2 (1.5)	5 (1.7)
Other[e]	0 (0.0)	3 (3.7)	2 (4.4)	3 (2.3)	8 (2.7)

BID = twice daily, FAS = Functional Analysis Set, N = number of subjects, n = number of subjects in pre-specified criteria.

a. Safety Analysis Set - all subjects who received at least one dose of study drug during Period B.
b. FAS-B - all subjects who were randomized and received at least 1 dose of the randomized study drug during Period B.
c. Per Protocol Analysis Set - a subset of FAS-B set that excluded subjects who had protocol deviations thought to affect the efficacy analysis during the study.
d. Subjects were defined as discontinued if they took Period B treatment but did not complete the first visit of Period C.
e. Other included all reasons not specified above.

Table 5. Subject Evaluation During the Tofacitinib Re-Treatment (Safety-C)

	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID n (%)	Placebo / Tofacitinib 5 mg BID n (%)	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID n (%)	Placebo / Tofacitinib 10 mg BID n (%)	Total N (%)
Safety Analysis Set[a]	27 (100)	75 (100)	42 (100)	120 (100)	264 (100)
Full Analysis Set (FAS)[b]	27 (100)	75 (100)	42 (100)	120 (100)	264 (100)
Completed	25 (92.6)	70 (93.3)	39 (92.9)	107 (89.2)	241 (91.3)
Discontinued[c]	2 (7.4)	5 (6.7)	3 (7.1)	13 (10.8)	23 (8.7)
Primary reason for discontinuation:					
Death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Adverse event(s)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
Related to study drug	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Not related to study drug	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
Insufficient clinical response (assessed by Investigator)	0 (0.0)	1 (1.3)	2 (4.8)	3 (2.5)	6 (2.3)
Lost to follow-up	1 (3.7)	1 (1.3)	1 (2.4)	1 (0.8)	4 (1.5)
No longer willing to participate in the study	0 (0.0)	2 (2.7)	0 (0.0)	4 (3.3)	6 (2.3)
Other[d]	1 (3.7)	1 (1.3)	0 (0.0)	4 (3.3)	6 (2.3)

BID = twice daily, FAS = Functional Analysis Set, N = number of subjects, n = number of subjects in pre-specified criteria.

a. Safety Analysis Set - all subjects who received at least one dose of study drug during Period C.
b. FAS - all subjects who were randomized and received at least 1 dose of the randomized study drug during Period C.
c. Subjects were defined as discontinued if they entered Period C and did not complete the EOS Visit.
d. 'Other' included all reasons not specified above.

Demographic characteristics were similar between treatment groups; approximately two-thirds of the subjects were male, <8% were aged 65 years or older, and approximately 90% were White (Table 6 and Table 7).

Table 6. Demographic Characteristics for Subjects Enrolled for the Initial Tofacitinib Treatment (Safety-A)

	Tofacitinib 5 mg BID n (%)		Tofacitinib 10 mg BID n (%)		Total N (%)	
	Male 68.9%	**Female 31.1%**	**Male 68.7%**	**Female 31.3%**	**Male 68.8%**	**Female 31.2%**
Age (years), n (%)						
n	228	103	230	105	458	208
Mean (SD)	43.4 (12.5)	43.9 (14.5)	46.6 (12.8)	45.2 (14.2)	45.0 (12.7)	44.6 (14.3)
18-<45	116 (50.9)	49 (47.6)	89 (38.7)	45 (42.9)	205 (44.8)	94 (45.2)
45-<65	100 (43.9)	49 (47.6)	126 (54.8)	52 (49.5)	226 (49.3)	101 (48.6)
≥65	12 (5.3)	5 (4.9)	15 (6.5)	8 (7.6)	27 (5.9)	13 (6.3)
Race, n (%)						
White	214 (93.9)	96 (93.2)	208 (90.4)	96 (91.4)	422 (92.1)	192 (92.3)
Black	5 (2.2)	6 (5.8)	6 (2.6)	5 (4.8)	11 (2.4)	11 (5.3)
Asian	4 (1.8)	0 (0.0)	11 (4.8)	3 (2.9)	15 (3.3)	3 (1.4)
Other	5 (2.2)	1 (1.0)	5 (2.2)	1 (1.0)	10 (2.2)	2 (1.0)
Ethnicity, n (%)						
Hispanic/Latino	44 (19.3)	16 (15.5)	40 (17.4)	17 (16.2)	84 (18.3)	33 (15.9)
Not Hispanic/Latino	184 (80.7)	87 (84.5)	190 (82.6)	88 (83.8)	374 (81.7)	175 (84.1)

BID = twice daily, N = number of subjects, n number of subjects in pre-specified criteria, SD = standard deviation.

Table 7. Demographic Characteristics for Subjects Enrolled for the Initial Tofacitinib Treatment (Safety-B)

	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID n (%)		Placebo / Tofacitinib 5 mg BID n (%)		Tofacitinib 10 mg BID / Tofacitinib 10 mg BID n (%)		Placebo / Tofacitinib 10 mg BID n (%)		Total N (%)	
	Male 64.5%	**Female 35.5%**	**Male 67.1%**	**Female 32.9%**	**Male 75.6%**	**Female 24.4%**	**Male 66.9**	**Female 33.1**	**Male 68**	**Female 32**
Age (years), n (%)										
n	20	11	55	27	34	11	89	44	198	93
Mean (SD)	41.6 (13.7)	49.2 (10.5)	45.1 (13.2)	45.6 (14.1)	50.0 (14.6)	43.7 (15.2)	46.1 (12.6)	45.9 (14.9)	46.0 (13.3)	46.0 (14.1)
18- <45	12 (60)	2 (18.2)	24 (43.6)	12 (44.4)	10 (29.4)	7 (63.6)	35 (39.3)	16 (36.4)	81 (40.9)	37 (39.8)
45- <65	8 (40)	9 (81.8)	26 (47.3)	14 (59.1)	18 (52.9)	2 (18.2)	50 (56.2)	25 (56.8)	102 (51.5)	50 (53.8)
≥65	0 (0.0)	0 (0.0)	5 (9.1)	1 (3.7)	6 (17.6)	2 (18.2)	4 (4.5)	3 (6.8)	15 (7.6)	6 (6.5)
Race, n (%)										
White	18 (90.0)	11 (100)	50 (90.9)	24 (88.9)	31 (91.2)	11 (100)	84 (94.4)	39 (88.6)	183 (92.4)	85 (91.4)
Black	1 (5.0)	0 (0.0)	2 (3.6)	2 (7.4)	0 (0.0)	0 (0.0)	1 (1.1)	3 (6.8)	4 (2.0)	5 (5.4)
Asian	1 (5.0)	0 (0.0)	1 (1.8)	0 (0.0)	2 (5.9)	0 (0.0)	2 (2.2)	1 (2.3)	6 (3.0)	1 (1.1)
Other	0 (0.0)	0 (0.0)	2 (3.6)	1 (3.7)	1 (2.9)	0 (0.0)	2 (2.2)	1 (2.3)	5 (2.5)	2 (2.2)
Ethnicity, n (%)										
Hispanic/ Latino	4 (20.0)	0 (0.0)	10 (18.2)	5 (18.5)	4 (11.8)	2 (18.2)	24 (27.0)	8 (18.2)	42 (21.2)	15 (16.1)
Not Hispanic/ Latino	16 (80.0)	11 (100)	45 (81.8)	22 (81.5)	30 (88.2)	9 (81.8)	65 (73.0)	36 (81.8)	156 (78.8)	78 (83.9)

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, SD = standard deviation.

Efficacy Results:

Primary Efficacy Endpoint:

Maintenance of PASI75 Response During the 16-Week Treatment Withdrawal (Period B):

A greater percent of subjects treated with Tofacitinib 5 mg BID (56.2%) and Tofacitinib 10 mg BID (62.3%) maintained PASI75 response over 16 weeks compared with those subjects who were treated with placebo (23.3% and 26.1%, respectively, Table 8).

The survival (maintenance) of PASI75 response was statistically significantly higher for the subjects who received Tofacitinib mg BID and 10 mg BID compared with those who received placebo (Logrank test: P-value=0.0008; and p-value <0.0001, respectively).

Table 8. Comparison of Tofacitinib vs Placebo (Survival Analysis Based on Windowed Visits) for Proportion of Subjects Maintaining PASI75 Response During the Treatment Withdrawal (Period B, FAS-B)

	Tofacitinib 5 mg BID (N = 31)	Placebo for 5 mg BID (N = 82)	Tofacitinib 10 mg BID (N = 45)	Placebo for 10 mg BID (N = 133)
Proportion of response by study visit, % (95% CI)[a]				
Week 4	90.3 (72.9 to 96.8)	63.4 (52.0 to 72.8)	91.1 (78.0 to 96.6)	61.4 (52.5 to 69.1)
Week 8	70.3 (50.6 to 83.3)	36.2 (25.8 to 46.7)	86.6 (72.5 to 93.7)	39.6 (31.2 to 47.9)
Week 12	63.2 (43.4 to 77.7)	32.4 (22.4 to 42.7)	77.2 (61.7 to 87.0)	33.4 (25.4 to 41.5)
Week 16	56.2 (36.7 to 71.8)	23.3 (14.7 to 33.1)	62.3 (45.8 to 75.0)	26.1 (18.8 to 33.9)
Total number of censored subjects n (%)	18 (58.1)	21 (25.6)	29 (64.4)	36 (27.3)
Estimated median time to event (loss of response) – Weeks (95% CI)	-	8.0 (-, -)	-	8.0 (-, -)
Logrank test p-Value (tofacitinib vs placebo)	0.0008		<0.0001	

PASI75 response was defined as at least 75% reduction in PASI relative to Baseline/Day 1.
BID = twice daily, CI = confidence interval, FAS = Full Analysis Set, N = number of subjects, n = number of subjects meeting pre-specified criteria, PASI = Psoriasis Area and Severity Index, vs = versus.
a. Cumulative probability up to the last day of visit window.
b. Due to <50% loss of response events and/or a censoring issue, median and/or CIs were not estimated.

PASI75 Response During Tofacitinib Re-Treatment (Period C)

Of the subjects who had a >50% reduction of the Visit A4/Week 24 PASI response during the treatment withdrawal (Period B), the proportions achieving a PASI75 response during tofacitinib re-treatment (Period C) were 31.6% and 50.9% (at Week 16) among subjects who received Tofacitinib at doses of 5 mg BID and 10 mg BID, respectively. The number of subjects who had a >50% reduction of the Visit A4/Week 24 PASI response during Period B in the continuous Tofacitinib 5 mg BID (N = 2) and 10 mg BID (N = 3) groups was small and therefore it is difficult to draw conclusions from these groups (Table 9).

Table 9. Proportion of Subjects With a PASI75 Response During the Tofacitinib Re-Treatment (Period C, FAS-C, NRI) for Those Who Had a >50% Reduction of Visit A4/Week 24 PASI Response During the Double-Blind Treatment Withdrawal (Period B)

	Treatment	N	n	Response Rate	SE	95% CI Lower	95% CI Upper
Baseline	CP 5 mg BID → CP 5 mg BID	2	1	50	35.355	0	100
	Placebo → CP 5 mg BID	38	0	0	0	0	0
	CP 10 mg BID → CP 10 mg BID	3	0	0	0	0	0
	Placebo → CP 10 mg BID	59	0	0	0	0	0
Week 4	CP 5 mg BID → CP 5 mg BID	2	2	100	0	100	100
	Placebo → CP 5 mg BID	38	5	13.16	5.484	2.41	23.91
	CP 10 mg BID → CP 10 mg BID	3	0	0	0	0	0
	Placebo → CP 10 mg BID	59	24	40.68	6.395	28.14	53.21
Week 8	CP 5 mg BID → CP 5 mg BID	2	2	100	0	100	100
	Placebo → CP 5 mg BID	38	12	31.58	7.541	16.8	46.36
	CP 10 mg BID → CP 10 mg BID	3	0	0	0	0	0
	Placebo → CP 10 mg BID	59	29	49.15	6.509	36.4	61.91
Week 16	CP 5 mg BID → CP 5 mg BID	2	1	50	35.355	0	100
	Placebo → CP 5 mg BID	38	12	31.58	7.541	16.8	46.36
	CP 10 mg BID → CP 10 mg BID	3	0	0	0	0	0
	Placebo → CP 10 mg BID	59	30	50.85	6.509	38.09	63.6

95% CI was constructed using the normal approximation to the binomial distribution of 1-sample proportion. PASI responses at each period were relative to Baseline-A. Any missing values were imputed as a non-responder.
BID = twice daily; CI = confidence interval; CP = Tofacitinib; FAS = Full Analysis Set; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-response imputation; PASI = Psoriasis Area and Severity Index; SE = standard error.

Maintenance of Physician's Global Assessment (PGA) Response During the 16-Week Treatment Withdrawal (Period B):

A greater percentage of subjects treated with tofacitinib 5 mg BID (49.9%) and tofacitinib 10 mg BID (63.9%) maintained PGA response over 16 weeks compared to those treated with placebo (22.9% and 18.0%, respectively).

The survival (maintenance) of a PGA response was statistically significantly higher for subjects who received tofacitinib 5 mg BID and tofacitinib 10 mg BID compared with those who received placebo (Logrank test: P-value = 0.0027, p-value <0.0001, respectively).

Table 10. Comparison of Tofacitinib vs placebo (Survival Analysis based on Windowed Visits) for Proportion of Subjects Maintaining PGA Response of "Clear" or "Almost Clear" During Treatment Withdrawal (Period B, FAS-B)

	Tofacitinib 5 mg BID (N = 31)	Placebo for 5 mg BID (N = 82)	Tofacitinib 10 mg BID (N = 45)	Placebo for 10 mg BID (N = 133)
Proportion of Subjects Maintaining Response by Study Visit, % (95% CI)[a]				
Week 4	80.6 (61.9 to 90.8)	57.3 (45.9 to 67.2)	80.0 (65.1 to 89.1)	52.3 (43.4 to 60.4)
Week 8	67.7 (48.4 to 81.2)	34.4 (24.2 to 44.8)	80.0 (65.1 to 89.1)	32.5 (24.6 to 40.6)
Week 12	60.6 (41.1 to 75.4)	26.7 (17.6 to 36.8)	66.3 (50.4 to 78.1)	23.8 (16.8 to 31.4)
Week 16	49.9 (31.0 to 66.2)	22.9 (14.4 to 32.6)	63.9 (48.0 to 76.1)	18.0 (11.9 to 25.2)
Total number of censored subjects – n (%)	16 (51.6)	20 (24.4)	29 (64.4)	26 (19.7)
Median time to lose response (95% CI)[b]	16.0 (12.0, -)	8.0 (4.0, 8.0)	-	8.0 (4.0, 8.0)
Logrank test p-Value (Tofacitinib vs placebo)	0.0027		<0.0001	

PGA response is defined as "clear" or "almost clear."
BID = twice daily, CI = confidence interval, FAS = Full Analysis Set, N = number of subjects, n = number of subjects meeting pre-specified criteria, PGA = Physician's Global Assessment, vs = versus.
a. Cumulative probability up to the last day of visit window.
b. Due to <50% loss of response events and/or a censoring issue, median and/or CIs were not estimated.

PGA Response During Tofacitinib Re-Treatment (Period C)

During Period C, 41.4% of subjects re-treated with tofacitinib 5 mg BID and 49.0% of subjects re-treated with tofacitinib 10 mg BID who lost PGA response on placebo during Period B, regained their PGA response after 16 weeks of re-treatment. The number of subjects who lost PGA response during Period B in the continuous tofacitinib 5 mg BID (N = 13) and 10 mg BID (N = 15) groups was small and therefore it is difficult to draw conclusions from these groups (Table 11).

Table 11. Proportion of Subjects With Physician's Global Assessment (PGA) Response of "Clear" or "Almost Clear" Response During Tofacitinib Re-treatment (Period C, FAS-C, NRI) for Those Subjects who had a PGA of "Mild," "Moderate," or "Severe" During Tofacitinib Treatment Withdrawal (Period B)

	Treatment	N	n	Response Rate (%)	SE	95% CI Lower	95% CI Upper
Baseline	CP 5 mg BID → CP 5 mg BID	13	3	23.1	11.7	0.2	46.0
	Placebo → CP 5 mg BID	58	3	5.2	2.9	0.0	10.9
	CP 10 mg BID → CP 10 mg BID	15	1	6.7	6.4	0.0	19.3
	Placebo → CP 10 mg BID	98	7	7.1	2.6	2.0	12.2
Week 4	CP 5 mg BID → CP 5 mg BID	13	3	23.1	11.7	0.2	46.0
	Placebo → CP 5 mg BID	58	15	25.9	5.8	14.6	37.1
	CP 10 mg BID → CP 10 mg BID	15	5	33.3	12.2	9.5	57.2
	Placebo → CP 10 mg BID	98	50	51.0	5.1	41.1	60.9
Week 8	CP 5 mg BID → CP 5 mg BID	13	4	30.8	12.8	5.7	55.9
	Placebo → CP 5 mg BID	58	23	39.7	6.4	27.1	52.2
	CP 10 mg BID → CP 10 mg BID	15	6	40.0	12.6	15.2	64.8
	Placebo → CP 10 mg BID	98	54	55.1	5.0	45.3	65.0
Week 16	CP 5 mg BID → CP 5 mg BID	13	4	30.8	12.8	5.7	55.9
	Placebo → CP 5 mg BID	58	24	41.4	6.5	28.7	54.1
	CP 10 mg BID → CP 10 mg BID	15	8	53.3	12.9	28.1	78.6
	Placebo → CP 10 mg BID	98	48	49.0	5.1	39.1	58.9

95% CI was constructed using the normal approximation to the binomial distribution of 1-sample proportion. Any missing values were imputed as a non-responder.
BID = twice daily; CI = confidence interval; CP = Tofacitinib; FAS = Full Analysis Set; N/n = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-response imputation; SE = standard error.

Secondary Efficacy Endpoints:

Time to PASI75 Response (Period A):

The median time to PASI75 response was 24.3 weeks for subjects who received tofacitinib 5 mg BID and 8.7 weeks for subjects who received tofacitinib 10 mg BID during Period A. The data are summarized in Table 12.

Table 12. Median Time to PASI75 Response During Initial Tofacitinib Treatment (Period A)

	Tofacitinib 5 mg (Period A)	Tofacitinib 10 mg BID (Period A)
N	330	333
Median	24.3	8.7
(95% Cl)	(24.1 to 24.6)	(8.1 to 15.4)

BID = twice daily, CI = confidence interval, N = number of subjects, PASI = Psoriasis Area and Severity Index.

Time to PGA Response (Period A):

Median time to PGA response was 8.1 weeks for subjects who received tofacitinib 10 mg BID compared with 24.1 weeks for those who received 5 mg BID. The data are summarized in Table 13.

Table 13. Median Time to PGA Response of Clear or Almost Clear During Initial Tofacitinib Treatment (Period A)

	Tofacitinib 5 mg (Period A)	Tofacitinib 10 mg BID (Period A)
N	329	333
Median	24.1	8.1
(95% Cl)	(16.6 to 24.4)	(NA to NA)

BID = twice daily, CI = confidence interval, N = number of subjects, NA = not applicable, PGA = Physician's Global Assessment.

Time to Loss of Adequate Response (>50% Reduction of Visit A4/Week 24 PASI Response, Period B):

The proportion of subjects maintaining adequate response, defined as >50% reduction in the Visit A4/Week 24 PASI response at each given timepoint during Period B, was significantly higher for subjects who received continuous tofacitinib treatment. The data are summarized in Table 14.

Table 14. Survival Analysis of Time to Loss of Adequate Response, Defined as >50% Reduction of the Visit A4/Week24 PASI Response During Treatment Withdrawal (Period B, FAS-B)

	Tofacitinib 5 mg BID (N = 31)	Placebo for 5 mg BID (N = 82)	Tofacitinib 10 mg BID (N = 45)	Placebo for 10 mg BID (N = 133)
Proportion of Subjects Maintaining Response by Study Visit, % (95% CI)[a]				
Week 4	100.00 (100.00, 100.00)	90.0 (81.0, 94.9)	100.00 (100.00, 100.00)	85.9 (78.6, 90.9)
Week 8	96.7 (78.6, 99.5)	72.0 (60.6, 80.6)	97.7 (84.6, 99.7)	68.4 (59.5, 75.7)
Week 12	96.7 (78.6, 99.5)	58.8 (47.0, 68.8)	93.0 (79.9, 97.7)	58.5 (49.4, 66.6)
Week 16	92.3 (72.1, 98.0)	32.8 (16.3, 50.4)	93.0 (79.9, 97.7)	42.9 (30.5, 54.6)
Total number of censored subjects – n (%)	29 (93.5)	43 (52.4)	42 (93.3)	69 (52.3)
Estimated median time to loss of response - Weeks (95% CI)	-	16.4 (12.6, -)	-	16.1 (14.1, -)
Logrank test p-Value (Tofacitinib vs placebo)	<0.0001		<0.0001	

Loss of adequate response is defined as a >50% reduction of the Visit A4/Week 24 PASI response.
BID = twice daily, CI = confidence interval, FAS = Full Analysis Set, N = number of subjects, n = number of subjects meeting pre-specified criteria, PASI = Psoriasis Area and Severity Index.
a. Cumulative probability up to the last day of the visit window.

Proportion of Subjects Achieving Both PASI50-75 Response and DLQI Improvement ≤5 Response During Initial Treatment (Period A):

At Week 24, the response rates were similar for both dose groups (10.9% and 10.2% for tofacitinib 5 mg and tofacitinib 10 mg BID, respectively). The data are summarized in Table 15.

