PFIZER INC.

These results are supplied for informational purposes only.
Prescribing decisions should be made based on the approved package insert.

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

PROTOCOL NO.: A3921078

PROTOCOL TITLE: A Phase 3, Multi-Site, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of 2 Oral Doses of CP-690,550 in Subjects with Moderate to Severe Chronic Plaque Psoriasis

Study Center(s): There were 71 centers that took part in the study and enrolled subjects: Canada (10), Colombia (2), Germany (10), Hungary (3), Japan (5) Mexico (1), Poland (4), Serbia (1), Taiwan (2), Ukraine (4), and United States (29). In addition, there were 2 study centers that received study drug, but did not randomize subjects.

Study Initiation Date and Primary Completion or Final Completion Dates:
15 March 2011 to 17 April 2013

Phase of Development: Phase 3

Study Objectives:

Primary Objectives: The primary objectives of this study were:

- To compare the efficacy of CP-690,550 (5 mg twice a day [BID] and 10 mg BID) versus placebo for the reduction in severity of plaque psoriasis after 16 weeks of treatment in subjects with moderate to severe chronic plaque psoriasis who were candidates for systemic therapy or phototherapy;

- To evaluate safety and tolerability over 52 weeks of treatment with CP-690,550 (5 mg BID and 10 mg BID) in subjects with moderate to severe chronic plaque psoriasis who were candidates for systemic therapy or phototherapy.

Secondary Objectives: The secondary objectives of this study were:

- To evaluate the onset of efficacy and durability of efficacy of CP-690,550 (5 mg BID and 10 mg BID) for the reduction in severity of plaque psoriasis at various timepoints during 52 weeks of treatment in subjects with moderate to severe chronic plaque psoriasis who were candidates for systemic therapy or phototherapy;

- To evaluate the pharmacokinetics (PK) of CP-690,550 and its relationship with clinical responses (efficacy and safety) during treatment in subjects with moderate to severe chronic plaque psoriasis who were candidates for systemic therapy or phototherapy;

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

METHODS

Study Design: This was a Phase 3, multi-site, randomized, double-blind, placebo-controlled, parallel-group, 52-week study of the efficacy and safety of 2 oral doses of CP-690,550 (5 mg BID and 10 mg BID) compared to placebo in subjects with moderate to severe chronic plaque psoriasis who were candidates for systemic therapy or phototherapy. Subjects were randomized in a 2:2:1 ratio to 1 of 3 parallel treatment groups (CP-690,550 5 mg BID or CP-690,550 10 mg BID or placebo) for a 16-week double-blind, placebo-controlled, treatment period. Following this placebo-controlled 16-week treatment period, subjects randomized into the placebo group at Baseline were re-randomized into 1 of the active groups (CP-690,550 5 mg BID or CP-690,550 10 mg BID) at Week 16 and continued through Week 52. Subjects in the CP-690,550 5 mg BID and the CP-690,550 10 mg BID groups continued to receive their respective treatments through Week 52. At the Week 16 visit, subjects received their originally randomized treatment at dose 1 and received CP-690,550 at dose 2 of the day's 2 doses. The dose of the active treatment was blinded.

Subjects not achieving Psoriasis Area and Severity Index 75 (PASI75) or Physician's Global Assessment (PGA) of "clear" or "almost clear" response at Week 28 (non-responders) were withdrawn.

Number of Subjects (Planned and Analyzed): Planned: 825 subjects (330 subjects in the CP-690,550 5 mg BID group, 330 subjects in the CP-690,550 10 mg BID group, and 165 subjects in the placebo group).

Actual: 901 subjects (363 subjects in the CP-690,550 5 mg BID group, 361 subjects in the CP-690,550 10 mg BID group, and 177 subjects in the placebo group) were randomized to treatment during Week 0 to Week 16 treatment period. At Week 16, 132 subjects in the placebo group were re-randomized to active treatment (66 subjects to receive CP-690,550 5 mg BID and 66 subjects to receive CP-690,550 10 mg BID), while 313 subjects in the CP-690,550 5 mg BID group and 320 subjects in the CP-690,550 10 mg BID group continued to receive their respective treatments through Week 52.

Diagnosis and Main Criteria for Inclusion: Eligible subjects were at least 18 years of age, willing and able to sign consent and comply with scheduled visits and study procedures, with a diagnosis of plaque-type psoriasis for at least 12 months prior to first dose of study drug covering at least 10% of total body surface area (BSA), a PASI score of ≥12, a PGA score of 3 or 4 at Baseline/Day 1, and considered by the Dermatologist Investigator to be a candidate for systemic therapy or phototherapy of psoriasis.

Subjects with current non-plaque forms of psoriasis, evidence of skin conditions (eg, eczema), current drug-induced psoriasis, any malignancies or history of malignancies (with the exception of adequately treated or excised non metastatic basal cell or squamous cell

cancer of the skin or cervical carcinoma in situ), a history of infection judged clinically significant by the Investigator within 6 months prior to first dose of study drug, or who were currently being treated for active tuberculosis infection were excluded from participation in the study. In addition, subjects who had any of the following laboratory values during the Screening visit: hemoglobin <11.0 g/dL (<110.0 g/L) or hematocrit <30% (<0.30 v/v); white blood cell count (WBC) <3.0 x 109/L (<3000/mm3); absolute neutrophil count of <1.5 x 109/L (<1500/mm3); platelet count <100 x 109/L (<100,000/mm3); estimated creatinine clearance <40 mL/min; and aspartate aminotransferase (AST) or alanine aminotransferase (ALT) values more than 2 times the upper limit of normal (ULN) were excluded from participation in the study.

Study Treatment: Subjects received either CP-690,550 5 mg BID or CP-690,550 10 mg BID or matching placebo tablets orally BID (approximately every 12 hours).

Efficacy and Pharmacokinetic Endpoints:

Efficacy Endpoints:

The PASI quantifies the severity of a subject's psoriasis based on both lesion severity and the percent of BSA affected. The PASI is a composite scoring by the Investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions, with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score varies in increments of 0.1 and ranges from 0 to 72, with higher scores representing greater severity of psoriasis.

The PGA score is based on a 5-point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling were scored separately over the whole body according to a 5-point severity scale (0 to 4) as defined by morphologic descriptors (0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, 4 = severe).

Assessment of BSA with psoriasis was performed separately for 4 body regions: head and neck, upper limbs, trunk (including axillae and groin), and lower limbs (including buttocks). The percent surface area with psoriasis was estimated by means of the handprint method.

The Nail Psoriasis Severity Index (NAPSI) was used to quantify the severity of nail psoriasis for subjects who presented with nail involvement at Baseline by evaluating the presence or absence of psoriatic manifestations on the nail matrix and nail bed. The total NAPSI score equals the sum of scores for all of the fingernails evaluated. The NAPSI total score (sum of all the scores from all nails) ranges from 0 to 80, with higher scores representing greater severity.

The Dermatology Life Quality Index (DLQI) is a general dermatology questionnaire that consists of 10 items that assess patient health-related quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). The DLQI total score ranges from 0 to 30, with lower scores indicating better health-related quality of life.

Pharmacokinetic Endpoints: PK endpoints included oral clearance and other PK parameters calculated from plasma CP-690,550 concentrations.

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

Statistical Methods: The data sets summarized and analyzed in this study were as follows: full analysis set (FAS), per protocol (PP) analysis set, and safety analysis set.

In tabular and graphic displays of study data, Week 0 refers to Baseline.

Efficacy Analyses

Analysis of Primary Endpoints

The primary efficacy endpoints of the study were:

- PGA response: the proportion of subjects achieving a PGA response of "clear" or "almost clear" at Week 16;

- PASI75 response: the proportion of subjects achieving at least a 75% reduction in PASI75 relative to Baseline at Week 16.

The primary objectives were to establish the superiority of 2 doses (5 mg BID and 10 mg BID) of CP-690,550 to placebo for the 2 primary endpoints. In order to control for the Type I error, a gate-keeping or step-down approach was used to assess each endpoint at each dose sequentially, where statistical significance was claimed for a given endpoint at a given dose only if the prior step in the sequence met the requirements for significance. For each comparison, the significance level (α) was set at 0.05 (2-sided) or equivalently at 0.025 (1-sided).

The sequence for the step-down procedure in this study was as follows:

1. Testing PGA response for CP-690,550 10 mg BID compared to placebo at Week 16;

2. Testing PASI75 response for CP-690,550 10 mg BID compared to placebo at Week 16;

3. Testing PGA response for CP-690,550 5 mg BID compared to placebo at Week 16;

4. Testing of PASI75 response for CP-690,550 5 mg BID compared to placebo at Week 16.

The high dose (10 mg BID) was considered significantly effective only if the 2 primary endpoints at high dose were significant; the low dose (5 mg BID) was considered significantly effective only if the 2 primary endpoints at both low and the high doses were significant.

For the analysis of the primary endpoints, the Cochran-Mantel Haenszel (CMH) statistics were used for the evaluation of the relationship between the treatment group and the response of the endpoint adjusting for the effect of site.

Analysis of Key and Other Secondary Endpoints

The binary endpoints, such as PASI75 response at Week 4 or other endpoints were evaluated by the CMH statistics and the normal approximation approach as described for the PGA and PASI75 responses in the primary analyses.

The continuous variables such as change from baseline in DLQI at Week 16 were analyzed by the mixed effect repeated measure model and the least square mean difference from placebo for each dose of CP-690,550 at each time was derived and used to test the superiority to each dose of CP-690,550 to placebo.

In order to control for the Type I error, a gate-keeping or step-down approach was used to assess each endpoint at each dose sequentially for the following key secondary efficacy endpoints.

- Percent change from baseline in BSA at Week 16;
- PASI90 response at Week 16;
- Change from baseline in DLQI total score at Week 16;
- PGA response at Week 4;
- PASI75 response at Week 4;
- Change from baseline in DLQI total score at Week 4;
- Percent change from baseline in NAPSI at Week 16 in subjects with nail psoriasis at Baseline.

To control the Type I error due to multiple testing, a Bonferroni correction was applied first to 2 doses, ie, to allocate half of the alpha to each dose when compared to placebo, and then the similar step-down approach was applied to the sequence in the order as listed above within each dose. The sequence within 1 dose of CP-690,550 was tested independently of the sequence within the other dose and each comparison to placebo was made at 0.025 (2-sided) significance level. The statistical significance could be claimed for the next endpoint only if the prior step in the sequence met the requirements for significance.

For the following key secondary efficacy endpoints there was no formal hypothesis testing and hence, no control of Type I error was needed.

- Proportion of subjects maintaining PGA response at Week 52 among subjects achieving PGA response at Week 16;

- Proportion of subjects maintaining PASI75 response at Week 52 among subjects achieving PASI75 response at Week 16;

- Proportion of subjects maintaining PASI90 response at Week 52 among subjects achieving PASI90 response at Week 16.

At Week 16, efficacy was assessed prior to re-randomization.

Pharmacokinetic Analysis: Concentration-time data for CP-690,550 and PK-clinical response (efficacy and safety) relationship was analyzed using a nonlinear mixed effects modeling approach to characterize the population PK in this patient population. Concentration-time data for CP-690,550 and PK-clinical response (efficacy and safety) relationship will be presented in separate reports.

