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

GENERIC DRUG NAME and/or COMPOUND NUMBER: Tofacitinib citrate / CP-690,550

PROTOCOL NO.: A3921137

PROTOCOL TITLE: A Phase 3, Multi Site, Randomized, Double Blind Study of the Long-Term Safety, Tolerability and Efficacy of 2 Oral Doses of CP-690,550 in Subjects with Moderate to Severe Plaque Psoriasis and/or Psoriatic Arthritis

Study Center(s): 16 centers in Japan.

Study Initiation Date and Final Completion Dates: 13 March 2012 to 08 January 2014

Phase of Development: Phase 3

Study Objective(s):

Primary Objectives

- To evaluate the long-term safety and tolerability of treatment with CP-690,550 (5 mg twice daily [BID] and 10 mg BID) in subjects with moderate to severe plaque psoriasis and/or psoriatic arthritis who are candidates for systemic therapy or phototherapy during 52 weeks of treatment.

- To compare the efficacy of 2 oral doses of CP-690,550 (5 mg BID and 10 mg BID) after 16 weeks of treatment in subjects with moderate to severe plaque psoriasis and/or psoriatic arthritis who are candidates for systemic therapy or phototherapy.

Secondary Objectives

- To evaluate the efficacy of CP-690,550 (5 mg BID and 10 mg BID) during 52 weeks of treatment in subjects with moderate to severe plaque psoriasis and/or psoriatic arthritis who are candidates for systemic therapy or phototherapy.

- To evaluate the effects on the patient reported outcome (PRO) measures during 52 weeks of treatment with CP-690,550 (5 mg BID and 10 mg BID) at various time points in subjects with moderate to severe plaque psoriasis and/or psoriatic arthritis who are candidates for systemic therapy or phototherapy.

METHODS

Study Design: This was a Phase 3, multi-site, randomized, double-blind study of the long-term safety, tolerability and efficacy of 2 oral doses of CP-690,550 (5 mg BID and 10 mg BID) in subjects with moderate to severe plaque psoriasis and/or psoriatic arthritis. At the baseline visit, the subjects were randomized into 1 of 2 treatment sequences (CP-690,550 5 mg BID or CP-690,550 10 mg BID) and continued therapy through Week 16 where the primary efficacy endpoints were assessed. At Week 16 visit, all subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 and 10 mg BID). At the time of study treatment completion or discontinuation, a follow-up visit was conducted 2-4 weeks after the subject's last dose. A schematic of the study design is shown in Figure 1.

Figure 1. Schematic of Study Design

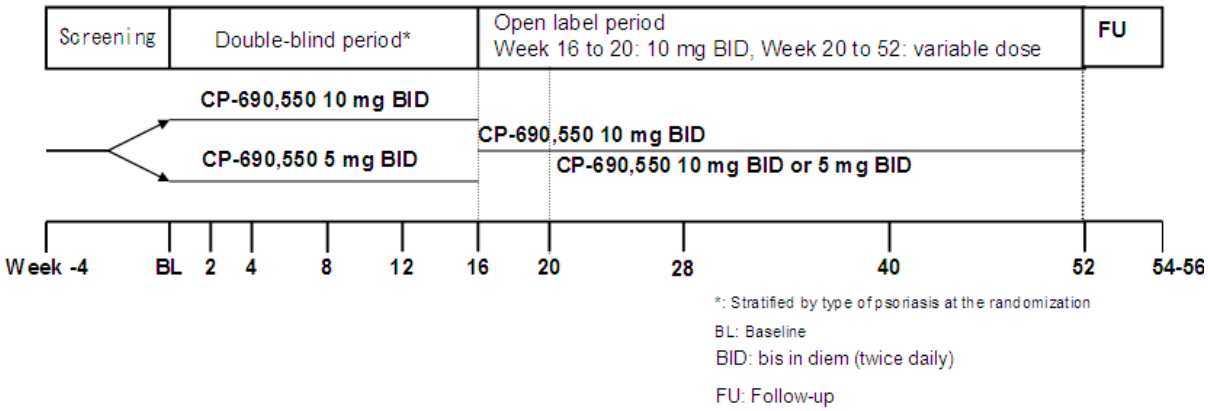

Table 1. Schedule of Activities

PROTOCOL ACTIVITY	SCREENING[1] VISIT 1		VISIT 2	VISIT 3	VISIT 4	VISIT 5	VISIT 6	VISIT 7	VISIT 8	VISIT 9	VISIT 10	VISIT 11	VISIT 12
	> 4 wks prior to D1 if required (± 3 days)	Within 4-2 weeks of D1 (± 3 days)	Baseline (D1)	Week 2 (D15) (± 3 days)	Week 4 (D29) (± 3 days)	Week 8 (D57) (± 3 days)	Week 12 (D85) (± 3 days)	Week 16 (D113) (± 3 days)	Week 20 (D141) (± 3 days)	Week 28 (D197) (± 7 days)	Week 40 (D281) (± 7 days)	Week 52 (D365) or ET visit[2] (± 7 days)	Follow-up visit / Week 54-56[3] (± 3 days)
Informed Consent	X	X[4]											
Register for Subject Identification Number	X	X[4]											
Psoriasis Diagnosis, Medical History	X	X											
Current/Prior Medications	X	X											
Complete Physical Examination	X	X	X									X	X
Targeted Physical Examination					X	X	X	X	X	X	X		
Vital Signs, including Temperature	X	X	X		X	X	X	X	X	X	X	X	X
Weight, Waist and Hips circumference		X	X		X	X		X		X	X	X	
Height		X											
12-Lead ECG	X	X	X					X				X	
QFT-G (or Mantoux/PPD Skin Test)[5]	X	X[4]											
Chest Radiographs	X	X[4]											
LABORATORY TESTING													
Hematology	X	X	X		X	X	X	X	X	X	X	X	X
HbA1c			X					X				X	
Serum Chemistry (9 hour fasting)	X	X	X		X	X	X	X	X	X	X	X	X
β-D-glucan and KL-6	X	X											
Lipid Panel (9 hour fasting)	X	X	X		X	X	X	X	X	X	X	X	X
Urinalysis	X	X	X		X			X		X	X	X	
Urine Pregnancy Test (HCG)[6]	X	X	X	X	X	X	X	X	X	X	X	X	X
hs-CRP	X	X	X		X			X				X	
CRP[7]			X	X	X	X	X	X	X	X	X	X	X
HBsAg, HBcAb, HBsAb , HCV Ab, HIV Serology	X	X[8]											
HBV-DNA quantitative test[9]	X	X			X			X		X	X	X	
Retained Pharmacogenomic Samples			X										
CLINICAL EVALUATION OF PSORIASIS													
PASI, BSA		X	X	X	X	X	X	X	X	X	X	X	X
PGA of psoriasis		X	X	X	X	X	X	X	X	X	X	X	X
NAPSI, Number of affected nails			X			X		X	X	X	X	X	

PROTOCOL ACTIVITY	SCREENING[1] VISIT 1		VISIT 2	VISIT 3	VISIT 4	VISIT 5	VISIT 6	VISIT 7	VISIT 8	VISIT 9	VISIT 10	VISIT 11	VISIT 12
	> 4 wks prior to D1 if required (± 3 days)	Within 4-2 weeks of D1 (± 3 days)	Baseline (D1)	Week 2 (D15) (± 3 days)	Week 4 (D29) (± 3 days)	Week 8 (D57) (± 3 days)	Week 12 (D85) (± 3 days)	Week 16 (D113) (± 3 days)	Week 20 (D141) (± 3 days)	Week 28 (D197) (± 7 days)	Week 40 (D281) (± 7 days)	Week 52 (D365) or ET visit[2] (± 7 days)	Follow-up visit / Week 54-56[3] (± 3 days)
ACR ASSESSMENTS[7]													
Tender/Painful Joint Count, Swollen Joint Count		X	X	X	X	X	X	X	X	X	X	X	X
PGA of Arthritis (VAS)			X	X	X	X	X	X	X	X	X	X	X
PATIENT REPORTED OUTCOMES (PRO)													
ISI			X-X[10]	X	X	X	X	X	X	X	X	X	X
DLQI			X	X	X	X	X	X	X	X	X	X	
SF-36			X					X		X		X	
WLQ			X		X			X		X		X	
PtGA of psoriasis			X	X	X	X	X	X	X	X	X	X	
JPA			X		X			X		X		X	
Patient Assessment of Arthritis Pain (VAS); Patient Global Assessment of Arthritis (VAS); HAQ-DI[7]			X	X	X	X	X	X	X	X	X	X	X
OTHER ACTIVITIES													
Randomization			X										
Review of Concomitant Medications			X	X	X	X	X	X	X	X	X	X	X
Adverse Event Reporting			X	X	X	X	X	X	X	X	X	X	X
Assessment for Adverse Events Requiring Adjudication[11]			X	X	X	X	X	X	X	X	X	X	X
Topical Emollient Dispensing, as needed	X	X	X	X	X	X	X	X	X	X	X	X	
Study Drug Dispensing			X	X[12]	X	X	X	X	X	X	X		
Regimen Adherence Review/ Drug Accountability				X	X	X	X	X	X	X	X	X	

Abbreviations: BSA = Body Surface Area, CRP = C-Reactive Protein, DLQI = Dermatology Life Quality Index, ECG = Electrocardiogram, HAQ-DI = Health Assessment Questionnaire-Disability Index, HbA1c = hemoglobin A1c, HBcAb = hepatitis B core antibody, HBsAb = hepatitis B surface antibody, HBsAg = Hepatitis B surface antigen, HBV-DNA = Hepatitis B virus DNA, HCG = human chorionic gonadotropin, HCV Ab = Hepatitis C virus antibody, HIV = human immunodeficiency virus, hs-CRP = high sensitivity C-reactive protein, ISI = Itch Severity Item, JPA = Joint Pain Assessment, NAPSI = Nail Psoriasis Severity Index, PASI = Psoriasis Area and Severity Index, PGA = Physician Global Assessment, PPD = Purified Protein Derivative, PtGA = Patient Global Assessment, QFT-G = QuantiFERON®-TB Gold, SF-36 = Short Form-36 Health Survey (Version 2, Acute), VAS = visual analog scale, WLQ = Work Limitation Questionnaire.

1. For subjects who were taking prohibited medications that required a washout period of 4 weeks or longer, a first screening visit was conducted to obtain written informed consent and determine if the eligibility criteria were met prior to initiation of the washout period.

2. ET visit: Early Termination visit
3. A follow-up visit was conducted 2-4 weeks after the subject's last dose of the study drug.
4. For subjects requiring a washout >4 weeks in duration, informed consent, registration for subject identification number, QFT-G (or Mantoux/PPD tuberculin skin test) and chest radiographs did not need to be repeated at the subsequent Screening visit.
5. QFT-G (or Mantoux/PPD tuberculin skin test) and chest radiographs were to be performed unless they had been previously performed within 3 months before a given Screening visit and the results had been documented prior to the randomization. QFT-G did not need to be performed if a subject had previously received a documented adequate course of therapy for either latent or active TB infection.
6. Urine pregnancy testing (HCG): required only for women of childbearing potential. The tests were allowed to be repeated more frequently if the subjects did not have a menstrual cycle or if the subjects had a menstrual cycle and still had a possibility of pregnancy.
7. Only for subjects who met the inclusion criteria for psoriatic arthritis.
8. For subjects requiring a washout >4 weeks in duration, if HBcAb and/or HBsAb were positive, these did not need to be repeated at the subsequent Screening visit.
9. Only for subjects with HBcAb positive and/or HBsAb positive at screening.
10. ISI: assessed daily starting 1 week prior to the baseline visit and continue through the day before Visit 2/baseline/Day 1 and Visit 3/Week 2. Subjects were provided with a daily ISI diary at the Screening visit and Visit 2/baseline/Day 1, which was to be completed at home throughout the time frame noted above. ISI for Visit 2/baseline/Day 1 was completed at the site.
11. Adjudication committees had been established for cardiovascular safety, opportunistic infection and hepatic events. Additional safety event adjudication committees were able to be established if the establishment was considered appropriate.
12. Only at the Week 2 visit, the study drug bottles were returned and delivered later to examine the compliance of taking the drug and the drug management.

Number of Subjects (Planned and Analyzed): A total of 88 subjects (including approximately 10 total subjects with psoriatic arthritis) were to be enrolled in the study and 94 subjects including 12 subjects with psoriatic arthritis were analyzed in this study.

Diagnosis and Main Criteria for Inclusion: Eligible subjects were at least 20 years of age and were candidates for systemic therapy or phototherapy; had a moderate to severe plaque psoriasis diagnosed ≥12 months with psoriasis involving at least 10% of total body surface area (BSA) and a Psoriasis Area and Severity Index (PASI) score of ≥12; and/or had psoriatic arthritis diagnosed ≥6 months; met the CASPAR (ClASsification criteria for Psoriatic ARthritis) criteria at screening; had active arthritis (≥3 tender/painful joints on motion and ≥3 swollen joints) and active plaque psoriasis with a qualifying lesion at least 2 cm in diameter.

Subjects were excluded from participation in the study for the following reasons: subjects currently had non plaque forms of psoriasis or drug induced psoriasis; subjects who could not discontinue systemic therapies and/or topical therapies for the treatment of psoriasis and could not discontinue phototherapy (UVB or PUVA); subjects had any uncontrolled significant medical condition.

Study Treatment: CP-690,550 (5 mg or 10 mg) or placebo was taken orally BID (once in the morning and once in the evening; approximately 12 hours apart). First dosing of the study drug occurred in the evening of Day 1.

CP-690,550 5 mg BID or 10 mg BID was taken for 16 weeks during the double blind period. During the first 4 weeks of the open label period (Week 16 to 20), CP-690,550 10 mg BID was taken. After Week 20 up to Week 52, the dermatologist investigator had the option to decrease the dose to 5 mg BID, at their discretion or based on safety abnormalities. The investigator could increase the dose back to 10 mg BID at subsequent study visits at their discretion. Changes in the dose were only permitted at scheduled study visits, unless a reduction to 5 mg BID was required due to safety abnormalities.

Efficacy, Pharmacokinetic, Pharmacodynamic, or Outcomes Research Endpoints:

<u>Primary endpoints</u>

Plaque Psoriasis

- PASI75 response, ie, the proportion of subjects achieving at least a 75% reduction in PASI relative to baseline at Week 16.

- Physician Global Assessment (PGA) response, ie, the proportion of subjects achieving a PGA of “Clear” or “Almost Clear”, at Week 16.

Psoriatic Arthritis

- ACR20 response, ie, the proportion of subjects achieving ACR20 (The American College of Rheumatology 20% improvement response criteria at Week 16.

Secondary analysis

Plaque Psoriasis

- PASI75 response at various time points through Week 52.
- PASI50 and PASI90 responses (the proportion of subjects achieving at least a 50% and 90% reduction in PASI relative to baseline, respectively) at various time points through Week 52.
- Time to PGA response up to Week 16.
- Time to PASI75, PASI50 and PASI90 response up to Week 16.
- Proportion of subjects with a PASI score ≥125% of the baseline PASI score at any time point through Week 52.
- The actual and change from baseline in PASI and PASI component scores at various time points through Week 52.
- PGA response at various time points through Week 52.
- Proportion of subjects in each PGA category at various time points through Week 52.
- Maintenance of PGA and PASI75 responses between Week 16 and Week 52 among the PGA or PASI75 responders at Week 16.
- The actual and change from baseline in Nail Psoriasis Severity Index (NAPSI) and number of affected nails at various time points through Week 52.
- The actual and change from baseline in the Itch Severity Item (ISI) score at various time points through Week 52.
- The actual and change from baseline on the Dermatology Life Quality Index (DLQI) score at various time points through Week 52.
- Other patient reported outcome (PRO) measures to be assessed at various time points through Week 52, including: Short Form-36 Health Survey (Version 2, Acute) (SF-36); Work Limitation Questionnaire (WLQ); Patient Global Assessment (PtGA); Joint Pain Assessment (JPA).

Psoriatic Arthritis

- ACR20/50/70 responses at various time points through Week 52.
- The actual and change from baseline on the HAQ-DI at various time points through Week 52.

- ACR response criteria components at various time points through Week 52.

There were no pharmacokinetic, pharmacodynamic and outcome research evaluations done in this study.

Safety Evaluations: Safety evaluations included physical examinations, vital signs (pulse rate, blood pressure), 12-lead electrocardiograms (ECGs), adverse events (AEs) and clinical laboratory tests through Week 52

Statistical Methods: For PASI75 and PGA responses at Week 16, the response rates and the 95% confidence intervals were calculated for each treatment group (5 mg BID, 10 mg BID) in the moderate to severe plaque psoriasis population. To support the interpretation of the primary analysis, the same primary analyses were conducted using per protocol analysis set (PPS) and the full analysis set (FAS), as sensitivity analyses.

Time to event data of PASI50, PASI75 and PGA responses to psoriasis until Week 16 were summarized for each treatment group in the moderate to severe plaque psoriasis population respectively, using descriptive statistics based on Kaplan-Meier method.

For ACR20 response at Week 16, the response rate and the 95% confidence interval were calculated for each treatment group in the psoriatic arthritis population.

Missing values in the primary endpoints were handled by setting the values to non-responsive (Non-responder imputation: NRI). Confidence intervals were calculated with the exact method.

All AEs, laboratory tests, vital signs, and other safety data were summarized in accordance with Pfizer Data Standards. Furthermore, common AEs, serious adverse events (SAEs), AEs causing withdrawal of subjects, other clinically significant AEs and significant changes in laboratory tests until Week 16 were summarized for each treatment group.

An interim analysis could be performed when all subjects had either completed the visit at Week 28 or discontinued from the study, but was not performed in this study.

RESULTS

Subject Disposition and Demography: Table 2 provides subject disposition.

Table 2. Subject Disposition

	CP-690,550		Total
	5 mg BID n (%)	10 mg BID n (%)	n (%)
Screened	-	-	114
Randomized	47	48	95
Safety Analysis Set	47 (100)	47 (97.9)	94 (98.9)
FAS	47 (100)	47 (97.9)	94 (98.9)
PPS	37 (78.7)	36 (75.0)	73 (76.8)
Moderate to Severe Plaque Psoriasis Population	43 (91.5)	44 (91.7)	87 (91.6)
Psoriatic Arthritis Population	4 (8.5)	8 (16.7)	12 (12.6)
Completed	40 (85.1)	33 (68.8)	73 (76.8)
Discontinued	7 (14.9)	14 (29.2)	21 (22.1)

Abbreviations: BID = twice daily, FAS = Full Analysis Set, n = number of subjects meeting prespecified criteria, PPS = Per Protocol Analysis Set.

A summary of demographic and other baseline characteristics is presented in Table 3.