Table 15 Percentage of Participants Achieving Both a PASI50-75 Response and Dermatology Life Quality Index (DLQI) ≤5 Response During Initial Tofacitinib Treatment (Period A)

N	Tofacitinib 5 mg BID (Period A) 331 Response Rate (95% CI)	Tofacitinib 10 mg BID (Period A) 335 Response Rate (95% CI)
Week 4	12.69 (9.10 to 16.27)	21.19 (16.82 to 25.57)
Week 8	18.73 (14.53 to 22.93)	19.40 (15.17 to 23.64)
Week 16	18.13 (13.98 to 22.28)	13.13 (9.52 to 16.75)
Week 24	10.88 (7.52 to 14.23)	10.15 (6.92 to 13.38)

BID = twice daily, CI = confidence interval, N = number of subjects, PASI = Psoriasis Area and Severity Index.

Proportion of Subjects With PASI Score ≥125% of Baseline-A or Development of a new Type of Psoriasis (pustular, erythrodermic) During the Period Between Week 24 and Week 32:

No subjects experienced were rebound (experiencing a PASI score ≥125% of Baseline-A or development of a new type of psoriasis [pustular, erythrodermic] during the period between Week 24 and Week 32 [within 8 weeks after treatment discontinuation]).

Proportion of Subjects With PASI Score ≥125% of Baseline-A or new Type of Psoriasis (Pustular, Erythrodermic) During the Period B:

One subject (1.15%) in the placebo for tofacitinib 10 mg BID group had a PASI score Baseline-A 12 weeks after treatment withdrawal. No subjects had any new type of psoriasis (pustular, erythrodermic) during this period.

Time to Loss of >50% of Week 24 PASI Response and PGA Response (Period B):

The proportion of subjects maintaining adequate PASI response and maintaining PGA response at each given time point during Period B was higher for subjects who received continuous tofacitinib treatment. All subjects (except 1) who lost adequate PASI response also lost PGA response. The data are summarized in Table 16.

Table 16. Median Time to Loss of >50% of the Visit A4/Week 24 PASI Response and Loss of PGA Response (Clear or Almost Clear) During the Double-Blind Treatment Withdrawal (Period B)

	Tofacitinib 5 mg BID (Period B)	Placebo for 5 mg Tofacitinib BID (Period B)	Tofacitinib 10 mg BID (Period B)	Placebo for 10 mg Tofacitinib BID (Period B)
N	31	82	45	132
Median (95% CI)	NA (NA to NA)	16.4 (12.6 to NA)	NA (NA to NA)	16.1 (14.1 to NA)

BID = twice daily, CI = confidence interval, N = number of subjects, PASI = Psoriasis Area and Severity Index, PGA = Physician's Global Assessment.

PGA Response During Tofacitinib Re-Treatment (Period C):

Median time to PGA response during Period C for those subjects who had a PGA response of "mild," "moderate," or "severe" during Period B was 16.3 and 13.1 weeks for those subjects (N = 10; N = 14) who received continuous therapy and 16.1 and 8.1 weeks for those re-treated in Period C with tofacitinib 5 mg (N = 55) and 10 mg BID (N = 91) after receiving placebo in Period B, respectively. The data are summarized in Table 17.

Table 17. Median Time to PGA Response of Clear or Almost Clear During Tofacitinib Re-Treatment (Period C) Among Participants Who Had a PGA of Mild, Moderate, or Severe at the Beginning of Period C

	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
N	10	55	14	91
Median (95% CI)	16.3 (16.1 to 16.4)	16.1 (8.4 to 16.6)	13.1 (6.0 to NA)	8.1 (5.0 to 16.1)

BID = twice daily, CI = confidence interval, n = number of subjects, PGA = Physician's Global Assessment.

Time to Regain PASI75 and PGA Response Clear or Almost Clear) During Tofacitinib Re-Treatment (Period C) Among Participants Who Lost Both PASI75 Response and PGA Response at the Beginning of Period C:

The median time to response was 16.4 weeks for the placebo to tofacitinib 5 mg BID group compared to 12.4 weeks for the placebo to tofacitinib 10 mg BID group. The data are summarized in Table 18.

Table 18. Median Time to Regain PASI75 and PGA Response (Clear or Almost Clear) During Tofacitinib Re-Treatment (Period C) Among Participants Who Lost Both PASI75 Response and PGA Response (Clear or Almost Clear) at the Beginning of Period C

	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
n	7	52	7	81
Median	16.4	16.4	NA	12.4
(95% CI)	(8.6 to NA)	(16.1 to 17.3)	(NA to NA)	(7.6 to NA)

BID = twice daily, CI = confidence interval, n = number of subjects, PASI = Psoriasis Area and Severity Index.

Proportion of Subjects Regaining PASI75 and PGA Response (Clear or Almost Clear) During Tofacitinib Re-Treatment (Period C) Among Participants Who Lost Both PASI75 Response and PGA Response (Clear or Almost Clear) at the Beginning of Period C:

At Week 16, the proportion of subjects regaining PASI75 and PGA response for placebo to tofacitinib 5 mg BID (N = 52) was 100.0% compared to a 57.2% for subjects who had received placebo to tofacitinib 10 mg BID (N = 81). The data are summarized in Table 19.

Table 19. Percentage of Participants Regaining PASI75 and PGA Response (Clear or Almost Clear) During Tofacitinib Re-Treatment (Period C) Among Participants Who Lost Both PASI75 Response and PGA Response (Clear or Almost Clear) at the Beginning of Period C

	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
n	7	52	7	81
	Response rate (95% CI)	Response rate (95% CI)	Response rate (95% CI)	Response rate (95% CI)
Week 4	14.3 (2.1 to 66.6)	7.7 (3.0 to 19.2)	14.3 (2.1 to 66.6)	37.0 (27.6 to 48.5)
Week 8	28.6 (8.0 to 74.2)	32.3 (21.2 to 47.3)	42.9 (16.3 to 82.8)	48.5 (38.2 to 60.0)
Week 16	64.3 (22.0 to 98.6)	100.0 (NA to NA)	42.9 (16.3 to 82.8)	57.2 (46.2 to 68.8)

BID = twice daily, CI = confidence interval, n = number of subjects, PASI = Psoriasis Area and Severity Index, PGA = Physician's Global Assessment.

PASI75 Response During Period A, Period B and Period C:

At Week 16, PASI75 response rates were 38.1% and 60.6%, and at Week 24 were 39.0% and 59.4% for the tofacitinib 5 mg BID and 10 mg BID treatment groups, respectively. The data are summarized in Table 20.

Table 20. Percentage of Participants With a PASI75 Response During the Initial Tofacitinib Treatment (Period A)

	Tofacitinib 5 mg BID (Period A)	Tofacitinib 10 mg BID (Period A)
n	331	335
	Response rate (95% CI)	Response rate (95% CI)
Week 4	7.85	22.39
	(4.96 to 10.75)	(17.92 to 26.85)
Week 8	23.87	50.45
	(19.27 to 28.46)	(45.09 to 55.80)
Week 16	38.07	60.60
	(32.84 to 43.30)	(55.36 to 65.83)
Week 24	38.97	59.40
	(33.72 to 44.23)	(54.14 to 64.66)

BID = twice daily, CI = confidence interval, n = number of subjects, PASI = Psoriasis Area and Severity Index.

At all Period B timepoints, PASI75 response rates were higher for subjects who continued tofacitinib treatment compared with those subjects who had received placebo. The data are summarized in Table 21.

Table 21. Percentage of Participants With a PASI75 Response During Double-Blind Withdrawal Treatment (Period B)

	Tofacitinib 5 mg BID (Period B)	Placebo for 5 mg Tofacitinib BID (Period B)	Tofacitinib 10 mg BID (Period B)	Placebo for 10 mg Tofacitinib BID (Period B)
n	31	82	45	133
	Response rate (95% CI)	Response rate	Response rate (95% CI)	Response rate
Week 4	87.10	63.41	86.67	59.40
	(7.94 to 39.43)		(14.29 to 40.24)	
Week 8	70.97	34.15	86.67	38.35
	(17.83 to 55.81)		(35.40 to 61.24)	
Week 12	67.74	30.49	77.78	33.83
	(18.02 to 56.49)		(29.38 to 58.51)	
Week 16	64.52	24.39	62.22	27.82
	(20.89 to 59.36)		(18.32 to 50.49)	

BID = twice daily, n = number of subjects, PASI = Psoriasis Area and Severity Index.

During Period C, the PASI75 response rates were generally stable over time for both treatment sequences in which subjects received continuous tofacitinib therapy. Response rates increased at each week for subjects re-treated during Period C up to Week 8, at which time the response was similar between those subjects who continuously received tofacitinib 10 mg BID (66.7%) and those re-treated with 10 mg BID after receiving placebo during Period B (68.3%). The data are summarized in Table 22.

Table 22. Percentage of Participants With a PASI75 Response During the Tofacitinib Re-Treatment (Period C)

	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
N	27	75	42	120
	Response rate (95% CI)	Response rate (95% CI)	Response rate (95% CI)	Response rate (95% CI)
Week 4	70.37 (53.15 to 87.59)	34.67 (23.90 to 45.44)	73.81 (60.51 to 87.11)	60.83 (52.10 to 69.57)
Week 8	62.96 (44.75 to 81.18)	48.00 (36.69 to 59.31)	66.67 (52.41 to 80.92)	68.33 (60.01 to 76.66)
Week 16	55.56 (36.81 to 74.30)	45.33 (34.07 to 56.60)	69.05 (55.07 to 83.03)	61.67 (52.97 to 70.37)

BID = twice daily, CI = confidence interval, N = number of subjects, PASI = Psoriasis Area and Severity Index.

PGA Response During Period A, Period B and Period C:

At all the timepoints during Period A, the PGA response rates were higher for tofacitinib 10 mg BID compared with 5 mg BID and generally stabilized by Week 16. The data are summarized in Table 23.

Table 23. Percentage of Participants With PGA Response of Clear or Almost Clear During the Initial Tofacitinib Treatment (Period A)

	Tofacitinib 5 mg BID (Period A)	Tofacitinib 10 mg BID (Period A)
N	331	335
	Response rate (95% CI)	Response rate (95% CI)
Week 4	14.20 (10.44 to 17.96)	37.91 (32.72 to 43.11)
Week 8	30.51 (25.55 to 35.47)	54.03 (48.69 to 59.37)
Week 16	37.16 (31.95 to 42.37)	58.81 (53.54 to 64.08)
Week 24	37.16 (31.95 to 42.37)	55.22 (49.90 to 60.55)

BID = twice daily, CI = confidence interval, N = number of subjects, PGA = Physician's Global Assessment

At all timepoints (as of Week 4) during Period B, the PGA response rates were statistically significantly higher for subjects who continued active tofacitinib treatment compared with those subjects who had received placebo. The data are summarized in Table 24.

Table 24. Percentage of Participants With PGA Response of Clear or Almost Clear During Double-Blind Withdrawal Treatment (Period B)

	Tofacitinib 5 mg BID (Period B)	Placebo for 5 mg Tofacitinib BID (Period B)	Tofacitinib 10 mg BID (Period B)	Placebo for 10 mg Tofacitinib BID (Period B)
N	31	82	45	133
	Response rate (95% CI)	Response rate	Response rate (95% CI)	Response rate
Week 4	77.42 (1.90 to 38.30)	57.32	77.78 (14.84 to 44.48)	48.12
Week 8	74.19 (22.81 to 59.73)	32.93	82.22 (35.40 to 62.88)	33.08
Week 12	70.97 (24.21 to 61.62)	28.05	66.67 (24.68 to 56.03)	26.32
Week 16	58.06 (10.11 to 49.92)	28.05	62.22 (25.40 to 56.94)	21.05

BID = twice daily, N = number of subjects, PGA = Physician's Global Assessment.

At all timepoints up to Week 16 during Period C, the PGA response rates were generally stable for each treatment sequence where subjects received continuous tofacitinib therapy. The data are summarized in Table 25.

Table 25. Percentage of Participants With PGA Response of Clear or Almost Clear During the Tofacitinib Re-Treatment (Period C)

	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
N	27	75	42	120
	Response rate (95% CI)	Response rate (95% CI)	Response rate (95% CI)	Response rate (95% CI)
Week 4	62.96 (44.75 to 81.18)	40.00 (28.91 to 51.09)	61.90 (47.22 to 76.59)	59.17 (50.37 to 67.96)
Week 8	62.96 (44.75 to 81.18)	49.33 (38.02 to 60.65)	54.76 (39.71 to 69.81)	63.33 (54.71 to 71.96)
Week 16	55.56 (36.81 to 74.30)	49.33 (38.02 to 60.65)	59.52 (44.68 to 74.37)	55.00 (46.10 to 63.90)

BID = twice daily, CI = confidence interval, N = number of subjects, PGA = Physician's Global Assessment.

Actual PASI scores at Period A, Period B and Period C:

In the FAS-A, the mean PASI scores at Baseline-A were 21.1, and 20.9 and at Week 24 were 7.6 and 4.4 for the tofacitinib 5 mg BID and 10 mg BID treatment groups, respectively. The data are summarized in Table 26. In the FAS-B, the mean PASI scores at Baseline were 1.6, 1.8, 1.7, and 1.5 for the tofacitinib 5 mg BID, placebo for 5 mg BID, tofacitinib 10 mg BID, and placebo for 10 mg BID treatment groups, respectively. In the FAS-C, the mean PASI scores at Baseline were 2.7, 9.9, 3.4, and 9.8 and at Week 16 were 2.9, 5.2, 3.5, and 3.5 for the tofacitinib 5 mg BID to 5 mg BID, placebo to 5 mg BID, tofacitinib 10 mg BID to 10 mg BID, and placebo to 10 mg BID treatment groups, respectively.

Table 26. Mean PASI Score During Initial Tofacitinib Treatment (Period A, Period B, and Period C)

	Period A		Period B				Period C			
	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Tofacitinib 5 mg BID	Placebo for 5 mg Tofacitinib BID	Tofacitinib 10 mg BID	Placebo for 10 mg Tofacitinib BID	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
N	331	335	31	82	45	133	27	75	42	120
	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE
Baseline										
n	331	335	31	82	45	133	27	75	42	120
	21.1±0.5	20.9±0.4	1.6±0.2	1.8±0.2	1.7±0.2	1.5±0.1	2.7±0.5	9.9±0.9	3.4±0.6	9.8±0.8
Week 4										
n	326	331	30	82	43	128	27	74	42	119
	13.5±0.5	10.4±0.4	2.0±0.3	5.0±0.6	1.8±0.3	5.3±0.6	2.5±0.4	7.8±1.0	3.3±0.6	5.0±0.5
Week 8										
n	322	323	30	70	43	104	26	72	41	118
	10.1±0.4	6.5±0.4	2.4±0.4	6.5±0.7	2.0±0.4	6.8±0.7	2.6±0.5	6.0±0.9	3.2±0.6	4.1±0.5
Week 12										
n	-	-	28	53	42	84	-	-	-	-
	-	-	2.3±0.4	6.4±0.7	2.5±0.4	5.6±0.6	-	-	-	-
Week 16										
n	311	307	28	45	38	70	23	67	39	101
	8.1±0.4	5.0±0.4	2.7±0.5	5.5±0.7	2.9±0.5	5.5±0.6	2.9±0.5	5.2±0.8	3.5±0.7	3.5±0.5
Week 24										
n	277	279	-	-	-	-	-	-	-	-
	7.6±0.4	4.4±0.4	-	-	-	-	-	-	-	-

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, PASI = Psoriasis Area and Severity Index, SE = standard error.

Change From Baseline of PASI Score During Period A, Period B and Period C:

There was a dose-dependent numerical decrease in then PASI score from Week 4 (-7.6, -10.5) to Week 24 (-13.4, -16.0) during Period A for the tofacitinib 5 mg BID and 10 mg BID groups, respectively. The data are summarized in Table 27. The mean PASI scores remained stable in the tofacitinib 5 mg BID and 10 mg BID groups, and increased for those subjects receiving placebo in Period B. Mean decreases (indicating improvement) in PASI scores were observed in the placebo to tofacitinib 5 mg BID group and the placebo to tofacitinib 10 mg BID at each week through Week 16

Table 27. Mean Change From Baseline PASI Score During Initial Tofacitinib Treatment (Period A, Period B, and Period C)

	Period A		Period B				Period C			
	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Tofacitinib 5 mg BID	Placebo for 5 mg Tofacitinib BID	Tofacitinib 10 mg BID	Placebo for 10 mg Tofacitinib BID	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
N	**326**	**331**	**30**	**82**	**43**	**128**	**27**	**74**	**42**	**119**
	Mean ± SE	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**
Week 4										
n	326	331	30	82	43	128	27	74	42	119
	-7.6±0.4	-10.5±0.4	0.4±0.2	3.3±0.6	0.2±0.2	3.8±0.5	-0.2±0.4	-2.3±0.7	-0.1±0.5	-4.8±0.6
Week 8										
n	322	323	30	70	43	104	26	72	41	118
	-11.1±0.4	14.2±0.5	0.9±0.4	4.9±0.7	0.3±0.3	5.4±0.6	0.0±0.5	-3.8±0.7	-0.2±0.4	-5.4±0.6
Week 12										
n	-	-	28	53	42	84	-	-	-	-
	-	-	0.7±0.4	4.8±0.7	0.9±0.4	4.5±0.6	-	-	-	-
Week 16										
n	311	307	28	45	38	70	23	67	39	101
	-13.1±0.5	-15.8±0.5	1.0±0.5	4.1±0.6	1.4±0.4	4.4±0.5	0.1±0.6	-4.5±0.9	-0.0±0.7	-5.9±0.6
Week 24										
n	277	279	-	-	-	-	-	-	-	-
	-13.4±0.5	-16.0±0.5	-	-	-	-	-	-	-	-

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, PASI = Psoriasis Area and Severity Index, SE = standard error.

Actual PASI Component Scores at Period A:

Descriptive statistics of PASI component actual scores at Period A (erythema, induration, and scaling) by body region are summarized in Table 28.

Table 28. Mean PASI Component Scores During Initial Tofacitinib Treatment (Period A)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID (Period A) N = 331 Mean ± SE	Tofacitinib 10 mg BID (Period A) N = 335 Mean ± SE
Erythema	Head/Neck	Baseline	331, 335	2.2±0.1	2.2±0.1
		Week 4	326, 331	1.4±0.1	1.1±0.1
		Week 8	322, 323	1.1±0.1	0.7±0.0
		Week 16	311, 307	1.0±0.1	0.7±0.1
		Week 24	277, 279	1.0±0.1	0.6±0.1
Induration	Head/Neck	Baseline	331, 335	2.0±0.1	1.9±0.1
		Week 4	326, 331	1.2±0.1	0.9±0.1
		Week 8	322, 323	0.9±0.1	0.6±0.0
		Week 16	311, 307	0.8±0.1	0.5±0.0
		Week 24	277, 279	0.8±0.1	0.5±0.0
Scaling	Head/Neck	Baseline	331, 335	2.2±0.1	2.1±0.1
		Week 4	326, 331	1.3±0.1	1.0±0.1
		Week 8	322, 323	1.0±0.1	0.6±0.0
		Week 16	311, 307	0.9±0.1	0.6±0.1
		Week 24	277, 279	0.9±0.1	0.6±0.1
Erythema	Upper limbs	Baseline	331, 335	2.8±0.0	2.8±0.0
		Week 4	326, 331	1.9±0.0	1.6±0.0
		Week 8	322, 323	1.6±0.1	1.2±0.0
		Week 16	311, 307	1.4±0.1	1.1±0.1
		Week 24	277, 279	1.4±0.1	1.0±0.1
Induration	Upper limbs	Baseline	331, 335	2.6±0.0	2.6±0.0
		Week 4	326, 331	1.9±0.0	1.5±0.1
		Week 8	322, 323	1.5±0.1	1.1±0.1
		Week 16	311, 307	1.4±0.1	1.0±0.1
		Week 24	277, 279	1.4±0.1	1.0±0.1
Scaling	Upper limbs	Baseline	331, 335	2.7±0.0	2.6±0.0
		Week 4	326, 331	1.9±0.0	1.5±0.1
		Week 8	322, 323	1.5±0.1	1.1±0.1
		Week 16	311, 307	1.4±0.1	1.0±0.1
		Week 24	277, 279	1.4±0.1	1.0±0.1
Erythema	Trunk	Baseline	331, 335	2.9±0.0	2.8±0.0
		Week 4	326, 331	1.9±0.1	1.6±0.1
		Week 8	322, 323	1.6±0.1	1.1±0.1
		Week 16	311, 307	1.4±0.1	0.9±0.1
		Week 24	277, 279	1.4±0.1	0.8±0.1
Induration	Trunk	Baseline	331, 335	2.6±0.0	2.6±0.0
		Week 4	326, 331	1.8±0.1	1.4±0.1
		Week 8	322, 323	1.4±0.1	0.9±0.1
		Week 16	311, 307	1.2±0.1	0.8±0.1
		Week 24	277, 279	1.2±0.1	0.7±0.1

Table 28. Mean PASI Component Scores During Initial Tofacitinib Treatment (Period A)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID (Period A) N = 331 Mean ± SE	Tofacitinib 10 mg BID (Period A) N = 335 Mean ± SE
Scaling	Trunk	Baseline	331, 335	2.6±0.0	2.5±0.0
		Week 4	326, 331	1.7±0.1	1.4±0.1
		Week 8	322, 323	1.3±0.1	0.9±0.1
		Week 16	311, 307	1.2±0.1	0.7±0.1
		Week 24	277, 279	1.1±0.1	0.7±0.1
Erythema	Lower limbs	Baseline	331, 335	3.1±0.0	3.1±0.0
		Week 4	326, 331	2.2±0.0	1.9±0.1
		Week 8	322, 323	1.9±0.1	1.4±0.1
		Week 16	311, 307	1.5±0.1	1.1±0.1
		Week 24	277, 279	1.4±0.1	1.0±0.1
Induration	Lower limbs	Baseline	331, 335	2.9±0.0	2.9±0.0
		Week 4	326, 331	2.1±0.0	1.6±0.1
		Week 8	322, 323	1.6±0.1	1.2±0.1
		Week 16	311, 307	1.3±0.1	0.9±0.1
		Week 24	277, 279	1.3±0.1	0.9±0.1
Scaling	Lower limbs	Baseline	331, 335	2.9±0.0	2.9±0.0
		Week 4	326, 331	2.0±0.1	1.8±0.1
		Week 8	322, 323	1.6±0.1	1.2±0.1
		Week 16	311, 307	1.3±0.1	1.0±0.1
		Week 24	277, 279	1.3±0.1	1.0±0.1

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, PASI = Psoriasis Area and Severity Index, SE = standard error.