*Safety Analysis: S*afety data were summarized according to the safety reporting standards. The Medical Dictionary for Regulatory Activities (MedDRA) (version 16.1) coding dictionary was applied to AEs and serious AEs (SAEs).

RESULTS

Subject Disposition and Demography: Of the 901 subjects randomized, a total of 900 subjects received at least 1 dose of study medication: 363 subjects in the CP-690,550 5 mg BID, 360 subjects in the CP-690,550 10 mg BID, and 177 subjects in the placebo groups. Subject disposition for the placebo-controlled 16-week treatment period is presented in Table 1 and subject disposition during the 52-week study is presented in Table 2.

Table 1. Subject Disposition During Week 0 to Week 16 (Placebo-Controlled Period) by Treatment Group

	CP-690,550			
	5 mg BID n (%)	10 mg BID n (%)	Placebo n (%)	Total n (%)
Screened				1294
Randomized	363	361[a]	177	901
Safety Analysis Set[b]	363 (100.0)	360 (100.0)	177 (100.0)	900 (100.0)
FAS[c]	363 (100.0)	360 (100.0)	177 (100.0)	900 (100.0)
PP Analysis Set[d]	355 (97.8)	354 (98.3)	175 (98.9)	884 (98.2)
Re-randomized[e]	313 (86.2)	320 (88.9)	132 (74.6)	765 (85.0)
Discontinued[f]	50 (13.8)	40 (11.1)	45 (25.4)	135 (15.0)
Primary reason for discontinuation:				
Subject died	1 (0.3)	0	0	
Related to study drug	25 (6.9)	19 (5.3)	29 (16.4)	
Adverse event[g]	5 (1.4)	4 (1.1)	4 (2.3)	
Insufficient clinical response	20 (5.5)	15 (4.2)	25 (14.1)	
Not related to study drug	24 (6.6)	21 (5.8)	16 (9.0)	
Adverse event[g]	6 (1.7)	4 (1.1)	7 (4.0)	
Lost to follow-up	3 (0.8)	5 (1.4)	3 (1.7)	
No longer willing to participate in study	8 (2.2)	5 (1.4)	4 (2.3)	
Other[h]	7 (1.9)	7 (1.9)	2 (1.1)	

Abbreviations: AE = adverse event, BID = twice daily, FAS = Full Analysis Set, n = number of subjects meeting prespecified criteria, PP = Per Protocol

[a] One subject (CP-690,550 10 mg BID) was randomized but not treated.

[b] Safety Analysis Set - All subjects who received at least 1 dose of study drug.

[c] Full Analysis Set (FAS) - All subjects who were randomized, and received at least 1 dose of the randomized study drug.

[d] Per Protocol Analysis Set - All FAS subjects who were considered not to have had any major protocol violations thought to impact the primary efficacy endpoint assessment.

[e] Re-Randomized is defined as subjects who have been re-randomized and dosed in the second period. [Note: Re-randomized is equivalent to 'completed' for this time period.

[f] Discontinued is defined as subjects who were not re-randomized and have discontinued per the subject summary page.

[g] Subjects marked as discontinued due to an AE were based on the subject withdrawal date.

[h] Category of 'Other' included Protocol Violation, Other, Does not meet entrance criteria, Withdrawn due to pregnancy and Study terminated by sponsor.

Table 2. Subject Disposition During Week 0 to Week 52 (Subjects Initially Randomized to CP-690,550) and Week 16 to Week 52 (Subjects Re-randomized from Placebo to Active Treatment) - by Treatment Sequence

	Week 0 to Week 52		Week 16 to Week 52	
	CP-690,550 5 mg BID n (%)	CP-690,550 10 mg BID n (%)	Placebo to CP-690,550 5 mg BID n (%)	Placebo to CP-690,550 10 mg BID n (%)
Safety Analysis Set[a]	363 (100.0)	360 (100.0)		
FAS[b]	363 (100.0)	360 (100.0)		
Re-randomized[c]			66	66
Completed	186 (51.2)	219 (60.8)	50 (75.8)	45 (68.2)
Discontinued	177 (48.8)	141 (39.2)	16 (24.2)	21 (31.8)
Primary reason for discontinuation:				
Subject died	2 (0.6)	0	0	0
Related to study drug	129 (35.5)	97 (26.9)	15 (22.7)	15 (22.7)
Adverse event[d]	10 (2.8)	11 (3.1)	1 (1.5)	2 (3.0)
Insufficient clinical response	119 (32.8)	86 (23.9)	14 (21.2)	13 (19.7)
Not related to study drug	46 (12.7)	44 (12.2)	1 (1.5)	6 (9.1)
Adverse event[d]	11 (3.0)	10 (2.8)	0	1 (1.5)
Lost to follow-up	6 (1.7)	6 (1.7)	0	1 (1.5)
No longer willing to participate in study	12 (3.3)	9 (2.5)	0	1 (1.5)
Other[e]	17 (4.7)	19 (5.3)	1 (1.5)	3 (4.5)

Abbreviations: AE = adverse event, BID = twice daily, FAS = Full Analysis Set, n = number of subjects meeting prespecified criteria.
[a] All subjects who were initially dosed to CP-690,550.
[b] All subjects who were initially randomized and dosed to CP-690,550.
[c] Re-Randomized is defined as subjects who have been re-randomized and dosed in the second period.
[d] Subjects marked as discontinued due to AE are based on the subject withdrawal date.
[e] Category of Other includes Protocol Violation, Other, Does not meet entrance criteria, Withdrawn due to pregnancy and Study terminated by sponsor.

The majority of treated subjects during Week 0 to Week 16 were male (643 subjects, 71.4%) and white (734 subjects, 81.6%). The mean age of subjects was 45.3 years (range 18 years to 79 years). The mean weight of subjects was 88.0 kg (range 40.8 kg to 175.0 kg), and mean body mass index (BMI) was 29.5 kg/m^2 (range 15.4 kg/m^2 to 64.8 kg/m^2). Demographic characteristics were similar between treatment groups.

Efficacy, Pharmacokinetic, Pharmacodynamic, or Outcomes Research Results:

Primary Efficacy Results (PASI75 and PGA Responses)

CP-690,550 5 mg BID and CP-690,550 10 mg BID both were superior to placebo for both PGA "clear" or "almost clear" and PASI75 at Week 16 (Table 3). PASI75 and PGA response rates were higher for CP-690,550 10 mg BID group than for CP-690,550 5 mg BID group.

Table 3. Proportion of Subjects Achieving PASI75 Response and PGA Response of "Clear" or "Almost Clear" at Week 16 (FAS, NRI)

	Treatment	Response			Difference from Placebo[a] (Active - Placebo)			Odds Ratio (OR) (Active/Placebo)	
		N	n (%)	SE[a]	Diff	SE	95% CI	OR (95% CI)[b]	p-value[c]
PASI75									
	CP-690,550 5 mg BID	363	145 (39.94)	2.57	33.73	3.15	27.56, 39.90	8.93 (5.25, 21.84)	<.0001
	CP-690,550 10 mg BID	360	213 (59.17)	2.59	52.95	3.16	46.75, 59.15	20.81 (11.90, 49.86)	<.0001
	Placebo	177	11 (6.21)	1.81					
PGA									
	CP-690,550 5 mg BID	363	152 (41.87)	2.59	32.83	3.37	26.23, 39.44	6.46 (4.40, 15.03)	<.0001
	CP-690,550 10 mg BID	360	213 (59.17)	2.59	50.13	3.37	43.52, 56.73	12.45 (9.01, 31.88)	<.0001
	Placebo	177	16 (9.04)	2.16					

Abbreviations: BID = twice daily, CI = confidence interval, Diff = difference, FAS = Full Analysis Set, N = number of subjects, n = number of subjects meeting prespecified criteria, NRI = Non-Responder Imputation, OR = odds ratio, PASI = Psoriasis Area and Severity Index, PGA = Physician Global Assessment, SE = standard error, vs = versus.

[a] Normal approximation

[b] Mantel-Haenszel common odds ratio and exact confidence limits, controlling for pooled investigator sites.

[c] P-value testing for the Cochran-Mantel-Haenszel statistics, controlling for pooled investigator sites.

PASI75 test of homogeneity, p = 0.0827 at Week 16 for 5 mg vs placebo.

PASI75 test of homogeneity, p = 0.4726 at Week 16 for 10 mg vs placebo.

PGA test of homogeneity, p = 0.0010 at Week 16 for 5 mg vs placebo.

PGA test of homogeneity, p = 0.0130 at Week 16 for 10 mg vs placebo.

Key Secondary Efficacy Results:

The CP-690,550 5 mg BID and CP-690,550 10 mg BID were superior to placebo for the key secondary efficacy endpoints assessed for the 16-week placebo-controlled treatment period (Table 4). Except for the mean change from Baseline in DLQI total score, where the groups were similar, the CP-690,550 10 mg BID group was superior to the CP-690,550 5 mg BID group for these key secondary efficacy endpoints.

Table 4. Summary of Key Secondary Efficacy Parameters Evaluated During the 16 Week Treatment Period

	CP-690,550		
	5 mg BID	**10 mg BID**	**Placebo**
Percent change from baseline in BSA at Week 16 (FAS, Observed Case)			
N[a]	359	358	177
LS Mean (SE)	-51.94 (2.45)	-67.20 (2.44)	1.62 (3.59)
LS Mean difference from placebo (SE)	-53.56 (4.34)	-68.82 (4.34)	
p-value	<.0001*	<.0001*	
PASI90 response at Week 16 (FAS, NRI)			
N	363	360	177
n (%)	72 (19.83)	142 (39.44)	1 (0.56)
Difference from placebo	19.27	38.88	
p-value[b]	<.0001*	<.0001*	
Change from baseline in DLQI total score at Week 16 (FAS, Observed Case)			
N[a]	358	357	177
LS Mean (SE)	-6.91 (0.30)	-8.90 (0.29)	-1.93 (0.44)
LS Mean difference from placebo (SE)	-4.98 (0.53)	-6.97 (0.53)	
p-value	<.0001*	<.0001*	
PGA response of "clear" or "almost clear" at Week 4 (FAS, NRI)			
N	363	360	177
n (%)	62 (17.08)	83 (23.06)	4 (2.26)
Difference from placebo	14.82	20.80	
p-value[b]	<.0001*	<.0001*	
PASI75 response at Week 4 (FAS, NRI)			
N	363	360	177
n (%)	38 (10.47)	56 (15.56)	3 (1.69)
Difference from placebo	8.77	13.86	
p-value[b]	0.0003*	<.0001*	
Change from baseline in DLQI total score at Week 4 (FAS, Observed Case)			
N[a]	358	357	177
LS Mean (SE)	-5.59 (0.25)	-6.40 (0.25)	-1.69 (0.35)
LS Mean difference from placebo (SE)	-3.90 (0.43)	-4.71 (0.43)	
p-value	<.0001*	<.0001*	
Percent change from baseline in NAPSI score at Week 16 in FAS subjects with nail psoriasis at baseline (Observed Case)			
N[a]	237	242	102
LS Mean (SE)	-14.15 (9.47)	-41.48 (9.22)	55.55 (14.84)
LS Mean difference from placebo (SE)	-69.70 (17.60)	-97.03 (17.47)	
p-value	<.0001*	<.0001*	

* Statistically significant based on step-down procedure for the hypothesis testing of key secondary endpoints
LS means and corresponding SE are derived from mixed model with fixed effects for treatment, visit, treatment-by-visit interaction and baseline value, repeated measures for visit (nested within subject) were included, unstructured covariance matrix was used.
Abbreviations: BID = twice daily, BSA = body surface area, DLQI = Dermatology Life Quality Index, FAS = full analysis set, LS = least squares, N = number of subjects, n= number of subjects meeting prespecified criteria, NAPSI = Nail Psoriasis Severity Index, NRI = Non-Responder Imputation, PASI = Psoriasis Area and Severity Index, PGA = Physician Global Assessment, SE = standard error.
[a] Total number of unique subjects in the longitudinal model
[b] P-value testing for the Cochran-Mantel-Haenszel statistics, controlling for pooled investigator sites

At Week 52, in the CP-690,550 5 mg BID and the CP-690,550 10 mg BID treatment groups the probability of maintaining PASI75 response was 73.75% and 79.94%, respectively, of

maintaining a PASI90 response was 61.79% and 70.58%, respectively, and of maintaining PGA response of "clear' or "almost clear" was 60.17% and 71.56%, respectively (Table 5) .