Table 3. Demographic and Baseline Clinical Characteristics (FAS)

	CP-690,550		Total
	5 mg BID N = 47	10 mg BID N = 47	N = 94
Age (years), n (%)			
Mean (SD)	50.9 (11.8)	46.4 (10.8)	48.7 (11.5)
Range	28-72	28-69	28-72
Sex, n (%)			
Male	39 (83.0)	39 (83.0)	78 (83.0)
Female	8 (17.0)	8 (17.0)	16 (17.0)
Race, n (%)			
Asian	47 (100)	47 (100)	94 (100.0)
Weight (kg)			
Mean (SD)	67.8 (13.4)	68.1 (14.6)	68.0 (14.0)
Range	43-117	39-106	39-117
Body Mass Index (kg/m^2)			
Mean (SD)	24.0 (4.1)	24.0 (4.2)	24.0 (4.1)
Range	17.8-37.7	15.8-36.1	15.8-37.7
Hip (cm)			
Mean (SD)	93.5 (9.7)	94.8 (9.1)	94.1 (9.4)
Range	75.3, 126.0	81.0, 128.0	75.3, 128.0
Duration of Disease (yrs) [a]			
Mean (SD)	13.14 (10.166)	13.48 (8.228)	13.31 (9.200)
PASI Score			
Mean (SD)	25.21 (12.193)	25.12 (12.886)	25.16 (12.477)
PASI Category, n (%)			
<20	17 (36.2)	20 (42.6)	37 (39.4)
≥20	30 (63.8)	27 (57.4)	57 (60.6)
Total Percent Psoriatic BSA (%)			
Mean (SD)	39.9 (22.75)	40.7 (24.61)	40.3 (23.58)

Abbreviations: BID = twice daily, BSA = body surface area, FAS = Full Analysis Set, N = number of subjects, n = number of subjects meeting prespecified criteria, PASI = Psoriasis Area and Severity Index, PGA = Physician Global Assessment, SD = standard deviation.

a. Duration of Disease (yrs) = (Screening Visit Date - Date of Primary Diagnosis +1)/365.25 The longer disease duration of primary diagnosis was used when a subject has both primary diagnoses of psoriasis and psoriatic arthropathy. As a result, the data indicates duration of psoriasis.

Efficacy, Pharmacokinetic, Pharmacodynamic, or Outcomes Research Results:

Primary Efficacy Endpoints

The proportion of subjects achieving a PASI75 response, a PGA response and ACR20 at Week 16 are summarized in Table 4.

Table 4. Proportion of Subjects Achieving a PASI75 Response, PGA Response and ACR20 at Week 16 (NRI)

End point	Visit	Analysis set	CP-690,550	Response			Comparison Between 10 mg versus 5 mg Response (10 - 5 mg BID) [a]		
				N	n (%)	SE	Diff	SE	95% CI
PASI75	Week 16	PsO	5 mg BID	43	27 (62.8)	7.371	9.94	9.971	-9.61, 29.48
			10 mg BID	44	32 (72.7)	6.714			
			Total	87	59 (67.8)	5.009			
PGA	Week 16	PsO	5 mg BID	43	29 (67.4)	7.146	0.74	10.018	-18.90, 20.38
			10 mg BID	44	30 (68.2)	7.022			
			Total	87	59 (67.8)	5.009			
ACR20	Week 16	PsA	5 mg BID	4	4 (100)	0.000	0.00	0.000	–
			10 mg BID	8	8 (100)	0.000			
			Total	12	12 (100)	0.000			

The PASI75 response rates were calculated as the proportion of patients achieving at least 75% reduction PASI score relative to baseline.
The PGA response rates were calculated as the proportion of patients achieving a PGA of "Clear" or "Almost Clear".
Missing data was imputed as non-responder for the data in this table.
Abbreviations: BID = twice daily, CI = confidence interval, N = number of subjects, n = number of subjects meeting prespecified criteria, NRI = non-responder imputation, PASI = Psoriasis Area and Severity Index, PGA = Physician Global Assessment, PsA = psoriatic arthritis population, PsO = moderate to severe plaque psoriasis population, SE = standard error.
a. Normal approximation.

Secondary Efficacy Endpoints

The proportion of subjects with a PASI75, PASI90, and PASI50 response, PASI score ≥125% of baseline, and PGA response during study (NRI) are summarized in Table 5.

Median time to PASI75 response was shorter in CP-690,550 10 mg BID group (8 weeks) than in CP-690,550 5 mg BID group (12 weeks) in the moderate to severe plaque psoriasis population (observed case). Median time to PASI90 response was shorter in CP-690,550 10 mg BID group (12 weeks) than in CP-690,550 5 mg BID group (couldn't be estimated by Week 16). Median time to PASI50 response was also shorter in CP-690,550 10 mg BID group (4 weeks) than in CP-690,550 5 mg BID group (8 weeks).

Table 5. Proportion of Subjects With a PASI75, PASI90 and PASI50 Response, PASI Score ≥125% of Baseline, and PGA Response During Study (Moderate to Severe Plaque Psoriasis Population)

End point		Visit		CP-690,550 [a]		
				5 mg BID	10 mg BID	Total
PASI75	NRI	Week 2	N	43	44	87
			n (%)	1 (2.3)	2 (4.5)	3 (3.4)
			SE	2.298	3.140	1.956
		Week 4	N	43	44	87
			n (%)	3 (7.0)	10 (22.7)	13 (14.9)
			SE	3.885	6.318	3.822
		Week 8	N	43	44	87
			n (%)	18 (41.9)	24 (54.5)	42 (48.3)
			SE	7.523	7.507	5.357
		Week 12	N	43	44	87
			n (%)	26 (60.5)	31 (70.5)	57 (65.5)
			SE	7.456	6.878	5.096
		Week 16	N	43	44	87
			n (%)	27 (62.8)	32 (72.7)	59 (67.8)
			SE	7.371	6.714	5.009
		Week 20	N	43	44	87
			n (%)	29 (67.4)	28 (63.6)	57 (65.5)
			SE	7.146	7.252	5.096
		Week 28	N	43	44	87
			n (%)	30 (69.8)	29 (65.9)	59 (67.8)
			SE	7.004	7.146	5.009
		Week 40	N	43	44	87
			n (%)	30 (69.8)	28 (63.6)	58 (66.7)
			SE	7.004	7.252	5.054
		Week 52	N	43	44	87
			n (%)	27 (62.8)	28 (63.6)	55 (63.2)
			SE	7.371	7.252	5.170
		Follow-up	N	43	44	87
			n (%)	18 (41.9)	17 (38.6)	35 (40.2)
			SE	7.523	7.341	5.257
PASI90	NRI	Week 2	N	43	44	87
			n (%)	0 (0.0)	0 (0.0)	0 (0.0)
			SE	0	0	0
		Week 4	N	43	44	87
			n (%)	2 (4.7)	6 (13.6)	8 (9.2)
			SE	3.211	5.174	3.098
		Week 8	N	43	44	87
			n (%)	7 (16.3)	13 (29.5)	20 (23.0)
			SE	5.630	6.878	4.511
		Week 12	N	43	44	87
			n (%)	16 (37.2)	20 (45.5)	36 (41.4)

Table 5. Proportion of Subjects With a PASI75, PASI90 and PASI50 Response, PASI Score ≥125% of Baseline, and PGA Response During Study (Moderate to Severe Plaque Psoriasis Population)

End point		Visit		CP-690,550 [a]		
				5 mg BID	10 mg BID	Total
			SE	7.371	7.507	5.280
		Week 16	N	43	44	87
			n (%)	16 (37.2)	24 (54.5)	40 (46.0)
			SE	7.371	7.507	5.343
		Week 20	N	43	44	87
			n (%)	25 (58.1)	25 (56.8)	50 (57.5)
			SE	7.523	7.467	5.300
		Week 28	N	43	44	87
			n (%)	24 (55.8)	20 (45.5)	44 (50.6)
			SE	7.573	7.507	5.360
		Week 40	N	43	44	87
			n (%)	25 (58.1)	21 (47.7)	46 (52.9)
			SE	7.523	7.530	5.352
		Week 52	N	43	44	87
			n (%)	22 (51.2)	21 (47.7)	43 (49.4)
			SE	7.623	7.530	5.360
		Follow-up	N	43	44	87
			n (%)	16 (37.2)	12 (27.3)	28 (32.2)
			SE	7.371	6.714	5.009
PASI50	NRI	Week 2	N	43	44	87
			n (%)	4 (9.3)	10 (22.7)	14 (16.1)
			SE	4.430	6.318	3.940
		Week 4	N	43	44	87
			n (%)	15 (34.9)	25 (56.8)	40 (46.0)
			SE	7.268	7.467	5.343
		Week 8	N	43	44	87
			n (%)	26 (60.5)	36 (81.8)	62 (71.3)
			SE	7.456	5.815	4.852
		Week 12	N	43	44	87
			n (%)	35 (81.4)	37 (84.1)	72 (82.8)
			SE	5.934	5.514	4.050
		Week 16	N	43	44	87
			n (%)	33 (76.7)	35 (79.5)	68 (78.2)
			SE	6.442	6.081	4.429
		Week 20	N	43	44	87
			n (%)	34 (79.1)	33 (75.0)	67 (77.0)
			SE	6.204	6.528	4.511
		Week 28	N	43	44	87
			n (%)	39 (90.7)	32 (72.7)	71 (81.6)
			SE	4.430	6.714	4.153
		Week 40	N	43	44	87

Table 5. Proportion of Subjects With a PASI75, PASI90 and PASI50 Response, PASI Score ≥125% of Baseline, and PGA Response During Study (Moderate to Severe Plaque Psoriasis Population)

End point		Visit		CP-690,550 [a]		
				5 mg BID	10 mg BID	Total
			n (%)	38 (88.4)	35 (79.5)	73 (83.9)
			SE	4.888	6.081	3.940
		Week 52	N	43	44	87
			n (%)	39 (90.7)	30 (68.2)	69 (79.3)
			SE	4.430	7.022	4.343
		Follow-up	N	43	44	87
			n (%)	24 (55.8)	26 (59.1)	50 (57.5)
			SE	7.573	7.412	5.300
PASI score ≥125% of baseline	Observed Case	Week 2	N	43	44	87
			n (%)	1 (2.3)	0 (0.0)	1 (1.1)
			SE	2.298	0.000	1.143
		Week 4	N	43	44	87
			n (%)	0 (0.0)	1 (2.3)	1 (1.1)
			SE	0.000	2.247	1.143
		Week 8	N	43	41	84
			n (%)	0 (0.0)	0 (0.0)	0 (0.0)
			SE	0.000	0.000	0.000
		Week 12	N	43	41	84
			n (%)	0 (0.0)	1 (2.4)	1 (1.2)
			SE	0.000	2.409	1.183
		Week 16	N	43	40	83
			n (%)	0 (0.0)	1 (2.5)	1 (1.2)
			SE	0.000	2.469	1.198
		Week 20	N	43	39	82
			n (%)	0 (0.0)	0 (0.0)	0 (0.0)
			SE	0.000	0.000	0.000
		Week 28	N	43	39	82
			n (%)	0 (0.0)	0 (0.0)	0 (0.0)
			SE	0.000	0.000	0.000
		Week 40	N	41	38	79
			n (%)	0 (0.0)	0 (0.0)	0 (0.0)
			SE	0.000	0.000	0.000
		Week 52	N	39	32	71
			n (%)	0 (0.0)	0 (0.0)	0 (0.0)
			SE	0.000	0.000	0.000
		Follow-up	N	32	30	62
			n (%)	1 (3.1)	2 (6.7)	3 (4.8)
			SE	3.076	4.554	2.725
PGA	NRI	Week 2	N	43	44	87
			n (%)	3 (7.0)	7 (15.9)	10 (11.5)
			SE	3.885	5.514	3.420

Table 5. Proportion of Subjects With a PASI75, PASI90 and PASI50 Response, PASI Score ≥125% of Baseline, and PGA Response During Study (Moderate to Severe Plaque Psoriasis Population)

End point	Visit		CP-690,550 [a]		
			5 mg BID	10 mg BID	Total
	Week 4	N	43	44	87
		n (%)	13 (30.2)	17 (38.6)	30 (34.5)
		SE	7.004	7.341	5.096
	Week 8	N	43	44	87
		n (%)	25 (58.1)	27 (61.4)	52 (59.8)
		SE	7.523	7.341	5.257
	Week 12	N	43	44	87
		n (%)	31 (72.1)	33 (75.0)	64 (73.6)
		SE	6.840	6.528	4.728
	Week 16	N	43	44	87
		n (%)	29 (67.4)	30 (68.2)	59 (67.8)
		SE	7.146	7.022	5.009
	Week 20	N	43	44	87
		n (%)	31 (72.1)	26 (59.1)	57 (65.5)
		SE	6.840	7.412	5.096
	Week 28	N	43	44	87
		n (%)	29 (67.4)	24 (54.5)	53 (60.9)
		SE	7.146	7.507	5.231
	Week 40	N	43	44	87
		n (%)	29 (67.4)	24 (54.5)	53 (60.9)
		SE	7.146	7.507	5.231
	Week 52	N	43	44	87
		n (%)	25 (58.1)	25 (56.8)	50 (57.5)
		SE	7.523	7.467	5.300
	Follow-up	N	43	44	87
		n (%)	16 (37.2)	19 (43.2)	35 (40.2)
		SE	7.371	7.467	5.257

The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. The PASI75 response rates were calculated as the proportion of patients achieving at least 75% reduction in PASI score relative to baseline. The PASI90 response rates were calculated as the proportion of patients achieving at least 90% reduction in PASI score relative to baseline. The PASI50 response rates were calculated as the proportion of patients achieving at least 50% reduction in PASI score relative to baseline. Proportion of the subjects with a PASI score ≥125% of the baseline was also calculated at any time points through Week 52.
The PGA response rates were calculated as the proportion of patients achieving a PGA of "Clear" or "Almost Clear". Missing data was imputed as non-responder for the data in this table.
Abbreviations: BID = twice daily, N = number of subjects, n = number of subjects meeting prespecified criteria, NRI = non-responder imputation, PASI = Psoriasis Area and Severity Index, PGA = Physician Global Assessment, SE = standard error.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Descriptive statistics of PASI score and PASI component score during study is presented in Table 6 and Table 7, respectively.

Table 6. Descriptive Statistics of PASI Score During Study (Moderate to Severe Plaque Psoriasis Population, Observed Case)

End point	Visit	CP-690,550 [a]	Actual value			Change from baseline			Least-Square Mean of Change from baseline	
			N	Mean	SD	N	Mean	SD	N	LS Mean	SE
PASI score	Baseline	5 mg BID	43	26.93	11.263	-	-	-	-	-	-
		10 mg BID	44	26.65	11.836	-	-	-	-	-	-
		Total	87	26.79	11.490	-	-	-	-	-	-
	Week 2	5 mg BID	43	21.74	12.159	43	-5.18	5.898	43	-5.14	0.993
		10 mg BID	44	19.29	12.918	44	-7.36	6.428	44	-7.38	0.982
		Total	87	20.50	12.536	87	-6.28	6.232	87	-6.28	0.702
	Week 4	5 mg BID	43	16.53	11.889	43	-10.40	7.518	43	-10.36	1.170
		10 mg BID	44	13.49	11.308	44	-13.16	8.739	44	-13.19	1.157
		Total	87	14.99	11.633	87	-11.79	8.229	87	-11.79	0.832
	Week 8	5 mg BID	43	10.98	10.513	43	-15.95	8.392	43	-15.91	1.256
		10 mg BID	41	6.61	6.459	41	-19.90	10.741	41	-19.28	1.262
		Total	84	8.85	8.991	84	-17.88	9.756	84	-17.58	0.912
	Week 12	5 mg BID	43	8.02	9.909	43	-18.91	8.918	43	-18.87	1.317
		10 mg BID	41	4.84	5.924	41	-21.68	11.598	41	-21.25	1.334
		Total	84	6.47	8.316	84	-20.26	10.344	84	-20.04	0.948
	Week 16	5 mg BID	43	7.40	10.280	43	-19.53	9.094	43	-19.49	1.404
		10 mg BID	40	4.50	6.100	40	-22.06	12.606	40	-21.53	1.426
		Total	83	6.00	8.599	83	-20.75	10.935	83	-20.50	1.007
	Week 20	5 mg BID	43	5.98	8.138	43	-20.95	9.239	-	-	-
		10 mg BID	39	4.57	5.786	39	-22.18	12.045	-	-	-
		Total	82	5.31	7.110	82	-21.53	10.617	-	-	-
	Week 28	5 mg BID	43	5.16	7.808	43	-21.77	10.196	-	-	-
		10 mg BID	39	5.28	6.509	39	-21.46	10.503	-	-	-
		Total	82	5.22	7.176	82	-21.62	10.280	-	-	-
	Week 40	5 mg BID	41	4.64	7.599	41	-22.20	10.181	-	-	-
		10 mg BID	38	4.95	6.896	38	-21.18	10.229	-	-	-
		Total	79	4.79	7.225	79	-21.71	10.151	-	-	-

Table 6. Descriptive Statistics of PASI Score During Study (Moderate to Severe Plaque Psoriasis Population, Observed Case)

End point	Visit	CP-690,550 [a]	Actual value			Change from baseline			Least-Square Mean of Change from baseline	
			N	Mean	SD	N	Mean	SD	N	LS Mean	SE
	Week 52	5 mg BID	39	5.02	6.818	39	-21.96	9.621	-	-	-
		10 mg BID	32	3.53	5.605	32	-22.11	10.598	-	-	-
		Total	71	4.35	6.301	71	-22.03	10.000	-	-	-
	Follow-up	5 mg BID	32	8.65	11.429	32	-17.08	10.705	-	-	-
		10 mg BID	30	7.19	11.502	30	-17.57	12.577	-	-	-
		Total	62	7.95	11.394	62	-17.32	11.554	-	-	-

Abbreviations: BID = twice daily, LS = least-square, N = number of subjects, PASI = Psoriasis Area and Severity Index, SD = standard deviation, SE = standard error.