Actual PASI component scores at Period B:

Descriptive statistics of PASI component actual scores at Period B (erythema, induration and scaling) by body region is summarized in Table 29.

Table 29. Mean PASI Component Scores During Double-Blind Treatment Withdrawal (Period B)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID (Period B) N = 31 Mean ± SE	Placebo for Tofacitinib 5 mg BID (Period B) N = 82 Mean ± SE	Tofacitinib 10 mg BID (Period B) N = 45 Mean ± SE	Placebo for 10 mg Tofacitinib (Period B) N = 133 Mean ± SE
Erythema	Head/Neck	Baseline	31, 82, 45, 133	0.5±0.1	0.4±0.1	0.3±0.1	0.3±0.0
		Week 4	30, 82, 43, 128	0.6±0.1	1.1±0.1	0.4±0.1	1.1±0.1
		Week 8	30, 70, 43, 104	0.7±0.2	1.2±0.1	0.3±0.1	1.3±0.1
		Week 12	28, 53, 42, 84	0.7±0.2	1.1±0.2	0.5±0.1	1.1±0.1
		Week 16	28, 45, 38, 70	0.7±0.2	0.8±0.1	0.5±0.1	1.0±0.1
Induration	Head/Neck	Baseline	31, 82, 45, 133	0.3±0.1	0.4±0.1	0.1±0.1	0.2±0.0
		Week 4	30, 82, 43, 128	0.4±0.1	0.9±0.1	0.3±0.1	0.9±0.1
		Week 8	30, 70, 43, 104	0.4±0.1	1.0±0.1	0.3±0.1	1.1±0.1
		Week 12	28, 53, 42, 84	0.4±0.1	0.9±0.1	0.4±0.1	0.9±0.1
		Week 16	28, 45, 38, 70	0.5±0.1	0.7±0.1	0.3±0.1	0.8±0.1
Scaling	Head/Neck	Baseline	31, 82, 45, 133	0.4±0.1	0.4±0.1	0.2±0.1	0.3±0.1
		Week 4	30, 82, 43, 128	0.4±0.1	1.0±0.1	0.3±0.1	1.1±0.1
		Week 8	30, 70, 43, 104	0.5±0.1	1.1±0.1	0.4±0.1	1.3±0.1
		Week 12	28, 53, 42, 84	0.6±0.1	1.1±0.1	0.5±0.1	1.1±0.1
		Week 16	28, 45, 38, 70	0.6±0.2	0.8±0.1	0.5±0.1	0.9±0.1
Erythema	Upper limbs	Baseline	31, 82, 45, 133	0.6±0.1	0.6±0.1	0.8±0.1	0.5±0.1
		Week 4	30, 82, 43, 128	0.8±0.1	1.3±0.1	0.8±0.1	1.3±0.1
		Week 8	30, 70, 43, 104	0.9±0.2	1.5±0.1	0.9±0.1	1.4±0.1
		Week 12	28, 53, 42, 84	1.0±0.2	1.5±0.1	0.9±0.1	1.3±0.1
		Week 16	28, 45, 38, 70	1.0±0.2	1.4±0.1	1.1±0.1	1.3±0.1
Induration	Upper limbs	Baseline	31, 82, 45, 133	0.7±0.1	0.6±0.1	0.6±0.1	0.5±0.1
		Week 4	30, 82, 43, 128	0.8±0.1	1.3±0.1	0.7±0.1	1.1±0.1
		Week 8	30, 70, 43, 104	0.8±0.2	1.5±0.1	0.8±0.1	1.4±0.1
		Week 12	28, 53, 42, 84	1.0±0.2	1.5±0.1	1.0±0.1	1.3±0.1
		Week 16	28, 45, 38, 70	1.1±0.2	1.3±0.2	1.1±0.1	1.4±0.1
Scaling	Upper limbs	Baseline	31, 82, 45, 133	0.8±0.2	0.6±0.1	0.7±0.1	0.5±0.1
		Week 4	30, 82, 43, 128	0.8±0.2	1.3±0.1	0.7±0.1	1.2±0.1
		Week 8	30, 70, 43, 104	0.9±0.2	1.4±0.1	0.8±0.1	1.4±0.1
		Week 12	28, 53, 42, 84	1.0±0.2	1.4±0.1	1.0±0.1	1.4±0.1
		Week 16	28, 45, 38, 70	1.1±0.2	1.3±0.2	1.3±0.2	1.4±0.1

Table 29. Mean PASI Component Scores During Double-Blind Treatment Withdrawal (Period B)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID (Period B) N = 31 Mean ± SE	Placebo for Tofacitinib 5 mg BID (Period B) N = 82 Mean ± SE	Tofacitinib 10 mg BID (Period B) N = 45 Mean ± SE	Placebo for 10 mg Tofacitinib (Period B) N = 133 Mean ± SE
Erythema	Trunk	Baseline	31, 82, 45, 133	0.5±0.1	0.4±0.1	0.4±0.1	0.4±0.1
		Week 4	30, 82, 43, 128	0.7±0.2	1.1±0.1	0.4±0.1	1.1±0.1
		Week 8	30, 70, 43, 104	0.9±0.2	1.5±0.1	0.5±0.1	1.4±0.1
		Week 12	28, 53, 42, 84	0.7±0.2	1.5±0.2	0.5±0.1	1.1±0.1
		Week 16	28, 45, 38, 70	0.9±0.2	1.3±0.2	0.5±0.1	1.1±0.1
Induration	Trunk	Baseline	31, 82, 45, 133	0.4±0.1	0.3±0.1	0.3±0.1	0.3±0.0
		Week 4	30, 82, 43, 128	0.4±0.1	0.9±0.1	0.3±0.1	0.8±0.1
		Week 8	30, 70, 43, 104	0.5±0.1	1.2±0.1	0.4±0.1	1.1±0.1
		Week 12	28, 53, 42, 84	0.5±0.2	1.2±0.1	0.5±0.1	0.9±0.1
		Week 16	28, 45, 38, 70	0.6±0.2	1.2±0.2	0.6±0.1	1.1±0.1
Scaling	Trunk	Baseline	31, 82, 45, 133	0.3±0.1	0.3±0.1	0.3±0.1	0.3±0.0
		Week 4	30, 82, 43, 128	0.4±0.1	0.9±0.1	0.3±0.1	0.8±0.1
		Week 8	30, 70, 43, 104	0.5±0.1	1.2±0.1	0.4±0.1	1.1±0.1
		Week 12	28, 53, 42, 84	0.4±0.1	1.2±0.1	0.5±0.1	0.9±0.1
		Week 16	28, 45, 38, 70	0.6±0.2	1.1±0.2	0.6±0.1	1.0±0.1
Erythema	Lower limbs	Baseline	31, 82, 45, 133	0.5±0.1	0.6±0.1	0.8±0.1	0.5±0.1
		Week 4	30, 82, 43, 128	0.6±0.1	1.3±0.1	0.8±0.1	1.3±0.1
		Week 8	30, 70, 43, 104	0.8±0.2	1.6±0.1	0.8±0.2	1.5±0.1
		Week 12	28, 53, 42, 84	0.8±0.2	1.6±0.2	0.9±0.2	1.4±0.1
		Week 16	28, 45, 38, 70	0.8±0.2	1.6±0.2	1.0±0.2	1.3±0.1
Induration	Lower limbs	Baseline	31, 82, 45, 133	0.5±0.1	0.5±0.1	0.6±0.1	0.3±0.0
		Week 4	30, 82, 43, 128	0.6±0.1	1.0±0.1	0.6±0.1	1.0±0.1
		Week 8	30, 70, 43, 104	0.6±0.2	1.4±0.1	0.6±0.1	1.3±0.1
		Week 12	28, 53, 42, 84	0.6±0.2	1.4±0.1	0.8±0.1	1.2±0.1
		Week 16	28, 45, 38, 70	0.6±0.1	1.4±0.2	0.9±0.2	1.2±0.1
Scaling	Lower limbs	Baseline	31, 82, 45, 133	0.5±0.1	0.4±0.1	0.6±0.1	0.4±0.0
		Week 4	30, 82, 43, 128	0.5±0.1	1.0±0.1	0.6±0.1	1.0±0.1
		Week 8	30, 70, 43, 104	0.7±0.2	1.3±0.1	0.6±0.1	1.3±0.1
		Week 12	28, 53, 42, 84	0.6±0.2	1.4±0.1	0.7±0.1	1.3±0.1
		Week 16	28, 45, 38, 70	0.6±0.2	1.4±0.2	0.9±0.2	1.3±0.1

Table 29. Mean PASI Component Scores During Double-Blind Treatment Withdrawal (Period B)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID (Period B)	Placebo for Tofacitinib 5 mg BID (Period B)	Tofacitinib 10 mg BID (Period B)	Placebo for 10 mg Tofacitinib (Period B)
				N = 31	N = 82	N = 45	N = 133
				Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, PASI = Psoriasis Area and Severity Index, SE = standard error.

Actual PASI Component Scores at Period C:

Descriptive statistics of PASI component actual scores at Period B (erythema, induration and scaling) by body region are summarized in Table 30.

Table 30. Mean PASI Component Scores During the Tofacitinib Re-Treatment (Period C)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID N = 27 Mean ± SE	Placebo BID / Tofacitinib 5 mg BID N = 75 Mean ± SE	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID N = 42 Mean ± SE	Placebo BID / Tofacitinib 10 mg BID N = 120 Mean ± SE
Erythema	Head/Neck	Baseline	27, 75, 42, 120	0.7±0.2	1.5±0.1	0.5±0.1	1.6±0.1
		Week 4	27, 74, 42, 119	0.6±0.1	1.1±0.1	0.6±0.1	0.7±0.1
		Week 8	26, 72, 41, 118	0.8±0.2	0.8±0.1	0.5±0.1	0.7±0.1
		Week 16	23, 67, 39, 101	0.7±0.2	1.0±0.1	0.4±0.1	0.6±0.1
Induration	Head/Neck	Baseline	27, 75, 42, 120	0.5±0.1	1.3±0.1	0.4±0.1	1.4±0.1
		Week 4	27, 74, 42, 119	0.3±0.1	0.9±0.1	0.4±0.1	0.6±0.1
		Week 8	26, 72, 41, 118	0.4±0.2	0.8±0.1	0.3±0.1	0.5±0.1
		Week 16	23, 67, 39, 101	0.4±0.1	0.7±0.1	0.2±0.1	0.5±0.1
Scaling	Head/Neck	Baseline	27, 75, 42, 120	0.6±0.2	1.4±0.1	0.5±0.1	1.6±0.1
		Week 4	27, 74, 42, 119	0.5±0.2	1.0±0.1	0.6±0.1	0.7±0.1
		Week 8	26, 72, 41, 118	0.7±0.2	0.9±0.1	0.5±0.1	0.6±0.1
		Week 16	23, 67, 39, 101	0.5±0.2	0.9±0.1	0.4±0.1	0.5±0.1
Erythema	Upper limbs	Baseline	27,75, 42, 120	1.0±0.2	1.9±0.1	1.2±0.2	1.8±0.1
		Week 4	27, 74, 42, 119	0.9±0.2	1.5±0.1	1.1±0.2	1.1±0.1
		Week 8	26, 72, 41, 118	0.8±0.2	1.2±0.1	1.0±0.1	1.0±0.1
		Week 16	23, 67, 39, 101	1.0±0.2	1.3±0.1	1.1±0.2	0.9±0.1
Induration	Upper limbs	Baseline	27, 75, 42, 120	1.1±0.2	1.9±0.1	1.1±0.1	1.7±0.1
		Week 4	27, 74, 42, 119	1.0±0.2	1.4±0.1	1.1±0.1	1.1±0.1
		Week 8	26, 72, 41, 118	1.0±0.2	1.2±0.1	1.0±0.1	1.0±0.1
		Week 16	23, 67, 39, 101	1.1±0.2	1.2±0.1	1.1±0.2	0.9±0.1
Scaling	Upper limbs	Baseline	27, 75, 42, 120	1.1±0.2	1.8±0.1	1.3±0.2	1.8±0.1
		Week 4	27, 74, 42, 119	1.1±0.2	1.5±0.1	1.1±0.1	1.1±0.1
		Week 8	26, 72, 41, 118	0.9±0.2	1.2±0.1	1.1±0.1	1.0±0.1
		Week 16	23, 67, 39, 101	1.2±0.2	1.3±0.1	1.1±0.2	0.9±0.1
Erythema	Trunk	Baseline	27, 75, 42, 120	0.9±0.2	1.9±0.1	0.7±0.2	1.8±0.1
		Week 4	27, 74, 42, 119	0.8±0.2	1.4±0.1	0.6±0.1	1.0±0.1
		Week 8	26, 72, 41, 118	0.8±0.2	1.2±0.1	0.7±0.1	0.8±0.1
		Week 16	23, 67, 39, 101	0.7±0.2	1.1±0.1	0.6±0.2	0.8±0.1
Induration	Trunk	Baseline	27, 75, 42, 120	0.7±0.2	1.7±0.1	0.7±0.2	1.5±0.1
		Week 4	27, 74, 42, 119	0.6±0.2	1.2±0.1	0.6±0.1	0.8±0.1

Table 30. Mean PASI Component Scores During the Tofacitinib Re-Treatment (Period C)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID N = 27 Mean ± SE	Placebo BID / Tofacitinib 5 mg BID N = 75 Mean ± SE	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID N = 42 Mean ± SE	Placebo BID / Tofacitinib 10 mg BID N = 120 Mean ± SE
		Week 8	26, 72, 41, 118	0.5±0.2	1.0±0.1	0.6±0.1	0.7±0.1
		Week 16	23, 67, 39, 101	0.5±0.2	0.9±0.1	0.6±0.1	0.7±0.1
Scaling	Trunk	Baseline	27, 75, 42, 120	0.7±0.2	1.6±0.1	0.7±0.2	1.5±0.1
		Week 4	27, 74, 42, 119	0.5±0.1	1.3±0.1	0.6±0.1	0.9±0.1
		Week 8	26, 72, 41, 118	0.5±0.1	1.0±0.1	0.6±0.1	0.7±0.1
		Week 16	23, 67, 39, 101	0.4±0.1	0.9±0.1	0.6±0.1	0.7±0.1
Erythema	Lower limbs	Baseline	27, 75, 42, 120	0.7±0.2	2.1±0.1	1.1±0.2	1.9±0.1
		Week 4	27, 74, 42, 119	0.7±0.2	1.6±0.1	1.0±0.2	1.3±0.1
		Week 8	26, 72, 41, 118	0.8±0.2	1.3±0.1	0.9±0.2	1.0±0.1
		Week 16	23, 67, 39, 101	1.0±0.2	1.3±0.1	0.9±0.2	0.9±0.1
Induration	Lower limbs	Baseline	27, 75, 42, 120	0.6±0.1	1.9±0.1	1.0±0.2	1.7±0.1
		Week 4	27, 74, 42, 119	0.7±0.2	1.5±0.1	0.9±0.2	1.0±0.1
		Week 8	26, 72, 41, 118	0.7±0.2	1.3±0.1	0.9±0.2	0.9±0.1
		Week 16	23, 67, 39, 101	0.9±0.2	1.1±0.1	0.9±0.2	0.8±0.1
Scaling	Lower limbs	Baseline	27, 75, 42, 120	0.6±0.2	1.8±0.1	1.0±0.2	1.8±0.1
		Week 4	27, 74, 42, 119	0.7±0.2	1.5±0.1	0.9±0.2	1.1±0.1
		Week 8	26, 72, 41, 118	0.7±0.2	1.2±0.1	0.8±0.2	1.0±0.1
		Week 16	23, 67, 39, 101	1.0±0.2	1.1±0.1	0.8±0.2	0.8±0.1

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, PASI = Psoriasis Area and Severity Index, SE = standard error.

Change From Baseline of PASI Component Scores at Period A:

Descriptive statistics of PASI component changes from Baseline scores at Period A (erythema, induration, and scaling) by body region are summarized in Table 31.

Table 31. Mean Change From Baseline in PASI Component Scores During Initial Tofacitinib Treatment (Period A)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID (Period A) N = 326 Mean ± SE	Tofacitinib 10 mg BID (Period A) N = 331 Mean ± SE
Erythema	Head/Neck	Week 4	326, 331	-0.8±0.1	-1.2±0.1
		Week 8	322, 323	-1.1±0.1	-1.5±0.1
		Week 16	311, 307	-1.2±0.1	-1.6±0.1
		Week 24	277, 279	-1.2±0.1	-1.6±0.1
Induration	Head/Neck	Week 4	326, 331	-0.8±0.0	-1.1±0.1
		Week 8	322, 323	-1.1±0.1	-1.4±0.1
		Week 16	311, 307	-1.2±0.1	-1.4±0.1
		Week 24	277, 279	-1.1±0.1	-1.4±0.1
Scaling	Head/Neck	Week 4	326, 331	-0.9±0.1	-1.1±0.1
		Week 8	322, 323	-1.2±0.1	-1.5±0.1
		Week 16	311, 307	-1.3±0.1	-1.5±0.1
		Week 24	277, 279	-1.2±0.1	-1.5±0.1
Erythema	Upper limbs	Week 4	326, 331	-0.9±0.0	-1.2±0.0
		Week 8	322, 323	-1.3±0.1	-1.5±0.1
		Week 16	311, 307	-1.4±0.1	-1.7±0.1
		Week 24	277, 279	-1.5±0.1	-1.8±0.1
Induration	Upper limbs	Week 4	326, 331	-0.8±0.0	-1.2±0.1
		Week 8	322, 323	-1.1±0.1	-1.5±0.1
		Week 16	311, 307	-1.2±0.1	-1.6±0.1
		Week 24	277, 279	-1.2±0.1	-1.6±0.1
Scaling	Upper limbs	Week 4	326, 331	-0.7±0.0	-1.1±0.1
		Week 8	322, 323	-1.1±0.1	-1.5±0.1
		Week 16	311, 307	-1.2±0.1	-1.6±0.1
		Week 24	277, 279	-1.3±0.1	-1.6±0.1
Erythema	Trunk	Week 4	326, 331	-0.9±0.0	-1.3±0.1
		Week 8	322, 323	-1.3±0.1	-1.7±0.1
		Week 16	311, 307	-1.5±0.1	-1.9±0.1
		Week 24	277, 279	-1.5±0.1	-2.0±0.1
Induration	Trunk	Week 4	326, 331	-0.8±0.0	-1.2±0.1
		Week 8	322, 323	-1.2±0.1	-1.7±0.1
		Week 16	311, 307	-1.4±0.1	-1.8±0.1
		Week 24	277, 279	-1.4±0.1	-1.9±0.1
Scaling	Trunk	Week 4	326, 331	-0.8±0.1	-1.1±0.1
		Week 8	322, 323	-1.2±0.1	-1.6±0.1
		Week 16	311, 307	-1.4±0.1	-1.8±0.1
		Week 24	277, 279	-1.4±0.1	-1.8±0.1
Erythema	Lower limbs	Week 4	326, 331	-0.9±0.0	-1.2±0.0
		Week 8	322, 323	-1.3±0.1	-1.7±0.1
		Week 16	311, 307	-1.6±0.1	-2.0±0.1

Table 31. Mean Change From Baseline in PASI Component Scores During Initial Tofacitinib Treatment (Period A)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID (Period A) N = 326 Mean ± SE	Tofacitinib 10 mg BID (Period A) N = 331 Mean ± SE
		Week 24	277, 279	-1.7±0.1	-2.1±0.1
Induration	Lower limbs	Week 4	326, 331	-0.8±0.0	-1.3±0.1
		Week 8	322, 323	-1.2±0.1	-1.7±0.1
		Week 16	311, 307	-1.5±0.1	-2.0±0.1
		Week 24	277, 279	-1.6±0.1	-2.0±0.1
Scaling	Lower limbs	Week 4	326, 331	-0.9±0.0	-1.2±0.1
		Week 8	322, 323	-1.3±0.1	-1.8±0.1
		Week 16	311, 307	-1.6±0.1	-2.0±0.1
		Week 24	277, 279	-1.6±0.1	-2.0±0.1

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, PASI = Psoriasis Area and Severity Index, SE = standard error.

Change From Baseline of PASI Component Scores at Period B:

Descriptive statistics of PASI component change from Baseline scores at Period B (erythema, induration, and scaling) by body region are summarized in Table 32.