Table 5. Probability of Maintaining a PASI75 Response, PASI90 Response, and PGA Response of "Clear" or "Almost Clear" at Week 52 (FAS Subjects Achieving Response at Week 16, Observed Cases)

	Response		
Probability of Maintaining Response[a]	N[b]	(%)	95% CI
PASI75 at Week 52			
CP-690,550 5 mg BID	145	73.75	(65.47, 80.33)
CP-690,550 10 mg BID	209	79.94	(73.75, 84.82)
PASI90 response at Week 52			
CP-690,550 5 mg BID	72	61.79	(49.37, 72.01)
CP-690,550 10 mg BID	140	70.58	(62.12, 77.49)
PGA response at Week 52			
CP-690,550 5 mg BID	151	60.17	(51.80, 67.56)
CP-690,550 10 mg BID	209	71.56	(64.81, 77.24)

Abbreviations: BID = twice daily, CI = confidence interval, FAS = Full Analysis Set, N = number of subjects, PASI = Psoriasis Area and Severity Index, PGA = Physician Global Assessment.
[a] Event is loss of response. Probability of maintaining response is (1-probability of loss of response).
[b] Includes FAS subjects with non-missing post-baseline response data.

Other Secondary Efficacy Results:

PASI

The PASI75 response was observed by Week 4, continued to improve beyond Week 16 and sustained improvement through Week 28 (Table 6). The efficacy responses were maintained through Week 52 for those subjects who remained on study after non-responders were discontinued at Week 28 as per protocol. PASI75 response rates were higher for CP-690,550 10 mg BID group than for CP-690,550 5 mg BID group. A statistically significant shorter time to PASI75 response was observed for both CP-690,550 treatment groups compared to placebo (p = 0.0000), and for the CP-690,550 10 mg BID treatment group compared to the CP-690,550 5 mg BID treatment group (p = 0.0000) (Table 8). The pattern of results was similar for the PASI50 response (Table 7 and Table 9). The PASI90 response was observed by Week 8 but otherwise the pattern of the results was the same (Table 10). The proportion of subjects who had a PASI score of ≥125% of the Baseline value in the CP-690,550 5 mg BID and CP-690,550 10 mg BID treatment groups was low at Week 16 and remained low at Week 28 (Table 11).

The efficacy of both doses of CP-690,550 was consistently observed for actual and mean changes in PASI scores (Table 12, Table 13, Table 14, Table 15, and Table 16).

Table 6. Proportion of Subjects Achieving PASI75 Response During Week 0 to Week 52 Sequence (FAS, NRI)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	**10 mg BID**	**5 mg BID**	**10 mg BID**
Week 2				
N	363	360	66	66
n (%)	5 (1.38)	8 (2.22)	0 (0.00)	0 (0.00)
95% CI	0.18, 2.58	0.70, 3.74	0.00, 0.00	0.00, 0.00
Week 4				
N	363	360	66	66
n (%)	38 (10.47)	56 (15.56)	3 (4.55)	0 (0.00)
95% CI	7.32, 13.62	11.81, 19.30	0.00, 9.57	0.00, 0.00
Week 8				
N	363	360	66	66
n (%)	86 (23.69)	132 (36.67)	4 (6.06)	0 (0.00)
95% CI	19.32, 28.07	31.69, 41.64	0.30, 11.82	0.00, 0.00
Week 12				
N	363	360	66	66
n (%)	129 (35.54)	199 (55.28)	4 (6.06)	5 (7.58)
95% CI	30.61, 40.46	50.14, 60.41	0.30, 11.82	1.19, 13.96
Week 16				
N	363	360	66	66
n (%)	145 (39.94)	213 (59.17)	6 (9.09)	5 (7.58)
95% CI	34.91, 44.98	54.09, 64.24	2.16, 16.03	1.19, 13.96
Week 20				
N	363	360	66	66
n (%)	164 (45.18)	214 (59.44)	21 (31.82)	16 (24.24)
95% CI	40.06, 50.30	54.37, 64.52	20.58, 43.06	13.90, 34.58
Week 28				
N	363	360	66	66
n (%)	181 (49.86)	227 (63.06)	39 (59.09)	45 (68.18)
95% CI	44.72, 55.01	58.07, 68.04	47.23, 70.95	56.94, 79.42
Week 40				
N	363	360	66	66
n (%)	165 (45.45)	205 (56.94)	43 (65.15)	45 (68.18)
95% CI	40.33, 50.58	51.83, 62.06	53.66, 76.65	56.94, 79.42
Week 52				
N	363	360	66	66
n (%)	141 (38.84)	185 (51.39)	36 (54.55)	43 (65.15)
95% CI	33.83, 43.86	46.23, 56.55	42.53, 66.56	53.66, 76.65

NRI (Non-responder Imputation): Setting missing values to be non-responsive.
Normal approximation
Abbreviations: BID = twice daily, CI = confidence interval, FAS = full analysis set, N = number of subjects, n = number of subjects meeting prespecified criteria, NRI = non-responder imputation, PASI = Psoriasis Area and Severity Index.

Table 7. Proportion of Subjects Achieving PASI50 Response During Week 0 to Week 52 Sequence (FAS, NRI)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	**10 mg BID**	**5 mg BID**	**10 mg BID**
Week 2				
N	363	360	66	66
n (%)	33 (9.09)	62 (17.22)	2 (3.03)	0 (0.00)
95% CI	6.13, 12.05	13.32, 21.12	0.00, 7.17	0.00, 0.00
Week 4				
N	363	360	66	66
n (%)	104 (28.65)	143 (39.72)	6 (9.09)	1 (1.52)
95% CI	24.00, 33.30	34.67, 44.78	2.16, 16.03	0.00, 4.46
Week 8				
N	363	360	66	66
n (%)	174 (47.93)	236 (65.56)	12 (18.18)	8 (12.12)
95% CI	42.79, 53.07	60.65, 70.46	8.88, 27.49	4.25, 20.00
Week 12				
N	363	360	66	66
n (%)	214 (58.95)	266 (73.89)	16 (24.24)	8 (12.12)
95% CI	53.89, 64.01	69.35, 78.43	13.90, 34.58	4.25, 20.00
Week 16				
N	363	360	66	66
n (%)	219 (60.33)	277 (76.94)	15 (22.73)	14 (21.21)
95% CI	55.30, 65.36	72.59, 81.30	12.62, 32.84	11.35, 31.08
Week 20				
N	363	360	66	66
n (%)	240 (66.12)	273 (75.83)	42 (63.64)	36 (54.55)
95% CI	61.25, 70.98	71.41, 80.26	52.03, 75.24	42.53, 66.56
Week 28				
N	363	360	66	66
n (%)	241 (66.39)	274 (76.11)	51 (77.27)	55 (83.33)
95% CI	61.53, 71.25	71.71, 80.52	67.16, 87.38	74.34, 92.32
Week 40				
N	363	360	66	66
n (%)	196 (53.99)	229 (63.61)	50 (75.76)	47 (71.21)
95% CI	48.87, 59.12	58.64, 68.58	65.42, 86.10	60.29, 82.14
Week 52				
N	363	360	66	66
n (%)	175 (48.21)	214 (59.44)	44 (66.67)	46 (69.70)
95% CI	43.07, 53.35	54.37, 64.52	55.29, 78.04	58.61, 80.78

NRI (Non-responder Imputation): Setting missing values to be non-responsive.
Normal approximation
Abbreviations: BID = twice daily, CI = confidence interval, FAS = full analysis set, N = number of subjects, n = number of subjects meeting prespecified criteria, NRI = non-responder imputation, PASI = Psoriasis Area and Severity Index

Table 8. Survival Analysis of Time to PASI75 Response During Week 0 to Week 16 (FAS, Observed Case)

		CP-690,550 5 mg BID	CP-690,550 10 mg BID	Placebo
Baseline	Number of subjects analyzed[a]	359	358	177
Week 2	n events - n (%)	5 (1.39)	8 (2.23)	0 (0.00)
	N Remaining	347	344	174
Week 4	n events - n (%)	33 (9.51)	50 (14.53)	3 (1.72)
	N Remaining	312	292	164
Week 8	n events - n (%)	51 (16.35)	80 (27.40)	2 (1.22)
	N Remaining	258	211	153
Week 12	n events - n (%)	47 (18.22)	70 (33.18)	7 (4.58)
	N Remaining	195	132	128
Week 16	n events - n (%)	31 (15.90)	30 (22.73)	3 (2.34)
	N Remaining	0	0	0
Week 2	Probability of response % (95% CI)	1.39 (0.58, 3.31)	2.23 (1.12, 4.42)	0.00 (0.00, 0.00)
Week 4	Probability of response % (95% CI)	10.77 (7.96, 14.50)	16.44 (12.96, 20.74)	1.72 (0.56, 5.25)
Week 8	Probability of response % (95% CI)	25.36 (21.13, 30.25)	39.34 (34.44, 44.66)	2.92 (1.23, 6.88)
Week 12	Probability of response % (95% CI)	38.95 (34.06, 44.29)	59.46 (54.36, 64.63)	7.36 (4.25, 12.61)
Week 16	Probability of response % (95% CI)	48.66 (43.48, 54.11)	68.68 (63.71, 73.53)	9.54 (5.85, 15.35)
Total censored n (%)		192 (53.48)	120 (33.52)	162 (91.53)
Estimated median time to event (response) - weeks (95% CI)		-- (16.0, --)	12.0 (-- , --)	-- (--,--)
Log-rank p-value	Active vs. Placebo	0.0000	0.0000	
	10 mg vs. 5 mg	0.0000		

Median time to event is the time after which 50% of subjects with a particular condition have the event. This time is not estimable if less than 50% of subjects had the event by the end of study.
Abbreviations: BID = twice daily, CI = confidence interval, FAS = Full Analysis Set, N = number of subjects, n = number of subjects meeting prespecified criteria, PASI = Psoriasis Area and Severity Index, -- = not estimable.
[a] Includes FAS subjects with non-missing post-baseline response data.