a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Table 7. Descriptive Statistics of PASI Component Score During Study (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Body region	Visit	CP-690,550 [a]	Erythema						Induration						Scaling					
			Actual value			Change from baseline			Actual value			Change from baseline			Actual value			Change from baseline		
			N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD
Head/ Neck	Baseline	5 mg BID	43	2.9	0.80	-	-	-	43	2.0	0.89	-	-	-	43	2.2	0.99	-	-	
		10 mg BID	44	2.7	0.78	-	-	-	44	2.0	0.98	-	-	-	44	2.1	0.88	-	-	
		Total	87	2.8	0.79	-	-	-	87	2.0	0.93	-	-	-	87	2.1	0.93	-	-	
	Week 2	5 mg BID	43	2.3	0.95	43	-0.5	0.83	43	1.6	0.98	43	-0.4	0.70	43	1.8	1.10	43	-0.4	0.66
		10 mg BID	44	1.9	0.91	44	-0.9	0.82	44	1.2	0.87	44	-0.8	0.89	44	1.2	0.92	44	-0.9	0.91
		Total	87	2.1	0.95	87	-0.7	0.84	87	1.4	0.94	87	-0.6	0.82	87	1.5	1.06	87	-0.7	0.83
	Week 4	5 mg BID	43	1.8	0.97	43	-0.8	1.02	43	1.3	0.92	43	-0.7	0.89	43	1.4	1.16	43	-0.8	0.86
		10 mg BID	44	1.5	1.07	44	-1.3	0.99	44	0.8	0.92	44	-1.2	1.09	44	0.9	0.88	44	-1.2	0.99
		Total	87	1.6	1.02	87	-1.0	1.02	87	1.1	0.95	87	-1.0	1.02	87	1.2	1.06	87	-1.0	0.95
	Week 8	5 mg BID	43	1.3	0.97	43	-1.4	1.13	43	0.7	0.88	43	-1.3	0.91	43	0.9	0.97	43	-1.3	0.90
		10 mg BID	41	1.0	0.74	41	-1.6	1.03	41	0.4	0.84	41	-1.6	1.10	41	0.6	0.90	41	-1.5	1.03
		Total	84	1.2	0.87	84	-1.5	1.08	84	0.6	0.87	84	-1.4	1.01	84	0.7	0.94	84	-1.4	0.96
	Week 12	5 mg BID	43	1.0	1.00	43	-1.7	1.10	43	0.5	0.86	43	-1.5	0.94	43	0.6	0.93	43	-1.7	0.92
		10 mg BID	41	0.8	0.86	41	-1.7	0.98	41	0.4	0.83	41	-1.6	1.12	41	0.4	0.74	41	-1.6	1.02
		Total	84	0.9	0.93	84	-1.7	1.04	84	0.5	0.84	84	-1.6	1.02	84	0.5	0.84	84	-1.6	0.96
	Week 16	5 mg BID	43	1.0	1.07	43	-1.7	1.14	43	0.5	0.77	43	-1.5	0.96	43	0.6	0.93	43	-1.6	0.95
		10 mg BID	40	0.8	0.87	40	-1.7	1.07	40	0.4	0.78	40	-1.6	1.17	40	0.5	0.82	40	-1.6	1.08
		Total	83	0.9	0.98	83	-1.7	1.10	83	0.5	0.77	83	-1.6	1.06	83	0.5	0.87	83	-1.6	1.01
	Week 20	5 mg BID	43	1.0	0.97	43	-1.8	1.15	43	0.4	0.76	43	-1.6	1.00	43	0.5	0.85	43	-1.7	0.94
		10 mg BID	39	0.7	0.91	39	-1.6	0.96	39	0.5	0.79	39	-1.5	1.12	39	0.6	0.82	39	-1.5	1.05
		Total	82	0.9	0.94	82	-1.7	1.07	82	0.5	0.77	82	-1.6	1.06	82	0.6	0.83	82	-1.6	0.99
	Week 28	5 mg BID	43	0.8	0.95	43	-1.8	1.11	43	0.4	0.66	43	-1.7	0.97	43	0.5	0.74	43	-1.7	1.01
		10 mg BID	39	0.8	0.83	39	-1.6	0.81	39	0.5	0.72	39	-1.6	0.99	39	0.6	0.87	39	-1.4	1.07
		Total	82	0.8	0.89	82	-1.7	0.98	82	0.4	0.68	82	-1.6	0.98	82	0.6	0.80	82	-1.6	1.04
	Week 40	5 mg BID	41	0.8	0.92	41	-1.9	1.10	41	0.4	0.70	41	-1.7	1.05	41	0.5	0.81	41	-1.8	0.97

Table 7. Descriptive Statistics of PASI Component Score During Study (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Body region	Visit	CP-690,550 [a]	Erythema						Induration						Scaling					
			Actual value			Change from baseline			Actual value			Change from baseline			Actual value			Change from baseline		
			N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD
		10 mg BID	38	0.7	0.87	38	-1.7	0.90	38	0.5	0.73	38	-1.5	1.08	38	0.6	0.89	38	-1.4	1.00
		Total	79	0.7	0.89	79	-1.8	1.01	79	0.4	0.71	79	-1.6	1.07	79	0.5	0.84	79	-1.6	0.99
	Week 52	5 mg BID	39	0.9	1.06	39	-1.9	1.17	39	0.4	0.67	39	-1.7	1.06	39	0.4	0.72	39	-1.8	0.98
		10 mg BID	32	0.5	0.76	32	-1.6	1.24	32	0.5	0.72	32	-1.5	1.22	32	0.6	0.84	32	-1.6	1.08
		Total	71	0.7	0.95	71	-1.8	1.20	71	0.4	0.69	71	-1.6	1.13	71	0.5	0.77	71	-1.7	1.02
	Follow-up	5 mg BID	32	1.3	1.33	32	-1.6	1.26	32	0.6	0.94	32	-1.5	1.11	32	0.7	0.90	32	-1.6	1.11
		10 mg BID	30	1.0	1.00	30	-1.1	1.31	30	0.8	0.97	30	-1.3	1.34	30	1.1	1.07	30	-1.0	1.26
		Total	62	1.2	1.18	62	-1.4	1.30	62	0.7	0.95	62	-1.4	1.22	62	0.9	1.01	62	-1.3	1.21
Upper limbs	Baseline	5 mg BID	43	2.9	0.80	-	-	-	43	2.6	0.73	-	-	-	43	2.3	0.83	-	-	-
		10 mg BID	44	2.7	0.78	-	-	-	44	2.4	0.81	-	-	-	44	2.4	0.75	-	-	-
		Total	87	2.8	0.79	-	-	-	87	2.5	0.78	-	-	-	87	2.3	0.79	-	-	-
	Week 2	5 mg BID	43	2.3	0.95	43	-0.5	0.67	43	2.1	0.87	43	-0.5	0.63	43	1.9	091	43	-0.4	0.59
		10 mg BID	44	1.9	0.91	44	-0.8	0.72	44	1.8	0.91	44	-0.6	0.75	44	1.6	0.84	44	-0.8	0.74
		Total	87	2.1	0.95	87	-0.6	0.70	87	1.9	0.90	87	-0.6	0.69	87	1.7	0.89	87	-0.6	0.69
	Week 4	5 mg BID	43	1.8	0.97	43	-1.1	0.81	43	1.5	0.91	43	-1.1	0.86	43	1.4	0.93	43	-0.9	0.70
		10 mg BID	44	1.5	1.07	44	-1.2	0.94	44	1.4	1.01	44	-1.0	0.85	44	1.2	0.88	44	-1.2	0.86
		Total	87	1.6	1.02	87	-1.1	0.87	87	1.4	0.96	87	-1.0	0.85	87	1.3	0.91	87	-1.0	0.79
	Week 8	5 mg BID	43	1.3	0.97	43	-1.5	0.93	43	1.0	0.87	43	-1.6	0.93	43	1.0	0.79	43	-1.3	0.80
		10 mg BID	41	1.0	0.74	41	-1.6	0.98	41	0.8	0.77	41	-1.6	0.89	41	0.7	0.68	41	-1.6	0.86
		Total	84	1.2	0.87	84	-1.5	0.95	84	0.9	0.83	84	-1.6	0.91	84	0.9	0.75	84	-1.5	0.84
	Week 12	5 mg BID	43	1.0	1.00	43	-1.9	0.99	43	0.9	0.88	43	-1.7	0.94	43	0.9	0.85	43	-1.4	0.91
		10 mg BID	41	0.8	0.86	41	-1.8	1.13	41	0.6	0.77	41	-1.8	0.99	41	0.6	0.81	41	-1.7	0.95
		Total	84	0.9	0.93	84	-1.8	1.05	84	0.8	0.84	84	-1.7	0.96	84	0.7	0.84	84	-1.6	0.94
	Week 16	5 mg BID	43	1.0	1.07	43	-1.9	1.13	43	0.8	0.91	43	-1.8	0.96	43	0.8	0.90	43	-1.5	0.93
		10 mg BID	40	0.8	0.87	40	-1.9	1.12	40	0.5	0.75	40	-1.8	1.01	40	0.6	0.90	40	-1.7	1.05

Table 7. Descriptive Statistics of PASI Component Score During Study (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Body region	Visit	CP-690,550 [a]	Erythema						Induration						Scaling					
			Actual value			Change from baseline			Actual value			Change from baseline			Actual value			Change from baseline		
			N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD
		Total	83	0.9	0.98	83	-1.9	1.12	83	0.7	0.85	83	-1.8	0.98	83	0.7	0.89	83	-1.6	0.99
	Week 20	5 mg BID	43	1.0	0.97	43	-1.9	0.97	43	0.7	0.88	43	-1.9	0.97	43	0.8	0.91	43	-1.5	0.96
		10 mg BID	39	0.7	0.91	39	-1.9	1.26	39	0.6	0.84	39	-1.7	1.14	39	0.7	0.94	39	-1.6	1.14
		Total	82	0.9	0.94	82	-1.9	1.11	82	0.7	0.86	82	-1.8	1.05	82	0.8	0.92	82	-1.5	1.04
	Week 28	5 mg BID	43	0.8	0.95	43	-2.1	1.09	43	0.6	0.82	43	-2.0	1.12	43	0.5	0.70	43	-1.8	1.05
		10 mg BID	39	0.8	0.83	39	-1.8	1.07	39	0.7	0.95	39	-1.7	1.10	39	0.7	0.86	39	-1.6	1.02
		Total	82	0.8	0.89	82	-2.0	1.08	82	0.6	0.88	82	-1.9	1.12	82	0.6	0.78	82	-1.7	1.03
	Week 40	5 mg BID	41	0.8	0.92	41	-2.1	1.05	41	0.6	0.83	41	-2.0	1.18	41	0.6	0.77	41	-1.7	1.10
		10 mg BID	38	0.7	0.87	38	-1.9	1.06	38	0.6	0.76	38	-1.8	0.98	38	0.5	0.73	38	-1.8	0.94
		Total	79	0.7	0.89	79	-2.0	1.06	79	0.6	0.79	79	-1.9	1.09	79	0.6	0.75	79	-1.7	1.02
	Week 52	5 mg BID	39	0.9	1.06	39	-2.0	1.15	39	0.7	0.92	39	-1.9	1.21	39	0.7	0.83	39	-1.6	1.02
		10 mg BID	32	0.5	0.76	32	-2.0	0.90	32	0.4	0.66	32	-2.0	0.97	32	0.3	0.58	32	-1.9	0.98
		Total	71	0.7	0.95	71	-2.0	1.04	71	0.5	0.82	71	-1.9	1.10	71	0.5	0.75	71	-1.7	1.01
	Follow-up	5 mg BID	32	1.3	1.33	32	-1.5	1.24	32	1.1	1.20	32	-1.5	1.46	32	0.9	0.98	32	-1.3	1.09
		10 mg BID	30	1.0	1.00	30	-1.5	1.33	30	0.6	0.81	30	-1.7	1.08	30	0.7	0.78	30	-1.5	1.11
		Total	62	1.2	1.18	62	-1.5	1.28	62	0.9	1.05	62	-1.6	1.29	62	0.8	0.88	62	-1.4	1.09
Trunk	Baseline	5 mg BID	43	3.0	0.71	-	-	-	43	2.7	0.76	-	-	-	43	2.3	0.78	-	-	-
		10 mg BID	44	3.0	0.66	-	-	-	44	2.7	0.71	-	-	-	44	2.5	0.70	-	-	-
		Total	87	3.0	0.68	-	-	-	87	2.7	0.73	-	-	-	87	2.4	0.74	-	-	-
	Week 2	5 mg BID	43	2.5	0.83	43	-0.6	0.67	43	2.3	0.83	43	-0.5	0.63	43	2.0	0.85	43	-0.3	0.57
		10 mg BID	44	2.2	0.86	44	-0.8	0.69	44	1.9	0.85	44	-0.7	0.59	44	1.7	0.87	44	-0.8	0.76
		Total	87	2.3	0.85	87	-0.7	0.69	87	2.1	0.85	87	-0.6	0.62	87	1.9	0.86	87	-0.6	0.71
	Week 4	5 mg BID	43	2.0	0.82	43	-1.0	0.64	43	1.8	0.91	43	-0.9	0.80	43	1.5	0.86	43	-0.9	0.71
		10 mg BID	44	1.7	0.85	44	-1.3	0.79	44	1.4	0.89	44	-1.3	0.82	44	1.3	0.87	44	-1.3	0.95
		Total	87	1.9	0.84	87	-1.1	0.72	87	1.6	0.92	87	-1.1	0.83	87	1.4	0.86	87	-1.1	0.87

Table 7. Descriptive Statistics of PASI Component Score During Study (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Body region	Visit	CP-690,550 [a]	Erythema						Induration						Scaling					
			Actual value			Change from baseline			Actual value			Change from baseline			Actual value			Change from baseline		
			N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD
	Week 8	5 mg BID	43	1.3	0.91	43	-1.7	0.91	43	1.1	0.88	43	-1.6	0.98	43	1.0	0.74	43	-1.4	0.82
		10 mg BID	41	1.0	0.87	41	-1.9	0.93	41	0.9	0.91	41	-1.7	1.03	41	0.7	0.84	41	-1.8	1.00
		Total	84	1.2	0.90	84	-1.8	0.92	84	1.0	0.89	84	-1.7	1.00	84	0.8	0.80	84	-1.6	0.93
	Week 12	5 mg BID	43	1.0	0.97	43	-2.1	1.08	43	0.7	0.88	43	-2.0	1.01	43	0.8	0.87	43	-1.6	1.05
		10 mg BID	41	0.9	0.88	41	-2.0	0.95	41	0.6	0.77	41	-2.0	1.00	41	0.7	0.91	41	-1.9	1.00
		Total	84	0.9	0.92	84	-2.0	1.01	84	0.7	0.82	84	-2.0	1.00	84	0.7	0.89	84	-1.7	1.03
	Week 16	5 mg BID	43	1.0	1.07	43	-2.1	1.10	43	0.7	0.89	43	-2.1	1.01	43	0.8	0.92	43	-1.6	0.96
		10 mg BID	40	1.0	1.01	40	-2.0	1.07	40	0.7	0.85	40	-2.0	1.01	40	0.7	0.93	40	-1.8	1.09
		Total	83	1.0	1.03	83	-2.0	1.08	83	0.7	0.87	83	-2.0	1.01	83	0.7	0.92	83	-1.7	1.02
	Week 20	5 mg BID	43	0.9	0.99	43	-2.2	1.04	43	0.7	0.89	43	-2.1	1.01	43	0.6	0.85	43	-1.7	0.93
		10 mg BID	39	0.9	0.92	39	-2.1	1.04	39	0.8	0.90	39	-1.9	1.07	39	0.7	0.83	39	-1.8	1.05
		Total	82	0.9	0.95	82	-2.1	1.04	82	0.7	0.89	82	-2.0	1.04	82	0.7	0.83	82	-1.8	0.99
	Week 28	5 mg BID	43	0.9	0.96	43	-2.1	1.13	43	0.7	0.83	43	-2.0	1.12	43	0.7	0.78	43	-1.7	0.99
		10 mg BID	39	0.9	0.98	39	-2.0	0.99	39	0.8	1.05	39	-1.8	1.16	39	0.8	0.93	39	-1.8	1.11
		Total	82	0.9	0.96	82	-2.1	1.06	82	0.8	0.93	82	-1.9	1.14	82	0.7	0.85	82	-1.7	1.05
	Week 40	5 mg BID	41	0.9	1.00	41	-2.1	1.04	41	0.8	1.03	41	-1.9	1.26	41	0.7	0.88	41	-1.7	0.93
		10 mg BID	38	0.7	0.79	38	-2.2	0.87	38	0.6	0.72	38	-2.1	0.93	38	0.6	0.82	38	-1.9	1.03
		Total	79	0.8	0.91	79	-2.2	0.95	79	0.7	0.89	79	-2.0	1.11	79	0.6	0.85	79	-1.8	0.98
	Week 52	5 mg BID	39	0.9	1.02	39	-2.2	1.01	39	0.8	1.14	39	-1.8	1.39	39	0.7	0.92	39	-1.6	0.96
		10 mg BID	32	0.7	0.81	32	-2.2	0.93	32	0.5	0.76	32	-2.1	1.03	32	0.6	0.80	32	-1.9	1.01
		Total	71	0.8	0.93	71	-2.2	0.97	71	0.7	0.99	71	-2.0	1.24	71	0.6	0.87	71	-1.7	0.98
	Follow-up	5 mg BID	32	1.4	1.27	32	-1.6	1.13	32	1.3	1.34	32	-1.5	1.41	32	1.0	1.06	32	-1.2	1.01
		10 mg BID	30	1.1	1.07	30	-1.8	1.14	30	0.7	0.87	30	-1.9	1.12	30	0.9	0.98	30	-1.5	1.14
		Total	62	1.3	1.18	62	-1.7	1.13	62	1.0	1.16	62	-1.7	1.29	62	1.0	1.02	62	-1.4	1.07
Lower	Baseline	5 mg BID	43	3.1	0.66	-	-	-	43	2.9	0.68	-	-	-	43	2.5	0.88	-	-	-

Table 7. Descriptive Statistics of PASI Component Score During Study (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Body region	Visit	CP-690,550 [a]	Erythema						Induration						Scaling					
			Actual value			Change from baseline			Actual value			Change from baseline			Actual value			Change from baseline		
			N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD
limbs		10 mg BID	44	3.0	0.70	-	-	-	44	2.7	0.73	-	-	-	44	2.7	0.71	-	-	-
		Total	87	3.0	0.68	-	-	-	87	2.8	0.71	-	-	-	87	2.6	0.80	-	-	-
	Week 2	5 mg BID	43	2.5	0.85	43	-0.7	0.69	43	2.4	0.76	43	-0.5	0.67	43	2.1	1.00	43	-0.4	0.70
		10 mg BID	44	2.2	0.88	44	-0.8	0.71	44	2.0	0.90	44	-0.7	0.71	44	2.0	0.88	44	-0.7	0.73
		Total	87	2.3	0.87	87	-0.7	0.70	87	2.2	0.85	87	-0.6	0.69	87	2.0	0.93	87	-0.6	0.73
	Week 4	5 mg BID	43	2.0	1.02	43	-1.1	0.91	43	1.8	0.85	43	-1.0	0.90	43	1.7	1.00	43	-0.8	0.72
		10 mg BID	44	1.8	1.03	44	-1.2	0.79	44	1.5	1.09	44	-1.2	0.98	44	1.3	1.01	44	-1.3	0.96
		Total	87	1.9	1.03	87	-1.2	0.85	87	1.7	0.99	87	-1.1	0.94	87	1.5	1.02	87	-1.1	0.89
	Week 8	5 mg BID	43	1.6	0.93	43	-1.5	0.91	43	1.3	0.88	43	-1.6	0.91	43	1.3	0.85	43	-1.3	0.82
		10 mg BID	41	1.2	0.86	41	-1.7	0.91	41	1.0	0.89	41	-1.7	0.98	41	0.9	0.93	41	-1.8	0.88
		Total	84	1.4	0.91	84	-1.6	0.91	84	1.1	0.90	84	-1.7	0.94	84	1.1	0.90	84	-1.5	0.88
	Week 12	5 mg BID	43	1.2	0.94	43	-1.9	0.92	43	0.9	0.88	43	-1.9	0.91	43	1.0	0.87	43	-1.5	0.85
		10 mg BID	41	1.0	0.89	41	-1.9	0.94	41	0.8	0.89	41	-1.9	1.06	41	0.8	0.92	41	-1.9	1.00
		Total	84	1.1	0.92	84	-1.9	0.92	84	0.8	0.88	84	-1.9	0.98	84	0.9	0.90	84	-1.7	0.95
	Week 16	5 mg BID	43	1.1	1.01	43	-2.0	1.03	43	0.8	0.90	43	-2.1	0.95	43	1.0	0.97	43	-1.6	0.93
		10 mg BID	40	1.0	1.00	40	-1.9	0.94	40	0.8	0.93	40	-2.0	1.08	40	0.8	1.03	40	-1.8	1.06
		Total	83	1.1	1.00	83	-2.0	0.99	83	0.8	0.91	83	-2.0	1.01	83	0.9	1.00	83	-1.7	1.00
	Week 20	5 mg BID	43	1.0	1.06	43	-2.1	1.04	43	0.7	0.89	43	-2.2	0.95	43	0.8	1.00	43	-1.7	0.92
		10 mg BID	39	0.8	0.93	39	-2.1	1.09	39	0.7	0.86	39	-2.0	1.06	39	0.8	1.05	39	-1.8	1.16
		Total	82	0.9	1.00	82	-2.1	1.05	82	0.7	0.87	82	-2.1	1.00	82	0.8	1.02	82	-1.8	1.04
	Week 28	5 mg BID	43	0.9	0.99	43	-2.3	1.05	43	0.7	0.84	43	-2.2	1.03	43	0.7	0.90	43	-1.8	1.09
		10 mg BID	39	1.0	1.01	39	-1.9	0.99	39	0.9	0.99	39	-1.8	1.14	39	0.9	1.00	39	-1.7	1.02
		Total	82	0.9	1.00	82	-2.1	1.03	82	0.8	0.92	82	-2.0	1.09	82	0.8	0.95	82	-1.7	1.05
	Week 40	5 mg BID	41	0.7	0.87	41	-2.4	1.05	41	0.7	0.94	41	-2.2	1.14	41	0.7	0.76	41	-1.9	1.11
		10 mg BID	38	0.9	0.94	38	-2.0	1.03	38	0.8	0.90	38	-1.9	1.03	38	0.8	1.00	38	-1.8	1.06