Table 32. Mean Change From Baseline in PASI Component Scores During Double-Blind Treatment Withdrawal (Period B)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID (Period B) N = 30 Mean ± SE	Placebo for Tofacitinib 5 mg BID (Period B) N = 82 Mean ± SE	Tofacitinib 10 mg BID (Period B) N = 45 Mean ± SE	Placebo for 10 mg Tofacitinib (Period B) N = 128 Mean ± SE
Erythema	Head/Neck	Week 4	30, 82, 43, 128	0.1±0.1	0.8±0.1	0.2±0.1	0.8±0.1
		Week 8	30, 70, 43, 104	0.2±0.2	0.9±0.1	0.1±0.1	1.1±0.1
		Week 12	28, 53, 42, 84	0.2±0.1	0.8±0.1	0.2±0.1	0.9±0.1
		Week 16	28, 45, 38, 70	0.1±0.1	0.6±0.1	0.2±0.1	0.8±0.1
Induration	Head/Neck	Week 4	30, 82, 43, 128	0.1±0.1	0.5±0.1	0.1±0.1	0.7±0.1
		Week 8	30, 70, 43, 104	0.1±0.1	0.7±0.1	0.2±0.1	0.9±0.1
		Week 12	28, 53, 42, 84	0.1±0.1	0.6±0.1	0.3±0.1	0.8±0.1
		Week 16	28, 45, 38, 70	0.1±0.1	0.5±0.1	0.2±0.1	0.7±0.1
Scaling	Head/Neck	Week 4	30, 82, 43, 128	0.0±0.1	0.6±0.1	0.2±0.1	0.8±0.1
		Week 8	30, 70, 43, 104	0.1±0.1	0.8±0.1	0.2±0.1	1.0±0.1
		Week 12	28, 53, 42, 84	0.1±0.1	0.7±0.1	0.3±0.1	1.0±0.1
		Week 16	28, 45, 38, 70	0.1±0.1	0.7±0.1	0.3±0.1	0.8±0.1
Erythema	Upper limbs	Week 4	30, 82, 43, 128	0.1±0.1	0.7±0.1	0.1±0.1	0.7±0.1
		Week 8	30, 70, 43, 104	0.3±0.1	0.9±0.1	0.2±0.1	0.9±0.1
		Week 12	28, 53, 42, 84	0.4±0.2	0.9±0.1	0.2±0.1	0.9±0.1
		Week 16	28, 45, 38, 70	0.4±0.1	0.8±0.1	0.4±0.1	0.9±0.1
Induration	Upper limbs	Week 4	30, 82, 43, 128	0.1±0.1	0.6±0.1	0.1±0.1	0.6±0.1
		Week 8	30, 70, 43, 104	0.2±0.1	0.9±0.1	0.2±0.1	0.9±0.1
		Week 12	28, 53, 42, 84	0.4±0.2	0.9±0.1	0.4±0.1	0.9±0.1
		Week 16	28, 45, 38, 70	0.4±0.2	0.9±0.1	0.5±0.1	0.9±0.1
Scaling	Upper limbs	Week 4	30, 82, 43, 128	0.1±0.1	0.7±0.1	0.1±0.1	0.7±0.1
		Week 8	30, 70, 43, 104	0.1±0.1	0.9±0.1	0.1±0.1	0.9±0.1
		Week 12	28, 53, 42, 84	0.3±0.1	0.9±0.1	0.3±0.1	1.0±0.1
		Week 16	28, 45, 38, 70	0.3±0.2	0.9±0.1	0.6±0.1	1.1±0.1
Erythema	Trunk	Week 4	30, 82, 43, 128	0.2±0.1	0.7±0.1	0.0±0.1	0.7±0.1
		Week 8	30, 70, 43, 104	0.4±0.1	1.0±0.1	0.1±0.1	1.0±0.1
		Week 12	28, 53, 42, 84	0.1±0.1	1.2±0.2	0.2±0.1	0.8±0.1
		Week 16	28, 45, 38, 70	0.3±0.2	1.0±0.2	0.2±0.1	0.8±0.1
Induration	Trunk	Week 4	30, 82, 43, 128	-0.0±0.1	0.6±0.1	0.0±0.1	0.5±0.1
		Week 8	30, 70, 43, 104	0.1±0.1	0.9±0.1	0.2±0.1	0.8±0.1

Table 32. Mean Change From Baseline in PASI Component Scores During Double-Blind Treatment Withdrawal (Period B)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID (Period B) N = 30 Mean ± SE	Placebo for Tofacitinib 5 mg BID (Period B) N = 82 Mean ± SE	Tofacitinib 10 mg BID (Period B) N = 45 Mean ± SE	Placebo for 10 mg Tofacitinib (Period B) N = 128 Mean ± SE
		Week 12	28, 53, 42, 84	0.1±0.1	1.0±0.1	0.3±0.1	0.7±0.1
		Week 16	28, 45, 38, 70	0.2±0.1	1.0±0.2	0.3±0.1	0.8±0.1
Scaling	Trunk	Week 4	30, 82, 43, 128	0.1±0.1	0.6±0.1	-0.0±0.1	0.5±0.1
		Week 8	30, 70, 43, 104	0.2±0.1	0.9±0.1	0.2±0.1	0.9±0.1
		Week 12	28, 53, 42, 84	0.1±0.1	0.9±0.1	0.2±0.1	0.6±0.1
		Week 16	28, 45, 38, 70	0.4±0.2	0.9±0.2	0.3±0.2	0.8±0.1
Erythema	Lower limbs	Week 4	30, 82, 43, 128	0.1±0.1	0.7±0.1	0.0±0.1	0.8±0.1
		Week 8	30, 70, 43, 104	0.3±0.2	1.0±0.1	-0.0±0.1	1.1±0.1
		Week 12	28, 53, 42, 84	0.3±0.2	1.0±0.1	0.1±0.2	1.0±0.1
		Week 16	28, 45, 38, 70	0.3±0.2	1.1±0.2	0.3±0.2	0.9±0.1
Induration	Lower limbs	Week 4	30, 82, 43, 128	0.1±0.1	0.5±0.1	0.0±0.1	0.7±0.1
		Week 8	30, 70, 43, 104	0.1±0.2	0.9±0.1	0.0±0.1	1.0±0.1
		Week 12	28, 53, 42, 84	0.1±0.2	0.9±0.1	0.2±0.1	0.9±0.1
		Week 16	28, 45, 38, 70	0.1±0.1	0.9±0.1	0.4±0.2	0.9±0.1
Scaling	Lower limbs	Week 4	30, 82, 43, 128	0.1±0.1	0.6±0.1	-0.0±0.1	0.6±0.1
		Week 8	30, 70, 43, 104	0.3±0.2	0.9±0.1	-0.0±0.1	0.9±0.1
		Week 12	28, 53, 42, 84	0.2±0.2	0.9±0.1	0.0±0.1	0.9±0.1
		Week 16	28, 45, 38, 70	0.2±0.2	1.0±0.1	0.3±0.2	1.0±0.1

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, PASI = Psoriasis Area and Severity Index, SE = standard error.

Change From Baseline of PASI Component Scores at Period C:

Descriptive statistics of PASI component change from Baseline scores at Period C (erythema, induration and scaling) by body region are summarized in Table 33.

Table 33. Mean Change From Baseline in PASI Component Scores During the Tofacitinib Re-Treatment (Period C)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID N = 27 Mean ± SE	Placebo BID / Tofacitinib 5 mg BID N = 74 Mean ± SE	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID N = 42 Mean ± SE	Placebo BID / Tofacitinib 10 mg BID N = 119 Mean ± SE
Erythema	Head/Neck	Week 4	27, 74, 42, 119	-0.1±0.1	-0.4±0.1	0.1±0.1	-0.9±0.1
		Week 8	26, 72, 41, 118	0.1±0.1	-0.7±0.1	-0.0±0.1	-0.9±0.1
		Week 16	23, 67, 39, 101	-0.1±0.1	-0.4±0.1	-0.1±0.1	-0.9±0.1
Induration	Head/Neck	Week 4	27, 74, 42, 119	-0.2±0.1	-0.4±0.1	0.0±0.1	-0.8±0.1
		Week 8	26, 72, 41, 118	-0.0±0.2	-0.5±0.1	-0.0±0.1	-0.8±0.1
		Week 16	23, 67, 39, 101	-0.1±0.1	-0.6±0.1	-0.2±0.1	-0.9±0.1
Scaling	Head/Neck	Week 4	27, 74, 42, 119	-0.1±0.1	-0.4±0.1	0.0±0.1	-0.9±0.1
		Week 8	26, 72, 41, 118	0.1±0.1	-0.5±0.1	-0.0±0.1	-0.9±0.1
		Week 16	23, 67, 39, 101	-0.1±0.1	-0.5±0.1	-0.2±0.1	-1.0±0.1
Erythema	Upper limbs	Week 4	27, 74, 42, 119	-0.0±0.1	-0.4±0.1	-0.0±0.1	-0.6±0.1
		Week 8	26, 72, 41, 118	-0.1±0.1	-0.7±0.1	-0.1±0.1	-0.8±0.1
		Week 16	23, 67, 39, 101	0.0±0.2	-0.6±0.1	-0.2±0.2	-0.8±0.1
Induration	Upper limbs	Week 4	27, 74, 42, 119	-0.0±0.1	-0.5±0.1	-0.0±0.1	-0.6±0.1
		Week 8	26, 72, 41, 118	-0.0±0.1	-0.7±0.1	-0.1±0.1	-0.8±0.1
		Week 16	23, 67, 39, 101	-0.0±0.2	-0.6±0.1	-0.1±0.2	-0.8±0.1
Scaling	Upper limbs	Week 4	27, 74, 42, 119	0.0±0.1	-0.3±0.1	-0.2±0.1	-0.7±0.1
		Week 8	26, 72, 41, 118	-0.0±0.2	-0.6±0.1	-0.1±0.1	-0.8±0.1
		Week 16	23, 67, 39, 101	0.0±0.2	-0.5±0.1	-0.2±0.2	-0.8±0.1
Erythema	Trunk	Week 4	27, 74, 42, 119	-0.1±0.1	-0.5±0.1	-0.1±0.1	-0.8±0.1
		Week 8	26, 72, 41, 118	-0.1±02	-0.7±01	0.0±0.2	-1.0±0.1
		Week 16	23, 67, 39, 101	-0.2±0.2	-0.8±0.1	-0.1±0.2	-1.0±0.1
Induration	Trunk	Week 4	27, 74, 42, 119	-0.1±0.1	-0.5±0.1	-0.1±0.1	-0.7±0.1
		Week 8	26, 72, 41, 118	-0.1±0.1	-0.7±0.1	-0.2±0.1	-0.8±0.1
		Week 16	23, 67, 39, 101	-0.2±0.2	-0.8±0.1	-0.2±0.2	-0.8±0.1
Scaling	Trunk	Week 4	27, 74, 42, 119	-0.2±0.2	-0.4±0.1	-0.1±0.1	-0.6±0.1
		Week 8	26, 72, 41, 118	0.0±0.1	-0.6±0.1	-0.1±0.1	-0.8±0.1
		Week 16	23, 67, 39, 101	-0.3±0.2	-0.7±0.1	-0.1±0.1	-0.8±0.1
Erythema	Lower limbs	Week 4	27, 74, 42, 119	0.0±0.1	-0.5±0.1	-0.1±0.1	-0.7±0.1
		Week 8	26, 72, 41, 118	0.1±0.1	-0.7±0.1	-0.2±0.1	-0.9±0.1
		Week 16	23, 67, 39, 101	0.2±0.2	-0.7±0.1	-0.2±0.2	-1.0±0.1

Table 33. Mean Change From Baseline in PASI Component Scores During the Tofacitinib Re-Treatment (Period C)

PASI Component Score	Body Region	Visit	n	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID N = 27 Mean ± SE	Placebo BID / Tofacitinib 5 mg BID N = 74 Mean ± SE	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID N = 42 Mean ± SE	Placebo BID / Tofacitinib 10 mg BID N = 119 Mean ± SE
Induration	Lower limbs	Week 4	27, 74, 42, 119	0.2±0.1	-0.4±0.1	-0.1±0.1	-0.7±0.1
		Week 8	26, 72, 41, 118	0.1±0.2	-0.6±0.1	-0.1±0.1	-0.8±0.1
		Week 16	23, 67, 39, 101	0.3±0.2	-0.7±0.1	-0.1±0.2	-0.9±0.1
Scaling	Lower limbs	Week 4	27, 74, 42, 119	0.1±0.1	-0.3±0.1	-0.1±0.1	-0.7±0.1
		Week 8	26, 72, 41, 118	0.1±0.2	-0.6±0.1	-0.1±0.1	-0.8±0.1
		Week 16	23, 67, 39, 101	0.3±0.2	-0.6±0.1	-0.2±0.2	-0.9±0.1

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, PASI = Psoriasis Area and Severity Index, SE = standard error.

Subjects Achieving at Least a 50%, 90%, and 100% Reduction in PASI Scores Relative to Baseline (PASI50, PASI90, and PASI100, Respectively) During Period A:

By Week 24, PASI50 response rates increased to 59.5% and 73.1%, for the tofacitinib 5 mg BID and 10 mg BID treatment groups, respectively. At Week 24, the response rate for tofacitinib 5 mg BID was 20.2% compared to 37.3% for tofacitinib 10 mg BID. The response rates at Week 24 were 8.2% for subjects treated with tofacitinib 5 mg BID compared to 17.3% for subjects treated with tofacitinib 10 mg BID. The data aresummarized in Table 34.

Table 34. Percentage of Participants Achieving at Least a 50%, 90%, and 100% Reduction in PASI Scores Relative to Baseline-A (PASI50, PASI90, and PASI100) During Period A

50% Reduction (PASI50)		90% Reduction (PASI90)		100% Reduction (PASI100)	
Tofacitinib 5 mg BID N = 331 Response rate (95% CI)	Tofacitinib 10 mg BID N = 335 Response rate (95% CI)	Tofacitinib 5 mg BID N = 331 Response rate (95% CI)	Tofacitinib 10 mg BID N = 335 Response rate (95% CI)	Tofacitinib 5 mg BID N = 331 Response rate (95% CI)	Tofacitinib 10 mg BID N = 335 Response rate (95% CI)
Week 4					
28.70 (23.83 to 33.57)	54.63 (49.30 to 59.96)	1.21 (0.03 to 2.39)	6.27 (3.67 to 8.86)	0.91 (0.0 to 1.93)	2.09 (0.56 to 3.62)
Week 8					
55.29 (49.93 to 60.64)	75.52 (70.92 to 80.13)	8.76 (5.72 to 11.81)	24.78 (20.15 to 29.40)	2.72 (0.97 to 4.47)	7.46 (4.65 to 10.28)
Week 16					
65.26 (60.13 to 70.39)	79.40 (75.07 to 83.73)	18.73 (14.53 to 22.93)	36.72 (31.55 to 41.88)	7.25 (4.46 to 10.04)	15.82 (11.91 to 19.73)
Week 24					
59.52 (54.23 to 64.80)	73.13 (68.39 to 77.88)	20.24 (15.91 to 24.57)	37.31 (32.13 to 42.49)	8.16 (5.21 to 11.11)	17.31 (13.26 to 21.37)

BID = twice daily, CI = confidence interval, N = number of subjects, PASI = Psoriasis Area and Severity Index.

Subjects Achieving at Least a 50%, 90%, and 100% Reduction in PASI Scores Relative to Baseline (PASI50, PASI90, and PASI100, Respectively) During Period C:

During Period C, the PASI50 response rates were generally stable for each treatment sequence in which subjects received continuous tofacitinib therapy. An increase in PASI50 response rates was seen at each week for those subjects who had received placebo during Period B and were re-treated during Period C. The data are summarized in Table 35.

Table 35. Percentage of Participants Achieving at Least a 50%, 90%, and 100% Reduction in PASI Scores Relative to Baseline-A (PASI50, PASI90, and PASI100) During Period C

	50% Reduction (PASI50)				90% Reduction (PASI90)				100% Reduction (PASI100)			
	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID N = 27 Response rate (95% CI)	Placebo BID / Tofacitinib 5 mg BID N = 75 Response rate (95% CI)	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID N = 42 Response rate (95% CI)	Placebo BID / Tofacitinib 10 mg BID N = 120 Response rate (95% CI)	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID N = 27 Response rate (95% CI)	Placebo BID / Tofacitinib 5 mg BID N = 75 Response rate (95% CI)	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID N = 42 Response rate (95% CI)	Placebo BID / Tofacitinib 10 mg BID N = 120 Response rate (95% CI)	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID N = 27 Response rate (95% CI)	Placebo BID / Tofacitinib 5 mg BID N = 75 Response rate (95% CI)	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID N = 42 Response rate (95% CI)	Placebo BID / Tofacitinib 10 mg BID N = 120 Response rate (95% CI)
Baseline	96.30 (89.17-100.00)	42.67 (31.47-53.86)	92.86 (85.07-100.00)	49.17 (40.22-58.11)	48.15 (29.30-66.99)	12.00 (4.65-19.35)	45.24 (30.19-60.29)	15.83 (9.30-22.36)	18.52 (3.87-33.17)	5.33 (0.25-10.42)	23.81 (10.93-36.69)	5.00 (1.10-8.90)
Week 4	100.00 (100.00-100.00)	69.33 (58.90-79.77)	92.86 (85.07-100.00)	84.17 (77.64-90.70)	48.15 (29.30-66.99)	17.33 (8.77-25.90)	47.62 (32.51-62.72)	35.00 (26.47-43.53)	18.52 (3.87-33.17)	9.33 (2.75-15.92)	21.43 (9.02-33.84)	15.00 (8.61-21.39)
Week 8	92.59 (82.71-100.00)	81.33 (72.52-90.15)	95.24 (88.80-100.00)	89.17 (83.61-94.73)	48.15 (29.3-66.99)	21.33 (12.06-30.60)	47.62 (32.51-62.72)	42.50 (33.66-51.34)	18.52 (3.87-33.17)	13.33 (5.64-21.03)	21.43 (9.02-33.84)	19.17 (12.12-26.21)
Week 16	85.19 (71.79-98.58)	82.67 (74.10-91.23)	85.71 (75.13-96.30)	79.17 (71.90-86.43)	33.33 (15.55-51.11)	21.33 (12.06-30.60)	45.24 (30.19-60.29)	44.17 (35.28-53.05)	14.81 (1.42-28.21)	10.67 (3.68-17.65)	26.19 (12.89-39.49)	20.83 (13.57-28.10)

BID = twice daily, CI = confidence interval, N = number of subjects, PASI = Psoriasis Area and Severity Index.

Subjects With a PASI Score ≥125% of the Baseline PASI Score at Period A:

The proportion of subjects who had a PASI score ≥125% of Baseline-A during initial treatment was low and similar for both doses of tofacitinib. The data are summarized in Table 36.

Table 36. Percentage of Participants With a PASI Score ≥125% of the Baseline-A PASI Score During Initial Tofacitinib Treatment (Period A)

Visit	n	Tofacitinib 5 mg BID (Period A) N = 329 Response rate (95% CI)	Tofacitinib 10 mg BID (Period A) N = 333 Response rate (95% CI)
Week 4	326, 331	0.92 (0.00 to 1.96)	0.60 (0.00 to 1.44)
Week 8	322, 323	0.62 (0.00 to 1.48)	0.62 (0.00 to 1.47)
Week 16	311, 307	0.96 (0.00 to 2.05)	0.98 (0.00 to 2.08)
Week 24	277, 279	1.08 (0.00 to 2.30)	0.36 (0.00 to 1.06)
Overall	329, 333	2.13 (0.57 to 3.69)	2.10 (0.56 to 3.64)

BID = twice daily, CI = confidence interval, N = number of subjects, n = number of subjects in pre-specified criteria, PASI = Psoriasis Area and Severity Index.

Subjects With a PASI Score ≥125% of the Baseline PASI Score at Period B:

One subject in the placebo tofacitinib 10 mg BID group had a PASI score ≥125% of Baseline-A 12 weeks after treatment withdrawal. The data are summarized in Table 37.

Table 37. Percentage of Participants With a PASI Score ≥125% of the Baseline-A PASI Score During Double-Blind Treatment Withdrawal (Period B)

Visit	n	Tofacitinib 5 mg BID (Period B) N = 31	Placebo for 5 mg Tofacitinib BID (Period B) N = 82	Tofacitinib 10 mg BID (Period B) N = 45	Placebo for 10 mg Tofacitinib BID (Period B) N = 132
Week 4	30, 82, 43, 128	0.00	0.00	0.00	0.00
Week 8	30, 70, 43, 104	0.00	0.00	0.00	0.00
Week 12	28, 53, 42, 84	0.00	0.00	0.00	1.19
Week 16	28, 45, 38, 70	0.00	0.00	0.00	0.00
Overall	31, 82, 45, 132	0.00	0.00	0.00	0.76

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, PASI = Psoriasis Area and Severity Index.

Subjects With a PASI Score ≥125% of the BASELINE PASI Score at Period C:

One subject in the tofacitinib 10 mg BID to 10 mg BID group had a PASI score ≥125% of Baseline-A at Week 16 during Period C. The data are summarized in Table 38.

Table 38. Percentage of Participants With a PASI Score ≥125% of the Baseline-A PASI Score During the Tofacitinib Re-Treatment (Period C)

Visit	n	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID 27 Response rate (95% CI)	Placebo BID / Tofacitinib 5 mg BID 75 Response rate (95% CI)	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID 42 Response rate (95% CI)	Placebo BID / Tofacitinib 10 mg BID 120 Response rate (95% CI)
Week 4	27, 74, 42, 119	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)
Week 8	26, 72, 41, 118	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)
Week 16	23, 67, 39, 101	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	2.56 (0.00 to 7.52)	0.00 (0.00 to 0.00)
Overal	27, 75, 42, 120	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	2.38 (0.00 to 6.99)	0.00 (0.00 to 0.00)

BID = twice daily, CI = confidence interval, N = number of subjects, n = number of subjects in pre-specified criteria, PASI = psoriasis area and severity index.

Actual Total Percent of Psoriatic BSA During Period A, Period B, and Period C:

Mean BSA values at Baseline were similar between the tofacitinib 5 mg and 10 mg BID doses (27.5% and 27.2%, respectively). Decreases seen at each time point were greater for subjects treated with tofacitinib 10 mg BID compared with 5 mg BID at Week 24 (mean BSA values at Week 24 were 6.4% and 12.0%, respectively). Mean BSA values were similar for subjects who received continuous tofacitinib treatment and less than either placebo group at each time point during Period B. Total percent psoriatic mean BSA values during Period C were 2.3%, 11.4%, 3.0%, and 12.0% at Baseline and 2.9%, 7.1%, 3.7%, and 4.5% at Week 16 for the tofacitinib 5 mg BID to 5 mg BID, placebo to 5 mg BID, 10 mg BID to 10 mg BID, and placebo to 10 mg BID treatment groups, respectively. The data are summarized in Table 39.