Table 9. Survival Analysis of Time to PASI50 Response During Week 0 to Week 16 (FAS, Observed Case)

		CP-690,550 5 mg BID	CP-690,550 10 mg BID	Placebo
Baseline	Number of subjects analyzed[a]	359	358	177
Week 2	n events - n (%)	33 (9.19)	62 (17.32)	4 (2.26)
	N Remaining	319	291	170
Week 4	n events - n (%)	73 (22.88)	84 (28.87)	5 (2.94)
	N Remaining	244	206	158
Week 8	n events - n (%)	73 (29.92)	93 (45.15)	15 (9.49)
	N Remaining	169	112	135
Week 12	n events - n (%)	52 (30.77)	39 (34.82)	9 (6.67)
	N Remaining	103	64	110
Week 16	n events - n (%)	21 (20.39)	13 (20.31)	5 (4.55)
	N Remaining	0	0	0
Week 2	Probability of response % (95% CI)	9.19 (6.62, 12.69)	17.32 (13.78, 21.65)	2.26 (0.85, 5.91)
Week 4	Probability of response % (95% CI)	29.97 (25.49, 35.05)	41.19 (36.26, 46.50)	5.13 (2.70, 9.64)
Week 8	Probability of response % (95% CI)	50.92 (45.81, 56.26)	67.74 (62.82, 72.57)	14.14 (9.71, 20.36)
Week 12	Probability of response % (95% CI)	66.02 (61.03, 70.96)	78.97 (74.56, 83.07)	19.86 (14.54, 26.81)
Week 16	Probability of response % (95% CI)	72.95 (68.10, 77.60)	83.24 (79.06, 87.01)	23.51 (17.66, 30.90)
Total censored n (%)		107 (29.81)	67 (18.72)	139 (78.53)
Estimated median time to event (response) - weeks (95% CI)		8.0 (8.0, 12.0)	8.0 (--, --)	-- (--, --)
Log-rank p-value	Active vs. Placebo	0.0000	0.0000	
	10 mg vs. 5 mg	0.0000		

Median time to event is the time after which 50% of subjects with a particular condition have the event. This time is not estimable if less than 50% of subjects had the event by the end of study.
Abbreviations: BID = twice daily, CI = confidence interval, FAS = Full Analysis Set, N = number of subjects, n = number of subjects meeting prespecified criteria, PASI = Psoriasis Area and Severity Index, -- = not estimable.
[a] Includes FAS subjects with non-missing post-baseline response data.

Table 10. Proportion of Subjects Achieving PASI90 Response During Week 0 to Week 52 Sequence (FAS, NRI)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	**10 mg BID**	**5 mg BID**	**10 mg BID**
Week 2				
N	363	360	66	66
n (%)	1 (0.28)	0 (0.00)	0 (0.00)	0 (0.00)
95% CI	0.00, 0.81	0.00, 0.00	0.00, 0.00	0.00, 0.00
Week 4				
N	363	360	66	66
n (%)	6 (1.65)	14 (3.89)	0 (0.00)	0 (0.00)
95% CI	0.34, 2.96	1.89, 5.89	0.00, 0.00	0.00, 0.00
Week 8				
N	363	360	66	66
n (%)	35 (9.64)	67 (18.61)	0 (0.00)	0 (0.00)
95% CI	6.61, 12.68	14.59, 22.63	0.00, 0.00	0.00, 0.00
Week 12				
N	363	360	66	66
n (%)	56 (15.43)	101 (28.06)	1 (1.52)	0 (0.00)
95% CI	11.71, 19.14	23.41, 32.70	0.00, 4.46	0.00, 0.00
Week 16				
N	363	360	66	66
n (%)	72 (19.83)	142 (39.44)	0 (0.00)	1 (1.52)
95% CI	15.73, 23.94	34.40, 44.49	0.00, 0.00	0.00, 4.46
Week 20				
N	363	360	66	66
n (%)	84 (23.14)	145 (40.28)	5 (7.58)	6 (9.09)
95% CI	18.80, 27.48	35.21, 45.34	1.19, 13.96	2.16, 16.03
Week 28				
N	363	360	66	66
n (%)	113 (31.13)	157 (43.61)	17 (25.76)	26 (39.39)
95% CI	26.37, 35.89	38.49, 48.73	15.21, 36.31	27.61, 51.18
Week 40				
N	363	360	66	66
n (%)	102 (28.10)	149 (41.39)	23 (34.85)	36 (54.55)
95% CI	23.48, 32.72	36.30, 46.48	23.35, 46.34	42.53, 66.56
Week 52				
N	363	360	66	66
n (%)	85 (23.42)	133 (36.94)	21 (31.82)	35 (53.03)
95% CI	19.06, 27.77	31.96, 41.93	20.58, 43.06	40.99, 65.07

NRI (Non-responder Imputation): Setting missing values to be non-responsive.
Normal approximation
Abbreviations: BID = twice daily, CI = confidence interval, FAS = full analysis set, N = number of subjects, n = number of subjects meeting prespecified criteria, NRI = non-responder imputation, PASI = Psoriasis Area and Severity Index

Table 11. Proportion of Subjects with PASI Score ≥125% of Baseline During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	**10 mg BID**	**5 mg BID**	**10 mg BID**
Week 2				
N	358	358	66	64
n (%)	2 (0.56)	4 (1.12)	3 (4.55)	2 (3.13)
95% CI	0.00, 1.33	0.03, 2.21	0.00, 9.57	0.00, 7.39
Week 4				
N	352	350	65	66
n (%)	4 (1.14)	2 (0.57)	1 (1.54)	3 (4.55)
95% CI	0.03, 2.24	0.00, 1.36	0.00, 4.53	0.00, 9.57
Week 8				
N	347	350	65	66
n (%)	7 (2.02)	1 (0.29)	2 (3.08)	5 (7.58)
95% CI	0.54, 3.50	0.00, 0.84	0.00, 7.28	1.19, 13.96
Week 12				
N	345	345	65	66
n (%)	10 (2.90)	4 (1.16)	4 (6.15)	6 (9.09)
95% CI	1.13, 4.67	0.03, 2.29	0.31, 12.00	2.16, 16.03
Week 16				
N	323	335	66	66
n (%)	8 (2.48)	3 (0.90)	4 (6.06)	8 (12.12)
95% CI	0.78, 4.17	0.00, 1.90	0.30, 11.82	4.25, 20.00
Week 20				
N	312	321	66	65
n (%)	5 (1.60)	2 (0.62)	1 (1.52)	3 (4.62)
95% CI	0.21, 3.00	0.00, 1.48	0.00, 4.46	0.00, 9.72
Week 28				
N	300	307	61	61
n (%)	3 (1.00)	1 (0.33)	0 (0.00)	0 (0.00)
95% CI	0.00, 2.13	0.00, 0.96	0.00, 0.00	0.00, 0.00
Week 40				
N	203	242	53	47
n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
Week 52				
N	180	219	47	46
n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
95% CI	0.00, 0.00	0.00, 0.00	0.00, 0.00	0.00, 0.00
Overall				
N	359	358	66	66
n (%)	22 (6.13)	9 (2.51)	5 (7.58)	11 (16.67)
95% CI	3.65, 8.61	0.89, 4.14	1.19, 13.96	7.68, 25.66

Normal approximation

Overall n indicates the total number of subjects with PASI Score ≥125% of baseline at least once during Weeks 1-52.

Abbreviations: BID = twice daily, CI = confidence interval, FAS = full analysis set, N = number of subjects, n = number of subjects meeting prespecified criteria, PASI = Psoriasis Area and Severity Index

Table 12. Descriptive Statistics of PASI Score During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	**10 mg BID**	**5 mg BID**	**10 mg BID**
Baseline				
N	363	360	66	66
Mean (SD)	21.95 (8.99)	22.73 (8.82)	21.19 (8.54)	23.03 (8.66)
Week 2				
N	358	358	66	64
Mean (SD)	18.28 (9.63)	17.30 (9.06)	19.81 (10.28)	22.11 (9.84)
Week 4				
N	352	350	65	66
Mean (SD)	14.39 (8.75)	13.10 (8.90)	18.36 (10.86)	20.63 (9.26)
Week 8				
N	347	350	65	66
Mean (SD)	11.41 (9.08)	8.97 (8.00)	17.17 (10.32)	20.13 (10.15)
Week 12				
N	345	345	65	66
Mean (SD)	9.85 (9.38)	6.94 (7.59)	16.52 (10.45)	19.38 (10.07)
Week 16				
N	323	335	66	66
Mean (SD)	8.42 (9.05)	5.74 (7.21)	16.08 (10.41)	19.71 (11.25)
Week 20				
N	312	321	66	65
Mean (SD)	6.82 (7.23)	4.95 (6.30)	9.18 (7.21)	11.79 (8.38)
Week 28				
N	300	307	61	61
Mean (SD)	5.80 (6.87)	4.01 (5.28)	5.20 (5.95)	5.23 (6.42)
Week 40				
N	203	242	53	47
Mean (SD)	3.05 (3.71)	2.64 (3.85)	3.22 (3.70)	1.64 (2.27)
Week 52				
N	180	219	47	46
Mean (SD)	3.28 (3.71)	2.47 (3.21)	3.16 (3.22)	1.64 (2.01)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, PASI = Psoriasis Area and Severity Index, SD = standard deviation