Table 7. Descriptive Statistics of PASI Component Score During Study (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Body region	Visit	CP-690,550 [a]	Erythema						Induration						Scaling					
			Actual value			Change from baseline			Actual value			Change from baseline			Actual value			Change from baseline		
			N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD
		Total	79	0.8	0.91	79	-2.2	1.05	79	0.7	0.92	79	-2.1	1.10	79	0.7	0.88	79	-1.8	1.08
	Week 52	5 mg BID	39	1.1	1.07	39	-2.1	1.11	39	0.8	1.02	39	-2.0	1.29	39	0.8	0.90	39	-1.7	1.15
		10 mg BID	32	0.7	0.82	32	-2.2	0.94	32	0.5	0.76	32	-2.2	0.97	32	0.6	0.88	32	-2.0	1.03
		Total	71	0.9	0.98	71	-2.1	1.03	71	0.7	0.92	71	-2.1	1.15	71	0.7	0.89	71	-1.8	1.10
	Follow-up	5 mg BID	32	1.4	1.34	32	-1.7	1.28	32	1.1	1.15	32	-1.7	1.28	32	1.0	1.03	32	-1.4	1.13
		10 mg BID	30	1.2	1.01	30	-1.7	1.12	30	0.8	0.92	30	-1.9	1.09	30	0.9	0.99	30	-1.7	1.03
		Total	62	1.3	1.18	62	-1.7	1.20	62	1.0	1.05	62	-1.8	1.19	62	0.9	1.01	62	-1.5	1.08

Abbreviations: BID = twice daily, N = number of subjects, PASI = Psoriasis Area and Severity Index, SD = standard deviation.

a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

PGA Category (observed case) is presented in Table 8.

At Week 16, the proportion of subjects achieving a PGA response of "Clear" for the moderate to severe plaque psoriasis population (NRI) was higher in CP-690,550 10 mg BID group (36.4% [16/44 subjects]) than that in CP-690,550 5 mg BID group (27.9% [12/43 subjects]); that for the moderate to severe plaque psoriasis population (observed case) was also higher in CP-690,550 10 mg BID group (40.0% [16/40 subjects]) than that in CP-690,550 5 mg BID group (27.9% [12/43 subjects]).

At Week 52, the proportion of subjects achieving a PGA response of "Clear" for the moderate to severe plaque psoriasis population (NRI) was 37.2% (16/43 subjects) and 31.8% (14/44 subjects) in the treatment sequences of the subjects who started with CP-690,550 5 mg BID and 10 mg BID, respectively; that for the moderate to severe plaque psoriasis population (observed case) was 41.0% (16/39 subjects) and 43.8% (14/32 subjects) in the treatment sequences of the subjects who started with CP-690,550 5 mg BID and 10 mg BID, respectively.

Median time to PGA response of "Clear" or "Almost Clear" was 8.0 weeks (95%CI: 8.0, 12.0) and 8.0 weeks (95%CI: 4.0, 12.0) in CP-690,550 5 mg BID and 10 mg BID group in the moderate to severe plaque psoriasis population (observed case), respectively.

The PGA response of "Clear" or "Almost Clear" among subjects who had PGA response of "Clear" or "Almost Clear" at Week 16 was maintained through Week 52 in the treatment sequences of the subjects who started with CP-690,550 5 mg BID (65.5%, 19/29 subjects) and 10 mg BID (60.0%, 18/30 subjects) in the moderate to severe plaque psoriasis population (NRI).

Table 8. PGA Category (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Visit	PGA Category	CP-690,550 [a]		
		5 mg BID n (%)	10 mg BID n (%)	Total n (%)
Baseline	Clear	0	0	0
	Almost Clear	0	0	0
	Mild	0	0	0
	Moderate	34 (79.1)	37 (84.1)	71 (81.6)
	Severe	9 (20.9)	7 (15.9)	16 (18.4)
	N (Total)	43	44	87
Week 2	Clear	0	0	0
	Almost Clear	3 (7.0)	7 (15.9)	10 (11.5)
	Mild	17 (39.5)	19 (43.2)	36 (41.4)
	Moderate	20 (46.5)	15 (34.1)	35 (40.2)
	Severe	3 (7.0)	3 (6.8)	6 (6.9)
	N (Total)	43	44	87
Week 4	Clear	0	5 (11.4)	5 (5.7)
	Almost Clear	13 (30.2)	12 (27.3)	25 (28.7)
	Mild	19 (44.2)	18 (40.9)	37 (42.5)
	Moderate	8 (18.6)	9 (20.5)	17 (19.5)
	Severe	3 (7.0)	0	3 (3.4)
	N (Total)	43	44	87
Week 8	Clear	3 (7.0)	11 (26.8)	14 (16.7)
	Almost Clear	22 (51.2)	16 (39.0)	38 (45.2)
	Mild	12 (27.9)	10 (24.4)	22 (26.2)
	Moderate	6 (14.0)	4 (9.8)	10 (11.9)
	Severe	0	0	0
	N (Total)	43	41	84
Week 12	Clear	6 (14.0)	15 (36.6)	21 (25.0)
	Almost Clear	25 (58.1)	18 (43.9)	43 (51.2)
	Mild	9 (20.9)	4 (9.8)	13 (15.5)
	Moderate	3 (7.0)	4 (9.8)	7 (8.3)
	Severe	0	0	0
	N (Total)	43	41	84
Week 16	Clear	12 (27.9)	16 (40.0)	28 (33.7)
	Almost Clear	17 (39.5)	14 (35.0)	31 (37.3)
	Mild	11 (25.6)	7 (17.5)	18 (21.7)
	Moderate	3 (7.0)	2 (5.0)	5 (6.0)
	Severe	0	1 (2.5)	1 (1.2)
	N (Total)	43	40	83
Week 20	Clear	12 (27.9)	15 (38.5)	27 (32.9)
	Almost Clear	19 (44.2)	11 (28.2)	30 (36.6)
	Mild	8 (18.6)	10 (25.6)	18 (22.0)
	Moderate	4 (9.3)	3 (7.7)	7 (8.5)
	Severe	0	0	0
	N (Total)	43	39	82
Week 28	Clear	16 (37.2)	13 (33.3)	29 (35.4)
	Almost Clear	13 (30.2)	11 (28.2)	24 (29.3)
	Mild	12 (27.9)	12 (30.8)	24 (29.3)
	Moderate	2 (4.7)	3 (7.7)	5 (6.1)
	Severe	0	0	0
	N (Total)	43	39	82
Week 40	Clear	18 (43.9)	13 (34.2)	31 (39.2)

Table 8. PGA Category (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Visit	PGA Category	CP-690,550 [a]		
		5 mg BID n (%)	10 mg BID n (%)	Total n (%)
	Almost Clear	11 (26.8)	11 (28.9)	22 (27.8)
	Mild	10 (24.4)	11 (28.9)	21 (26.6)
	Moderate	2 (4.9)	3 (7.9)	5 (6.3)
	Severe	0	0	0
	N (Total)	41	38	79
Week 52	Clear	16 (41.0)	14 (43.8)	30 (42.3)
	Almost Clear	9 (23.1)	11 (34.4)	20 (28.2)
	Mild	12 (30.8)	6 (18.8)	18 (25.4)
	Moderate	2 (5.1)	1 (3.1)	3 (4.2)
	Severe	0	0	0
	N (Total)	39	32	71
Follow-up	Clear	11 (34.4)	5 (16.7)	16 (25.8)
	Almost Clear	5 (15.6)	14 (46.7)	19 (30.6)
	Mild	7 (21.9)	8 (26.7)	15 (24.2)
	Moderate	9 (28.1)	3 (10.0)	12 (19.4)
	Severe	0	0	0
	N (Total)	32	30	62

Abbreviations: BID = twice daily, N = number of subjects, n = number of subjects meeting prespecified criteria, PGA = Physician Global Assessment.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Mean change from baseline in NAPSI score in subjects with baseline nail psoriasis is presented in Table 9. The number of affected nails is presented in Table 10.

The proportion of subjects achieving at least a 75% reduction in NAPSI relative to baseline (NAPSI75 response) was similar in both CP-690,550 5 mg BID group (15.6% [5/32 subjects]) and 10 mg BID group (16.7% [5/30 subjects]) at Week 16. The proportion of subjects achieving a NAPSI75 response at Week 52 was 59.4% (19/32 subjects) and 56.7% (17/30 subjects) in the treatment sequences of subjects who started with CP-690,550 5 mg BID and 10 mg BID in the moderate to severe plaque psoriasis population (NRI), respectively.

The proportion of subjects achieving at least a 100% reduction in NAPSI relative to baseline (NAPSI100 response) was similar in both CP-690,550 5 mg BID group 6.3% (2/32 subjects) and 6.7% (2/30 subjects) at Week 16. The proportion of subjects achieving a NAPSI100 response at Week 52 was 40.6% (13/32 subjects) and 33.3% (10/30 subjects) in the treatment sequences of subjects who started with CP-690,550 5 mg BID and 10 mg BID in the moderate to severe plaque psoriasis population (NRI), respectively.

Table 9. Descriptive Statistics of Change from Baseline NAPSI Score in Subjects with Baseline Nail Psoriasis (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Visit	CP-690,550 [a]		
	5 mg BID	10 mg BID	Total
Baseline			
N	32	30	62
Mean (SD)	29.5 (21.10)	24.0 (18.02)	26.8 (19.71)
Week 8 (Change from Baseline)			
N	32	28	60
Mean (SD)	-3.3 (9.63)	-1.8 (7.72)	-2.6 (8.75)
Week 16 (Change from Baseline)			
N	32	28	60
Mean (SD)	-11.2 (15.27)	-9.4 (12.66)	-10.4 (14.02)
Week 20 (Change from Baseline)			
N	32	27	59
Mean (SD)	-15.0 (15.29)	-14.1 (13.03)	-14.6 (14.18)
Week 28 (Change from Baseline)			
N	32	27	59
Mean (SD)	-21.1 (15.83)	-16.4 (15.27)	-18.9 (15.62)
Week 40 (Change from Baseline)			
N	31	26	57
Mean (SD)	-22.2 (16.18)	-16.2 (14.13)	-19.5 (15.45)
Week 52 (Change from Baseline)			
N	30	22	52
Mean (SD)	-20.6 (15.16)	-16.2 (15.62)	-18.7 (15.36)

Abbreviations: BID = twice daily, N = number of subjects, NAPSI = Nail Psoriasis Severity Index, SD = standard deviation.

a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Table 10. Number of Affected Nails (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Visit	CP-690,550 [a]		
	5 mg BID	10 mg BID	Total
Baseline			
N	32	30	62
Mean (SD)	7.94 (2.82)	7.13 (3.07)	7.55 (2.95)
Week 8			
N	32	28	60
Mean (SD)	7.66 (3.17)	7.11 (3.02)	7.40 (3.09)
Week 16			
N	32	28	60
Mean (SD)	6.91 (3.43)	5.75 (3.56)	6.37 (3.51)
Week 20			
N	32	27	59
Mean (SD)	6.16 (3.60)	4.59 (4.02)	5.44 (3.85)
Week 28			
N	32	27	59
Mean (SD)	4.53 (3.87)	3.59 (3.96)	4.10 (3.91)
Week 40			
N	31	26	57
Mean (SD)	3.32 (3.94)	3.77 (3.81)	3.53 (3.85)
Week 52			
N	30	22	52
Mean (SD)	3.73 (4.25)	2.50 (3.07)	3.21 (3.81)

Abbreviations: BID = twice daily, N = number of subjects, SD = standard deviation.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Proportions of subjects achieving an ACR20, ACR50 and ACR70 response are presented in Table 11.

Table 11. Proportion of Subjects Achieving ACR20, ACR50 and ACR70 Response (Psoriatic Arthritis Population, NRI)

Endpoint	Visit	CP-690,550 [a]	Response		
			N	n (%)	SE
ACR20	Week 2	5 mg BID	4	0 (0.0)	0.000
		10 mg BID	8	5 (62.5)	17.116
		Total	12	5 (41.7)	14.232
	Week 4	5 mg BID	4	2 (50.0)	25.000
		10 mg BID	8	6 (75.0)	15.309
		Total	12	8 (66.7)	13.608
	Week 8	5 mg BID	4	3 (75.0)	21.651
		10 mg BID	8	8 (100)	0.000
		Total	12	11 (91.7)	7.979
	Week 12	5 mg BID	4	4 (100)	0.000
		10 mg BID	8	7 (87.5)	11.693
		Total	12	11 (91.7)	7.979
	Week 16	5 mg BID	4	4 (100)	0.000
		10 mg BID	8	8 (100)	0.000
		Total	12	12 (100)	0.000
	Week 20	5 mg BID	4	4 (100)	0.000
		10 mg BID	8	7 (87.5)	11.693
		Total	12	11 (91.7)	7.979
	Week 28	5 mg BID	4	4 (100)	0.000
		10 mg BID	8	8 (100)	0.000
		Total	12	12 (100)	0.000
	Week 40	5 mg BID	4	3 (75.0)	21.651
		10 mg BID	8	8 (100)	0.000
		Total	12	11 (91.7)	7.979
	Week 52	5 mg BID	4	2 (50.0)	25.000
		10 mg BID	8	8 (100)	0.000
		Total	12	10 (83.3)	10.758
	Follow-up	5 mg BID	4	1 (25.0)	21.651
		10 mg BID	8	6 (75.0)	15.309
		Total	12	7 (58.3)	14.232
ACR50	Week 2	5 mg BID	4	0 (0.0)	0.000
		10 mg BID	8	2 (25.0)	15.309
		Total	12	2 (16.7)	10.758
	Week 4	5 mg BID	4	1 (25.0)	21.651
		10 mg BID	8	4 (50.0)	17.678
		Total	12	5 (41.7)	14.232
	Week 8	5 mg BID	4	2 (50.0)	25.000
		10 mg BID	8	5 (62.5)	17.116
		Total	12	7 (58.3)	14.232
	Week 12	5 mg BID	4	3 (75.0)	21.651
		10 mg BID	8	6 (75.0)	15.309
		Total	12	9 (75.0)	12.500
	Week 16	5 mg BID	4	3 (75.0)	21.651
		10 mg BID	8	7 (87.5)	11.693
		Total	12	10 (83.3)	10.758
	Week 20	5 mg BID	4	4 (100)	0.000
		10 mg BID	8	7 (87.5)	11.693
		Total	12	11 (91.7)	7.979
	Week 28	5 mg BID	4	4 (100)	0.000
		10 mg BID	8	6 (75.0)	15.309

Table 11. Proportion of Subjects Achieving ACR20, ACR50 and ACR70 Response (Psoriatic Arthritis Population, NRI)

Endpoint	Visit	CP-690,550 [a]	Response		
			N	n (%)	SE
		Total	12	10 (83.3)	10.758
	Week 40	5 mg BID	4	3 (75.0)	21.651
		10 mg BID	8	7 (87.5)	11.693
		Total	12	10 (83.3)	10.758
	Week 52	5 mg BID	4	2 (50.0)	25.000
		10 mg BID	8	7 (87.5)	11.693
		Total	12	9 (75.0)	12.500
	Follow-up	5 mg BID	4	1 (25.0)	21.651
		10 mg BID	8	4 (50.0)	17.678
		Total	12	5 (41.7)	14.232
ACR70	Week 2	5 mg BID	4	0 (0.0)	0.000
		10 mg BID	8	0 (0.0)	0.000
		Total	12	0 (0.0)	0.000
	Week 4	5 mg BID	4	0 (0.0)	0.000
		10 mg BID	8	3 (37.5)	17.116
		Total	12	3 (25.0)	12.500
	Week 8	5 mg BID	4	1 (25.0)	21.651
		10 mg BID	8	5 (62.5)	17.116
		Total	12	6 (50.0)	14.434
	Week 12	5 mg BID	4	2 (50.0)	25.000
		10 mg BID	8	5 (62.5)	17.116
		Total	12	7 (58.3)	14.232
	Week 16	5 mg BID	4	2 (50.0)	25.000
		10 mg BID	8	5 (62.5)	17.116
		Total	12	7 (58.3)	14.232
	Week 20	5 mg BID	4	3 (75.0)	21.651
		10 mg BID	8	6 (75.0)	15.309
		Total	12	9 (75.0)	12.500
	Week 28	5 mg BID	4	3 (75.0)	21.651
		10 mg BID	8	4 (50.0)	17.678
		Total	12	7 (58.3)	14.232
	Week 40	5 mg BID	4	2 (50.0)	25.000
		10 mg BID	8	6 (75.0)	15.309
		Total	12	8 (66.7)	13.608
	Week 52	5 mg BID	4	2 (66.7)	25.000
		10 mg BID	8	6 (75.0)	15.309
		Total	12	8 (72.7)	13.608
	Follow-up	5 mg BID	4	0 (0.0)	0.000
		10 mg BID	8	4 (57.1)	17.678
		Total	12	4 (50.0)	13.608

Abbreviations: ACR = American College of Rheumatology, BID = twice daily, N = number of subjects, n = number of subjects meeting prespecified criteria, NRI = non-responder imputation, SE = standard error.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Descriptive statistics of HAQ-DI is presented in Table 12.