Table 39. Mean Total Percent of Psoriatic BSA During Tofacitinib Re-Treatment (Period A, Period B, and Period C)

	Period A		Period B				Period C			
	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Tofacitinib 5 mg BID	Placebo for 5 mg Tofacitinib BID	Tofacitinib 10 mg BID	Placebo for 10 mg Tofacitinib BID	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
N	331	335	31	82	45	133	27	75	42	120
	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE
Baseline										
n	331	335	31	82	45	133	27	75	42	120
	27.5±0.9	27.2±0.9	1.9±0.4	3.8±0.8	2.0±0.3	2.7±0.4	2.3±0.5	11.4±1.3	3.0±0.8	12.0±1.2
Week 4										
n	326	331	30	82	43	128	27	74	42	119
	22.3±0.9	18.1±0.8	1.9±0.4	6.1±0.8	1.8±0.4	6.8±0.9	2.1±0.4	10.6±1.7	3.1±0.9	7.2±0.9
Week 8										
n	322	323	30	70	43	104	26	72	41	118
	17.2±0.9	12.1±0.8	2.2±0.4	7.7±1.2	2.0±0.4	8.7±1.2	2.5±0.5	9.0±1.6	3.3±1.0	6.1±0.8
Week 12										
n	-	-	28	53	42	84	-	-	-	-
	-	-	2.0±0.4	7.2±1.0	2.3±0.5	6.2±0.9	-	-	-	-
Week 16										
n	311	306	28	45	38	70	23	67	39	101
	13.3±0.8	8.1±0.7	2.2±0.5	6.0±0.9	2.6±0.7	6.0±0.8	2.9±0.5	7.1±1.2	3.7±1.3	4.5±0.8
Week 24										
n	277	279	-	-	-	-	-	-	-	-
	12.0±0.8	6.4±0.7	-	-	-	-	-	-	-	-

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, BSA = body surface area, SE = standard error.

Change From Baseline in Total Percent of Psoriatic BSA During Period A, Period B, and Period C:

Descriptive statistics of the change from Baseline in psoriatic BSA by body region during initial treatment are summarized in Table 40.

Table 40. Mean Change From Baseline in Total Percent of Psoriatic BSA During Tofacitinib Re-Treatment (Period A, Period B, and Period C)

	Period A			Period B				Period C		
	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Tofacitinib 5 mg BID	Placebo for 5 mg Tofacitinib BID	Tofacitinib 10 mg BID	Placebo for 10 mg Tofacitinib BID	Tofacitinib 5 BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
N	**326**	**331**	**30**	**82**	**43**	**128**	**27**	**75**	**42**	**119**
	Mean ± SE	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**
Week 4										
n	326	331	30	82	43	128	27	74	42	119
	-5.3±0.5	-9.0±0.7	0.0±0.4	2.3±0.9	-0.3±0.3	4.1±0.6	-0.2±0.3	1.0±1.0	0.1±0.9	-4.9±0.8
Week 8										
n	322	323	30	70	43	104	26	72	41	118
	-10.4±0.7	-14.5±0.8	0.3±0.4	4.1±0.9	-0.1±0.4	6.3±0.9	0.1±0.5	-2.3±1.0	0.3±0.9	-5.5±0.8
Week 12										
n	-	-	28	53	42	84	-	-	-	-
	-	-	0.1±0.5	4.8±1.0	0.3±0.6	4.7±0.7	-	-	-	-
Week 16										
n	311	306	28	45	38	70	23	67	39	101
	-14.4±0.8	-18.5±0.9	0.3±0.5	3.7±0.7	0.5±0.7	4.5±0.7	0.5±0.6	-4.0±1.1	0.6±1.2	-6.8±0.8
Week 24										
n	277	279	-	-	-	-	-	-	-	-
	-15.2±0.9	19.4±0.9	-	-	-	-	-	-	-	-

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, BSA = body surface area, SE = standard error.

Percent of Psoriatic BSA by Body Region During Period A:

Descriptive statistics of percent psoriatic BSA by body region (head/neck, upper limbs, trunk, and lower limbs) during initial treatment (Period A) are summarized in Table 41.

Table 41. Descriptive Statistics of Percent Psoriatic BSA (%) by Body Region During the Initial Tofacitinib Treatment (Period A, FAS-A, Observed Case)

Body Region	Visit	Treatment	N	Mean	SE
Head/Neck	Baseline/Day 1	Tofacitinib 5 mg BID	331	2.9	0.12
		Tofacitinib 10 mg BID	335	2.6	0.12
	Week 4	Tofacitinib 5 mg BID	326	2.1	0.12
		Tofacitinib 10 mg BID	331	1.4	0.1
	Week 8	Tofacitinib 5 mg BID	322	1.5	0.11
		Tofacitinib 10 mg BID	323	1	0.1
	Week 16	Tofacitinib 5 mg BID	311	1.3	0.11
		Tofacitinib 10 mg BID	306	0.8	0.09
	Week 24	Tofacitinib 5 mg BID	277	1.3	0.12
		Tofacitinib 10 mg BID	279	0.6	0.09
Upper Limbs	Baseline/Day 1	Tofacitinib 5 mg BID	331	5.3	0.21
		Tofacitinib 10 mg BID	335	5.2	0.21
	Week 4	Tofacitinib 5 mg BID	326	4.4	0.2
		Tofacitinib 10 mg BID	331	3.5	0.18
	Week 8	Tofacitinib 5 mg BID	322	3.4	0.19
		Tofacitinib 10 mg BID	323	2.3	0.17
	Week 16	Tofacitinib 5 mg BID	311	2.7	0.18
		Tofacitinib 10 mg BID	306	1.6	0.14
	Week 24	Tofacitinib 5 mg BID	277	2.4	0.2
		Tofacitinib 10 mg BID	279	1.3	0.13
Trunk	Baseline/Day 1	Tofacitinib 5 mg BID	331	7.8	0.37
		Tofacitinib 10 mg BID	335	7.8	0.35
	Week 4	Tofacitinib 5 mg BID	326	6.2	0.35
		Tofacitinib 10 mg BID	331	5.2	0.31
	Week 8	Tofacitinib 5 mg BID	322	5	0.33
		Tofacitinib 10 mg BID	323	3.4	0.28
	Week 16	Tofacitinib 5 mg BID	311	4.1	0.32
		Tofacitinib 10 mg BID	306	2.6	0.29
	Week 24	Tofacitinib 5 mg BID	277	3.7	0.31
		Tofacitinib 10 mg BID	279	2.1	0.25
Lower Limbs	Baseline/Day 1	Tofacitinib 5 mg BID	331	11.5	0.46
		Tofacitinib 10 mg BID	335	11.6	0.45
	Week 4	Tofacitinib 5 mg BID	326	9.6	0.45
		Tofacitinib 10 mg BID	331	8.1	0.4
	Week 8	Tofacitinib 5 mg BID	322	7.4	0.42
		Tofacitinib 10 mg BID	323	5.4	0.37
	Week 16	Tofacitinib 5 mg BID	311	5.2	0.38
		Tofacitinib 10 mg BID	306	3.2	0.32
	Week 24	Tofacitinib 5 mg BID	277	4.5	0.36
		Tofacitinib 10 mg BID	279	2.5	0.28

Baseline was defined as the last observation up to first dosing date in Period A.
BID = twice daily, BSA = body surface area, FAS = Full Analysis Set, N = number of subjects, SE = standard error.

Percent of Psoriatic BSA by Body Region During Period B:

Descriptive statistics of percent psoriatic BSA by body region (head/neck, upper limbs, trunk, and lower limbs) during initial treatment (Period B) are summarized in Table 42.

Table 42. Descriptive Statistics of Percent Psoriatic BSA (%) by Body Region During the Double-Blind Treatment Withdrawal (Period B, FAS-B, Observed Case)

Body Region	Visit	Treatment	N	Mean	SE
Head/Neck	Baseline	Tofacitinib 5 mg BID	31	0.4	0.15
		Placebo for CP 5 mg BID	82	0.3	0.08
		Tofacitinib 10 mg BID	45	0.1	0.03
		Placebo for CP 10 mg BID	133	0.3	0.07
	Week 4	Tofacitinib 5 mg BID	30	0.4	0.14
		Placebo for CP 5 mg BID	82	1.1	0.2
		Tofacitinib 10 mg BID	43	0.2	0.04
		Placebo for CP 10 mg BID	128	1.2	0.16
	Week 8	Tofacitinib 5 mg BID	30	0.5	0.18
		Placebo for CP 5 mg BID	70	1.3	0.23
		Tofacitinib 10 mg BID	43	0.1	0.05
		Placebo for CP 10 mg BID	104	1.5	0.2
	Week 12	Tofacitinib 5 mg BID	28	0.4	0.1
		Placebo for CP 5 mg BID	53	1.4	0.3
		Tofacitinib 10 mg BID	42	0.3	0.07
		Placebo for CP 10 mg BID	84	1.2	0.2
	Week 16	Tofacitinib 5 mg BID	28	0.4	0.12
		Placebo for CP 5 mg BID	45	0.9	0.21
		Tofacitinib 10 mg BID	38	0.2	0.08
		Placebo for CP 10 mg BID	70	1	0.18
Upper Limbs	Baseline	Tofacitinib 5 mg BID	31	0.4	0.08
		Placebo for CP 5 mg BID	82	1	0.2
		Tofacitinib 10 mg BID	45	0.6	0.11
		Placebo for CP 10 mg BID	133	0.6	0.1
	Week 4	Tofacitinib 5 mg BID	30	0.5	0.1
		Placebo for CP 5 mg BID	82	1.5	0.24
		Tofacitinib 10 mg BID	43	0.6	0.11
		Placebo for CP 10 mg BID	128	1.5	0.19
	Week 8	Tofacitinib 5 mg BID	30	0.6	0.12
		Placebo for CP 5 mg BID	70	1.8	0.28
		Tofacitinib 10 mg BID	43	0.7	0.14
		Placebo for CP 10 mg BID	104	1.8	0.25
	Week 12	Tofacitinib 5 mg BID	28	0.6	0.12
		Placebo for CP 5 mg BID	53	1.8	0.28
		Tofacitinib 10 mg BID	42	0.7	0.12
		Placebo for CP 10 mg BID	84	1.3	0.2
	Week 16	Tofacitinib 5 mg BID	28	0.6	0.14
		Placebo for CP 5 mg BID	45	1.3	0.23
		Tofacitinib 10 mg BID	38	0.7	0.13
		Placebo for CP 10 mg BID	70	1.4	0.26
Trunk	Baseline	Tofacitinib 5 mg BID	31	0.5	0.16
		Placebo for CP 5 mg BID	82	1	0.26
		Tofacitinib 10 mg BID	45	0.5	0.16
		Placebo for CP 10 mg BID	133	0.8	0.18
	Week 4	Tofacitinib 5 mg BID	30	0.5	0.16
		Placebo for CP 5 mg BID	82	1.5	0.3
		Tofacitinib 10 mg BID	43	0.5	0.16
		Placebo for CP 10 mg BID	128	1.8	0.32
	Week 8	Tofacitinib 5 mg BID	30	0.6	0.17
		Placebo for CP 5 mg BID	70	2.2	0.52
		Tofacitinib 10 mg BID	43	0.4	0.11
		Placebo for CP 10 mg BID	104	2.4	0.39
	Week 12	Tofacitinib 5 mg BID	28	0.5	0.18
		Placebo for CP 5 mg BID	53	1.3	0.2
		Tofacitinib 10 mg BID	42	0.4	0.12
		Placebo for CP 10 mg BID	84	1.6	0.31
	Week 16	Tofacitinib 5 mg BID	28	0.6	0.22

Table 42. Descriptive Statistics of Percent Psoriatic BSA (%) by Body Region During the Double-Blind Treatment Withdrawal (Period B, FAS-B, Observed Case)

Body Region	Visit	Treatment	N	Mean	SE
		Placebo for CP 5 mg BID	45	1.4	0.27
		Tofacitinib 10 mg BID	38	0.5	0.27
		Placebo for CP 10 mg BID	70	1.7	0.31
Lower Limbs	Baseline	Tofacitinib 5 mg BID	31	0.5	0.15
		Placebo for CP 5 mg BID	82	1.5	0.41
		Tofacitinib 10 mg BID	45	0.8	0.18
		Placebo for CP 10 mg BID	133	1	0.2
	Week 4	Tofacitinib 5 mg BID	30	0.5	0.13
		Placebo for CP 5 mg BID	82	2	0.3
		Tofacitinib 10 mg BID	43	0.6	0.15
		Placebo for CP 10 mg BID	128	2.3	0.36
	Week 8	Tofacitinib 5 mg BID	30	0.6	0.14
		Placebo for CP 5 mg BID	70	2.4	0.43
		Tofacitinib 10 mg BID	43	0.7	0.21
		Placebo for CP 10 mg BID	104	3	0.52
	Week 12	Tofacitinib 5 mg BID	28	0.5	0.14
		Placebo for CP 5 mg BID	53	2.8	0.5
		Tofacitinib 10 mg BID	42	1	0.32
		Placebo for CP 10 mg BID	84	2.1	0.38
	Week 16	Tofacitinib 5 mg BID	28	0.5	0.17
		Placebo for CP 5 mg BID	45	2.4	0.52
		Tofacitinib 10 mg BID	38	1.2	0.41
		Placebo for CP 10 mg BID	70	2	0.31

Baseline was defined as the last observation up to first dosing date in Period B.
BID = twice daily, BSA = body surface area, CP = tofacitinib, FAS = Full Analysis Set, N = number of subjects, SE = standard error.

Percent of Psoriatic BSA by Body Region During Period C:

Descriptive statistics of percent psoriatic BSA by body region (head/neck, upper limbs, trunk, and lower limbs) during initial treatment (Period C) are summarized in Table 43.

Table 43. Descriptive Statistics of Percent Psoriatic BSA (%) by Body Region During Tofacitinib Re-treatment (FAS-C, Period C, Observed Case)

Body Region	Visit	Treatment	N	Mean	SE
Head/Neck	Baseline	CP 5 mg BID → CP 5 mg BID	27	0.4	0.12
		Placebo → CP 5 mg BID	75	1.9	0.26
		CP 10 mg BID → CP 10 mg BID	42	0.2	0.06
		Placebo → CP 10 mg BID	120	1.8	0.2
	Week 4	CP 5 mg BID → CP 5 mg BID	27	0.4	0.13
		Placebo → CP 5 mg BID	74	1.2	0.21
		CP 10 mg BID → CP 10 mg BID	42	0.3	0.08
		Placebo → CP 10 mg BID	119	0.8	0.11
	Week 8	CP 5 mg BID → CP 5 mg BID	26	0.4	0.12
		Placebo → CP 5 mg BID	72	1	0.2
		CP 10 mg BID → CP 10 mg BID	41	0.3	0.11
		Placebo → CP 10 mg BID	118	0.6	0.1
	Week 16	CP 5 mg BID → CP 5 mg BID	23	0.5	0.15
		Placebo → CP 5 mg BID	67	1	0.2
		CP 10 mg BID → CP 10 mg BID	39	0.1	0.05
		Placebo → CP 10 mg BID	101	0.6	0.13
Upper Limbs	Baseline	CP 5 mg BID → CP 5 mg BID	27	0.6	0.14
		Placebo → CP 5 mg BID	75	2.5	0.35
		CP 10 mg BID → CP 10 mg BID	42	0.7	0.13
		Placebo → CP 10 mg BID	120	2.6	0.28
	Week 4	CP 5 mg BID → CP 5 mg BID	27	0.7	0.16
		Placebo → CP 5 mg BID	74	2.2	0.38
		CP 10 mg BID → CP 10 mg BID	42	0.8	0.18
		Placebo → CP 10 mg BID	119	1.7	0.25
	Week 8	CP 5 mg BID → CP 5 mg BID	26	0.8	0.2
		Placebo → CP 5 mg BID	72	1.8	0.37
		CP 10 mg BID → CP 10 mg BID	41	0.7	0.18
		Placebo → CP 10 mg BID	118	1.3	0.19
	Week 16	CP 5 mg BID → CP 5 mg BID	23	0.8	0.2
		Placebo → CP 5 mg BID	67	1.4	0.27
		CP 10 mg BID → CP 10 mg BID	39	0.9	0.25
		Placebo → CP 10 mg BID	101	1.1	0.2
Trunk	Baseline	CP 5 mg BID → CP 5 mg BID	27	0.7	0.23
		Placebo → CP 5 mg BID	75	3.3	0.52
		CP 10 mg BID → CP 10 mg BID	42	0.6	0.25
		Placebo → CP 10 mg BID	120	3.3	0.41
	Week 4	CP 5 mg BID → CP 5 mg BID	27	0.6	0.2
		Placebo → CP 5 mg BID	74	3.3	0.7
		CP 10 mg BID → CP 10 mg BID	42	1	0.52
		Placebo → CP 10 mg BID	119	2	0.33
	Week 8	CP 5 mg BID → CP 5 mg BID	26	0.7	0.22
		Placebo → CP 5 mg BID	72	3.1	0.65
		CP 10 mg BID → CP 10 mg BID	41	1.1	0.53
		Placebo → CP 10 mg BID	118	1.8	0.35
	Week 16	CP 5 mg BID → CP 5 mg BID	23	0.9	0.29
		Placebo → CP 5 mg BID	67	2.1	0.46
		CP 10 mg BID → CP 10 mg BID	39	1.4	0.7
		Placebo → CP 10 mg BID	101	1.4	0.35
Lower Limbs	Baseline	CP 5 mg BID → CP 5 mg BID	27	0.6	0.18
		Placebo → CP 5 mg BID	75	3.8	0.48
		CP 10 mg BID → CP 10 mg BID	42	1.5	0.46
		Placebo → CP 10 mg BID	120	4.2	0.51
	Week 4	CP 5 mg BID → CP 5 mg BID	27	0.5	0.11
		Placebo → CP 5 mg BID	74	3.8	0.72
		CP 10 mg BID → CP 10 mg BID	42	1	0.38
		Placebo → CP 10 mg BID	119	2.8	0.43
	Week 8	CP 5 mg BID → CP 5 mg BID	26	0.5	0.15

Table 43. Descriptive Statistics of Percent Psoriatic BSA (%) by Body Region During Tofacitinib Re-treatment (FAS-C, Period C, Observed Case)

Body Region	Visit	Treatment	N	Mean	SE
	Week 16	Placebo → CP 5 mg BID	72	3.2	0.69
		CP 10 mg BID → CP 10 mg BID	41	1.2	0.44
		Placebo → CP 10 mg BID	118	2.3	0.37
		CP 5 mg BID → CP 5 mg BID	23	0.7	0.18
		Placebo → CP 5 mg BID	67	2.6	0.5
		CP 10 mg BID → CP 10 mg BID	39	1.2	0.53
		Placebo → CP 10 mg BID	101	1.4	0.25

Baseline was defined as the last observation up to first dosing date in Period C.
BID = twice daily, BSA = body surface area, CP = tofacitinib, FAS = Full Analysis Set, N = number of subjects, SE = standard error.

Change From Baseline in of Psoriatic BSA by Body Region During Period A:

Descriptive statistics of the change from Baseline in psoriatic BSA by body region during initial treatment are summarized in Table 44.

Table 44. Descriptive Statistics of Change from Baseline-A Percent Psoriatic BSA (%) by Body Region During the Initial Tofacitinib Treatment (Period A, FAS-A, Observed Case)

Body Region	Visit	Treatment	N	Mean	SE
Head/Neck	Week 4	Tofacitinib 5 mg BID	326	-0.8	0.07
		Tofacitinib 10 mg BID	331	-1.2	0.09
	Week 8	Tofacitinib 5 mg BID	322	-1.4	0.1
		Tofacitinib 10 mg BID	323	-1.6	0.1
	Week 16	Tofacitinib 5 mg BID	311	-1.5	0.11
		Tofacitinib 10 mg BID	306	-1.8	0.11
	Week 24	Tofacitinib 5 mg BID	277	-1.5	0.12
		Tofacitinib 10 mg BID	279	-1.9	0.11
Upper Limbs	Week 4	Tofacitinib 5 mg BID	326	-1	0.12
		Tofacitinib 10 mg BID	331	-1.8	0.16
	Week 8	Tofacitinib 5 mg BID	322	-1.9	0.15
		Tofacitinib 10 mg BID	323	-2.8	0.18
	Week 16	Tofacitinib 5 mg BID	311	-2.6	0.18
		Tofacitinib 10 mg BID	306	-3.5	0.21
	Week 24	Tofacitinib 5 mg BID	277	-2.8	0.2
		Tofacitinib 10 mg BID	279	-3.7	0.2
Trunk	Week 4	Tofacitinib 5 mg BID	326	-1.7	0.2
		Tofacitinib 10 mg BID	331	-2.6	0.26
	Week 8	Tofacitinib 5 mg BID	322	-3	0.26
		Tofacitinib 10 mg BID	323	-4.1	0.31
	Week 16	Tofacitinib 5 mg BID	311	-3.9	0.29
		Tofacitinib 10 mg BID	306	-5.1	0.35
	Week 24	Tofacitinib 5 mg BID	277	-4	0.34
		Tofacitinib 10 mg BID	279	-5.3	0.34
Lower Limbs	Week 4	Tofacitinib 5 mg BID	326	-1.9	0.23
		Tofacitinib 10 mg BID	331	-3.5	0.34
	Week 8	Tofacitinib 5 mg BID	322	-4.2	0.33
		Tofacitinib 10 mg BID	323	-5.9	0.4
	Week 16	Tofacitinib 5 mg BID	311	-6.3	0.41
		Tofacitinib 10 mg BID	306	-8.1	0.44
	Week 24	Tofacitinib 5 mg BID	277	-6.8	0.44
		Tofacitinib 10 mg BID	279	-8.5	0.43

Baseline-A was defined as the last observation up to first dosing date in Period A.
BID = twice daily, BSA = body surface area, FAS = Full Analysis Set, N = number of subjects, SE = standard error.

Change From Baseline in of Psoriatic BSA by Body Region During Period B:

Descriptive statistics of the change from Baseline in psoriatic BSA by body region during initial treatment are summarized in Table 45.