Table 13. Descriptive Statistics of PASI Component Scores (Erythema, Induration, Scaling) by Body Region During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Erythema (head\neck)								
Baseline	363	2.31 (0.99)	360	2.23 (1.01)	66	2.38 (0.99)	66	2.26 (0.90)
Week 2	358	1.84 (1.05)	358	1.72 (1.05)	66	2.14 (0.99)	64	2.17 (0.88)
Week 4	352	1.45 (1.03)	350	1.33 (1.06)	65	1.89 (1.11)	66	1.92 (0.97)
Week 8	347	1.23 (1.05)	350	0.95 (0.98)	65	1.92 (1.11)	66	1.86 (1.05)
Week 12	345	1.10 (1.09)	345	0.83 (0.96)	65	1.78 (0.96)	66	1.85 (1.00)
Week 16	323	1.01 (1.07)	335	0.75 (0.95)	66	1.73 (1.05)	66	1.91 (1.09)
Week 20	312	0.94 (1.02)	321	0.66 (0.94)	66	1.08 (0.93)	65	1.23 (0.95)
Week 28	300	0.83 (0.99)	307	0.65 (0.93)	61	0.54 (0.81)	61	0.51 (0.87)
Week 40	203	0.55 (0.87)	242	0.54 (0.85)	53	0.51 (0.87)	47	0.32 (0.69)
Week 52	180	0.50 (0.76)	219	0.42 (0.78)	47	0.55 (0.83)	46	0.39 (0.74)
Erythema (upper limbs)								
Baseline	363	2.87 (0.64)	360	2.88 (0.64)	66	2.83 (0.54)	66	2.92 (0.54)
Week 2	358	2.40 (0.80)	358	2.26 (0.86)	66	2.64 (0.62)	64	2.83 (0.68)
Week 4	352	2.00 (0.88)	350	1.85 (0.90)	65	2.42 (0.81)	66	2.73 (0.69)
Week 8	347	1.76 (0.98)	350	1.48 (0.93)	65	2.43 (0.77)	66	2.61 (0.74)
Week 12	345	1.60 (1.07)	345	1.28 (0.96)	65	2.35 (0.76)	66	2.53 (0.75)
Week 16	323	1.46 (1.12)	335	1.13 (1.00)	66	2.30 (0.80)	66	2.53 (0.83)
Week 20	312	1.29 (1.04)	321	1.05 (1.01)	66	1.48 (0.79)	65	1.80 (0.85)
Week 28	300	1.20 (1.08)	307	0.96 (1.00)	61	1.16 (0.92)	61	1.05 (0.88)
Week 40	203	0.87 (0.97)	242	0.76 (0.92)	53	1.06 (0.93)	47	0.55 (0.90)
Week 52	180	0.93 (0.95)	219	0.72 (0.87)	47	1.06 (0.94)	46	0.50 (0.81)
Erythema (trunk)								
Baseline	363	2.85 (0.77)	360	2.91 (0.73)	66	2.79 (0.85)	660	3.08 (0.56)
Week 2	358	2.39 (0.92)	358	2.28 (0.89)	66	2.58 (0.88)	64	2.91 (0.73)
Week 4	352	1.99 (0.99)	350	1.83 (1.00)	65	2.42 (0.97)	66	2.74 (0.69)
Week 8	347	1.67 (1.11)	350	1.37 (1.02)	65	2.31 (1.01)	66	2.55 (0.91)
Week 12	345	1.53 (1.18)	345	1.12 (1.07)	65	2.35 (0.98)	66	2.53 (0.95)
Week 16	323	1.40 (1.17)	335	1.01 (1.09)	66	2.14 (1.11)	66	2.58 (1.08)
Week 20	312	1.23 (1.09)	321	0.89 (1.06)	66	1.36 (0.97)	65	1.68 (1.02)
Week 28	300	1.09 (1.14)	307	0.77 (1.04)	61	0.92 (0.90)	61	0.95 (0.97)

Table 13. Descriptive Statistics of PASI Component Scores (Erythema, Induration, Scaling) by Body Region During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Week 40	203	0.68 (0.95)	242	0.52 (0.87)	53	0.68 (0.89)	47	0.57 (0.77)
Week 52	180	0.64 (0.91)	219	0.59 (0.93)	47	0.66 (0.94)	46	0.50 (0.86)
Erythema (lower limbs)								
Baseline	363	3.21 (0.60)	360	3.19 (0.62)	66	3.14 (0.58)	66	3.27 (0.62)
Week 2	358	2.75 (0.81)	358	2.60 (0.83)	66	2.98 (0.64)	64	3.14 (0.69)
Week 4	352	2.35 (0.90)	350	2.15 (0.91)	65	2.78 (0.78)	66	2.97 (0.68)
Week 8	347	1.99 (1.08)	350	1.71 (0.98)	65	2.62 (0.78)	66	2.91 (0.76)
Week 12	345	1.81 (1.13)	345	1.39 (1.06)	65	2.54 (0.79)	66	2.77 (0.86)
Week 16	323	1.63 (1.19)	335	1.25 (1.10)	66	2.52 (0.83)	66	2.82 (0.89)
Week 20	312	1.45 (1.17)	321	1.13 (1.09)	66	1.71 (0.82)	65	1.94 (0.98)
Week 28	300	1.27 (1.19)	307	0.97 (1.09)	61	1.21 (0.97)	61	1.15 (1.00)
Week 40	203	0.88 (1.05)	242	0.72 (0.97)	53	0.92 (1.00)	47	0.55 (0.83)
Week 52	180	0.93 (1.05)	219	0.67 (0.98)	47	0.87 (0.99)	46	0.63 (0.85)
Induration (head\neck)								
Baseline	363	2.08 (0.97)	360	1.96 (1.01)	66	2.14 (0.97)	66	2.02 (0.90)
Week 2	358	1.70 (1.05)	358	1.48 (1.03)	66	1.94 (0.99)	64	1.92 (0.95)
Week 4	352	1.28 (0.98)	350	1.11 (0.99)	65	1.74 (1.06)	66	1.74 (1.03)
Week 8	347	1.04 (1.01)	350	0.75 (0.88)	65	1.68 (1.03)	66	1.67 (1.00)
Week 12	345	0.90 (1.02)	345	0.65 (0.86)	65	1.54 (0.97)	66	1.56 (1.01)
Week 16	323	0.83 (0.97)	335	0.60 (0.88)	66	1.42 (1.01)	66	1.58 (1.12)
Week 20	312	0.78 (0.93)	321	0.55 (0.83)	66	0.83 (0.83)	65	0.97 (0.85)
Week 28	300	0.66 (0.89)	307	0.47 (0.76)	61	0.44 (0.70)	61	0.31 (0.72)
Week 40	203	0.44 (0.73)	242	0.45 (0.76)	53	0.43 (0.82)	47	0.23 (0.52)
Week 52	180	0.47 (0.71)	219	0.32 (0.66)	47	0.40 (0.68)	46	0.24 (0.57)
Induration (upper limbs)								
Baseline	363	2.69 (0.71)	360	2.65 (0.67)	66	2.71 (0.58)	66	2.68 (0.59)
Week 2	358	2.27 (0.83)	358	2.11 (0.86)	66	2.36 (0.76)	64	2.58 (0.71)
Week 4	352	1.87 (0.90)	350	1.73 (0.91)	65	2.25 (0.83)	66	2.53 (0.79)
Week 8	347	1.62 (0.93)	350	1.39 (0.93)	65	2.15 (0.80)	66	2.44 (0.70)
Week 12	345	1.48 (1.02)	345	1.17 (0.95)	65	2.05 (0.78)	66	2.32 (0.84)
Week 16	323	1.34 (1.10)	335	1.06 (0.99)	66	2.06 (0.87)	66	2.33 (0.93)

Table 13. Descriptive Statistics of PASI Component Scores (Erythema, Induration, Scaling) by Body Region During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Week 20	312	1.21 (1.03)	321	0.99 (1.00)	66	1.38 (0.78)	65	1.52 (0.83)
Week 28	300	1.10 (1.05)	307	0.90 (1.01)	61	1.00 (0.84)	61	0.79 (0.82)
Week 40	203	0.79 (0.93)	242	0.72 (0.87)	53	1.00 (0.88)	47	0.36 (0.67)
Week 52	180	0.86 (0.94)	219	0.70 (0.87)	47	0.98 (0.82)	46	0.43 (0.75)
Induration (trunk)								
Baseline	363	2.60 (0.80)	360	2.63 (0.77)	66	2.53 (0.83)	66	2.71 (0.78)
Week 2	358	2.20 (0.90)	358	2.10 (0.92)	66	2.32 (0.90)	64	2.58 (0.75)
Week 4	352	1.80 (0.95)	350	1.66 (1.00)	65	2.15 (1.03)	66	2.53 (0.81)
Week 8	347	1.44 (1.02)	350	1.26 (1.02)	65	2.03 (1.07)	66	2.38 (0.99)
Week 12	345	1.34 (1.09)	345	0.98 (1.03)	65	1.89 (0.99)	66	2.27 (0.99)
Week 16	323	1.22 (1.08)	335	0.85 (1.05)	66	1.83 (1.14)	66	2.29 (1.08)
Week 20	312	1.06 (1.03)	321	0.78 (1.02)	66	1.17 (1.02)	65	1.43 (1.02)
Week 28	300	0.93 (1.03)	307	0.69 (1.00)	61	0.75 (0.85)	61	0.80 (1.08)
Week 40	203	0.56 (0.80)	242	0.48 (0.81)	53	0.57 (0.75)	47	0.32 (0.59)
Week 52	180	0.56 (0.81)	219	0.54 (0.86)	47	0.53 (0.80)	46	0.35 (0.77)
Induration (lower limbs)								
Baseline	363	2.91 (0.69)	360	2.90 (0.66)	66	2.83 (0.69)	66	2.98 (0.69)
Week 2	358	2.50 (0.82)	358	2.38 (0.84)	66	2.62 (0.80)	64	2.72 (0.74)
Week 4	352	2.06 (0.90)	350	1.93 (0.92)	65	2.48 (0.87)	66	2.71 (0.78)
Week 8	347	1.74 (1.02)	350	1.47 (0.97)	65	2.35 (0.87)	66	2.67 (0.83)
Week 12	345	1.58 (1.08)	345	1.17 (0.98)	65	2.26 (0.82)	66	2.55 (0.88)
Week 16	323	1.38 (1.07)	335	1.01 (1.02)	66	2.20 (0.92)	66	2.52 (0.86)
Week 20	312	1.24 (1.04)	321	0.96 (1.03)	66	1.52 (0.85)	65	1.66 (1.00)
Week 28	300	1.09 (1.08)	307	0.79 (0.99)	61	0.98 (0.83)	61	0.87 (0.90)
Week 40	203	0.70 (0.91)	242	0.62 (0.91)	53	0.85 (0.77)	47	0.32 (0.59)
Week 52	180	0.84 (0.96)	219	0.61 (0.89)	47	0.79 (0.88)	46	0.39 (0.65)
Scaling (head\neck)								
Baseline	363	2.32 (1.05)	360	2.23 (1.08)	66	2.33 (1.10)	66	2.24 (1.07)
Week 2	358	1.85 (1.11)	358	1.67 (1.11)	66	2.03 (1.07)	64	2.08 (1.13)
Week 4	352	1.43 (1.10)	350	1.23 (1.07)	65	1.80 (1.16)	66	1.94 (1.07)
Week 8	347	1.18 (1.12)	350	0.83 (0.97)	65	1.80 (1.11)	66	1.88 (1.09)