Table 12. Descriptive Statistics of HAQ-DI (Psoriatic Arthritis Population, Observed Case)

Visit	Actual value			Change from baseline		
	CP-690,550 [a]		Total	CP-690,550 [a]		Total
	5 mg BID	10 mg BID		5 mg BID	10 mg BID	
Baseline						
N	4	8	12			
Mean (SD)	0.63 (0.829)	0.44 (0.417)	0.50 (0.554)			
Week 2						
N	4	8	12	4	8	12
Mean (SD)	0.44 (0.591)	0.16 (0.257)	0.25 (0.395)	-0.19 (0.239)	-0.28 (0.376)	-0.25 (0.329)
Week 4						
N	4	8	12	4	8	12
Mean (SD)	0.34 (0.534)	0.08 (0.115)	0.17 (0.321)	-0.28 (0.329)	-0.36 (0.381)	-0.33 (0.351)
Week 8						
N	4	8	12	4	8	12
Mean (SD)	0.34 (0.688)	0.02 (0.044)	0.13 (0.395)	-0.28 (0.359)	-0.42 (0.433)	-0.38 (0.399)
Week 12						
N	4	8	12	4	8	12
Mean (SD)	0.34 (0.688)	0.02 (0.044)	0.13 (0.395)	-0.28 (0.359)	-0.42 (0.433)	-0.38 (0.399)
Week 16						
N	4	8	12	4	8	12
Mean (SD)	0.31 (0.625)	0.02 (0.044)	0.11 (0.359)	-0.31 (0.375)	-0.42 (0.433)	-0.39 (0.400)
Week 20						
N	4	8	12	4	8	12
Mean (SD)	0.34 (0.688)	0.02 (0.044)	0.13 (0.395)	-0.28 (0.359)	-0.42 (0.433)	-0.38 (0.399)
Week 28						
N	4	8	12	4	8	12
Mean (SD)	0.28 (0.563)	0.02 (0.044)	0.10 (0.323)	-0.34 (0.400)	-0.42 (0.433)	-0.40 (0.405)
Week 40						
N	4	8	12	4	8	12
Mean (SD)	0.53 (0.664)	0.02 (0.044)	0.19 (0.431)	-0.09 (0.640)	-0.42 (0.433)	-0.31 (0.507)
Week 52						
N	3	8	11	3	8	11
Mean (SD)	0.13 (0.217)	0.02 (0.044)	0.05 (0.116)	-0.13 (0.573)	-0.42 (0.433)	-0.34 (0.465)
Follow-up						
N	1	7	8	1	7	8
Mean (SD)	0.00 (-)	0.04 (0.061)	0.03 (0.058)	-0.75 (-)	-0.46 (0.400)	-0.50 (0.384)

Abbreviations: BID = twice daily, HAQ-DI = Health Assessment Questionnaire - Disability Index, N = number of subjects, SD = standard deviation.

a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Change from baseline in ACR components in psoriatic arthritis population is presented in Table 13.

Table 13. Descriptive Statistics of Change From Baseline in ACR Components (Psoriatic Arthritis Population, Observed Case)

ACR Component	Visit	CP-690,550 [a]		Total
		5 mg BID	10 mg BID	
Tender / Painful Joint Count	Baseline			
	N	4	8	12
	Mean (SD)	15.0 (9.31)	15.0 (11.92)	15.0 (10.68)
	Week 2			
	N	4	8	12
	Mean (SD)	-1.8 (1.50)	-3.5 (2.78)	-2.9 (2.50)
	Week 4			
	N	4	8	12
	Mean (SD)	-6.3 (6.70)	-9.3 (11.37)	-8.3(9.84)
	Week 8			
	N	4	8	12
	Mean (SD)	-11.5 (10.08)	-11.6 (10.24)	-11.6 (9.72)
	Week 12			
	N	4	8	12
	Mean (SD)	-13.8 (10.78)	-12.5 (11.95)	-12.9 (11.09)
	Week 16			
	N	4	8	12
	Mean (SD)	-13.0 (9.59)	-13.0 (12.17)	-13.0 (10.92)
	Week 20			
	N	4	8	12
	Mean (SD)	-14.3 (9.11)	-12.4 (12.87)	-13.0 (11.35)
	Week 28			
	N	4	8	12
	Mean (SD)	-14.0 (9.38)	-12.4 (12.52)	-12.9 (11.16)
	Week 40			
	N	4	8	12
	Mean (SD)	-14.3 (10.14)	-13.4 (12.09)	-13.7 (11.02)
	Week 52			
	N	3	8	11
	Mean (SD)	-11.3 (9.24)	-13.5 (12.08)	-12.9 (10.97)
	Follow-up			
	N	1	7	8
	Mean (SD)	-20.0 (-)	-13.6 (12.55)	-14.4 (11.84)
Swollen Joint Count	Baseline			
	N	4	8	12
	Mean (SD)	7.8 (7.63)	10.1 (4.88)	9.3 (5.69)
	Week 2			
	N	4	8	12
	Mean (SD)	-1.8 (2.22)	-3.8 (5.55)	-3.1 (4.68)
	Week 4			
	N	4	8	12
	Mean (SD)	-5.0 (4.69)	-5.3 (5.80)	-5.2 (5.24)
	Week 8			
	N	4	8	12
	Mean (SD)	-6.0 (7.35)	-6.4 (4.37)	-6.3 (5.19)
	Week 12			
	N	4	8	12
	Mean (SD)	-6.5 (6.35)	-7.0 (4.44)	-6.8 (4.86)
	Week 16			
	N	4	8	12

Table 13. Descriptive Statistics of Change From Baseline in ACR Components (Psoriatic Arthritis Population, Observed Case)

ACR Component	Visit	CP-690,550 [a]		Total
		5 mg BID	10 mg BID	
	Mean (SD)	-7.3 (7.85)	-7.8 (3.85)	-7.6 (5.12)
	Week 20			
	N	4	8	12
	Mean (SD)	-7.0 (8.00)	-8.9 (4.42)	-8.3 (5.55)
	Week 28			
	N	4	8	12
	Mean (SD)	-7.3 (7.85)	-7.6 (4.03)	-7.5 (5.21)
	Week 40			
	N	4	8	12
	Mean (SD)	-7.3 (7.85)	-8.8 (4.20)	-8.3 (5.34)
	Week 52			
	N	3	8	11
	Mean (SD)	-3.0 (0.00)	-8.8 (4.13)	-7.2 (4.38)
	Follow-up			
	N	1	7	8
	Mean (SD)	-2.0 (-)	-7.7 (6.26)	-7.0 (6.14)
Patient Global Assessment of Arthritis (VAS)	Baseline			
	N	4	8	12
	Mean (SD)	58.8 (16.52)	57.3 (21.08)	57.8 (18.91)
	Week 2			
	N	4	8	12
	Mean (SD)	-8.0 (8.87)	-32.6 (27.55)	-24.4 (25.53)
	Week 4			
	N	4	8	12
	Mean (SD)	-20.5 (11.27)	-43.4 (27.47)	-35.8 (25.33)
	Week 8			
	N	4	8	12
	Mean (SD)	-23.3 (19.69)	-51.3 (20.53)	-41.9 (23.75)
	Week 12			
	N	4	8	12
	Mean (SD)	-45.0 (8.83)	-52.1 (21.35)	-49.8 (17.99)
	Week 16			
	N	4	8	12
	Mean (SD)	-40.0 (13.64)	-53.0 (20.96)	-48.7 (19.27)
	Week 20			
	N	4	8	12
	Mean (SD)	-49.5 (20.09)	-49.6 (20.26)	-49.6 (19.27)
	Week 28			
	N	4	8	12
	Mean (SD)	-52.3 (11.18)	-46.3 (26.67)	-48.3 (22.26)
	Week 40			
	N	4	8	12
	Mean (SD)	-20.8 (30.24)	-50.8 (20.78)	-40.8 (27.24)
	Week 52			
	N	3	8	11
	Mean (SD)	-40.7 (16.80)	-55.3 (20.51)	-51.3 (19.94)
	Follow-up			
	N	1	7	8
	Mean (SD)	-54.0 (-)	-43.6 (23.13)	-44.9 (21.73)

Table 13. Descriptive Statistics of Change From Baseline in ACR Components (Psoriatic Arthritis Population, Observed Case)

ACR Component	Visit	CP-690,550 [a]		Total
		5 mg BID	10 mg BID	
Physician Global Assessment of Arthritis (VAS)	Baseline			
	N	4	8	12
	Mean (SD)	57.0 (25.70)	56.9 (15.71)	56.9 (18.36)
	Week 2			
	N	4	8	12
	Mean (SD)	-15.3 (18.01)	-28.5 (18.60)	-24.1 (18.74)
	Week 4			
	N	4	8	12
	Mean (SD)	-32.5 (22.28)	-34.6 (19.39)	-33.9 (19.38)
	Week 8			
	N	4	8	12
	Mean (SD)	-29.5 (30.01)	-41.8 (21.87)	-37.7 (24.21)
	Week 12			
	N	4	8	12
	Mean (SD)	-39.8 (21.00)	-45.8 (22.76)	-43.8 (21.42)
	Week 16			
	N	4	8	12
	Mean (SD)	-49.8 (23.34)	-47.9 (20.09)	-48.5 (20.16)
	Week 20			
	N	4	8	12
	Mean (SD)	-50.8 (25.29)	-45.3 (26.81)	-47.1 (25.28)
	Week 28			
	N	4	8	12
	Mean (SD)	-49.5 (25.96)	-42.8 (22.79)	-45.0 (22.92)
	Week 40			
	N	4	8	12
	Mean (SD)	-38.5 (39.03)	-49.5 (18.54)	-45.8 (25.76)
	Week 52			
	N	3	8	11
	Mean (SD)	-29.0 (20.30)	-46.8 (25.08)	-41.9 (24.32)
	Follow-up			
	N	1	7	8
	Mean (SD)	-44.0 (-)	-37.7 (22.79)	-38.5 (21.22)
Patient Assessment of Arthritis Pain (VAS)	Baseline			
	N	4	8	12
	Mean (SD)	51.3 (24.19)	50.6 (23.71)	50.8 (22.74)
	Week 2			
	N	4	8	12
	Mean (SD)	-13.3 (8.30)	-29.5 (23.40)	-24.1 (20.77)
	Week 4			
	N	4	8	12
	Mean (SD)	-13.0 (23.41)	-41.4 (25.29)	-31.9 (27.42)
	Week 8			
	N	4	8	12
	Mean (SD)	-16.0 (19.78)	-43.6 (22.68)	-34.4 (24.88)
	Week 12			
	N	4	8	12
	Mean (SD)	-34.5 (19.71)	-46.0 (23.42)	-42.2 (22.07)
	Week 16			
	N	4	8	12

Table 13. Descriptive Statistics of Change From Baseline in ACR Components (Psoriatic Arthritis Population, Observed Case)

ACR Component	Visit	CP-690,550 [a]		Total
		5 mg BID	10 mg BID	
	Mean (SD)	-27.3 (15.22)	-46.0 (22.44)	-39.8 (21.65)
	Week 20			
	N	4	8	12
	Mean (SD)	-44.0 (22.82)	-45.3 (21.53)	-44.8 (20.91)
	Week 28			
	N	4	8	12
	Mean (SD)	-45.8 23.26)	-45.8 (20.46)	-45.8 (20.34)
	Week 40			
	N	4	8	12
	Mean (SD)	-20.0 (54.86)	-46.9 (22.66)	-37.9 (36.37)
	Week 52			
	N	3	8	11
	Mean (SD)	-33.0 (31.19)	-48.4 (22.14)	-44.2 (24.28)
	Follow-up			
	N	1	7	8
	Mean (SD)	-45.0 (-)	-46.7 (22. 07)	-46.5 (20.45)
CRP (mg/dL)	Baseline			
	N	4	8	12
	Mean (SD)	1.33 (2.387)	1.75 (2.280)	1.61 (2.215)
	Week 2			
	N	4	8	12
	Mean (SD)	-1.20 (2.137)	-1.68 (2.231)	-1.52 (2.114)
	Week 4			
	N	4	8	12
	Mean (SD)	-1.20 (2.267)	-1.69 (2.272)	-1.53 (2.178)
	Week 8			
	N	4	8	12
	Mean (SD)	-1.28 (2.354)	-1.70 (2.222)	-1.56 (2.167)
	Week 12			
	N	4	8	12
	Mean (SD)	-1.28 (2.351)	-1.68 (2.235)	-1.54 (2.174)
	Week 16			
	N	4	8	12
	Mean (SD)	-1.30 (2.337)	-1.69 (2.189)	-1.56 (2.139)
	Week 20			
	N	4	8	12
	Mean (SD)	-1.33 (2.387)	-1.59 (2.336)	-1.50 (2.246)
	Week 28			
	N	4	8	12
	Mean (SD)	-1.30 (2.337)	-1.15 (2.770)	-1.20 (2.526)
	Week 40			
	N	4	7	11
	Mean (SD)	-1.15 (2.037)	-1.84 (2.461)	-1.59 (2.236)
	Week 52			
	N	3	8	11
	Mean (SD)	-0.03 (0.058)	-1.65 (2.295)	-1.21 (2.064)
	Follow-up			
	N	1	7	8
	Mean (SD)	0.10 (-)	-0.93 (1.237)	-0.80 (1.201)

Table 13. Descriptive Statistics of Change From Baseline in ACR Components (Psoriatic Arthritis Population, Observed Case)

ACR Component	Visit	CP-690,550 [a]		Total
		5 mg BID	10 mg BID	

Abbreviations: ACR = American College of Rheumatology, BID = twice daily, CRP = C-reactive protein, N = number of subjects, SD = standard deviation, VAS = visual analog scale.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Substantial burden of disease at baseline was observed with the PROs studied (ISI, DLQI, SF-36, and PtGA).

Descriptive statistics of ISI scores is presented in Table 14. An ISI score of '0' represents "no itching".

At Week 16, the proportion of subjects achieving an ISI score of '≤1' in subjects with ISI score >1 at baseline was 66.7% (28/42 subjects) and 68.3% (28/41 subjects) in the treatment sequences of the subjects who started with CP-690,550 5 mg BID and 10 mg BID in the moderate to severe plaque psoriasis population (NRI), respectively. At Week 52, the proportion of subjects achieving an ISI score of '≤1' in subjects with ISI score >1 at baseline was 69.0% (29/42 subjects) and 51.2% (21/41 subjects) in the treatment sequences of the subjects who started with CP-690,550 5 mg BID and 10 mg BID in the moderate to severe plaque psoriasis population (NRI), respectively.

Table 14. Descriptive Statistics of ISI Scores (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Visit	CP-690,550 [a]		Total
	5 mg BID	10 mg BID	
Baseline			
N	43	44	87
Mean (SD)	6.16 (2.669)	5.32 (2.967)	5.74 (2.839)
Week 2			
N	43	44	87
Mean (SD)	5.19 (2.797)	3.30 (2.530)	4.23 (2.815)
Week 4			
N	43	44	87
Mean (SD)	3.65 (2.379)	2.27 (2.472)	2.95 (2.510)
Week 8			
N	43	41	84
Mean (SD)	2.26 (2.381)	1.22 (1.739)	1.75 (2.145)
Week 12			
N	43	41	84
Mean (SD)	1.77 (2.379)	1.20 (1.833)	1.49 (2.137)
Week 16			
N	43	40	83
Mean (SD)	1.67 (2.378)	0.90 (1.257)	1.30 (1.949)
Week 20			
N	43	39	82
Mean (SD)	0.95 (1.618)	1.28 (1.589)	1.11 (1.603)
Week 28			
N	43	39	82
Mean (SD)	1.12 (1.651)	1.62 (2.196)	1.35 (1.933)
Week 40			
N	41	38	79
Mean (SD)	0.90 (1.814)	1.13 (1.848)	1.01 (1.822)
Week 52			
N	39	32	71
Mean (SD)	1.15 (2.084)	0.91 (1.329)	1.04 (1.776)
Follow-up			
N	32	30	62
Mean (SD)	4.50 (3.162)	3.13 (3.192)	3.84 (3.225)

Abbreviations: BID = twice daily, ISI = Itch Severity Item, N = number of subjects, SD = standard deviation.

a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Descriptive statistics of DLQI is presented in Table 15. The DLQI total score of '0' or '1' represents no impact (of psoriasis) on quality of life.

At Week 16, the proportion of subjects achieving a DLQI total score ≤1 in subjects with DLQI total score >1 at baseline was 64.3% (27/42 subjects) and 56.1% (23/41 subjects) in the treatment sequences of the subjects who started with CP-690,550 5 mg BID and 10 mg BID in the moderate to severe plaque psoriasis population (NRI), respectively. At Week 52,

the proportion of subjects achieving a DLQI total score ≤1 in subjects with DLQI total score >1 at baseline was 61.9% (26/42 subjects) and 53.7% (22/41 subjects) in the treatment sequences of the subjects who started with CP-690,550 5 mg BID and 10 mg BID in the moderate to severe plaque psoriasis population (NRI), respectively.

Table 15. Descriptive Statistics of DLQI Total Score (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Visit	CP-690,550 [a]	N	Mean	SD
Baseline	5 mg BID	43	11.3	6.25
	10 mg BID	44	8.6	5.91
	Total	87	9.9	6.19
Week 2	5 mg BID	43	7.8	5.20
	10 mg BID	44	5.8	5.32
	Total	87	6.8	5.32
Week 4	5 mg BID	43	5.9	5.07
	10 mg BID	43	4.2	4.63
	Total	86	5.1	4.90
Week 8	5 mg BID	43	4.0	3.95
	10 mg BID	41	2.8	3.30
	Total	84	3.4	3.67
Week 12	5 mg BID	43	2.6	2.86
	10 mg BID	41	1.8	2.68
	Total	84	2.2	2.79
Week 16	5 mg BID	43	2.2	3.04
	10 mg BID	40	1.9	2.73
	Total	83	2.1	2.88
Week 20	5 mg BID	43	1.9	3.13
	10 mg BID	39	1.8	2.54
	Total	82	1.9	2.84
Week 28	5 mg BID	43	1.7	2.66
	10 mg BID	39	2.9	3.68
	Total	82	2.3	3.23
Week 40	5 mg BID	41	1.8	2.81
	10 mg BID	38	2.3	4.11
	Total	79	2.0	3.48
Week 52	5 mg BID	39	1.6	2.42
	10 mg BID	32	2.2	4.00
	Total	71	1.9	3.22

Abbreviations: BID = twice daily, DLQI = Dermatology Life Quality Index, N = number of subjects, SD = standard deviation.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Descriptive statistics of change from baseline in SF-36 domain score and component Summary score are presented in Table 16 and Table 17, respectively.