Table 45. Descriptive Statistics of Change From Baseline-B Percent Psoriatic BSA (%) by Body Region During the Double-Blind Treatment Withdrawal (Period B, FAS-B, Observed Case)

Body Region	Visit	Treatment	N	Mean	SE
Head/Neck	Week 4	Tofacitinib 5 mg BID	30	0	0.1
		Placebo for CP 5 mg BID	82	0.8	0.15
		Tofacitinib 10 mg BID	43	0.1	0.04
		Placebo for CP 10 mg BID	128	0.9	0.15
	Week 8	Tofacitinib 5 mg BID	30	0	0.14
		Placebo for CP 5 mg BID	70	1	0.19
		Tofacitinib 10 mg BID	43	0.1	0.05
		Placebo for CP 10 mg BID	104	1.3	0.19
	Week 12	Tofacitinib 5 mg BID	28	-0.1	0.16
		Placebo for CP 5 mg BID	53	1.2	0.27
		Tofacitinib 10 mg BID	42	0.2	0.07
		Placebo for CP 10 mg BID	84	1	0.2
	Week 16	Tofacitinib 5 mg BID	28	-0.1	0.14
		Placebo for CP 5 mg BID	45	0.8	0.17
		Tofacitinib 10 mg BID	38	0.1	0.07
		Placebo for CP 10 mg BID	70	0.8	0.17
Upper Limbs	Week 4	Tofacitinib 5 mg BID	30	0.1	0.07
		Placebo for CP 5 mg BID	82	0.5	0.23
		Tofacitinib 10 mg BID	43	0	0.06
		Placebo for CP 10 mg BID	128	0.9	0.15
	Week 8	Tofacitinib 5 mg BID	30	0.2	0.09
		Placebo for CP 5 mg BID	70	0.8	0.2
		Tofacitinib 10 mg BID	43	0.1	0.11
		Placebo for CP 10 mg BID	104	1.2	0.19
	Week 12	Tofacitinib 5 mg BID	28	0.2	0.1
		Placebo for CP 5 mg BID	53	1	0.23
		Tofacitinib 10 mg BID	42	0.1	0.1
		Placebo for CP 10 mg BID	84	0.9	0.17
	Week 16	Tofacitinib 5 mg BID	28	0.2	0.11
		Placebo for CP 5 mg BID	45	0.5	0.15
		Tofacitinib 10 mg BID	38	0.1	0.09
		Placebo for CP 10 mg BID	70	1	0.19
Trunk	Week 4	Tofacitinib 5 mg BID	30	0	0.15
		Placebo for CP 5 mg BID	82	0.6	0.35
		Tofacitinib 10 mg BID	43	0	0.15
		Placebo for CP 10 mg BID	128	1	0.22
	Week 8	Tofacitinib 5 mg BID	30	0.1	0.16
		Placebo for CP 5 mg BID	70	1.2	0.4
		Tofacitinib 10 mg BID	43	0	0.17
		Placebo for CP 10 mg BID	104	1.7	0.29
	Week 12	Tofacitinib 5 mg BID	28	0	0.2
		Placebo for CP 5 mg BID	53	0.9	0.22
		Tofacitinib 10 mg BID	42	-0.1	0.19
		Placebo for CP 10 mg BID	84	1.1	0.23
	Week 16	Tofacitinib 5 mg BID	28	0.1	0.22
		Placebo for CP 5 mg BID	45	1	0.24
		Tofacitinib 10 mg BID	38	0	0.33
		Placebo for CP 10 mg BID	70	1.2	0.21
Lower Limbs	Week 4	Tofacitinib 5 mg BID	30	-0.1	0.17
		Placebo for CP 5 mg BID	82	0.5	0.37
		Tofacitinib 10 mg BID	43	-0.3	0.16
		Placebo for CP 10 mg BID	128	1.3	0.27
	Week 8	Tofacitinib 5 mg BID	30	0.1	0.17
		Placebo for CP 5 mg BID	70	1.1	0.33
		Tofacitinib 10 mg BID	43	-0.2	0.26
		Placebo for CP 10 mg BID	104	2.1	0.39

Table 45. Descriptive Statistics of Change From Baseline-B Percent Psoriatic BSA (%) by Body Region During the Double-Blind Treatment Withdrawal (Period B, FAS-B, Observed Case)

Body Region	Visit	Treatment	N	Mean	SE
	Week 12	Tofacitinib 5 mg BID	28	-0.1	0.19
		Placebo for CP 5 mg BID	53	1.8	0.48
		Tofacitinib 10 mg BID	42	0.1	0.34
		Placebo for CP 10 mg BID	84	1.5	0.33
	Week 16	Tofacitinib 5 mg BID	28	0	0.2
		Placebo for CP 5 mg BID	45	1.3	0.38
		Tofacitinib 10 mg BID	38	0.3	0.34
		Placebo for CP 10 mg BID	70	1.5	0.31

Baseline was defined as the last observation up to first dosing date in Period B.
BID = twice daily, BSA = body surface area, CP = tofacitinib, FAS = Full Analysis Set, N = number of subjects, SE = standard error.

Change From Baseline in of Psoriatic BSA by Body Region During Period C:

Descriptive statistics of the change from Baseline in psoriatic BSA by body region during initial treatment are summarized in Table 46.

Table 46. Descriptive Statistics of Change From Baseline-C Percent Psoriatic BSA (%) by Body Region During Tofacitinib Re-treatment (FAS-C, Period C, Observed Case)

Body Region	Visit	Treatment	N	Mean	SE
Head/Neck	Week 4	CP 5 mg BID → CP 5 mg BID	27	0	0.09
		Placebo → CP 5 mg BID	74	-0.6	0.14
		CP 10 mg BID → CP 10 mg BID	42	0.1	0.08
		Placebo → CP 10 mg BID	119	-1.1	0.15
	Week 8	CP 5 mg BID → CP 5 mg BID	26	0	0.11
		Placebo → CP 5 mg BID	72	-0.9	0.17
		CP 10 mg BID → CP 10 mg BID	41	0.1	0.09
		Placebo → CP 10 mg BID	118	-1.1	0.15
	Week 16	CP 5 mg BID → CP 5 mg BID	23	0	0.14
		Placebo → CP 5 mg BID	67	-0.8	0.2
		CP 10 mg BID → CP 10 mg BID	39	-0.1	0.08
		Placebo → CP 10 mg BID	101	-1.2	0.18
Upper Limbs	Week 4	CP 5 mg BID → CP 5 mg BID	27	0	0.05
		Placebo → CP 5 mg BID	74	-0.3	0.18
		CP 10 mg BID → CP 10 mg BID	42	0.1	0.14
		Placebo → CP 10 mg BID	119	-1	0.19
	Week 8	CP 5 mg BID → CP 5 mg BID	26	0.2	0.1
		Placebo → CP 5 mg BID	72	-0.6	0.17
		CP 10 mg BID → CP 10 mg BID	41	0	0.11
		Placebo → CP 10 mg BID	118	-1.3	0.22
	Week 16	CP 5 mg BID → CP 5 mg BID	23	0.1	0.19
		Placebo → CP 5 mg BID	67	-1	0.23
		CP 10 mg BID → CP 10 mg BID	39	0.2	0.2
		Placebo → CP 10 mg BID	101	-1.5	0.24
Trunk	Week 4	CP 5 mg BID → CP 5 mg BID	27	-0.1	0.06
		Placebo → CP 5 mg BID	74	0	0.34
		CP 10 mg BID → CP 10 mg BID	42	0.4	0.56
		Placebo → CP 10 mg BID	119	-1.4	0.26
	Week 8	CP 5 mg BID → CP 5 mg BID	26	0	0.13
		Placebo → CP 5 mg BID	72	-0.3	0.31
		CP 10 mg BID → CP 10 mg BID	41	0.5	0.58
		Placebo → CP 10 mg BID	118	-1.4	0.27
	Week 16	CP 5 mg BID → CP 5 mg BID	23	0.2	0.24
		Placebo → CP 5 mg BID	67	-1.2	0.43
		CP 10 mg BID → CP 10 mg BID	39	0.8	0.74
		Placebo → CP 10 mg BID	101	-1.7	0.31
Lower Limbs	Week 4	CP 5 mg BID → CP 5 mg BID	27	-0.1	0.15
		Placebo → CP 5 mg BID	74	0	0.58
		CP 10 mg BID → CP 10 mg BID	42	-0.4	0.37
		Placebo → CP 10 mg BID	119	-1.4	0.39
	Week 8	CP 5 mg BID → CP 5 mg BID	26	0	0.21
		Placebo → CP 5 mg BID	72	-0.5	0.6
		CP 10 mg BID → CP 10 mg BID	41	-0.3	0.31
		Placebo → CP 10 mg BID	118	-1.7	0.34
	Week 16	CP 5 mg BID → CP 5 mg BID	23	0.1	0.24
		Placebo → CP 5 mg BID	67	-0.9	0.46
		CP 10 mg BID → CP 10 mg BID	39	-0.3	0.46
		Placebo → CP 10 mg BID	101	-2.4	0.37

Baseline was defined as the last observation up to first dosing date in Period C.
BID = twice daily, BSA = body surface area, CP = tofacitinib, FAS = Full Analysis Set, N = number of subjects, SE = standard error.

Actual Itch Severity Item (ISI) Scores at Period A, Period B, and Period C:

Mean ISI scores were similar between the tofacitinib 5 mg and 10 mg BID treatments at

Baseline (6.7 and 6.9, respectively), indicating a moderately high level of itching. At Baseline, mean ISI scores for subjects who continued tofacitinib 5 mg BID and 10 mg BID treatment were 1.5 and 0.6, respectively, and for subjects who received placebo mean ISI scores were 1.2 and 0.8, respectively. During Period C, subjects in the placebo group compared with the tofacitinib 10 mg BID group showed greater improvement than subjects in the placebo group compared with the tofacitinib 5 mg BID group. Baseline-C scores were respectively 2.3 and 1.7 for the tofacitinib 5 mg compared with the 5 mg BID group and tofacitinib 10 mg compared with the 10 mg BID group, respectively; and 4.9 and 5.2 for the placebo group compared with the 5 mg group and placebo compared with the 10 mg group, respectively. The data are summarized in Table 47.

Table 47. Mean Itch Severity Item (ISI) Score During the Initial Tofacitinib Treatment (Period A, Period B, and Period C)

	Period A			Period B				Period C		
	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Tofacitinib 5 mg BID	Placebo for 5 mg Tofacitinib BID	Tofacitinib 10 mg BID	Placebo for 10 mg Tofacitinib BID	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
N	**331**	**335**	**31**	**82**	**45**	**133**	**27**	**75**	**42**	**120**
	Mean ± SE	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**
Baseline										
n	331	335	31	82	45	133	27	75	42	120
	6.7±0.1	6.9±0.1	1.5±0.4	1.2±0.2	0.6±0.2	0.8±0.1	2.3±0.5	4.9±0.3	1.7±0.4	5.2±0.3
Week 4										
n	326	331	30	82	43	127	27	74	42	119
	3.2±0.1	2.2±0.1	1.7±0.4	3.6±0.3	0.7±0.2	4.1±0.3	2.6±0.5	2.6±0.2	1.7±0.4	2.1±0.2
Week 8										
n	322	321	30	69	43	104	26	72	41	118
	2.8±0.1	1.6±0.1	1.5±0.4	4.0±0.4	1.2±0.3	4.1±0.3	2.4±0.5	2.3±0.2	1.5±0.3	1.8±0.2
Week 12										
n	-	-	29	53	41	84	-	-	-	-
	-	-	1.9±0.4	4.0±0.4	1.3±0.3	3.8±0.3	-	-	-	-
Week 16										
n	310	307	28	45	38	70	23	67	39	100
	2.9±0.2	1.7±0.1	2.2±0.5	3.7±0.4	1.6±0.4	4.0±0.4	2.3±0.5	2.2±0.3	1.4±0.4	1.6±0.2
Week 24										
n	274	278	-	-	-	-	-	-	-	-
	2.9±0.2	1.6±0.1	-	-	-	-	-	-	-	-

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, SE = standard error.

Change From Baseline ISI Score at Period A, Period B and Period C:

Greater change from Baseline in ISI score was observed in the placebo group compared with the tofacitinib 5 mg BID group and the placebo group compared with the tofacitinib 10 mg BID treatment group at Week 16 than when comparing the placebo group with those groups treated with continuous tofacitinib treatment, whose ISI scores remained fairly stable. The data are summarized in Table 48.

Table 48. Mean Change From Baseline in ISI Score During the Initial Tofacitinib Treatment (Period A, Period B, and Period C)

	Period A			Period B				Period C		
	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Tofacitinib 5 mg BID	Placebo for 5 mg Tofacitinib BID	Tofacitinib 10 mg BID	Placebo for 10 mg Tofacitinib BID	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
N	**326**	**331**	**30**	**82**	**43**	**127**	**27**	**74**	**42**	**119**
	Mean ± SE	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**
Week 4										
n	326	331	30	82	43	127	27	74	42	119
	-3.6±0.1	-4.6±0.2	0.2±0.3	2.4±0.3	0.1±0.2	3.3±0.3	0.3±0.4	-2.3±0.3	0.0±0.2	-3.1±0.3
Week 8										
n	322	321	30	69	43	104	26	72	41	118
	-3.9±0.2	-5.3±0.2	-0.0±0.3	2.9±0.3	0.6±0.2	3.4±0.3	0.1±0.4	-2.6±0.3	-0.2±0.2	-3.4±0.3
Week 12										
n	-	-	29	53	41	84	-	-	-	-
	-	-	0.3±0.2	2.8±0.3	0.7±0.2	3.2±0.3	-	-	-	-
Week 16										
n	310	307	28	45	38	70	23	67	39	100
	-3.8±0.2	-5.2±0.2	0.6±0.3	2.7±0.4	0.9±0.3	3.6±0.4	0.4±0.4	-2.6±0.4	-0.3±0.3	-3.6±0.3
Week 24										
n	274	278	-	-	-	-	-	-	-	-
	-3.7±0.2	-5.3±0.2	-	-	-	-	-	-	-	-

BID = twice daily, ISI = Itch Severity Item, N = number of subjects, n = number of subjects in pre-specified criteria, SE = standard error.

Subjects Achieving an ISI Score of '0', Point Reduction From Baseline in ISI Score at Period A and Period C:

The percentage of subjects achieving an ISI score of 0 ("no itching") during initial treatment and re-treatment (Period A and Period C) is summarized in Table 49.

Table 49. Percentage of Participants With an ISI Score of 0 During Tofacitinib Re-Treatment (Period A and Period C)

Period A		Period C			
Tofacitinib 5 mg BID	**Tofacitinib 10 mg BID**	**Tofacitinib 5 mg BID / Tofacitinib 5 mg BID**	**Placebo BID / Tofacitinib 5 mg BID**	**Tofacitinib 10 mg BID / CP 690,550 10 mg BID**	**Placebo BID / Tofacitinib 10 mg BID**
N = 325	**N = 327**	**N = 18**	**N = 71**	**N = 27**	**N = 104**
Response rate (95% CI)	**Response rate (95% CI)**	**Response rate (95% CI)**	**Response rate (95% CI)**	**Response rate (95% CI)**	**Response rate (95% CI)**
Baseline					
-	-	0.00	0.00	0.00	0.00
-	-	(0.00 to 0.00)	(0.00 to 0.00)	(0.00 to 0.00)	(0.00 to 0.00)
Week 4					
12.92	25.69	0.00	11.27	7.41	23.08
(9.28 to 16.57)	(20.95 to 30.42)	(0.00 to 0.00)	(3.91 to 18.62)	(0.00 to 17.29)	(14.98 to 31.17)
Week 8					
16.92	41.28	5.56	18.31	18.52	38.46
(12.85 to 21.00)	(35.95 to 46.62)	(0.00 to 16.14)	(9.31 to 27.31)	(3.87 to 33.17)	(29.11 to 47.81)
Week 16					
20.00	37.92	11.11	15.49	25.93	28.85
(15.65 to 24.35)	(32.66 to 43.18)	(0.00 to 25.63)	(7.08 to 23.91)	(9.40 to 42.46)	(20.14 to 37.55)
Week 24					
19.38	37.31	-	-	-	-
(15.09 to 23.68)	(32.07 to 42.55)	-	-	-	-

BID = twice daily, CI = confidence interval, ISI = Itch Severity Item, N = number of subjects.

Actual Dermatology Life Quality Index (DLQI) During Periods A, B and C:

The mean DLQI score at Baseline was 12.6 for both the tofacitinib 5 mg BID and 10 mg BID groups, indicating a large burden on quality of life. Descriptive statistics for actual DLQI during Period A are presented in Table 50.

Table 50. Descriptive Statistics of DLQI During the Initial Tofacitinib Treatment (Period A, FAS-A, Observed Case)

Visit	Treatment	N	Mean	SE
Baseline	Tofacitinib 5 mg BID	330	12.6	0.4
	Tofacitinib 10 mg BID	333	12.6	0.4
Week 4	Tofacitinib 5 mg BID	326	6.8	0.3
	Tofacitinib 10 mg BID	330	4.8	0.3
Week 8	Tofacitinib 5 mg BID	321	5.4	0.3
	Tofacitinib 10 mg BID	319	3.4	0.3
Week 16	Tofacitinib 5 mg BID	310	4.7	0.3
	Tofacitinib 10 mg BID	303	2.9	0.3
Week 24	Tofacitinib 5 mg BID	273	5.1	0.4
	Tofacitinib 10 mg BID	277	2.6	0.3

Baseline was defined as the last observation up to first dosing date in Period A
BID = twice daily, DLQI = Dermatology Life Quality Index, FAS = full analysis set, N = number of subjects, SE = standard error.

Mean scores for subjects in tofacitinib 5 mg BID and tofacitinib 10 mg BID groups remained stable from Baseline through Week 16. In contrast, mean scores for subjects in the placebo for tofacitinib 5 mg BID and placebo for tofacitinib 10 mg BID groups increased (ie, worsened) during Period B. Descriptive statistics for actual DLQI during Period B are presented in Table 51.

Table 51. Descriptive Statistics of DLQI During the Double-Blind Treatment Withdrawal (Period B, FAS-B, Observed Case)

Visit	Treatment	N	Mean	SE
Baseline	Tofacitinib 5 mg BID	31	2.6	0.7
	Placebo for CP 5 mg BID	82	1.8	0.3
	Tofacitinib 10 mg BID	45	1.2	0.3
	Placebo for CP 10 mg BID	133	1.2	0.2
Week 4	Tofacitinib 5 mg BID	30	3.4	0.9
	Placebo for CP 5 mg BID	82	4.7	0.5
	Tofacitinib 10 mg BID	43	1.3	0.4
	Placebo for CP 10 mg BID	127	5.9	0.6
Week 8	Tofacitinib 5 mg BID	30	3.1	0.9
	Placebo for CP 5 mg BID	68	5.9	0.8
	Tofacitinib 10 mg BID	43	1.6	0.5
	Placebo for CP 10 mg BID	104	6.4	0.7
Week 12	Tofacitinib 5 mg BID	28	3.3	1.1
	Placebo for CP 5 mg BID	52	4.7	0.6
	Tofacitinib 10 mg BID	41	1.9	0.4
	Placebo for CP 10 mg BID	83	5.3	0.7
Week 16	Tofacitinib 5 mg BID	28	3.5	1
	Placebo for CP 5 mg BID	44	5	0.7
	Tofacitinib 10 mg BID	38	2	0.4
	Placebo for CP 10 mg BID	68	6.2	0.8

Baseline was defined as the last observation up to first dosing date in Period B
BID = twice daily, CP = tofacitinib, DLQI = Dermatology Life Quality Index, FAS = full analysis set, N = number of subjects, SE = standard error.

Descriptive statistics for actual DLQI during Period C are presented in Table 52.

Table 52. Descriptive Statistics of DLQI During Tofacitinib Re-Treatment (Period C, FAS-C, Observed Case)

Visit	Treatment	N	Mean	SE
Baseline	CP 5 mg BID → CP 5 mg BID	27	3.6	1
	Placebo → CP 5 mg BID	75	7	0.8
	CP 10 mg BID → CP 10 mg BID	42	2.2	0.5
	Placebo → CP 10 mg BID	120	8.8	0.7
Week 4	CP 5 mg BID → CP 5 mg BID	27	3.4	1
	Placebo → CP 5 mg BID	74	4.3	0.5
	CP 10 mg BID → CP 10 mg BID	42	2.2	0.5
	Placebo → CP 10 mg BID	119	3.9	0.4
Week 8	CP 5 mg BID → CP 5 mg BID	26	3.9	1.3
	Placebo → CP 5 mg BID	71	3.1	0.4
	CP 10 mg BID → CP 10 mg BID	41	2.2	0.5
	Placebo → CP 10 mg BID	118	2.7	0.4
Week 16	CP 5 mg BID → CP 5 mg BID	22	3	1
	Placebo → CP 5 mg BID	66	3.4	0.5
	CP 10 mg BID → CP 10 mg BID	39	2.1	0.7
	Placebo → CP 10 mg BID	101	2.4	0.4

Baseline was defined as the last observation up to first dosing date in Period C.
BID = twice daily, CP = tofacitinib, DLQI = Dermatology Life Quality Index, FAS = full analysis set, N = number of subjects, SE = standard error.

Change From Baseline on Dermatology Life Quality Index (DLQI) During Periods A, B and C:

Descriptive statistics for change from Baseline on DLQI during Period A are presented in Table 53.

Table 53. Descriptive Statistics of Change from Baseline-A DLQI During the Initial Tofacitinib Treatment (Period A, FAS-A, Observed Case)

Visit	Treatment	N	Mean	SE
Week 4	Tofacitinib 5 mg BID	325	-5.8	0.3
	Tofacitinib 10 mg BID	328	-7.6	0.3
Week 8	Tofacitinib 5 mg BID	320	-7.1	0.3
	Tofacitinib 10 mg BID	317	-9.1	0.4
Week 16	Tofacitinib 5 mg BID	309	-7.6	0.4
	Tofacitinib 10 mg BID	301	-9.4	0.4
Week 24	Tofacitinib 5 mg BID	272	-7.1	0.4
	Tofacitinib 10 mg BID	275	-9.7	0.4

BID = twice daily, DLQI = Dermatology Life Quality Index, FAS = full analysis set, N = number of subjects, SE = standard error.