Table 13. Descriptive Statistics of PASI Component Scores (Erythema, Induration, Scaling) by Body Region During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Week 12	345	1.03 (1.06)	345	0.72 (0.91)	65	1.77 (1.01)	66	1.76 (1.10)
Week 16	323	0.94 (1.04)	335	0.67 (0.91)	66	1.59 (1.02)	66	1.76 (1.10)
Week 20	312	0.86 (0.97)	321	0.63 (0.94)	66	0.98 (0.90)	65	1.09 (1.06)
Week 28	300	0.77 (0.95)	307	0.57(0.85)	61	0.56 (0.76)	61	0.44 (0.85)
Week 40	203	0.53 (0.82)	242	0.52 (0.90)	53	0.51 (0.78)	47	0.30 (0.59)
Week 52	180	0.51 (0.77)	219	0.42 (0.78)	47	0.62 (0.87)	46	0.39 (0.74)
Scaling (upper limbs)								
Baseline	363	2.75 (0.78)	360	2.71 (0.75)	66	2.55 (0.59)	66	2.76 (0.70)
Week 2	358	2.29 (0.93)	358	2.08 (0.91)	66	2.26 (0.75)	64	2.58 (0.87)
Week 4	352	1.88 (0.98)	350	1.71 (0.93)	65	2.14 (0.68)	66	2.42 (0.79)
Week 8	347	1.66 (1.02)	350	1.37 (0.96)	65	2.05 (0.78)	66	2.35 (0.79)
Week 12	345	1.50 (1.07)	345	1.18 (0.98)	65	2.03 (0.90)	66	2.27 (0.83)
Week 16	323	1.41 (1.09)	335	1.07 (0.98)	66	2.08 (0.90)	66	2.29 (0.89)
Week 20	312	1.23 (1.00)	321	1.02 (1.03)	66	1.50 (0.88)	65	1.63 (0.94)
Week 28	300	1.15 (1.06)	307	0.90 (0.99)	61	1.08 (0.86)	61	0.98 (0.92)
Week 40	203	0.85 (0.97)	242	0.71 (0.91)	53	1.06 (0.82)	47	0.49 (0.80)
Week 52	180	0.91 (0.97)	219	0.74 (0.88)	47	1.06 (0.87)	46	0.57 (0.83)
Scaling (trunk)								
Baseline	363	2.60 (0.86)	360	2.60 (0.83)	66	2.36 (0.82)	66	2.77 (0.86)
Week 2	358	2.12 (1.00)	358	2.00 (1.00)	66	2.14 (1.04)	64	2.50 (0.99)
Week 4	352	1.79 (1.03)	350	1.57 (1.01)	65	1.98 (1.01)	66	2.41 (0.94)
Week 8	347	1.41 (1.09)	350	1.19 (1.05)	65	1.83 (1.01)	66	2.20 (1.06)
Week 12	345	1.30 (1.12)	345	0.95 (1.01)	65	1.89 (1.05)	66	2.26 (1.09)
Week 16	323	1.15 (1.01)	335	0.84 (0.99)	66	1.83 (1.12)	66	2.12 (1.10)
Week 20	312	0.99 (0.94)	321	0.76 (1.00)	66	1.20 (1.03)	65	1.49 (1.17)
Week 28	300	0.89 (0.97)	307	0.64 (0.90)	61	0.80 (0.87)	61	0.90 (1.14)
Week 40	203	0.53 (0.79)	242	0.44 (0.77)	53	0.58 (0.75)	47	0.47 (0.78)
Week 52	180	0.54 (0.81)	219	0.51 (0.79)	47	0.57 (0.83)	46	0.43 (0.81)
Scaling (lower limbs)								
Baseline	363	2.98 (0.72)	360	2.91 (0.72)	66	2.77 (0.72)	66	2.97 (0.78)
Week 2	358	2.50 (0.91)	358	2.33 (0.92)	66	2.53 (0.85)	64	2.75 (0.82)

Table 13. Descriptive Statistics of PASI Component Scores (Erythema, Induration, Scaling) by Body Region During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Week 4	352	2.11 (0.96)	350	1.93 (1.00)	65	2.32 (0.92)	66	2.64 (0.80)
Week 8	347	1.80 (1.07)	350	1.45 (1.03)	65	2.22 (0.96)	66	2.55 (0.91)
Week 12	345	1.56 (1.10)	345	1.14 (0.98)	65	2.14 (0.95)	66	2.53 (1.00)
Week 16	323	1.42 (1.06)	335	1.01 (1.02)	66	2.15 (1.00)	66	2.50 (1.06)
Week 20	312	1.30 (1.04)	321	0.96 (1.03)	66	1.55 (1.00)	65	1.80 (1.18)
Week 28	300	1.15 (1.07)	307	0.79 (0.99)	61	1.02 (0.90)	61	1.08 (1.08)
Week 40	203	0.78 (0.97)	242	0.62 (0.90)	53	0.85 (0.86)	47	0.45 (0.75)
Week 52	180	0.89 (0.98)	219	0.58 (0.90)	47	0.91 (0.95)	46	0.50 (0.75)

Baseline is the latest predose measurement
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, PASI = Psoriasis Area and Severity Index , SD = standard deviation

Table 14. Descriptive Statistics of Change from Baseline PASI Component Scores (Erythema, Induration, Scaling) by Body Region During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Erythema (head\neck)								
Week 2	358	-0.45 (0.78)	358	-0.51 (0.82)	66	-0.24 (0.61)	64	-0.06 (0.66)
Week 4	352	-0.84 (1.04)	350	-0.90 (1.01)	65	-0.48 (0.87)	66	-0.33 (0.71)
Week 8	347	-1.05 (1.16)	350	-1.28 (1.11)	65	-0.45 (1.03)	66	-0.39 (0.99)
Week 12	345	-1.18 (1.21)	345	-1.41 (1.16)	65	-0.58 (1.03)	66	-0.41 (0.96)
Week 16	323	-1.28 (1.26)	335	-1.48 (1.19)	66	-0.65 (0.97)	66	-0.35 (1.02)
Week 20	312	-1.37 (1.20)	321	-1.57 (1.25)	66	-1.30 (0.99)	65	-1.02 (0.99)
Week 28	300	-1.47 (1.24)	307	-1.59 (1.23)	61	-1.80 (1.08)	61	-1.70 (0.99)
Week 40	203	-1.78 (1.15)	242	-1.69 (1.16)	53	-1.83 (1.14)	47	-1.81 (1.15)
Week 52	180	-1.81 (1.08)	219	-1.75 (1.18)	47	-1.70 (1.20)	46	-1.74 (1.04)
Erythema (upper limbs)								
Week 2	358	-0.46 (0.68)	358	-0.63 (0.71)	66	-0.20 (0.47)	64	-0.09 (0.56)
Week 4	352	-0.86 (0.88)	350	-1.03 (0.84)	65	-0.42(0.73)	66	-0.20 (0.64)
Week 8	347	-1.10 (1.04)	350	-1.41(0.99)	65	-0.40(0.70)	66	-0.32 (0.73)
Week 12	345	-1.26 (1.15)	345	-1.61(1.06)	65	-0.48(0.79)	66	-0.39 (0.72)
Week 16	323	-1.41 (1.19)	335	-1.76 (1.12)	66	-0.53 (0.86)	66	-0.39 (0.74)
Week 20	312	-1.58 (1.18)	321	-1.84 (1.13)	66	-1.35 (0.92)	65	-1.12 (0.93)
Week 28	300	-1.67 (1.24)	307	-1.92 (1.13)	61	-1.67 (1.04)	61	-1.89 (1.00)
Week 40	203	-2.02 (1.15)	242	-2.11 (1.09)	53	-1.75 (1.12)	47	-2.40 (0.99)
Week 52	180	-1.95 (1.13)	219	-2.13 (1.04)	47	-1.77 (1.16)	46	-2.46 (0.98)
Erythema (trunk)								
Week 2	358	-0.46 (0.69)	358	-0.63 (0.74)	66	-0.21 (0.51)	64	-0.17 (0.49)
Week 4	352	-0.86 (0.88)	350	-1.08 (0.95)	65	-0.37 (0.86)	66	-0.33 (0.59)
Week 8	347	-1.18 (1.10)	350	-1.54 (1.03)	65	-0.52 (0.87)	66	-0.53 (0.81)
Week 12	345	-1.32 (1.22)	345	-1.80 (1.15)	65	-0.43 (1.00)	66	-0.55 (0.83)
Week 16	323	-1.45 (1.23)	335	-1.90 (1.18)	66	-0.65 (1.10)	66	-0.50 (1.00)
Week 20	312	-1.63 (1.20)	321	-2.03 (1.16)	66	-1.42 (1.02)	65	-1.40 (1.06)
Week 28	300	-1.77 (1.29)	307	-2.15 (1.17)	61	-1.89 (0.98)	61	-2.13 (1.02)
Week 40	203	-2.19 (1.14)	242	-2.40 (1.03)	53	-2.11 (0.95)	47	-2.45 (0.93)
Week 52	180	-2.22 (1.12)	219	-2.31 (1.13)	47	-2.15 (1.02)	46	-2.52 (1.03)

Table 14. Descriptive Statistics of Change from Baseline PASI Component Scores (Erythema, Induration, Scaling) by Body Region During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Erythema (lower limbs)								
Week 2	358	-0.47 (0.70)	358	-0.59 (0.74)	66	-0.15 (0.44)	64	-0.13 (0.58)
Week 4	352	-0.86 (0.89)	350	-1.04 (0.87)	65	-0.35 (0.62)	66	-0.30 (0.70)
Week 8	347	-1.22 (1.10)	350	-1.48 (1.00)	65	-0.51 (0.73)	66	-0.36 (0.65)
Week 12	345	-1.40 (1.17)	345	-1.79 (1.10)	65	-0.60 (0.72)	66	-0.50 (0.79)
Week 16	323	-1.59 (1.23)	335	-1.94 (1.17)	66	-0.62 (0.84)	66	-0.45 (0.79)
Week 20	312	-1.77 (1.20)	321	-2.06 (1.18)	66	-1.42 (0.82)	65	-1.34 (1.08)
Week 28	300	-1.95 (1.22)	307	-2.23 (1.22)	61	-1.92 (0.99)	61	-2.11 (0.98)
Week 40	203	-2.34 (1.10)	242	-2.45 (1.11)	53	-2.21 (1.10)	47	-2.68 (0.89)
Week 52	180	-2.29 (1.16)	219	-2.50 (1.12)	47	-2.26 (1.13)	46	-2.61 (0.98)
Induration (head\neck)								
Week 2	358	-0.37 (0.67)	358	-0.48 (0.78)	66	-0.20 (0.53)	64	-0.08 (0.57)
Week 4	352	-0.79 (0.97)	350	-0.85 (1.00)	65	-0.40 (0.68)	66	-0.27 (0.69)
Week 8	347	-1.02 (1.10)	350	-1.21 (1.10)	65	-0.45 (0.87)	66	-0.35 (1.03)
Week 12	345	-1.16 (1.18)	345	-1.32 (1.15)	65	-0.60 (0.97)	66	-0.45 (0.91)
Week 16	323	-1.22 (1.22)	335	-1.37 (1.16)	66	-0.71 (1.00)	66	-0.44 (1.10)
Week 20	312	-1.29 (1.20)	321	-1.44 (1.18)	66	-1.30 (0.96)	65	-1.03 (1.03)
Week 28	300	-1.40 (1.20)	307	-1.53 (1.16)	61	-1.69 (1.13)	61	-1.64 (1.03)
Week 40	203	-1.68 (1.10)	242	-1.56 (1.14)	53	-1.72 (1.26)	47	-1.72 (1.16)
Week 52	180	-1.65 (1.11)	219	-1.69 (1.13)	47	-1.68 (1.09)	46	-1.72 (1.13)
Induration (upper limbs)								
Week 2	358	-0.42 (0.67)	358	-0.53 (0.74)	66	-0.35 (0.62)	64	-0.11 (0.54)
Week 4	352	-0.82 (0.88)	350	-0.91 (0.85)	65	-0.46 (0.69)	66	-0.15 (0.66)
Week 8	347	-1.07 (0.98)	350	-1.26 (0.99)	65	-0.55 (0.75)	66	-0.24 (0.66)
Week 12	345	-1.21 (1.14)	345	-1.47 (1.05)	65	-0.66 (0.78)	66	-0.36 (0.82)
Week 16	323	-1.35 (1.19)	335	-1.58 (1.14)	66	-0.65 (0.83)	66	-0.35 (0.95)
Week 20	312	-1.48 (1.18)	321	-1.65 (1.13)	66	-1.33 (0.79)	65	-1.15 (1.00)
Week 28	300	-1.58 (1.23)	307	-1.75 (1.13)	61	-1.70 (0.95)	61	-1.92 (1.02)
Week 40	203	-1.94 (1.09)	242	-1.93 (1.04)	53	-1.70 (1.01)	47	-2.32 (0.98)
Week 52	180	-1.86 (1.12)	219	-1.95 (1.07)	47	-1.70 (1.04)	46	-2.24 (1.02)