Table 16. Descriptive Statistics of Change From Baseline in SF-36 Domain Scores (Moderate to Severe Plaque Psoriasis Population, Observed Case)

SF-36 Domain	Visit	CP-690,550 [a]		Total
		5 mg BID	10 mg BID	
Physical functioning (PF)	Baseline			
	N	43	44	87
	Mean (SD)	53.304 (5.2950)	51.437 (9.2461)	52.360 (7.5710)
	Week 16			
	N	43	40	83
	Mean (SD)	1.951 (5.1880)	4.809 (9.1822)	3.329 (7.4800)
	Week 28			
	N	43	39	82
	Mean (SD)	1.571 (6.3446)	4.303 (10.3695)	2.870 (8.5558)
	Week 52			
	N	39	32	71
	Mean (SD)	2.151 (5.6134)	3.773 (7.3533)	2.882 (6.4585)
Role limitations due to physical problems (RP)	Baseline			
	N	43	44	87
	Mean (SD)	48.522 (10.0178)	50.170 (10.3125)	49.355 (10.1426)
	Week 16			
	N	43	40	83
	Mean (SD)	6.160 (9.3615)	5.130 (11.1600)	5.664 (10.2172)
	Week 28			
	N	43	39	82
	Mean (SD)	5.882 (10.6375)	5.017 (11.4671)	5.471 (10.9795)
	Week 52			
	N	39	32	71
	Mean (SD)	6.669 (10.0520)	4.623 (9.7340)	5.747 (9.8926)
Bodily pain (BP)	Baseline			
	N	43	44	87
	Mean (SD)	44.688 (11.9452)	46.542 (10.9753)	45.626 (11.4360)
	Week 16			
	N	43	40	83
	Mean (SD)	11.808 (13.8431)	10.663 (12.2936)	11.256 (13.0524)
	Week 28			
	N	43	39	82
	Mean (SD)	10.113 (15.9485)	8.394 (12.5405)	9.295 (14.3670)
	Week 52			
	N	39	32	71
	Mean (SD)	12.335 (12.1413)	10.673 (9.7128)	11.586 (11.0678)
General health perceptions (GH)	Baseline			
	N	43	44	87
	Mean (SD)	43.580 (7.3253)	42.266 (7.6749)	42.915 (7.4897)
	Week 16			
	N	43	40	83
	Mean (SD)	2.392 (7.0933)	4.333 (7.0145)	3.328 (7.0799)
	Week 28			
	N	43	39	82
	Mean (SD)	2.644 (5.9230)	3.517 (7.1375)	3.059 (6.5025)
	Week 52			
	N	39	32	71
	Mean (SD)	2.758 (6.0866)	4.888 (6.8235)	3.718 (6.4707)

Table 16. Descriptive Statistics of Change From Baseline in SF-36 Domain Scores (Moderate to Severe Plaque Psoriasis Population, Observed Case)

SF-36 Domain	Visit	CP-690,550 [a]		Total
		5 mg BID	10 mg BID	
Vitality (VT)	Baseline			
	N	43	44	87
	Mean (SD)	50.771 (9.3334)	49.913 (9.7007)	50.337 (9.4753)
	Week 16			
	N	43	40	83
	Mean (SD)	4.664 (9.5406)	3.517 (11.4421)	4.112 (10.4509)
	Week 28			
	N	43	39	82
	Mean (SD)	4.038 (10.0116)	3.608 (10.0742)	3.833 (9.9815)
	Week 52			
	N	39	32	71
	Mean (SD)	4.068 (10.5612)	5.052 (8.5160)	4.511 (9.6390)
Social functioning (SF)	Baseline			
	N	43	44	87
	Mean (SD)	47.024 (9.3947)	45.526 (12.0240)	46.266 (10.7685)
	Week 16			
	N	43	40	83
	Mean (SD)	7.629 (9.9734)	7.932 (8.8645)	7.775 (9.3992)
	Week 28			
	N	43	39	82
	Mean (SD)	6.628 (11.3068)	6.205 (10.4347)	6.427 (10.8358)
	Week 52			
	N	39	32	71
	Mean (SD)	8.411 (9.4598)	8.402 (9.2577)	8.407 (9.3024)
Role limitations due to emotional problems (RE)	Baseline			
	N	43	44	87
	Mean (SD)	45.466 (11.0693)	47.075 (11.8419)	46.279 (11.4285)
	Week 16			
	N	43	40	83
	Mean (SD)	7.219 (11.5898)	5.584 (11.5654)	6.431 (11.5365)
	Week 28			
	N	43	39	82
	Mean (SD)	7.395 (11.8846)	6.310 (12.9504)	6.879 (12.3375)
	Week 52			
	N	39	32	71
	Mean (SD)	8.445 (11.0018)	5.915 (10.3091)	7.305 (10.6949)
Mental health (MH)	Baseline			
	N	43	44	87
	Mean (SD)	43.909 (11.4542)	45.234 (11.6074)	44.579 (11.4840)
	Week 16			
	N	43	40	83
	Mean (SD)	5.928 (12.8757)	5.125 (13.3613)	5.541 (13.0378)
	Week 28			
	N	43	39	82
	Mean (SD)	6.701 (12.4375)	5.328 (12.8129)	6.048 (12.5580)
	Week 52			
	N	39	32	71
	Mean (SD)	7.317 (11.6243)	6.926 (12.6861)	7.141 (12.0276)

Table 16. Descriptive Statistics of Change From Baseline in SF-36 Domain Scores (Moderate to Severe Plaque Psoriasis Population, Observed Case)

SF-36 Domain	Visit	CP-690,550 [a]		Total
		5 mg BID	10 mg BID	
Health Transition (TR)	Baseline			
	N	43	44	87
	Mean (SD)	3.326 (0.8083)	3.386 (0.7538)	3.356 (0.7772)
	Week 16			
	N	43	40	83
	Mean (SD)	-0.372 (1.0006)	-0.425 (0.7808)	-0.398 (0.8963)
	Week 28			
	N	43	39	82
	Mean (SD)	-0.442 (1.0534)	-0.462 (0.8840)	-0.451 (0.9706)
	Week 52			
	N	39	32	71
	Mean (SD)	-0.385 (0.8771)	-0.375 (0.7513)	-0.380 (0.8171)

Abbreviations: BID = twice daily, SD = standard deviation, SF-36 = Short Form-36.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Table 17. Descriptive Statistics of Change From Baseline in SF-36 Component Summary Scores (Moderate to Severe Plaque Psoriasis Population, Observed Case)

SF-36 Domain	Visit	CP-690,550 [a]		Total
		5 mg BID	10 mg BID	
Physical Health Component Summary (PCS)	Baseline			
	N	43	44	87
	Mean (SD)	49.853 (6.2695)	49.286 (8.1790)	49.566 (7.2613)
	Week 16			
	N	43	40	83
	Mean (SD)	4.719 (6.6806)	6.146 (8.5192)	5.407 (7.6087)
	Week 28			
	N	43	39	82
	Mean (SD)	3.770 (7.7829)	4.799 (8.8893)	4.259 (8.2914)
	Week 52			
	N	39	32	71
	Mean (SD)	4.676 (5.7405)	5.250 (5.7614)	4.935 (5.7159)
Mental Health Component Summary (MCS)	Baseline			
	N	43	44	87
	Mean (SD)	44.494 (10.7413)	45.298 (11.3501)	44.901 (10.9965)
	Week 16			
	N	43	40	83
	Mean (SD)	6.767 (11.0945)	5.029 (11.4967)	5.929 (11.2548)
	Week 28			
	N	43	39	82
	Mean (SD)	7.085 (11.3660)	5.364 (10.9089)	6.266 (11.1159)
	Week 52			
	N	39	32	71
	Mean (SD)	7.878 (10.1983)	6.826 (10.5988)	7.404 (10.3192)

Abbreviations: BID = twice daily, N = number of subjects, SD = standard deviation, SF-36 = Short Form-36.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Descriptive statistics of change from baseline in WLQ is presented in Table 18.

Table 18. Descriptive Statistics of Change From Baseline in WLQ (Moderate to Severe Plaque Psoriasis Population, Observed Case)

	Visit	CP-690,550 [a]		
		5 mg BID	10 mg BID	Total
The Time Management Scale	Baseline			
	N	34	37	71
	Mean (SD)	44.49 (37.783)	42.36 (33.716)	43.38 (35.479)
	Week 4			
	N	31	35	66
	Mean (SD)	-9.44 (49.429)	-11.93 (44.026)	-10.76 (46.293)
	Week 16			
	N	30	33	63
	Mean (SD)	-9.18 (35.950)	-11.44 (41.236)	-10.36 (38.515)
	Week 28			
	N	32	32	64
	Mean (SD)	-4.14 (42.883)	-15.08 (52.250)	-9.61 (47.735)
	Week 52			
	N	29	29	58
	Mean (SD)	2.41 (43.391)	-11.98 (45.754)	-4.78 (44.788)
The Physical Demands Scale	Baseline			
	N	33	35	68
	Mean (SD)	66.67 (33.522)	78.40 (31.122)	72.71 (32.606)
	Week 4			
	N	29	33	62
	Mean (SD)	13.51 (40.397)	6.69 (27.080)	9.88 (33.845)
	Week 16			
	N	29	29	58
	Mean (SD)	18.18 (38.515)	2.34 (27.109)	10.26 (33.963)
	Week 28			
	N	30	30	60
	Mean (SD)	9.69 (38.540)	3.58 (21.514)	6.64 (31.098)
	Week 52			
	N	27	26	53
	Mean (SD)	9.95 (37.778)	7.44 (32.094)	8.72 (34.791)
The Mental/Interpersonal Demands Scale	Baseline			
	N	34	38	72
	Mean (SD)	28.61 (29.012)	31.52 (30.930)	30.15 (29.865)
	Week 4			
	N	31	36	67
	Mean (SD)	-8.17 (30.950)	-7.96 (33.575)	-8.06 (32.144)
	Week 16			
	N	30	34	64
	Mean (SD)	-11.03 (32.392)	-12.85 (33.364)	-11.99 (32.664)
	Week 28			
	N	31	33	64
	Mean (SD)	-5.90 (17.561)	-13.57 (34.144)	-9.86 (27.458)
	Week 52			
	N	29	29	58
	Mean (SD)	-1.97 (39.005)	-10.24 (34.567)	-6.11 (36.765)
The Output Demands Scale	Baseline			
	N	33	37	70
	Mean (SD)	22.61 (26.832)	30.27 (35.295)	26.66 (31.602)
	Week 4			
	N	30	35	65

Table 18. Descriptive Statistics of Change From Baseline in WLQ (Moderate to Severe Plaque Psoriasis Population, Observed Case)

	Visit	CP-690,550 [a]		
		5 mg BID	10 mg BID	Total
	Mean (SD)	-6.17 (26.868)	-12.00 (36.465)	-9.31 (32.281)
	Week 16			
	N	31	32	63
	Mean (SD)	-10.81 (27.450)	-10.00 (35.696)	-10.40 (31.652)
	Week 28			
	N	31	33	64
	Mean (SD)	-4.68 (23.271)	-14.09 (37.091)	-9.53 (31.291)
	Week 52			
	N	28	28	56
	Mean (SD)	-0.04 (39.798)	-14.64 (40.641)	-7.34 (40.529)
WLQ Index Score	Baseline			
	N	34	38	72
	Mean (SD)	9.55 (6.716)	10.74 (8.045)	10.18 (7.420)
	Week 4			
	N	31	36	67
	Mean (SD)	-1.89 (7.381)	-1.81 (9.278)	-1.85 (8.391)
	Week 16			
	N	31	34	65
	Mean (SD)	-2.55 (7.262)	-2.49 (7.991)	-2.52 (7.593)
	Week 28			
	N	32	34	66
	Mean (SD)	-1.55 (6.936)	-3.00 (8.587)	-2.30 (7.805)
	Week 52			
	N	30	30	60
	Mean (SD)	-0.13 (9.633)	-2.70 (8.741)	-1.41 (9.211)

Abbreviations: BID = twice daily, N = number of subjects, WLQ = Work Limitation Questionnaire, SD = standard deviation.

a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

PtGA category during study is presented in Table 19.

Table 19. PtGA Category (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Visit	PGA Category	CP-690,550 [a]		
		5 mg BID n (%)	10 mg BID n (%)	Total n (%)
Baseline	Clear	0	0	0
	Almost Clear	0	0	0
	Mild	0	1 (2.3)	1 (1.1)
	Moderate	18 (41.9)	19 (43.2)	37 (42.5)
	Severe	25 (58.1)	24 (54.5)	49 (56.3)
	N (Total)	43	44	87
Week 2	Clear	0	0	0
	Almost Clear	1 (2.3)	0	1 (1.1)
	Mild	1 (2.3)	13 (29.5)	14 (16.1)
	Moderate	26 (60.5)	16 (36.4)	42 (48.3)
	Severe	15 (34.9)	15 (34.1)	30 (34.5)
	N (Total)	43	44	87
Week 4	Clear	0	1 (2.3)	1 (1.2)
	Almost Clear	2 (4.7)	4 (9.3)	6 (7.0)
	Mild	8 (18.6)	11 (25.6)	19 (22.1)
	Moderate	23 (53.5)	21 (48.8)	44 (51.2)
	Severe	10 (23.3)	6 (14.0)	16 (18.6)
	N (Total)	43	43	86
Week 8	Clear	2 (4.7)	3 (7.3)	5 (6.0)
	Almost Clear	6 (14.0)	7 (17.1)	13 (15.5)
	Mild	14 (32.6)	14 (34.1)	28 (33.3)
	Moderate	17 (39.5)	14 (34.1)	31 (36.9)
	Severe	4 (9.3)	3 (7.3)	7 (8.3)
	N (Total)	43	41	84
Week 12	Clear	1 (2.3)	3 (7.3)	4 (4.8)
	Almost Clear	9 (20.9)	11 (26.8)	20 (23.8)
	Mild	15 (34.9)	17 (41.5)	32 (38.1)
	Moderate	15 (34.9)	7 (17.1)	22 (26.2)
	Severe	3 (7.0)	3 (7.3)	6 (7.1)
	N (Total)	43	41	84
Week 16	Clear	2 (4.7)	4 (10.0)	6 (7.2)
	Almost Clear	14 (32.6)	9 (22.5)	23 (27.7)
	Mild	10 (23.3)	14 (35.0)	24 (28.9)
	Moderate	14 (32.6)	9 (22.5)	23 (27.7)
	Severe	3 (7.0)	4 (10.0)	7 (8.4)
	N (Total)	43	40	83
Week 20	Clear	3 (7.0)	5 (12.8)	8 (9.8)
	Almost Clear	16 (37.2)	9 (23.1)	25 (30.5)
	Mild	11 (25.6)	13 (33.3)	24 (29.3)
	Moderate	10 (23.3)	10 (25.6)	20 (24.4)
	Severe	3 (7.0)	2 (5.1)	5 (6.1)
	N (Total)	43	39	82
Week 28	Clear	5 (11.6)	2 (5.1)	7 (8.5)
	Almost Clear	16 (37.2)	14 (35.9)	30 (36.6)
	Mild	10 (23.3)	8 (20.5)	18 (22.0)
	Moderate	9 (20.9)	13 (33.3)	22 (26.8)
	Severe	3 (7.0)	2 (5.1)	5 (6.1)
	N (Total)	43	39	82
Week 40	Clear	3 (7.3)	7 (18.4)	10 (12.7)

Table 19. PtGA Category (Moderate to Severe Plaque Psoriasis Population, Observed Case)

Visit	PGA Category	CP-690,550 [a]		
		5 mg BID n (%)	10 mg BID n (%)	Total n (%)
	Almost Clear	19 (46.3)	12 (31.6)	31 (39.2)
	Mild	8 (19.5)	7 (18.4)	15 (19.0)
	Moderate	9 (22.0)	10 (26.3)	19 (24.1)
	Severe	2 (4.9)	2 (5.3)	4 (5.1)
	N (Total)	41	38	79
Week 52	Clear	8 (20.5)	6 (18.8)	14 (19.7)
	Almost Clear	8 (20.5)	10 (31.3)	18 (25.4)
	Mild	11 (28.2)	8 (25.0)	19 (26.8)
	Moderate	6 (15.4)	7 (21.9)	13 (18.3)
	Severe	6 (15.4)	1 (3.1)	7 (9.9)
	N (Total)	39	32	71

Abbreviations: BID = twice daily, N = number of subjects, n = number of subjects meeting prespecified criteria, PtGA = Patient Global Assessment.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Descriptive Statistics of Change from baseline in JPA score is presented in Table 20.

Table 20. Descriptive Statistics of Change From Baseline in JPA (Subjects With a Medical History of Ongoing Psoriatic Arthritis[a], Observed Case)

Visit	CP-690,550 [b]	N	Mean	SD
Baseline	5 mg BID	8	5.25	3.327
	10 mg BID	15	4.60	2.558
	Total	23	4.83	2.790
Week 4	5 mg BID	8	-1.25	1.753
	10 mg BID	14	-3.36	2.560
	Total	22	-2.59	2.482
Week 16	5 mg BID	8	-3.38	3.068
	10 mg BID	15	-4.00	2.138
	Total	23	-3.78	2.449
Week 28	5 mg BID	8	-3.50	2.777
	10 mg BID	14	-3.86	2.248
	Total	22	-3.73	2.394
Week 52	5 mg BID	4	-4.75	3.775
	10 mg BID	13	-4.15	2.304
	Total	17	-4.29	2.592

Abbreviations: BID = twice daily, JPA = Joint Pain Assessment, N = number of subjects, SD = standard deviation.
a. Defined as the MedDRA preferred term for psoriatic arthropathy.
b. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (from baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 mg BID and 10 mg BID).

Safety Results: The incidence of treatment emergent AEs (not including SAEs) reported during the period Week 0-52 and through follow-up are summarized in Table 21 (all causality) and Table 22 (treatment related). At the time of study treatment completion or discontinuation, a follow-up visit was conducted 2-4 weeks after the subject's last dose.

During the period Week 0-52 and through follow-up, the proportion of subjects with all causality AEs (not including SAEs) was 78.7% and 85.1% in the treatment sequences of the subjects who started with CP-690,550 5 mg BID and 10 mg BID, respectively. The proportion of subjects with treatment-related AEs (not including SAEs) was 55.3% and 72.3% in the treatment sequences of the subjects who started with CP-690,550 5 mg BID and 10 mg BID, respectively.