Descriptive statistics for change from Baseline on DLQI during Period B are presented in Table 54.

Table 54. Descriptive Statistics of Change From Baseline-B DLQI During the Double-Blind Treatment Withdrawal (Period B, FAS-B, Observed Case)

Visit	Treatment	N	Mean	SE
Week 4	Tofacitinib 5 mg BID	30	0.8	0.7
	Placebo for CP 5 mg BID	82	3	0.5
	Tofacitinib 10 mg BID	43	0.1	0.3
	Placebo for CP 10 mg BID	127	4.6	0.5
Week 8	Tofacitinib 5 mg BID	30	0.5	0.3
	Placebo for CP 5 mg BID	68	4.1	0.7
	Tofacitinib 10 mg BID	43	0.3	0.5
	Placebo for CP 10 mg BID	104	5.4	0.6
Week 12	Tofacitinib 5 mg BID	28	0.9	0.5
	Placebo for CP 5 mg BID	52	3.4	0.5
	Tofacitinib 10 mg BID	41	0.6	0.4
	Placebo for CP 10 mg BID	83	4.5	0.7
Week 16	Tofacitinib 5 mg BID	28	1.1	0.5
	Placebo for CP 5 mg BID	44	3.6	0.6
	Tofacitinib 10 mg BID	38	0.5	0.3
	Placebo for CP 10 mg BID	68	5.4	0.8

BID = twice daily, CP = tofacitinib, DLQI = Dermatology Life Quality Index, FAS = full analysis set, N = number of subjects, SE = standard error.

Descriptive statistics for change from Baseline on DLQI during Period C are presented in Table 55.

Table 55. Descriptive Statistics of Change From Baseline-C DLQI During Tofacitinib Re-treatment (Period C, FAS-C, Observed Case)

Visit	Treatment	N	Mean	SE
Week 4	CP 5 mg BID → CP 5 mg BID	27	-0.2	0.2
	Placebo → CP 5 mg BID	74	-2.9	0.5
	CP 10 mg BID → CP 10 mg BID	42	0	0.4
	Placebo → CP 10 mg BID	119	-4.9	0.6
Week 8	CP 5 mg BID → CP 5 mg BID	26	0.2	0.4
	Placebo → CP 5 mg BID	71	-3.4	0.5
	CP 10 mg BID → CP 10 mg BID	41	0	0.5
	Placebo → CP 10 mg BID	118	-5.9	0.6
Week 16	CP 5 mg BID → CP 5 mg BID	22	0.5	0.8
	Placebo → CP 5 mg BID	66	-3.3	0.8
	CP 10 mg BID → CP 10 mg BID	39	0	0.7
	Placebo → CP 10 mg BID	101	-6.3	0.7

BID = twice daily, CP = tofacitinib, DLQI = Dermatology Life Quality Index, FAS = full analysis set, N = number of subjects, SE = standard error.

Subjects achieving an ISI score of ≤1-point reduction from Baseline in ISI score at Period A and Period C:

The percentage of subjects who had an ISI score of ≤1 (indicating little to no itching) during initial treatment (Period A) among subjects with an ISI score of >1 at Baseline. The proportion of subjects in the placebo to tofacitinib groups who regained response during Period C was 41.9% and 50.5% for the 5 mg BID and 10 mg BID groups, respectively. The data are summarized in Table 56.

Table 56. Percentage of Participants Achieving an ISI Score of ≤1 During the Initial Tofacitinib Treatment (Period A and Period C)

Period A		Period C			
Tofacitinib 5 mg BID	**Tofacitinib 10 mg BID**	**Tofacitinib 5 mg BID / Tofacitinib 5 mg BID**	**Placebo BID / Tofacitinib 5 mg BID**	**Tofacitinib 10 mg BID / Tofacitinib 10 mg BID**	**Placebo BID / Tofacitinib 10 mg BID**
N = 315	**N = 315**	**N = 14**	**N = 62**	**N = 14**	**N = 95**
Response rate (95% CI)	**Response rate (95% CI)**	**Response rate (95% CI)**	**Response rate (95% CI)**	**Response rate (95% CI)**	**Response rate (95% CI)**
Baseline					
-	-	0.00	0.00	0.00	0.00
-	-	(0.00 to 0.00)	(0.00 to 0.00)	(0.00 to 0.00)	(0.00 to 0.00)
Week 4					
27.62	46.03	14.29	22.58	14.29	41.05
(22.68 to 32.56)	(40.53 to 51.54)	(0.00 to 32.62)	(12.17 to 32.99)	(0.00 to 32.62)	(31.16 to 50.94)
Week 8					
34.29	60.00	21.43	33.87	21.43	55.79
(29.04 to 39.53)	(54.59 to 65.41)	(0.00 to 42.92)	(22.09 to 45.65)	(0.00 to 42.92)	(45.80 to 65.78)
Week 16					
34.92	60.00	21.43	41.94	35.71	50.53
(29.66 to 40.19)	(54.59 to 65.41)	(0.00 to 42.92)	(29.65 to 54.22)	(10.61 to 60.81)	(40.47 to 60.58)
Week 24					
31.11	55.24	-	-	-	-
(26.00 to 36.22)	(49.75 to 60.73)	-	-	-	-

BID = twice daily, CI = confidence interval, ISI = Itch Severity Item, N = number of subjects.

Subjects Achieving an ISI Score of ≥2-Point Reduction From Baseline in ISI Score at Period A and Period C:

The percentage of subjects achieving an ISI point reduction of ≥2 (representing a clinically meaningful response) during initial treatment (Period A) reached 81.6% and 88.9% for the tofacitinib 5 mg BID and 10 mg BID groups, respectively, at Week 4 and remained high (>65%) throughout Period A. A large proportion of subjects in both placebo to tofacitinib groups achieved their ISI response during Period C. The data are summarized in Table 57.

Table 57. Percentage of Participants Achieving an ISI Score of ≥2-Point Reduction During the Initial Tofacitinib Treatment (Period A and Period C)

Period A		Period C			
Tofacitinib 5 mg BID N = 315 Response rate (95% CI)	**Tofacitinib 10 mg BID N = 315 Response rate (95% CI)**	**Tofacitinib 5 mg BID / Tofacitinib 5 mg BID N = 14 Response rate (95% CI)**	**Placebo BID / Tofacitinib 5 mg BID N = 62 Response rate (95% CI)**	**Tofacitinib 10 mg BID / Tofacitinib 10 mg BID N = 14 Response rate (95% CI)**	**Placebo BID / Tofacitinib 10 mg BID N = 95 Response rate (95% CI)**
Week 4					
81.59	88.89	28.57	61.29	14.29	80.00
(77.31 to 85.87)	(85.42 to 92.36)	(4.91 to 52.24)	(49.17 to 73.41)	(0.00 to 32.62)	(71.96 to 88.04)
Week 8					
80.32	87.94	28.57	64.52	28.57	78.95
(75.93 to 84.71)	(84.34 to 91.53)	(4.91 to 52.24)	(52.61 to 76.43)	(4.91 to 52.24)	(70.75 to 87.15)
Week 16					
73.97	84.76	21.43	62.90	28.57	69.47
(69.12 to 78.81)	(80.79 to 88.73)	(0.00 to 42.92)	(50.88 to 74.93)	(4.91 to 52.24)	(60.21 to 78.73)
Week 24					
65.71	74.92	-	-	-	-
(60.47 to 70.96)	(70.13 to 79.71)	-	-	-	-

BID = twice daily, CI = confidence interval, ISI = Itch Severity Item, N = number of subjects.

Short Form-36 (SF-36) Physical Component Summary (PCS), and Mental Component Summary (MCS) Scores (Period A and Period C):

In Period A, both tofacitinib BID doses, 5 mg and 10 mg, demonstrated statistically significant (p-value <0.0001, both) improvements in the subjects' physical and mental health as evidenced by the increased scores on the SF-36 PCS and MCS. The data are summarized in Table 58.

Table 58. Mean Short-Form 36 (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores During the Initial Tofacitinib Treatment (Period A)

N	Tofacitinib 5 mg BID 330 Mean ± SE	Tofacitinib 10 mg BID 334 Mean ± SE
Baseline		
n	330	334
Physical Health Score	48.1±0.5	47.8±0.5
Week 24		
n	273	276
Physical Health Score	50.5±0.5	52.9±0.5
Baseline		
n	330	334
Mental Health Score	45.2±0.7	46.1±0.6
Week 24		
n	273	276
Mental Health Score	48.9±0.6	51.2±0.6

BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria, SE = standard error.

In Period C, both tofacitinib BID doses, 5 mg and 10 mg, demonstrated statistically significant (p-value=0.0035 and p-value=0.0490, respectively) improvements from Baseline in subjects' physical health as evidenced by increased scores on the SF-36 PCS. The data are summarized in Table 59.

Table 59. Mean SF-36 PCS and MCS Scores During Tofacitinib Re-Treatment (Period C)

	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID N = 27 Mean ± SE	Placebo BID / Tofacitinib 5 mg BID N = 75 Mean ± SE	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID N = 42 Mean ± SE	Placebo BID / Tofacitinib 10 mg BID N = 120 Mean ± SE
Baseline				
n	27	75	42	120
Physical Health Score	51.8±1.8	49.9±1.1	53.8±1.1	49.7±0.8
Week 56				
n	22	65	34	98
Physical Health Score	52.9±1.8	52.7±1.0	52.9±1.4	51.2±0.9
Baseline				
n	27	75	42	120
Mental Health Score	51.7±1.9	51.0±1.1	50.8±1.9	48.3±1.0
Week 56				
n	22	65	34	98
Mental Health Score	50.8±1.8	50.9±1.2	52.4±1.5	53.7±0.8

BID = twice daily, MCS = mental component summary, N = number of subjects, n = number of subjects in pre-specified criteria, PCS = physical component summary, SE = standard error, SF-36 = Short-Form 36.

Pharmacokinetic Results

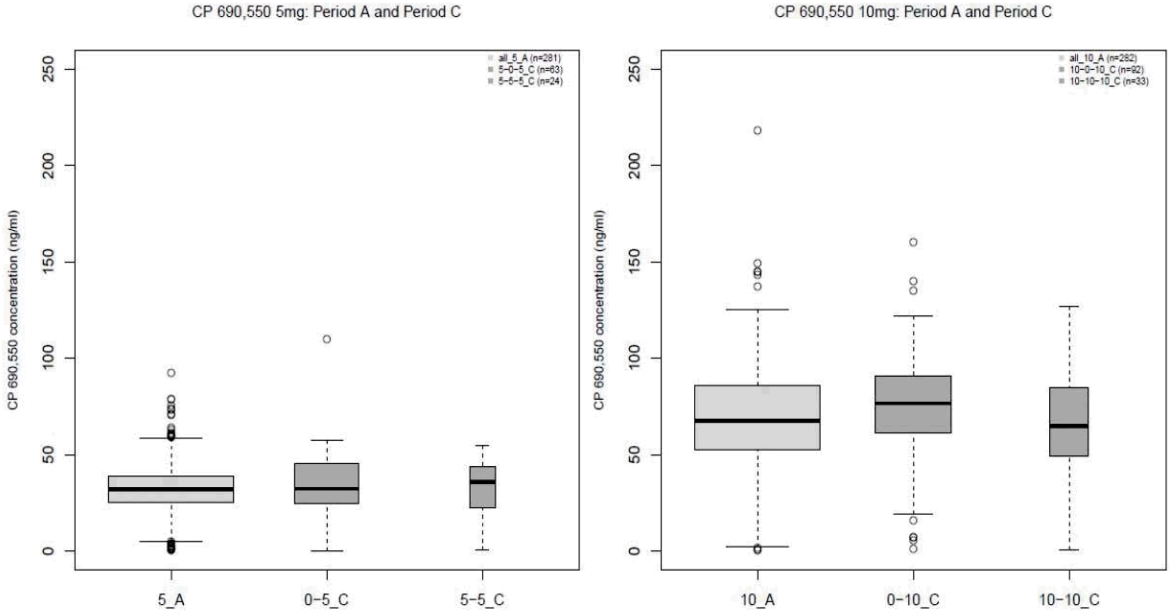
Plasma concentration-time data for tofacitinib (2 hours post-dose) were summarized by treatment during Periods A and C, respectively, as shown in Table 60 and Figure 2. For both tofacitinib 5 mg BID and 10 mg BID dose levels, mean tofacitinib systemic exposures (2 hours post-dose) were similar between Period A (initial treatment) and Period C (re-treatment), across respective treatment groups, and were dose-proportional.

Table 60. Pharmacokinetic (PK) Data Summary for the Initial Tofacitinib Treatment (Period A) and Re-Treatment (Period C)

	Period A	Period C		Period A	Period C	
	Tofacitinib 5 mg BID	Placebo / CP 5 mg BID	CP 5 mg BID / CP 5 mg BID	Tofacitinib 10 mg BID	Placebo / CP 10 mg BID	CP 10 mg BID / CP 10 mg BID
Number of subjects	281	63	24	282	92	33
Mean conc. (SD)	33	33.1	31.2	69.1	75.5	65
ng/mL	(14.9)	(18.5)	(16.1)	(30.6)	(29.4)	(28.2)
Median conc. (range)	32.1	32.3	35.7	67.8	76.6	64.8
ng/mL	(0.61, 92.2)	(0.22, 110)	(0.43, 54.5)	(0.25, 218)	(1.07, 160)	(0.75, 127)

The lower limit of quantification was 0.100 ng/mL; BLOQ (below limit of quantification) values were set to 0 and excluded from the analysis. 18 other concentration values were excluded (subject identifiers and reasons for exclusion are on file and not reported).
BID = twice daily; conc = concentration; CP = tofacitinib; PK = pharmacokinetic; SD = standard deviation.

Figure 2. Box Plots for Pharmacokinetic Data for the Initial Tofacitinib Treatment (Period A) and Re-Treatment (Period C)



The lower limit of quantification was 0.100 ng/mL; BLOQ (below limit of quantification) values were set to 0. Labels for X axis: 5_A and 10_A represent tofacitinib 5 mg BID and tofacitinib 10 mg BID, respectively in Period A; 0-5_C and 0-10_C represent placebo to 5 mg BID and placebo to 10 mg BID, respectively in Period C; 5-5_C and 10-10_C represent 5 mg BID to 5 mg BID and 10 mg BID to 10 mg BID, respectively in Period C.
BID = twice daily.

Patient Global Assessment (PtGA) of Psoriasis (Period A, Period B, and Period C):

At Baseline in Period A, the majority of subjects reported their psoriasis as being "severe" (66.1% and 63.9% for the tofacitinib 5 mg BID and 10 mg BID groups, respectively) and no subjects self-reported as "clear." Numerical mean decreases in PtGA scores were greater in the tofacitinib 10 mg BID group compared with the 5 mg BID group. The data are summarized in Table 61, Table 62, and Table 63.

Table 61. Percentage of Participants With PtGA Response of Clear or Almost Clear During the Initial Tofacitinib Treatment (Period A)

	Tofacitinib 5 mg BID (Period A)	Tofacitinib 10 mg BID (Period A)
N	**331**	**335**
	Response rate (95% CI)	**Response rate (95% CI)**
Week 4	11.78	21.19
	(8.31 to 15.26)	(16.82 to 25.57)
Week 8	22.36	45.37
	(17.87 to 26.84)	(40.04 to 50.70)
Week 16	30.51	54.63
	(25.55 to 35.47)	(49.30 to 59.96)
Week 24	29.61	51.64
	(24.69 to 34.53)	(46.29 to 56.99)

BID = twice daily, CI = confidence interval, N = number of subjects, PtGA = patient global assessment.

Table 62. Percentage of Participants With PtGA Response of Clear or Almost Clear During Tofacitinib Re-Treatment (Period C) Among Participants Who Had a PtGA of Mild, Moderate, or Severe During Tofacitinib Treatment Withdrawal (Period B)

Tofacitinib 5 mg BID / Tofacitinib 5 mg BID N = 14 Response rate (95% CI)	Placebo BID / Tofacitinib 5 mg BID N = 63 Response rate (95% CI)	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID N = 17 Response rate (95% CI)	Placebo BID / Tofacitinib 10 mg BID N = 100 Response rate (95% CI)
Baseline			
14.29 (0.00 to 32.62)	6.35 (0.33 to 12.37)	23.53 (3.37 to 43.69)	8.00 (2.68 to 13.32)
Week 4			
21.43 (0.00 to 42.92)	19.05 (9.35 to 28.74)	35.29 (12.58 to 58.01)	42.00 (32.33 to 51.67)
Week 8			
21.43 (0.00 to 42.92)	34.92 (23.15 to 46.69)	41.18 (17.78 to 64.57)	54.00 (44.23 to 63.77)
Week 16			
21.43 (0.00 to 42.92)	41.27 (29.11 to 53.43)	58.82 (35.43 to 82.22)	53.00 (43.22 to 62.78)

BID = twice daily, CI = confidence interval, N = number of subjects, PtGA = Patient Global Assessment.

Table 63. Percentage of Participants Maintaining PtGA Response of Clear or Almost Clear During the Double-Blind Treatment Withdrawal (Period B) Among Participants Who Had a Response of Clear or Almost Clear at Beginning of Period B

	Tofacitinib 5 mg BID (Period B)	Placebo for 5 mg Tofacitinib BID (Period B)	Tofacitinib 10 mg BID (Period B)	Placebo for 10 mg Tofacitinib BID (Period B)
N	**19**	**66**	**39**	**107**
	Response rate (95% CI)	**Response rate (95% CI)**	**Response rate (95% CI)**	**Response rate (95% CI)**
Week 4	94.7 (68.1 to 99.2)	50.7 (38.0 to 62.0)	82.0 (65.9 to 91.0)	55.5 (45.5 to 64.4)
Week 8	89.2 (63.1 to 97.2)	32.8 (21.6 to 44.4)	71.4 (54.3 to 83.0)	33.3 (24.5 to 42.4)
Week 12	77.3 (50.1 to 90.8)	21.3 (12.2 to 32.2)	68.8 (51.6 to 80.9)	24.2 (16.4 to 32.9)
Week 16	77.3 (50.1 to 90.8)	16.0 (7.5 to 27.3)	0.0 (NA to NA)	0.0 (NA to NA)

BID = twice daily, CI = confidence interval, N = number of subjects, PtGA = Patient Global Assessment.

EuroQol 5 Dimensions (EQ-5D) and Visual Analog Scale (VAS), Period A and Period C:

Descriptive statistics and change from Baseline-A of EQ-5D utility score for quality of life in 5 domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and VAS were measured. Numerical mean decreases in EQ-5D and VAS scores were slightly greater in the tofacitinib 10 mg BID group compared with the 5 mg BID group; however, these increases were not statistically significant. The descriptive statistics during the initial treatment (Period A) are summarized in Table 64.

Table 64. Mean EuroQol 5 Dimensions (EQ-5D) Health State Profile Utility Score and VAS Scores During the Initial Tofacitinib Treatment Period (Period A)

	Tofacitinib 5 mg BID (Period A) N = 329 Mean ± SE	Tofacitinib 10 mg BID (Period A) N = 332 Mean ± SE
Baseline		
n	329	332
Utility score,	0.7±0.0	0.7±0.0
Week 24		
n	270	272
Utility score	0.8±0.0	0.9±0.0
Baseline		
n	329	332
VAS	69.9±1.3	70.6±1.3
Week 24		
n	269	274
VAS	75.6±1.2	80.3±1.0

BID = twice daily, EQ-5D = EuroQuality of Life 5 Dimensions; N = number of subjects, n = number of subjects in pre-specified criteria, SE = standard error, VAS = visual analog scale.

Descriptive statistics and change from Baseline-C of EQ-5D utility scores, and VAS during re-treatment are summarized in Table 65.

Table 65. Mean EQ-5D Utility Score and VAS Scores During Tofacitinib Re-Treatment (Period C)

	Tofacitinib 5 mg BID / Tofacitinib 5 mg BID	Placebo BID / Tofacitinib 5 mg BID	Tofacitinib 10 mg BID / Tofacitinib 10 mg BID	Placebo BID / Tofacitinib 10 mg BID
N	**27**	**75**	**42**	**120**
	Mean ± SE	**Mean ± SE**	**Mean ± SE**	**Mean ± SE**
Baseline				
n	27	75	42	120
Utility Score	0.8±0.0	0.8±0.0	0.9±0.0	0.8±0.0
Week 56				
n	22	65	34	96
Utility Score	0.9±0.0	0.9±0.0	0.9±0.0	0.9±0.0
Baseline				
n	27	75	42	120
VAS	79.6±3.4	76.5±2.2	76.8±3.5	75.3±1.8
Week 56				
n	22	65	34	96
VAS	82.0±2.5	82.3±1.7	82.7±2.7	83.8±1.2

BID = twice daily, EQ-5D = EuroQol 5 Dimensions, N = number of subjects, SE = standard error, VAS = visual analog scale.

Safety Results:

During Period A, the most frequently reported TEAEs (all causalities) were nasopharyngitis, which occurred in the tofacitinib 5 mg BID group and tofacitinib 10 mg BID group; followed by upper respiratory tract infection, which occurred in the tofacitinib 5 mg BID group and tofacitinib 10 mg BID group.

During Period B, the most frequently reported TEAE (all causalities) was nasopharyngitis, which occurred in the tofacitinib 5 mg BID, placebo for 5 mg, tofacitinib 10 mg BID, and placebo for 10 mg groups, respectively.

During Period C, the most frequently reported TEAEs (all causalities) was nasopharyngitis, which occurred in the tofacitinib 5 mg BID, placebo to 5 mg, tofacitinib 10 mg BID, and placebo to 10 mg groups, respectively. The treatment-emergent non-serious adverse events at a frequency rate ≥5 is summarized in Table 66.