Table 14. Descriptive Statistics of Change from Baseline PASI Component Scores (Erythema, Induration, Scaling) by Body Region During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Induration (trunk)								
Week 2	358	-0.40 (0.72)	358	-0.53 (0.74)	66	-0.21 (0.48)	64	-0.14 (0.50)
Week 4	352	-0.79 (0.89)	350	-0.95 (0.90)	65	-0.37 (0.88)	66	-0.18 (0.63)
Week 8	347	-1.14 (1.05)	350	-1.36 (1.06)	65	-0.54 (0.89)	66	-0.33 (0.88)
Week 12	345	-1.25 (1.17)	345	-1.65 (1.14)	65	-0.63 (0.88)	66	-0.44 (0.90)
Week 16	323	-1.37 (1.18)	335	-1.75 (1.21)	66	-0.70 (1.01)	66	-0.42 (0.95)
Week 20	312	-1.53 (1.16)	321	-1.83 (1.21)	66	-1.36 (1.00)	65	-1.28 (0.96)
Week 28	300	-1.66 (1.19)	307	-1.92 (1.21)	61	-1.80 (1.01)	61	-1.93 (1.14)
Week 40	203	-2.09 (1.02)	242	-2.15 (1.10)	53	-2.00 (0.98)	47	-2.30 (1.10)
Week 52	180	-2.08 (1.03)	219	-2.11 (1.16)	47	-2.04 (1.04)	46	-2.24 (1.14)
Induration (lower limbs)								
Week 2	358	-0.41 (0.66)	358	-0.52 (0.65)	66	-0.21 (0.45)	64	-0.27 (0.48)
Week 4	352	-0.85 (0.85)	350	-0.96 (0.82)	65	-0.35 (0.60)	66	-0.27 (0.62)
Week 8	347	-1.16 (1.06)	350	-1.42 (0.99)	65	-0.48 (0.69)	66	-0.32 (0.79)
Week 12	345	-1.33 (1.18)	345	-1.72 (1.09)	65	-0.57 (0.68)	66	-0.44 (0.84)
Week 16	323	-1.54 (1.22)	335	-1.88 (1.19)	66	-0.64 (0.76)	66	-0.47 (0.92)
Week 20	312	-1.68 (1.22)	321	-1.93 (1.21)	66	-1.32 (0.95)	65	-1.32 (1.05)
Week 28	300	-1.81 (1.27)	307	-2.11 (1.21)	61	-1.89 (1.00)	61	-2.11 (1.10)
Week 40	203	-2.29 (1.10)	242	-2.28 (1.15)	53	-2.04 (1.00)	47	-2.64 (1.03)
Week 52	180	-2.17 (1.17)	219	-2.30 (1.18)	47	-2.13 (1.10)	46	-2.54 (1.03)
Scaling (head\neck)								
Week 2	358	-0.47 (0.67)	358	-0.56 (0.86)	66	-0.30 (0.80)	64	-0.17 (0.55)
Week 4	352	-0.88 (1.00)	350	-0.99 (1.07)	65	-0.54 (0.95)	66	-0.30 (0.74)
Week 8	347	-1.12 (1.17)	350	-1.39 (1.16)	65	-0.52 (1.03)	66	-0.36 (1.06)
Week 12	345	-1.28 (1.20)	345	-1.52 (1.20)	65	-0.57 (1.06)	66	-0.48 (1.08)
Week 16	323	-1.37 (1.26)	335	-1.57 (1.24)	66	-0.74 (1.06)	66	-0.48 (1.01)
Week 20	312	-1.47 (1.21)	321	-1.63 (1.26)	66	-1.35 (1.17)	65	-1.15 (1.11)
Week 28	300	-1.55 (1.28)	307	-1.71 (1.23)	61	-1.72 (1.29)	61	-1.79 (1.13)
Week 40	203	-1.85 (1.18)	242	-1.77 (1.27)	53	-1.87 (1.35)	47	-1.96 (1.23)
Week 52	180	-1.86 (1.16)	219	-1.87 (1.23)	47	-1.68 (1.29)	46	-1.89 (1.20)

Table 14. Descriptive Statistics of Change from Baseline PASI Component Scores (Erythema, Induration, Scaling) by Body Region During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Scaling (upper limbs)								
Week 2	358	-0.45 (0.72)	358	-0.63 (0.81)	66	-0.29 (0.55)	64	-0.20 (0.72)
Week 4	352	-0.86 (0.97)	350	-1.00 (0.93)	65	-0.40 (0.72)	66	-0.33 (0.73)
Week 8	347	-1.08 (1.07)	350	-1.33 (1.08)	65	-0.49 (0.77)	66	-0.41 (0.86)
Week 12	345	-1.24 (1.22)	345	-1.52 (1.17)	65	-0.51 (0.95)	66	-0.48 (0.83)
Week 16	323	-1.35 (1.22)	335	-1.63 (1.20)	66	-0.47 (0.88)	66	-0.47 (0.88)
Week 20	312	-1.52 (1.18)	321	-1.69 (1.21)	66	-1.05 (1.01)	65	-1.14 (1.13)
Week 28	300	-1.59 (1.28)	307	-1.81 (1.22)	61	-1.48 (1.03)	61	-1.84 (1.07)
Week 40	203	-1.95 (1.22)	242	-2.01 (1.19)	53	-1.55 (0.99)	47	-2.34 (1.05)
Week 52	180	-1.87 (1.20)	219	-1.99 (1.11)	47	-1.53 (1.10)	46	-2.26 (1.00)
Scaling (trunk)								
Week 2	358	-0.48 (0.75)	358	-0.60 (0.81)	66	-0.23 (0.70)	64	-0.30 (0.61)
Week 4	352	-0.81 (0.93)	350	-1.03 (0.96)	65	-0.37 (0.84)	66	-0.36 (0.69)
Week 8	347	-1.18 (1.11)	350	-1.40 (1.12)	65	-0.57 (0.87)	66	-0.58 (0.86)
Week 12	345	-1.30 (1.19)	345	-1.65 (1.16)	65	-0.46 (0.90)	66	-0.52 (0.88)
Week 16	323	-1.44 (1.16)	335	-1.76 (1.17)	66	-0.53 (1.00)	66	-0.65 (0.89)
Week 20	312	-1.60 (1.12)	321	-1.84 (1.20)	66	-1.17 (1.02)	65	-1.28 (1.10)
Week 28	300	-1.72 (1.23)	307	-1.97 (1.14)	61	-1.61 (1.07)	61	-1.90 (1.14)
Week 40	203	-2.15 (1.07)	242	-2.20 (1.07)	53	-1.81 (1.06)	47	-2.26 (1.01)
Week 52	180	-2.17 (1.05)	219	-2.16 (1.08)	47	-1.85 (1.12)	46	-2.28 (1.07)
Scaling (lower limbs)								
Week 2	358	-0.48 (0.74)	358	-0.57 (0.74)	66	-0.24 (0.66)	64	-0.23 (0.61)
Week 4	352	-0.87 (0.96)	350	-0.97 (0.94)	65	-0.45 (0.73)	66	-0.33 (0.71)
Week 8	347	-1.17 (1.11)	350	-1.44 (1.09)	65	-0.55 (0.81)	66	-0.42 (0.84)
Week 12	345	-1.41 (1.17)	345	-1.76 (1.13)	65	-0.63 (0.84)	66	-0.44 (0.95)
Week 16	323	-1.56 (1.17)	335	-1.89 (1.22)	66	-0.62 (0.91)	66	-0.47 (1.01)
Week 20	312	-1.68 (1.19)	321	-1.94 (1.23)	66	-1.23 (1.11)	65	-1.18 (1.16)
Week 28	300	-1.81 (1.24)	307	-2.12 (1.21)	61	-1.80 (1.09)	61	-1.95 (1.12)
Week 40	203	-2.20 (1.16)	242	-2.30 (1.19)	53	-2.00 (1.09)	47	-2.57 (0.90)
Week 52	180	-2.12 (1.16)	219	-2.35 (1.16)	47	-1.98 (1.24)	46	-2.52 (0.98)

Table 14. Descriptive Statistics of Change from Baseline PASI Component Scores (Erythema, Induration, Scaling) by Body Region During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)

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

Table 15. Least-Square Mean of Change from Baseline PASI Score from the Longitudinal Model During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	**10 mg BID**	**5 mg BID**	**10 mg BID**
Week 2				
N	359	358	66	66
LS Mean (SE)	-3.87 (0.29)	-5.31 (0.29)	-1.79 (0.66)	-0.81 (0.67)
Week 4				
N	359	358	66	66
LS Mean (SE)	-7.61 (0.35)	-9.48 (0.35)	-3.14 (0.81)	-2.18 (0.81)
Week 8				
N	359	358	66	66
LS Mean (SE)	-10.61 (0.41)	-13.58 (0.41)	-4.45 (0.95)	-2.68 (0.95)
Week 12				
N	359	358	66	66
LS Mean (SE)	-12.02 (0.44)	-15.62 (0.44)	-4.97 (1.02)	-3.43 (1.02)
Week 16				
N	359	358	66	66
LS Mean (SE)	-12.90 (0.48)	-16.55 (0.48)	-5.51 (1.09)	-3.10 (1.09)
Week 20				
N	359	358	66	66
LS Mean (SE)	-14.36 (0.44)	-17.11 (0.44)	-12.41 (1.00)	-11.18 (1.00)
Week 28				
N	359	358	66	66
LS Mean (SE)	-15.53 (0.44)	-18.02 (0.43)	-16.21 (0.98)	-17.63 (0.98)
Week 40				
N	359	358	66	66
LS Mean (SD)	-15.15 (0.47)	-17.51 (0.46)	-16.16 (1.03)	-18.54 (1.05)
Week 52				
N	359	358	66	66
LS Mean (SE)	-14.70 (0.48)	-17.16 (0.47)	-15.69 (1.04)	-18.62 (1.06)

Least Square means and corresponding standard error are derived from mixed model with fixed effects for treatment, visit, treatment-by-visit interaction and baseline value, repeated measures for visit (nested within subject) were included, unstructured covariance matrix was used.
Abbreviations: BID = twice daily, FAS = full analysis set, LS = least square, N = total number of unique subjects in the longitudinal model, PASI = Psoriasis Area and Severity Index, SE = standard error.