Table 21. Incidence of TEAEs (not including SAEs) Reported During Period Week 0-52 and Through Follow-up – All Causalities by SOC and Preferred Term (Safety Analysis Set)

MedDRA SOC Preferred Term	CP-690,550 [a]					
	5 mg BID N = 47 n (%)		10 mg BID N = 47 n (%)		Total N = 94 n (%)	
Number of Subjects With TEAEs (All Causality)	37	(78.7)	40	(85.1)	77	(81.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0		2	(4.3)	2	(2.1)
Anaemia	0		1	(2.1)	1	(1.1)
Lymphadenitis	0		1	(2.1)	1	(1.1)
Lymphadenopathy	0		1	(2.1)	1	(1.1)
EAR AND LABYRINTH DISORDERS	0		2	(4.3)	2	(2.1)
Vertigo	0		2	(4.3)	2	(2.1)
EYE DISORDERS	2	(4.3)	1	(2.1)	3	(3.2)
Asthenopia	1	(2.1)	0		1	(1.1)
Cataract	0		1	(2.1)	1	(1.1)
Conjunctival deposit	0		1	(2.1)	1	(1.1)
Eyelid oedema	1	(2.1)	0		1	(1.1)
Presbyopia	1	(2.1)	0		1	(1.1)
GASTROINTESTINAL DISORDERS	7	(14.9)	8	(17.0)	15	(16.0)
Abdominal discomfort	0		1	(2.1)	1	(1.1)
Abdominal pain upper	2	(4.3)	1	(2.1)	3	(3.2)
Colitis	0		1	(2.1)	1	(1.1)
Constipation	1	(2.1)	1	(2.1)	2	(2.1)
Dental caries	3	(6.4)	1	(2.1)	4	(4.3)
Diarrhoea	0		2	(4.3)	2	(2.1)
Gastrooesophageal reflux disease	1	(2.1)	0		1	(1.1)
Lip erosion	1	(2.1)	0		1	(1.1)
Nausea	0		1	(2.1)	1	(1.1)
Toothache	0		1	(2.1)	1	(1.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2	(4.3)	7	(14.9)	9	(9.6)
Fatigue	1	(2.1)	1	(2.1)	2	(2.1)
Malaise	1	(2.1)	0		1	(1.1)
Oedema	0		1	(2.1)	1	(1.1)
Oedema peripheral	1	(2.1)	2	(4.3)	3	(3.2)
Pyrexia	0		3	(6.4)	3	(3.2)
HEPATOBILIARY DISORDERS	2	(4.3)	2	(4.3)	4	(4.3)
Hepatic function abnormal	2	(4.3)	2	(4.3)	4	(4.3)
INFECTIONS AND INFESTATIONS	24	(51.1)	27	(57.4)	51	(54.3)
Bronchitis	1	(2.1)	0		1	(1.1)
Enteritis infectious	0		1	(2.1)	1	(1.1)
Folliculitis	2	(4.3)	2	(4.3)	4	(4.3)
Furuncle	1	(2.1)	1	(2.1)	2	(2.1)
Gastroenteritis	3	(6.4)	0		3	(3.2)
Gastroenteritis norovirus	0		1	(2.1)	1	(1.1)
Gastroenteritis viral	0		2	(4.3)	2	(2.1)
Herpes zoster	3	(6.4)	10	(21.3)	13	(13.8)
Hordeolum	1	(2.1)	0		1	(1.1)
Influenza	3	(6.4)	3	(6.4)	6	(6.4)
Nasopharyngitis	14	(29.8)	14	(29.8)	28	(29.8)
Oral herpes	0		1	(2.1)	1	(1.1)
Otitis media acute	1	(2.1)	1	(2.1)	2	(2.1)

Table 21. Incidence of TEAEs (not including SAEs) Reported During Period Week 0-52 and Through Follow-up – All Causalities by SOC and Preferred Term (Safety Analysis Set)

MedDRA SOC Preferred Term	CP-690,550 [a]					
	5 mg BID N = 47 n (%)		10 mg BID N = 47 n (%)		Total N = 94 n (%)	
Periodontitis	0		1	(2.1)	1	(1.1)
Pertussis	0		1	(2.1)	1	(1.1)
Pharyngitis	0		2	(4.3)	2	(2.1)
Pneumonia	1	(2.1)	1	(2.1)	2	(2.1)
Rhinitis	0		1	(2.1)	1	(1.1)
Salpingitis	1	(2.1)	0		1	(1.1)
Sinusitis	0		1	(2.1)	1	(1.1)
Subcutaneous abscess	1	(2.1)	0		1	(1.1)
Tinea infection	1	(2.1)	1	(2.1)	2	(2.1)
Tinea pedis	4	(8.5)	6	(12.8)	10	(10.6)
Tinea versicolour	0		1	(2.1)	1	(1.1)
Upper respiratory tract infection	2	(4.3)	0		2	(2.1)
Vaginitis gardnerella	1	(2.1)	0		1	(1.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3	(6.4)	4	(8.5)	7	(7.4)
Arthropod bite	0		1	(2.1)	1	(1.1)
Arthropod sting	0		1	(2.1)	1	(1.1)
Epicondylitis	1	(2.1)	0		1	(1.1)
Excoriation	1	(2.1)	0		1	(1.1)
Fall	0		1	(2.1)	1	(1.1)
Hand fracture	0		1	(2.1)	1	(1.1)
Muscle strain	1	(2.1)	0		1	(1.1)
Rib fracture	0		1	(2.1)	1	(1.1)
Thermal burn	0		1	(2.1)	1	(1.1)
Traumatic haematoma	0		1	(2.1)	1	(1.1)
INVESTIGATIONS	6	(12.8)	13	(27.7)	19	(20.2)
Alanine aminotransferase increased	1	(2.1)	3	(6.4)	4	(4.3)
Aspartate aminotransferase increased	1	(2.1)	2	(4.3)	3	(3.2)
Blood bilirubin increased	0		1	(2.1)	1	(1.1)
Blood cholesterol increased	0		1	(2.1)	1	(1.1)
Blood creatine phosphokinase increased	3	(6.4)	2	(4.3)	5	(5.3)
Blood triglycerides increased	0		1	(2.1)	1	(1.1)
Gamma-glutamyltransferase increased	0		3	(6.4)	3	(3.2)
Haemoglobin decreased	1	(2.1)	4	(8.5)	5	(5.3)
Liver function test abnormal	0		2	(4.3)	2	(2.1)
Low density lipoprotein increased	0		1	(2.1)	1	(1.1)
Occult blood positive	1	(2.1)	0		1	(1.1)
Platelet count decreased	0		1	(2.1)	1	(1.1)
Weight decreased	0		1	(2.1)	1	(1.1)
Weight increased	0		1	(2.1)	1	(1.1)
White blood cell count decreased	0		1	(2.1)	1	(1.1)
METABOLISM AND NUTRITION DISORDERS	4	(8.5)	2	(4.3)	6	(6.4)
Diabetes mellitus	2	(4.3)	0		2	(2.1)
Dyslipidaemia	1	(2.1)	1	(2.1)	2	(2.1)
Hypercholesterolaemia	1	(2.1)	0		1	(1.1)
Hyperlipidaemia	0		1	(2.1)	1	(1.1)

Table 21. Incidence of TEAEs (not including SAEs) Reported During Period Week 0-52 and Through Follow-up – All Causalities by SOC and Preferred Term (Safety Analysis Set)

MedDRA SOC Preferred Term	CP-690,550 [a] 5 mg BID N = 47 n (%)	 10 mg BID N = 47 n (%)	 Total N = 94 n (%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	3 (6.4)	4 (8.5)	7 (7.4)
Arthralgia	1 (2.1)	2 (4.3)	3 (3.2)
Back pain	2 (4.3)	1 (2.1)	3 (3.2)
Joint swelling	0	1 (2.1)	1 (1.1)
Musculoskeletal pain	0	1 (2.1)	1 (1.1)
Myalgia	1 (2.1)	0	1 (1.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	4 (8.5)	4 (4.3)
Anogenital warts	0	1 (2.1)	1 (1.1)
Seborrhoeic keratosis	0	1 (2.1)	1 (1.1)
Skin papilloma	0	1 (2.1)	1 (1.1)
Uterine leiomyoma	0	1 (2.1)	1 (1.1)
NERVOUS SYSTEM DISORDERS	3 (6.4)	7 (14.9)	10 (10.6)
Cervicobrachial syndrome	1 (2.1)	1 (2.1)	2 (2.1)
Headache	1 (2.1)	3 (6.4)	4 (4.3)
Hypoaesthesia	1 (2.1)	0	1 (1.1)
Neuropathy peripheral	0	1 (2.1)	1 (1.1)
Post herpetic neuralgia	0	3 (6.4)	3 (3.2)
RENAL AND URINARY DISORDERS	2 (4.3)	2 (4.3)	4 (4.3)
Calculus ureteric	0	1 (2.1)	1 (1.1)
Nephrolithiasis	1 (2.1)	0	1 (1.1)
Pollakiuria	1 (2.1)	1 (2.1)	2 (2.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (4.3)	2 (4.3)	4 (4.3)
Atrophic vulvovaginitis	0	1 (2.1)	1 (1.1)
Cervical polyp	0	1 (2.1)	1 (1.1)
Endometriosis	1 (2.1)	0	1 (1.1)
Prostatitis	1 (2.1)	0	1 (1.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (2.1)	1 (2.1)	2 (2.1)
Oropharyngeal pain	1 (2.1)	0	1 (1.1)
Upper respiratory tract inflammation	0	1 (2.1)	1 (1.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	12 (25.5)	12 (25.5)	24 (25.5)
Acne	0	3 (6.4)	3 (3.2)
Alopecia	1 (2.1)	0	1 (1.1)
Dermatitis contact	2 (4.3)	1 (2.1)	3 (3.2)
Dyshidrotic eczema	0	1 (2.1)	1 (1.1)
Eczema	1 (2.1)	1 (2.1)	2 (2.1)
Hirsutism	1 (2.1)	0	1 (1.1)
Psoriasis	4 (8.5)	6 (12.8)	10 (10.6)
Purpura	1 (2.1)	0	1 (1.1)
Seborrhoeic dermatitis	1 (2.1)	0	1 (1.1)
Solar dermatitis	2 (4.3)	0	2 (2.1)
Urticaria	1 (2.1)	2 (4.3)	3 (3.2)
VASCULAR DISORDERS	0	2 (4.3)	2 (2.1)

Table 21. Incidence of TEAEs (not including SAEs) Reported During Period Week 0-52 and Through Follow-up – All Causalities by SOC and Preferred Term (Safety Analysis Set)

MedDRA SOC Preferred Term	CP-690,550 [a]		
	5 mg BID N = 47 n (%)	10 mg BID N = 47 n (%)	Total N = 94 n (%)
Hypertension	0	2 (4.3)	2 (2.1)

MedDRA coding dictionary v16.1
Abbreviations: BID = twice daily, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects, n = number of subjects meeting prespecified criteria, SAE = serious adverse event, SOC = system organ class, TEAE = treatment emergent adverse event.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (From baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 and 10 mg BID).

Table 22. Incidence of TEAEs (not including SAEs) Reported During Period Week 0-52 and Through Follow-up – Treatment Related by SOC and Preferred Term (Safety Analysis Set)

MedDRA SOC Preferred Term	CP-690,550 [a]				Total	
	5 mg BID N = 47 n (%)		10 mg BID N = 47 n (%)		N = 94 n (%)	
Number of Subjects With TEAEs (Treatment Related)	26	(55.3)	34	(72.3)	60	(63.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0		2	(4.3)	2	(2.1)
Anaemia	0		1	(2.1)	1	(1.1)
Lymphadenopathy	0		1	(2.1)	1	(1.1)
EAR AND LABYRINTH DISORDERS	0		1	(2.1)	1	(1.1)
Vertigo	0		1	(2.1)	1	(1.1)
EYE DISORDERS	1	(2.1)	0		1	(1.1)
Eyelid oedema	1	(2.1)	0		1	(1.1)
GASTROINTESTINAL DISORDERS	2	(4.3)	3	(6.4)	5	(5.3)
Abdominal pain upper	1	(2.1)	1	(2.1)	2	(2.1)
Constipation	0		1	(2.1)	1	(1.1)
Gastrooesophageal reflux disease	1	(2.1)	0		1	(1.1)
Nausea	0		1	(2.1)	1	(1.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2	(4.3)	5	(10.6)	7	(7.4)
Fatigue	1	(2.1)	1	(2.1)	2	(2.1)
Oedema	0		1	(2.1)	1	(1.1)
Oedema peripheral	1	(2.1)	1	(2.1)	2	(2.1)
Pyrexia	0		2	(4.3)	2	(2.1)
HEPATOBILIARY DISORDERS	2	(4.3)	2	(4.3)	4	(4.3)
Hepatic function abnormal	2	(4.3)	2	(4.3)	4	(4.3)
INFECTIONS AND INFESTATIONS	15	(31.9)	20	(42.6)	35	(37.2)
Folliculitis	2	(4.3)	1	(2.1)	3	(3.2)
Furuncle	1	(2.1)	1	(2.1)	2	(2.1)
Gastroenteritis	3	(6.4)	0		3	(3.2)
Gastroenteritis viral	0		2	(4.3)	2	(2.1)
Herpes zoster	3	(6.4)	10	(21.3)	13	(13.8)
Hordeolum	1	(2.1)	0		1	(1.1)
Influenza	1	(2.1)	1	(2.1)	2	(2.1)
Nasopharyngitis	5	(10.6)	5	(10.6)	10	(10.6)
Oral herpes	0		1	(2.1)	1	(1.1)
Otitis media acute	1	(2.1)	1	(2.1)	2	(2.1)
Periodontitis	0		1	(2.1)	1	(1.1)
Pertussis	0		1	(2.1)	1	(1.1)
Pharyngitis	0		1	(2.1)	1	(1.1)
Pneumonia	1	(2.1)	1	(2.1)	2	(2.1)
Tinea infection	1	(2.1)	1	(2.1)	2	(2.1)
Tinea pedis	2	(4.3)	4	(8.5)	6	(6.4)
Tinea versicolour	0		1	(2.1)	1	(1.1)
Upper respiratory tract infection	1	(2.1)	0		1	(1.1)
Vaginitis gardnerella	1	(2.1)	0		1	(1.1)
INVESTIGATIONS	6	(12.8)	12	(25.5)	18	(19.1)
Alanine aminotransferase increased	1	(2.1)	3	(6.4)	4	(4.3)
Aspartate aminotransferase increased	1	(2.1)	2	(4.3)	3	(3.2)
Blood bilirubin increased	0		1	(2.1)	1	(1.1)
Blood cholesterol increased	0		1	(2.1)	1	(1.1)
Blood creatine phosphokinase increased	3	(6.4)	1	(2.1)	4	(4.3)

Table 22. Incidence of TEAEs (not including SAEs) Reported During Period Week 0-52 and Through Follow-up – Treatment Related by SOC and Preferred Term (Safety Analysis Set)

MedDRA SOC Preferred Term	CP-690,550 [a]		Total
	5 mg BID N = 47 n (%)	10 mg BID N = 47 n (%)	N = 94 n (%)
Blood triglycerides increased	0	1 (2.1)	1 (1.1)
Gamma-glutamyltransferase increased	0	3 (6.4)	3 (3.2)
Haemoglobin decreased	1 (2.1)	4 (8.5)	5 (5.3)
Liver function test abnormal	0	2 (4.3)	2 (2.1)
Low density lipoprotein increased	0	1 (2.1)	1 (1.1)
Occult blood positive	1 (2.1)	0	1 (1.1)
Platelet count decreased	0	1 (2.1)	1 (1.1)
Weight decreased	0	1 (2.1)	1 (1.1)
Weight increased	0	1 (2.1)	1 (1.1)
White blood cell count decreased	0	1 (2.1)	1 (1.1)
METABOLISM AND NUTRITION DISORDERS	1 (2.1)	1 (2.1)	2 (2.1)
Dyslipidaemia	1 (2.1)	1 (2.1)	2 (2.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (2.1)	1 (2.1)	2 (2.1)
Arthralgia	0	1 (2.1)	1 (1.1)
Back pain	1 (2.1)	0	1 (1.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	3 (6.4)	3 (3.2)
Anogenital warts	0	1 (2.1)	1 (1.1)
Skin papilloma	0	1 (2.1)	1 (1.1)
Uterine leiomyoma	0	1 (2.1)	1 (1.1)
NERVOUS SYSTEM DISORDERS	1 (2.1)	4 (8.5)	5 (5.3)
Headache	0	1 (2.1)	1 (1.1)
Hypoaesthesia	1 (2.1)	0	1 (1.1)
Neuropathy peripheral	0	1 (2.1)	1 (1.1)
Post herpetic neuralgia	0	2 (4.3)	2 (2.1)
RENAL AND URINARY DISORDERS	1 (2.1)	1 (2.1)	2 (2.1)
Pollakiuria	1 (2.1)	1 (2.1)	2 (2.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	1 (2.1)	1 (1.1)
Cervical polyp	0	1 (2.1)	1 (1.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (2.1)	1 (2.1)	2 (2.1)
Oropharyngeal pain	1 (2.1)	0	1 (1.1)
Upper respiratory tract inflammation	0	1 (2.1)	1 (1.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	4 (8.5)	8 (17.0)	12 (12.8)
Acne	0	2 (4.3)	2 (2.1)
Alopecia	1 (2.1)	0	1 (1.1)
Dermatitis contact	1 (2.1)	1 (2.1)	2 (2.1)
Eczema	0	1 (2.1)	1 (1.1)
Hirsutism	1 (2.1)	0	1 (1.1)
Psoriasis	1 (2.1)	3 (6.4)	4 (4.3)
Purpura	1 (2.1)	0	1 (1.1)
Solar dermatitis	1 (2.1)	0	1 (1.1)
Urticaria	0	1 (2.1)	1 (1.1)
VASCULAR DISORDERS	0	2 (4.3)	2 (2.1)

Table 22. Incidence of TEAEs (not including SAEs) Reported During Period Week 0-52 and Through Follow-up – Treatment Related by SOC and Preferred Term (Safety Analysis Set)

MedDRA SOC Preferred Term	CP-690,550 [a] 5 mg BID N = 47 n (%)	CP-690,550 [a] 10 mg BID N = 47 n (%)	Total N = 94 n (%)
Hypertension	0	2 (4.3)	2 (2.1)

MedDRA coding dictionary v16.1
Abbreviations: AE = adverse event, BID = twice daily, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects, n = number of subjects meeting prespecified criteria, SOC = system organ class, TEAE = treatment emergent adverse event.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (From baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 and 10 mg BID).

No deaths were reported during the period Week 0 to Week 52 in any treatment sequences.

The incidence of treatment emergent SAEs reported during the period Week 0-52 and through follow-up is summarized in Table 23 (all causality) and Table 24 (treatment related).

Table 23. Incidence of TESAEs Reported During Period Week 0-52 and Through Follow-up –All Causality by SOC and Preferred Term (Safety Analysis Set)

MedDRA SOC Preferred Term	CP-690,550 [a] 5 mg BID N = 47 n (%)	CP-690,550 [a] 10 mg BID N = 47 n (%)	Total N = 94 n (%)
Number of Subjects With TESAEs (All Causality)	3 (6.4)	3 (6.4)	6 (6.4)
EAR AND LABYRINTH DISORDERS	0	1 (2.1)	1 (1.1)
Vertigo	0	1 (2.1)	1 (1.1)
INFECTIONS AND INFESTATIONS	3 (6.4)	1 (2.1)	4 (4.3)
Herpes zoster	3 (6.4)	0	3 (3.2)
Impetigo	0	1 (2.1)	1 (1.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	2 (4.3)	2 (2.1)
Erythrodermic psoriasis	0	1 (2.1)	1 (1.1)
Psoriasis	0	1 (2.1)	1 (1.1)

MedDRA coding dictionary v16.1
Abbreviations: BID = twice daily, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects, n = number of subjects meeting prespecified criteria, SOC = system organ class, TESAE = treatment emergent serious adverse event.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (From baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 and 10 mg BID).