One subject, treated with tofacitinib 5 mg BID, died due to acute myocardial infarction during Period A. The event was considered not related to the study drug by the Investigator.

Table 66. Treatment-Emergent Non-Serious Adverse Events by System Organ Class and Preferred Term (All causalities) in >5% of Subjects

	Tofacitinib 5 mg BID			Tofacitinib 5 mg BID / 5 mg BID / 5 mg BID			Tofacitinib 5 mg BID / Placebo / 5 mg BID			Tofacitinib 10 mg BID			Tofacitinib 10 mg BID / 10 mg BID / 10 mg BID			Tofacitinib 10 mg BID / Placebo / 10 mg BID		
Number (%) of Subjects with AEs System Organ Class MedDRA (v16.1) Preferred Term	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**
Evaluable for adverse events	217			31			83			156			45			134		
With adverse events	75 (34.6)			20 (64.5)			54 (65.1)			58 (37.2)			34 (75.6)			91 (67.9)		
Gastrointestinal disorders	12 (5.5)	12	6	0	0	0	8 (9.6)	8	2	7 (4.5)	7	0	6 (13.3)	7	3	10 (7.5)	13	9
Constipation	5 (2.3)	5	2	0	0	0	5 (6.0)	5	1	2 (1.3)	2	0	2 (4.4)	3	1	3 (2.2)	3	2
Diarrhoea	7 (3.2)	7	4	0	0	0	3 (3.6)	3	1	5 (3.2)	5	0	4 (8.9)	4	2	8 (6.0)	10	7
Infections and infestations	36 (16.6)	43	11	8 (25.8)	10	2	41 (49.4)	54	10	36 (23.1)	43	7	18 (40.0)	27	5	60 (44.8)	91	18
Bronchitis	0	0	0	0	0	0	2 (2.4)	2	0	3 (1.9)	3	1	2 (4.4)	3	1	10 (7.5)	12	4
Folliculitis	1 (0.5)	1	0	1 (3.2)	1	0	1 (1.2)	1	1	2 (1.3)	2	0	0	0	0	7 (5.2)	9	2
Influenza	1 (0.5)	1	0	2 (6.5)	2	0	6 (7.2)	6	2	4 (2.6)	8	3	1 (2.2)	1	0	3 (2.2)	3	1
Nasopharyngitis	18 (8.3)	18	4	3 (9.7)	4	2	15 (18.1)	17	3	15 (9.6)	16	0	8 (17.8)	11	1	23 (17.2)	28	3
Sinusitis	3 (1.4)	3	0	0	0	0	2 (2.4)	2	0	2 (1.3)	2	1	3 (6.7)	3	0	4 (3.0)	4	2
Upper respiratory tract infection	9 (4.1)	11	1	2 (6.5)	2	0	14 (16.9)	19	3	7 (4.5)	7	1	5 (11.1)	5	3	18 (13.4)	23	4
Urinary tract infection	7 (3.2)	9	6	1 (3.2)	1	0	6 (7.2)	7	1	5 (3.2)	5	1	4 (8.9)	4	0	9 (6.7)	12	2
Injury, poisoning and procedural complications	1 (0.5)	1	0	2 (6.5)	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Joint injury	1 (0.5)	1	0	2 (6.5)	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Investigations	12 (5.5)	15	6	3 (9.7)	3	1	11 (13.3)	11	6	11 (7.1)	12	10	15 (33.3)	25	15	17 (12.7)	24	12
Alanine aminotransferase increased	1 (0.5)	2	2	2 (6.5)	2	1	2 (2.4)	2	2	3 (1.9)	3	3	1 (2.2)	1	1	1 (0.7)	1	0
Blood cholesterol increased	3 (1.4)	3	1	0	0	0	2 (2.4)	2	1	3 (1.9)	3	3	4 (8.9)	4	4	4 (3.0)	5	5
Blood creatine phosphokinase increased	10 (4.6)	10	3	1 (3.2)	1	0	6 (7.2)	6	2	5 (3.2)	5	4	12 (26.7)	16	6	14 (10.4)	17	6
Low density lipoprotein increased	0	0	0	0	0	0	1 (1.2)	1	1	1 (0.6)	1	0	4 (8.9)	4	4	1 (0.7)	1	1
Metabolism and nutrition disorders	4 (1.8)	4	2	5 (16.1)	6	5	8 (9.6)	8	5	8 (5.1)	8	4	5 (11.1)	6	6	12 (9.0)	12	8
Dyslipidaemia	2 (0.9)	2	0	2 (6.5)	2	2	3 (3.6)	3	2	0	0	0	0	0	0	1 (0.7)	1	0
Hypercholesterolaemia	0	0	0	1 (3.2)	1	1	0	0	0	7 (4.5)	7	3	4 (8.9)	4	4	4 (3.0)	4	2
Hyperlipidaemia	1 (0.5)	1	1	1 (3.2)	1	0	5 (6.0)	5	3	1 (0.6)	1	1	1 (2.2)	1	1	4 (3.0)	4	3
Hypertriglyceridaemia	1 (0.5)	1	1	2 (6.5)	2	2	0	0	0	0	0	0	1 (2.2)	1	1	3 (2.2)	3	3
Musculoskeletal and connective tissue disorders	11 (5.1)	13	0	0	0	0	3 (3.6)	4	0	3 (1.9)	3	0	3 (6.7)	3	0	15 (11.2)	16	2
Arthralgia	3 (1.4)	3	0	0	0	0	2 (2.4)	3	0	3 (1.9)	3	0	0	0	0	10 (7.5)	10	2
Back pain	9 (4.1)	10	0	0	0	0	1 (1.2)	1	0	0	0	0	3 (6.7)	3	0	6 (4.5)	6	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	4 (12.9)	5	0	0	0	0	0	0	0	0	0	0	0	0	0
Seborrhoeic keratosis	0	0	0	2 (6.5)	3	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 66. Treatment-Emergent Non-Serious Adverse Events by System Organ Class and Preferred Term (All causalities) in >5% of Subjects

	Tofacitinib 5 mg BID			Tofacitinib 5 mg BID / 5 mg BID / 5 mg BID			Tofacitinib 5 mg BID / Placebo / 5 mg BID			Tofacitinib 10 mg BID			Tofacitinib 10 mg BID / 10 mg BID / 10 mg BID			Tofacitinib 10 mg BID / Placebo / 10 mg BID		
Number (%) of Subjects with AEs System Organ Class MedDRA (v16.1) Preferred Term	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**
Skin papilloma	0	0	0	2 (6.5)	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Nervous system disorders	6 (2.8)	6	4	2 (6.5)	3	0	5 (6.0)	5	2	6 (3.8)	6	4	4 (8.9)	7	3	17 (12.7)	18	8
Headache	6 (2.8)	6	4	2 (6.5)	3	0	5 (6.0)	5	2	6 (3.8)	6	4	4 (8.9)	7	3	17 (12.7)	18	8
Respiratory, thoracic and mediastinal disorders	9 (4.1)	10	2	5 (16.1)	7	0	3 (3.6)	4	0	3 (1.9)	3	1	4 (8.9)	4	1	10 (7.5)	10	2
Cough	4 (1.8)	5	0	2 (6.5)	2	0	3 (3.6)	3	0	0	0	0	1 (2.2)	1	0	8 (6.0)	8	1
Oropharyngeal pain	5 (2.3)	5	2	5 (16.1)	5	0	1 (1.2)	1	0	3 (1.9)	3	1	3 (6.7)	3	1	2 (1.5)	2	1
Vascular disorders	5 (2.3)	5	0	1 (3.2)	1	0	5 (6.0)	5	1	5 (3.2)	5	1	2 (4.4)	2	1	7 (5.2)	7	1
Hypertension	5 (2.3)	5	0	1 (3.2)	1	0	5 (6.0)	5	1	5 (3.2)	5	1	2 (4.4)	2	1	7 (5.2)	7	1

Except for 'n1' and 'n2' subjects are only counted once per treatment for each row.
Includes data up to 999 days after last dose of study drug.
Percentages of gender specific events are calculated using the corresponding gender count as denominator.
BID = twice daily, MedDRA = medical dictionary for regulatory activities; n = the number of subjects in this reporting group affected by any occurrence of this adverse event, all causalities; n1 = the number of occurrences of treatment-emergent all causalities adverse events; n2 = the number of occurrences of treatment-emergent causally related to treatment adverse events, v = version.

During the initial treatment (Period A), 18 subjects experienced SAEs, during Period B, 3 subjects reported SAEs and during Period C, 7 subjects reported SAEs.

Treatment-emergent serious adverse events (All Causalities treatment related) are summarized in Table 67.

Table 67. Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term

	Tofacitinib 5 mg BID			Tofacitinib 5 mg BID / 5 mg BID / 5 mg BID			Tofacitinib 5 mg BID / Placebo / 5 mg BID			Tofacitinib 10 mg BID			Tofacitinib 10 mg BID / 10 mg BID / 10 mg BID			Tofacitinib 10 mg BID / Placebo / 10 mg BID		
Number (%) of Subjects with AEs System Organ Class MedDRA (v16.1) Preferred Term	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**
Evaluable for AEs	217			31			83			156			45			134		
With adverse events	6 (2.8)			1 (3.2)			3 (3.6)			9 (5.8)			4 (8.9)			4 (3.0)		
Cardiac disorders	2 (0.9)	3	0	0	0	0	0	0	0	1 (0.6)	1	0	0	0	0	1 (0.7)	1	0
Acute myocardial infarction	1 (0.5)	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Atrial fibrillation	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.7)	1	0
Coronary artery disease	1 (0.5)	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Myocardial infarction	1 (0.5)	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ventricular tachycardia	0	0	0	0	0	0	0	0	0	1 (0.6)	1	0	0	0	0	0	0	0
Endocrine disorders	0	0	0	0	0	0	1 (1.2)	1	0	0	0	0	0	0	0	0	0	0
Goitre	0	0	0	0	0	0	1 (1.2)	1	0	0	0	0	0	0	0	0	0	0
Gastrointestinal disorders	1 (0.5)	1	0	0	0	0	0	0	0	1 (0.6)	1	0	0	0	0	0	0	0
Diverticular perforation	1 (0.5)	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pancreatitis acute	0	0	0	0	0	0	0	0	0	1 (0.6)	1	0	0	0	0	0	0	0
General disorders and administration site conditions	1 (0.5)	1	0	1 (3.2)	1	1	0	0	0	0	0	0	0	0	0	0	0	0
Chest pain	0	0	0	1 (3.2)	1	1	0	0	0	0	0	0	0	0	0	0	0	0
Drug ineffective	1 (0.5)	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Infections and infestations	0	0	0	0	0	0	0	0	0	1 (0.6)	1	1	2 (4.4)	2	1	0	0	0
Bronchitis	0	0	0	0	0	0	0	0	0	0	0	0	1 (2.2)	1	0	0	0	0
Herpes zoster cutaneous disseminated	0	0	0	0	0	0	0	0	0	1 (0.6)	1	1	0	0	0	0	0	0
Peritonsillar abscess	0	0	0	0	0	0	0	0	0	0	0	0	1 (2.2)	1	1	0	0	0
Injury, poisoning and procedural complications	0	0	0	0	0	0	0	0	0	0	0	0	1 (2.2)	1	0	1 (0.7)	1	0
Pulmonary contusion	0	0	0	0	0	0	0	0	0	0	0	0	1 (2.2)	1	0	0	0	0
Respiratory fume inhalation disorder	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.7)	1	0
Investigations	1 (0.5)	1	0	0	0	0	0	0	0	1 (0.6)	1	1	0	0	0	0	0	0
Pregnancy test positive	1 (0.5)	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Transaminases increased	0	0	0	0	0	0	0	0	0	1 (0.6)	1	1	0	0	0	0	0	0
Metabolism and nutrition disorders	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.7)	1	0
Hypokalaemia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.7)	1	0
Musculoskeletal and connective tissue disorders	1 (0.5)	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2 (1.5)	2	0
Intervertebral disc degeneration	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.7)	1	0

Table 67. Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term

	Tofacitinib 5 mg BID			Tofacitinib 5 mg BID / 5 mg BID			Tofacitinib 5 mg BID / Placebo / 5 mg BID			Tofacitinib 10 mg BID			Tofacitinib 10 mg BID / 10 mg BID / 10 mg BID			Tofacitinib 10 mg BID / Placebo / 10 mg BID		
Number (%) of Subjects with AEs **System Organ Class** **MedDRA (v16.1) Preferred Term**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**	**n (%)**	**n1**	**n2**
Osteoarthritis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.7)	1	0
Osteonecrosis	1 (0.5)	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	0	0	0	0	0	0	3 (1.9)	4	1	0	0	0	0	0	0
Adenocarcinoma pancreas	0	0	0	0	0	0	0	0	0	1 (0.6)	1	0	0	0	0	0	0	0
Colon cancer metastatic	0	0	0	0	0	0	0	0	0	1 (0.6)	1	0	0	0	0	0	0	0
Metastases to liver	0	0	0	0	0	0	0	0	0	1 (0.6)	1	0	0	0	0	0	0	0
Prostate cancer	0	0	0	0	0	0	0	0	0	1 (0.6)	1	1	0	0	0	0	0	0
Psychiatric disorders	0	0	0	0	0	0	1 (1.2)	1	0	0	0	0	1 (2.2)	1	0	0	0	0
Depression	0	0	0	0	0	0	0	0	0	0	0	0	1 (2.2)	1	0	0	0	0
Hypomania	0	0	0	0	0	0	1 (1.2)	1	0	0	0	0	0	0	0	0	0	0
Renal and urinary disorders	0	0	0	0	0	0	1 (1.2)	1	0	0	0	0	0	0	0	1 (0.7)	1	0
Nephrolithiasis	0	0	0	0	0	0	1 (1.2)	1	0	0	0	0	0	0	0	0	0	0
Renal failure acute	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.7)	1	0
Respiratory, thoracic and mediastinal disorders	0	0	0	1 (3.2)	1	0	0	0	0	1 (0.6)	1	0	0	0	0	0	0	0
Asthma	0	0	0	0	0	0	0	0	0	1 (0.6)	1	0	0	0	0	0	0	0
Chronic obstructive pulmonary disease	0	0	0	1 (3.2)	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	1 (0.5)	1	1	0	0	0	0	0	0	2 (1.3)	3	3	0	0	0	0	0	0
Erythrodermic psoriasis	0	0	0	0	0	0	0	0	0	2 (1.3)	2	2	0	0	0	0	0	0
Psoriasis	1 (0.5)	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pustular psoriasis	0	0	0	0	0	0	0	0	0	1 (0.6)	1	1	0	0	0	0	0	0

Except for 'n1' and 'n2' subjects are only counted once per treatment for each row.
Includes data up to 999 days after last dose of study drug.
Percentages of gender specific events are calculated using the corresponding gender count as denominator.
BID = twice daily, AE = adverse event; MedDRA = medical dictionary for regulatory activities; n = the number of subjects in this reporting group affected by any occurrence of this adverse event, all causalities; n1 = the number of occurrences of treatment-emergent all causalities adverse events; n2 = the number of occurrences of treatment-emergent causally related to treatment adverse event, v = versions.

During initial treatment (Period A), the incidence of AEs resulting in withdrawal from the study was overall low and similar between the 2 dose groups (11 [3.3%] and 15 [4.5%] subjects in the tofacitinib 5 mg and 10 mg groups, respectively). Two additional subjects experienced AEs that started in Period A, but resulted in discontinuation during Period B (Table 68).

Table 68. Incidence of AEs Resulting in Withdrawal During the Initial Tofacitinib Treatment (Period A, Safety-A) – by Preferred Term

Preferred Term	Tofacitinib 5 mg BID (N = 331) n (%)	Tofacitinib 10 mg BID (N = 335) n (%)
Number of subjects withdrew from study due to AEs	11 (3.3)	15 (4.5)
Abdominal pain	0 (0.0)	1 (0.3)
Acute myocardial infarction	1 (0.3)	0 (0.0)
Adenocarcinoma pancreas	0 (0.0)	1 (0.3)
Affective disorder	1 (0.3)	0 (0.0)
Coronary artery disease	1 (0.3)	0 (0.0)
Diverticular perforation	1 (0.3)	0 (0.0)
Drug ineffective	1 (0.3)	0 (0.0)
Dysgeusia	1 (0.3)	0 (0.0)
Erythrodermic psoriasis	0 (0.0)	1 (0.3)
Haematocrit decreased	1 (0.3)	0 (0.0)
Haemoglobin decreased	1 (0.3)	0 (0.0)
Herpes zoster multi-dermatomal	0 (0.0)	1 (0.3)
Liver function test abnormal	1 (0.3)	0 (0.0)
Metastases to liver	0 (0.0)	1 (0.3)
Nausea	0 (0.0)	1 (0.3)
Pancreatitis acute	0 (0.0)	1 (0.3)
Prostate cancer	0 (0.0)	1 (0.3)
Psoriasis	1 (0.3)	5 (1.5)
Pustular psoriasis	0 (0.0)	1 (0.3)
Staphylococcal infection	1 (0.3)	0 (0.0)
Transaminases increased	0 (0.0)	1 (0.3)
Upper respiratory tract infection	1 (0.3)	0 (0.0)
Urticaria	1 (0.3)	1 (0.3)
Ventricular tachycardia	0 (0.0)	1 (0.3)
Weight decreased	1 (0.3)	0 (0.0)
Weight increased	1 (0.3)	0 (0.0)

AEs = adverse events, BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria.

During treatment withdrawal (Period B), the incidence of AEs resulting in withdrawal from the study was overall low (5 subjects) and similar across the treatment groups (Table 69).

Table 69. Incidence of AEs Resulting in Withdrawal During Treatment Withdrawal (Period B, Safety-B) –by Preferred Term

Preferred Term	Tofacitinib 5 mg BID (N = 31) n (%)	Placebo for CP 5 mg BID (N = 82) n (%)	Tofacitinib 10 mg BID (N = 45) n (%)	Placebo for CP 10 mg BID (N = 133) n (%)
Number of subjects withdrew from study due to AEs	1 (3.2)	0 (0.0)	1 (2.2)	3 (2.3)
Alanine aminotransferase increased	1 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)
Anaemia	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
Aspartate aminotransferase increased	1 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)
Liver function test abnormal	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
Peritonsillar abscess	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)
Psoriatic arthropathy	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)

AEs = adverse events, BID = twice daily, N = number of subjects, n = number of subjects in pre-specified criteria.

No notable changes from Baseline were found for any of the laboratory and clinical parameters in any of the treatment groups during Periods A and C with the exception of weight where a median increase of approximately 1 kg was observed in each of the tofacitinib treatment groups.

CONCLUSIONS:

- Treatment with both doses of tofacitinib was statistically significantly better than placebo in maintaining PASI75 and PGA response during the 16-week withdrawal period. Of those who lost adequate response on placebo during the withdrawal period, 31.6% and 41.4% of subjects on 5 mg BID and 50.9% and 49.0% of subjects on 10 mg BID regained their PASI75 and PGA response, respectively, after 16 weeks of re-treatment with CP-690.550.

- The median time to loss of PASI75 and PGA response was 8 weeks, independent of dose. Median time to regain PASI75 and PGA responses was shorter for 10 mg BID than 5 mg BID.

- The efficacy response rate was higher for tofacitinib 10 mg BID than for 5 mg BID as evidenced by several endpoints (PASI75, PASI 90, PGA of clear/almost clear, DLQI, PtGA, and ISI). The median time to initial response (PASI75 and the PGA of clear/almost clear) was shorter with tofacitinib 10 mg BID than for 5 mg BID.

- No subjects experienced rebound. One subject in the tofacitinib 10 mg BID to 10 mg BID group had a PASI score ≥125% of Baseline-A at Week 16 during Period C

- In general for the PROs, the trend was for scores to improve at a greater rate for subjects treated with tofacitinib 10 mg BID compared to 5 mg BID during Period A, to worsen in Period B (loss of response) for subjects who were randomized to placebo, and for scores to improve (regain response) during Period C. This was seen with the ISI, DLQI, PtGA, EQ-5D, and SF-36.

- Both the tofacitinib 5 mg and 10 mg BID doses were well tolerated during Period A, and there were few safety events during Period B and Period C.

- The most frequent SOC AE category across all 3 periods was infections/infestations.

- Three (3) subjects in the tofacitinib 10 mg group had serious infection: 1 multidermatomal herpes zoster in Period A, 1 peritonsillar abscess in Period B, and 1 bronchitis during Period C.

- During the study, 8 subjects had herpes zoster; 7 of the 8 herpes zoster events occurred with tofacitinib 10 mg BID treatment. Aside from 1 serious infection, all cases were non-serious and not multi-dermatomal.

- There were 3 malignancies (excluding non-melanoma skin cancer) during Period A, during tofacitinib 10 mg BID dosing: pancreatic (n=1), colon (n=1), and prostate cancer (n=1). For 2 of the 3 malignancies, signs and symptoms were present before exposure to study drug (the subject with colon cancer had a history of abdominal pain prior to Baseline, and the subject with prostate cancer had a history of elevated prostate-specific antigen prior to Baseline).

- There was 1 diverticular perforation in a subject with acute diverticulitis in the tofacitinib 5 mg BID group during Period A.

- Adjudicated cardiovascular events were reported for 3 subjects: 2 in the tofacitinib 5 mg BID group during Period A (fatal myocardial infarction and coronary artery bypass grafting) and 1 in the tofacitinib 10 mg BID group during Period B (peripheral vascular disease and percutaneous transluminal coronary angioplasty).

- There was 1 death (fatal myocardial infarction) in the tofacitinib 5 mg BID group during Period A.

- No apparent dose effect was noted for mean decreases in neutrophils, which were small and tended to return to Baseline on active study drug; there was no clear effect of treatment withdrawal.

- A small initial increase was seen in lymphocytes which returned to Baseline during Period A, with further small reductions seen upon treatment withdrawal (Period B). Three subjects had confirmed lymphocyte values $<0.5 \times 10^3/mm^3$.