Table 24. Incidence of TESAEs Reported During Period Week 0-52 and Through Follow-up – Treatment Related by SOC and Preferred Term (Safety Analysis Set)

MedDRA SOC Preferred Term	CP-690,550 [a] 5 mg BID N = 47 n (%)	CP-690,550 [a] 10 mg BID N = 47 n (%)	Total N = 94 n (%)
Number of Subjects With TESAEs (Treatment Related)	3 (6.4)	3 (6.4)	6 (6.4)
INFECTIONS AND INFESTATIONS	3 (6.4)	1 (2.1)	4 (4.3)
Herpes zoster	3 (6.4)	0	3 (3.2)
Impetigo	0	1 (2.1)	1 (1.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	1 (2.1)	1 (1.1)
Erythrodermic psoriasis	0	1 (2.1)	1 (1.1)

MedDRA coding dictionary v16.1
Abbreviations: BID = twice daily, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects, n = number of subjects meeting prespecified criteria, SOC = system organ class, TESAE = treatment emergent serious adverse event.
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (From baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 and 10 mg BID).

The proportion of subjects reporting AEs leading to discontinuation is summarized in Table 25.

Table 25. Incidence of Discontinuations Due to TEAEs During Period Week 0 to Week 52 – by SOC and Preferred Term (Safety Analysis Set)

MedDRA SOC Preferred Term	CP-690,550 [a] 5 mg BID N = 47 n (%)	CP-690,550 [a] 10 mg BID N = 47 n (%)	Total N = 94 n (%)
Number of Subjects With Discontinuation due to TEAEs	4 (8.5)	4 (8.5)	8 (8.5)
HEPATOBILIARY DISORDERS	1 (2.1)	0	1 (1.1)
Hepatic function abnormal	1 (2.1)	0	1 (1.1)
INFECTIONS AND INFESTATIONS	3 (6.4)	0	3 (3.2)
Herpes zoster	3 (6.4)	0	3 (3.2)
INVESTIGATIONS	0	1 (2.1)	1 (1.1)
Liver function test abnormal	0	1 (2.1)	1 (1.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	3 (6.4)	3 (3.2)
Psoriasis	0	3 (6.4)	3 (3.2)

MedDRA coding dictionary v16.1
Abbreviations: BID = twice daily, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects, n = number of subjects meeting prespecified criteria, SOC = system organ class, TEAE = treatment emergent adverse event..
a. Results in the open label period (Week 16 through Week 52) were presented by the treatment groups in the double-blind period (From baseline through Week 16). At Week 16 visit, subjects were switched to the open label period and received therapy through Week 52 (Week 16-20: CP-690,550 10 mg BID, Week 20-52: variable 5 and 10 mg BID).

No serious infections were reported in either group during the period Week 0 to Week 16. During the period Week 0-52 and through follow-up, serious infections were reported for 3 (6.4%) subjects in the treatment sequence of the subjects who started with CP-690,550 5 mg BID (each had herpes zoster), and 1 (2.1%) subject in the treatment sequence of the subjects who started with CP-690,550 10 mg BID (impetigo during follow-up post therapy).

Two subjects experienced herpes zoster during the period Week 0 to Week 16 (none of which were serious: all were in the CP-690,550 10 mg BID group). During the period Week 0 to Week 52, herpes zoster was reported for 6 (12.8%) subjects in the treatment sequence of the subjects who started with CP-690,550 5 mg BID, and 10 (21.3%) subjects in the treatment sequence of the subjects who started with CP-690,550 10 mg BID (3 events which occurred after Week 16 were serious). Of those, 1 subject experienced herpes zoster 3 days (Day 323) after the last dose of 10 mg BID on Day 320. No additional herpes zoster was reported during follow-up period. Doses at onset of herpes zoster were 5 mg BID in 2 subjects and 10 mg BID in 13 subjects; in 1 subject, herpes zoster occurred 3 days after the last dose of 10 mg BID as described above.

Treated infections occurred at the same rates during the period Week 0 to Week 16: 27.7% in the CP-690,550 5 mg BID group, and 25.5% in the CP-690,550 10 mg BID group. During the period Week 0-52 and through follow-up, treated infections occurred at similar rates in both treatment sequences of subjects who started with CP-690,550 5 mg BID (44.7%) and CP-690,550 10 mg BID (53.2%).

No malignancy events were reported in this study.

No adjudicated cardiovascular events were reported in this study.

No subject experienced pustular, erythrodermic or guttate psoriasis during the period Week 0 to Week 16. During follow-up period, 1 (2.1%) subject in the treatment sequence of the subjects who started with CP-690,550 10 mg BID experienced erythrodermic psoriasis on post dose day 7. The event was considered serious and moderate in severity, and resolving.

As a clinically confirmed safety events of interest, pneumonia was reported: 1 subject in the treatment sequence of the subjects who started with the CP-690,550 5 mg BID, and 1 subject in the treatment sequence of the subjects who started with the CP-690,550 10 mg BID. For both of the events, the study drug was stopped temporarily; the events were considered not serious and moderate in severity, and resolved.

No gastrointestinal perforation was reported.

No Drug-Induced Liver Injury (DILI) was observed.

The following laboratory outcomes were noted:

Small decreases from baseline in mean neutrophil counts were observed for both treatment groups from baseline to Week 4 (mean [SD] change from baseline: −0.60 [1.319] × 10^3/mm^3 for the CP-690,550 5 mg BID group and −1.41 [1.808] × 10^3/mm^3 for the CP-690,550 10 mg BID group). Mean levels remained stable between Weeks 4 and 16 in both treatment groups.

After Week 16, mean levels slightly decreased in the treatment sequence of the subjects who started with CP-690,550 5 mg BID through Week 52 (mean [SD] change from baseline: −0.90 [1.161] × 10^3/mm^3 at Week 52), while that in the treatment sequence of the subjects who started with CP-690,550 10 mg BID remained similar through Week 52 (mean [SD] change from baseline: −1.27 [1.341] × 10^3/mm^3 at Week 52). After Week 52 through follow-up, mean level in the treatment sequence of the subjects who started with CP-690,550 5 mg BID nearly returned to the level at baseline, while that in the treatment sequence of the subjects who started with CP-690,550 10 mg BID increased but still below the level at baseline. There were no confirmed (confirmed on 2 consecutive measurements or occurring at the final visit) neutrophil levels <0.5×10^3/mm^3.

A small increase in mean lymphocyte count was observed at Week 4 (mean [SD] change from baseline: 0.41 [0.427] × 10^3/mm^3 for the CP-690,550 5 mg BID group and 0.32 [0.360] × 10^3/mm^3 for the CP-690,550 10 mg BID group), and it remained stable through Week 16 in both treatment groups. After Week 16 and Week 20 for the treatment sequences of the subjects who started with CP-690,550 10 mg BID and 5 mg BID, respectively, mean lymphocyte counts decreased in both treatment sequences (mean [SD] change from baseline: −0.03 [0.584] × 10^3/mm^3 for the CP-690,550 5 mg BID group and −0.11 [0.412] × 10^3/mm^3 for the CP-690,550 10 mg BID group at Week 52). There were no subjects with confirmed (confirmed on 2 consecutive measurements or occurring at the final visit) lymphocyte levels <0.5×10^3/mm^3.

Mean hemoglobin concentrations in the CP-690,550 5 mg BID group remained at similar levels from baseline through Week 16, while that in the CP-690,550 10 mg BID group slightly decreased between Weeks 4 and 16 (mean [SD] change from baseline: −0.43 [1.091] g/dL at Week 16). After Week 16, mean hemoglobin concentrations for the treatment sequence of subjects who started with CP-690,550 5 mg BID slightly decreased through follow-up (mean [SD] change from baseline: −0.18 [1.012] g/dL at Week 52 and −0.20 [0.932] g/dL at follow-up). For the treatment sequence of subjects who started with CP-690,550 10 mg BID, mean hemoglobin concentrations returned to baseline by Week 28 (mean [SD] change from baseline: 0.07 [0.828] g/dL), then slightly decreased thereafter (mean [SD] change from baseline: −0.26 [1.082] g/dL at Week 52 and −0.35 [0.887] g/dL at follow-up). There were no subjects with confirmed (confirmed on 2 consecutive measurements or occurring at the final visit) hemoglobin values <10 g/dL.

Mean serum creatinine levels were stable across all time points and values were similar between both treatment sequences.

Mean CPK levels gradually increased dose dependently by Week 16 (mean [SD] change from baseline at Week 16: 80.5 [107.35] U/L for the CP-690,550 5 mg BID group and 134.7 [234.00] U/L for the CP-690,550 10 mg BID group). After Week 16, it increased through Week 28 (mean [SD] change from baseline: 154.9 [229.76] U/L) and then decreased through Week 52 (mean [SD] change from baseline: 93.8 [79.90] U/L) in the treatment sequence of the subjects who started with CP-690,550 5 mg BID. For the treatment sequence of the subjects who started with CP-690,550 10 mg BID, it decreased until Week 52 (mean [SD] change from baseline: 106.4 [86.57] U/L). Then it decreased to baseline through follow-up for both treatment sequences. No rhabdomyolysis events were reported in the study.

The overall incidence of subjects with post dose confirmed ALT ≥3 × ULN was low for both treatment sequences. There was no subject with post dose confirmed AST ≥3 × ULN or total bilirubin value ≥2 × ULN for both treatment sequences. No Hy's Law cases were found in any of the treatment sequences.

An increase in mean LDL-C, HDL-C and total cholesterol was observed for both treatment groups at Week 4; then it increased through Week 16 for LDL-C; then they appeared to be stable thereafter through Week 12 or Week 16 for both treatment groups for HDL-C and total cholesterol; and the effect appeared to be stable thereafter by Week 52, which then returned to baseline level through follow-up.

CONCLUSION(S):

Double-blind period (Week 0 to Week 16):

- PASI75 response at Week 16 was higher in CP-690,550 10 mg BID group (72.7%) than in CP-690,550 5 mg BID group (62.8%) in the moderate to severe plaque psoriasis population (NRI).

- Proportion of subjects achieving a PGA response of "Clear" or "Almost Clear" at Week 16 was similar in both treatment groups: 67.4% for CP-690,550 5 mg BID group and 68.2% for CP-690,550 10 mg BID group in the moderate to severe plaque psoriasis population (NRI), respectively.

- All 12 subjects in the psoriatic arthritis population achieved an ACR20 response at Week 16 in both CP-690,550 treatment groups.

- Median time to PASI75 response was shorter in CP-690,550 10 mg BID group (8 weeks) than in CP-690,550 5 mg BID group (12 weeks) in the moderate to severe plaque psoriasis population (observed case). Median time to PASI90 response was shorter in CP-690,550 10 mg BID group (12 weeks) than in CP-690,550 5 mg BID group (could not be estimated by Week 16). Median time to PASI50 response was also shorter in CP-690,550 10 mg BID group (4 weeks) than in CP-690,550 5 mg BID group (8 weeks).

- Proportion of subjects achieving a PGA response of "Clear" was higher in CP-690,550 10 mg BID group (36.4%) than that in CP-690,550 5 mg BID group (27.9%) for the moderate to severe plaque psoriasis population (NRI) at Week 16.

- Median time to PGA response of "Clear" or "Almost Clear" was similar between CP-690,550 5 mg BID group (8 weeks) and CP-690,550 10 mg BID group (8 weeks) in the moderate to severe plaque psoriasis population (observed case).

- Mean ISI score was 1.67 and 0.90 in the CP-690,550 5 mg BID and 10 mg BID groups, respectively, in the moderate to severe plaque psoriasis population (observed case) at Week 16.

- Mean DLQI total score at Week 16 was 2.2 and 1.9 in CP-690,550 5 mg BID and 10 mg BID group in the moderate to severe plaque psoriasis population (observed case), respectively.

- No serious infections were reported in either group during the period Week 0 to Week 16.

- No malignancies were reported in either group during the period Week 0 to Week 16.

- Two subjects experienced herpes zoster during the period Week 0 to Week 16 (none of which were serious: all were in the CP-690,550 10 mg BID group).

Double-blind period and open label period (Week 0 through Week 52):

- Proportion of subjects achieving a PASI75 and PASI90 response in the treatment sequence of subjects who started with CP-690,550 5 mg BID increased after Week 16 when the dose was increased to 10 mg BID in these subjects in the moderate to severe plaque psoriasis population (NRI).

- Proportion of subjects achieving a PASI75 and PASI90 response was maintained after Week 16 through Week 52 in the moderate to severe plaque psoriasis population (NRI).

- PGA response of "Clear" or "Almost Clear" among subjects who had PGA response at Week 16 was maintained through Week 52 in the moderate to severe plaque psoriasis population (NRI).

- At Week 52, the proportion of subjects achieving a NAPSI75 response was 59.4% and 56.7% in both treatment sequences of subjects who started with CP-690,550 5 mg BID and 10 mg BID in the moderate to severe plaque psoriasis population (NRI), respectively.

- Proportion of subjects achieving a NAPSI100 response at Week 52 was 40.6% and 33.3% in the treatment sequences of subjects who started with CP-690,550 5 mg BID and 10 mg BID in the moderate to severe plaque psoriasis population, respectively.

- Proportions of subjects achieving an ACR20, ACR50 and ACR70 response were maintained through Week 52 after Week 16 in the treatment sequence of subjects who started with CP-690,550 10 mg BID in the psoriatic arthritis population (NRI). Proportions of subjects achieving an ACR20 and ACR50 response at Week 52 were decreased relative to Week 16 in the treatment sequence of the subjects who started with CP-690,550 5 mg BID in the psoriatic arthritis population (NRI). Proportion of subjects achieving an ACR70 response at Week 52 was similar at Week 16 in the treatment sequence of the subjects who started with CP-690,550 5 mg BID in the psoriatic arthritis population (NRI).

- Substantial decrease in HAQ-DI (mean) was maintained through Week 52 in the treatment sequence of subjects who started with CP-690,550 10 mg BID (−0.42) in the

psoriatic arthritis population (observed case). For the treatment sequence of subjects who started with CP-690,550 5 mg BID, decrease relative to baseline in HAQ-DI (mean) was observed until Week 40 (−0.34) and then return to baseline level was observed at Week 52 (−0.13).

Patient Reported Outcomes (PROs):

- Substantial burden of disease at baseline was observed with the PROs studied (ISI, DLQI, SF-36, and PtGA).
- Mean ISI score at Week 52 was 1.15 and 0.91 in the treatment sequences of the subjects who started with CP-690,550 5 mg BID and 10 mg BID, respectively, in the moderate to severe plaque psoriasis population (observed case).
- Mean DLQI total score at Week 52 was 1.6 (n=39) and 2.2 (n=32) in the treatment sequences of the subjects who started with CP-690,550 5 mg BID and 10 mg BID in the moderate to severe plaque psoriasis population (observed case), respectively.
- Proportion of subjects achieving a DLQI total score ≤1 at Week 52 in subjects with DLQI total score >1 at baseline was 61.9% (26/42 subjects) and 53.7% (22/41 subjects) in the treatment sequences of the subjects who started with CP-690,550 5 mg BID and 10 mg BID in the moderate to severe plaque psoriasis population (NRI), respectively.
- Improvements in the PROs studied (ISI, DLQI, SF-36, WLQ, and PtGA) were observed.
- Improvement in JPA by Week 16 was maintained in the subset of subjects (n=23) with a medical history of ongoing psoriatic arthritis (that was defined as the MedDRA preferred term for psoriatic arthropathy regardless of meeting the inclusion criteria for the psoriatic arthritis) as well as the psoriatic arthritis population (n=12) through Week 52 (observed case).

- CP-690,550 (5 mg BID and 10 mg BID) was well tolerated in subjects with moderate to severe plaque psoriasis and/or psoriatic arthritis during 52 weeks of treatment.
- There were no deaths reported in this study.
- Serious infections were reported for 3 (6.4%) subjects in the CP-690,550 5 mg BID group (each had herpes zoster) and 1 (2.1%) subject in the CP-690,550 10 mg BID group (impetigo) during the period Week 0-52 and through follow-up.
- Herpes zoster was reported for 6 (12.8%) subjects in the treatment sequence of the subjects who started with CP-690,550 5 mg BID, and 10 (21.3%) subjects in the treatment sequence of the subjects who started with CP-690,550 10 mg BID (3 events which occurred after Week 16 were serious) during the period Week 0-52 and through

follow-up. Doses at onset of herpes zoster were 5 mg BID in 2 subjects and 10 mg BID in 13 subjects; in 1 subject, herpes zoster occurred 3 days after the last dose of 10 mg BID.

- No malignancy events were reported in this study.
- No adjudicated cardiovascular events were reported in this study.
- No gastrointestinal perforation was reported.
- Change in laboratory parameters was small and generally reversible on treatment withdrawal.
  - Small decreases from baseline in mean neutrophil counts were observed for both treatment groups from baseline to Week 4 (mean [SD] change from baseline: −0.60 [1.319] × 10^3/mm^3 for the CP-690,550 5 mg BID group and −1.41 [1.808] × 10^3/mm^3 for the CP-690,550 10 mg BID group). Mean levels remained similar between Weeks 4 and 16 in both treatment groups. After Week 16, mean neutrophil counts slightly decreased in the treatment sequence of the subjects who started with CP-690,550 5 mg BID through Week 52 (mean [SD] change from baseline: −0.90 [1.161] × 10^3/mm^3 at Week 52), while those in the treatment sequence of the subjects who started with CP-690,550 10 mg BID remained at similar levels through Week 52 (mean [SD] change from baseline: −1.27 [1.341] × 10^3/mm^3 at Week 52). There were no confirmed cases of neutrophil levels <0.5×10^3/mm^3.
  - A small increase in mean lymphocyte count was observed at Week 4 (mean [SD] change from baseline: 0.41 [0.427] × 10^3/mm^3 for the CP-690,550 5 mg BID group and 0.32 [0.360] × 10^3/mm^3 for the CP-690,550 10 mg BID group), and it remained stable through Week 16 in both treatment groups. Mean lymphocyte counts decreased through Week 52 after Week 16 and Week 20 for the treatment sequences of the subjects who started with CP-690,550 10 mg BID and 5 mg BID, respectively. There were no confirmed cases of subjects with lymphocyte levels <0.5×10^3/mm^3.
  - For the treatment sequence of subjects who started with CP-690,550 10 mg BID, mean hemoglobin concentrations slightly decreased between Weeks 4 and 16 (mean [SD] change from baseline: −0.43 [1.091] g/dL at Week 16), returned to baseline by Week 28, then slightly decreased thereafter. For the treatment sequence of subjects who started with CP-690,550 5 mg BID, mean hemoglobin concentrations slightly decreased after Week 16 through follow-up. There were no confirmed cases of subjects with hemoglobin values <10 g/dL.
  - An increase in mean LDL-C, HDL-C and total cholesterol was observed for both treatment groups at Week 4; then it increased through Week 16 for LDL-C; then they appeared to be stable thereafter through Week 12 or Week 16 for both treatment groups for HDL-C and total cholesterol; and the effect appeared to be stable thereafter by Week 52, which then returned to baseline level through follow-up.