Table 16. Least-Square Mean Percent Change from Baseline PASI Score from the Longitudinal Model During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Week 2				
N	359	358	66	66
LS Mean (SE)	-18.50 (1.11)	-24.86 (1.11)	-8.99 (2.59)	-5.85 (2.61)
Week 4				
N	359	358	66	66
LS Mean (SE)	-34.60 (1.45)	-43.08 (1.46)	-15.75 (3.38)	-10.76 (3.38)
Week 8				
N	359	358	66	66
LS Mean (SE)	-47.72 (1.68)	-60.48 (1.68)	-20.27 (3.89)	-13.02 (3.88)
Week 12				
N	359	358	66	66
LS Mean (SE)	-54.07 (1.83)	-69.11 (1.83)	-23.02 (4.21)	-15.26 (4.21)
Week 16				
N	359	358	66	66
LS Mean (SE)	-57.25 (1.97)	-72.71 (1.96)	-25.66 (4.51)	-13.33 (4.51)
Week 20				
N	359	358	66	66
LS Mean (SE)	-63.73 (1.74)	-75.05 (1.73)	-56.71 (3.93)	-49.48 (3.94)
Week 28				
N	359	358	66	66
LS Mean (SE)	-68.62 (1.69)	-78.91 (1.67)	-73.49 (3.75)	-76.64 (3.78)
Week 40				
N	359	358	66	66
LS Mean (SD)	-67.06 (1.82)	-76.36 (1.77)	-73.52 (3.93)	-81.21 (4.01)
Week 52				
N	359	358	66	66
LS Mean (SE)	-64.15 (1.91)	-74.61 (1.85)	-70.60 (4.11)	-80.94 (4.17)

Least Square means and corresponding standard error are derived from mixed model with fixed effects for treatment, visit, treatment-by-visit interaction and baseline value, repeated measures for visit (nested within subject) were included, unstructured covariance matrix was used.
Abbreviations: BID = twice daily, FAS = full analysis set, LS = least squares, N = total number of unique subjects in the longitudinal model, PASI = Psoriasis Area and Severity Index, SE = standard error.

PGA

The PGA response of "clear" or "almost clear" was observed by Week 4, continued to improve beyond Week 16 and sustained improvement through Week 28 (Table 17). The efficacy responses were maintained through Week 52 for those subjects who remained on study after non-responders were discontinued at Week 28 as per protocol. PGA response rates were higher for CP-690,550 10 mg BID group than for CP-690,550 5 mg BID group. A statistically significant shorter time to PGA response was observed for both CP-690,550 treatment groups compared to placebo (p = 0.0000), and for the CP-690,550 10 mg BID treatment group compared to the CP-690,550 5 mg BID treatment group (p = 0.0000) (Table 18).

The efficacy of both doses of CP-690,550 was consistently observed for changes in PGA scores (Table 19).

Table 17. Proportion of Subjects Achieving Physician Global Assessment (PGA) Response of "Clear" or "Almost Clear" During Week 0 to Week 52 Sequence (FAS, NRI)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Week 2				
N	363	360	66	66
n (%)	19 (5.23)	36 (10.00)	2 (3.03)	0 (0.00)
95% CI	2.94, 7.53	6.90, 13.10	0.00, 7.17	0.00, 0.00
Week 4				
N	363	360	66	66
n (%)	62 (17.08)	83 (23.06)	4 (6.06)	0 (0.00)
95% CI	13.21, 20.95	18.70, 27.41	0.30, 11.82	0.00, 0.00
Week 8				
N	363	360	66	66
n (%)	114 (31.40)	167 (46.39)	6 (9.09)	4 (6.06)
95% CI	26.63, 36.18	41.24, 51.54	2.16, 16.03	0.30, 11.82
Week 12				
N	363	360	66	66
n (%)	137 (37.74)	204 (56.67)	8 (12.12)	6 (9.09)
95% CI	32.75, 42.73	51.55, 61.79	4.25, 20.00	2.16, 16.03
Week 16				
N	363	360	66	66
n (%)	152 (41.87)	213 (59.17)	9 (13.64)	7 (10.61)
95% CI	36.80, 46.95	54.09, 64.24	5.36, 21.92	3.18, 18.03
Week 20				
N	363	360	66	66
n (%)	165 (45.45)	204 (56.67)	26 (39.39)	20 (30.30)
95% CI	40.33, 50.58	51.55, 61.79	27.61, 51.18	19.22, 41.39
Week 28				
N	363	360	66	66
n (%)	177 (48.76)	224 (62.22)	44 (66.67)	43 (65.15)
95% CI	43.62, 53.90	57.21, 67.23	55.29, 78.04	53.66, 76.65
Week 40				
N	363	360	66	66
n (%)	155 (42.70)	191 (53.06)	35 (53.03)	42 (63.64)
95% CI	37.61, 47.79	47.90, 58.21	40.99, 65.07	52.03, 75.24
Week 52				
N	363	360	66	66
n (%)	129 (35.54)	168 (46.67)	29 (43.94)	39 (59.09)
95% CI	30.61, 40.46	41.51, 51.82	31.97, 55.91	47.23, 70.95

NRI (Non-responder Imputation): Setting missing values to be non-responsive.
Normal approximation
Abbreviations: BID = twice daily, CI = confidence interval, FAS = Full Analysis Set, N = number of subjects, n = number of subjects meeting prespecified criteria, NRI = Non-responder imputation, PGA = physician global assessment.

Table 18. Survival Analysis of Time to Physician Global Assessment (PGA) Response of "Clear" or "Almost Clear" During Week 0 to Week 16 (FAS, Observed Case)

		CP-690,550 5 mg BID	CP-690,550 10 mg BID	Placebo
Baseline	Number of subjects analyzed [a]	359	358	177
Week 2	n events - n (%)	19 (5.29)	36 (10.06)	3 (1.69)
	N Remaining	333	316	171
Week 4	n events - n (%)	46 (13.81)	54 (17.09)	3 (1.75)
	N Remaining	285	260	162
Week 8	n events - n (%)	60 (21.05)	82 (31.54)	7 (4.32)
	N Remaining	222	177	147
Week 12	n events - n (%)	35 (15.77)	54 (30.51)	7 (4.76)
	N Remaining	172	114	123
Week 16	n events - n (%)	29 (16.86)	20 (17.54)	4 (3.25)
	N Remaining	0	0	0
Week 2	Probability of response % (95% CI)	5.29 (3.41, 8.17)	10.06 (7.36, 13.67)	1.69 (0.55, 5.16)
Week 4	Probability of response % (95% CI)	18.38 (14.71, 22.82)	25.43 (21.21, 30.30)	3.42 (1.55, 7.45)
Week 8	Probability of response % (95% CI)	35.56 (30.80, 40.81)	48.95 (43.85, 54.30)	7.59 (4.48, 12.72)
Week 12	Probability of response % (95% CI)	45.72 (40.66, 51.10)	64.52 (59.50, 69.51)	11.99 (7.90, 17.99)
Week 16	Probability of response % (95% CI)	54.87 (49.66, 60.24)	70.75 (65.86, 75.48)	14.86 (10.19, 21.39)
Total censored n (%)		170 (47.35)	112 (31.28)	153 (86.44)
Estimated median time to event (response) - weeks (95% CI)		16.0 (12.0, --)	12.0 (8.0,12.0)	-- (--, --)
Log-rank p-value	Active vs. Placebo	0.0000	0.0000	
	10 mg vs. 5 mg	0.0000		

Median time to event is the time after which 50% of subjects with a particular condition have the event. This time is not estimable if less than 50% of subjects had the event by the end of study.
Abbreviations: BID = twice daily, CI = confidence interval, FAS = full analysis set, N = number of subjects, n = number of subjects meeting prespecified criteria, PGA = physician global assessment, -- = not estimable.
[a] Includes FAS subjects with non-missing post-baseline response data.

Table 19. Descriptive Statistics of Physician Global Assessment (PGA) During Period Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID n (%)	10 mg BID n (%)	5 mg BID n (%)	10 mg BID n (%)
Baseline				
0=Clear	0	0	0	0
1=Almost clear	0	0	0	0
2=Mild	1 (<1.0)	1 (<1.0)	0	0
3=Moderate	320 (88.2)	320 (88.9)	64 (97.0)	61 (92.4)
4=Severe	42 (11.6)	39 (10.8)	2 (3.0)	5 (7.6)
N (Total)	363	360	66	66
Week 2				
0=Clear	0	0	0	0
1=Almost clear	19 (5.3)	36 (10.1)	2 (3.0)	0
2=Mild	117 (32.7)	139 (38.8)	20 (30.3)	12 (18.8)
3=Moderate	204 (57.0)	165 (46.1)	42 (63.6)	45 (70.3)
4=Severe	18 (5.0)	18 (5.0)	2 (3.0)	7 (10.9)
N (Total)	358	358	66	64
Week 4				
0=Clear	5 (1.4)	12 (3.4%)	0	0
1=Almost clear	57 (16.2)	71 (20.3%)	4 (6.2%)	0
2=Mild	154 (43.8)	159 (45.4%)	22 (33.8%)	14 (21.2%)
3=Moderate	125 (35.5)	99 (28.3%)	36 (55.4%)	47 (71.2%)
4=Severe	11 (3.1)	9 (2.6)	3 (4.6)	5 (7.6)
N (Total)	352	350	65	66
Week 8				
0=Clear	13 (3.7)	37 (10.6)	0	0
1=Almost clear	101 (29.1)	130 (37.1)	6 (9.2)	4 (6.1)
2=Mild	140 (40.3)	126 (36.0)	22 (33.8)	16 (24.2)
3=Moderate	84 (24.2)	51 (14.6)	35 (53.8)	43 (65.2)
4=Severe	9 (2.6)	6 (1.7)	2 (3.1)	3 (4.5)
N (Total)	347	350	65	66
Week 12				
0=Clear	27 (7.8)	60 (17.4)	1 (1.5)	0
1=Almost clear	110 (31.9)	144 (41.7)	7 (10.8)	6 (9.1)
2=Mild	131 (38.0)	90 (26.1)	28 (43.1)	17 (25.8)
3=Moderate	67 (19.4)	45 (13.0)	27 (41.5)	36 (54.5)
4=Severe	10 (2.9)	6 (1.7)	2 (3.1)	7 (10.6)
N (Total)	345	345	65	66
Week 16				
0=Clear	39 (12.1)	86 (25.7)	0	2 (3.0)
1=Almost clear	113 (35.0)	127 (37.9)	9 (13.6)	5 (7.6)
2=Mild	106 (32.8)	79 (23.6)	31 (47.0)	14 (21.2)
3=Moderate	57 (17.6)	38 (11.3)	23 (34.8)	41 (62.1)
4=Severe	8 (2.5)	5 (1.5)	3 (4.5)	4 (6.1)
N (Total)	323	335	66	66
Week 20				
0=Clear	51 (16.3)	100 (31.2)	5 (7.6)	6 (9.2)
1=Almost clear	114 (36.5)	104 (32.4)	21 (31.8)	14 (21.5)
2=Mild	99 (31.7)	78 (24.3)	35 (53.0)	28 (43.1)
3=Moderate	46 (14.7)	37 (11.5)	5 (7.6)	15 (23.1)
4=Severe	2 (<1.0)	2 (<1.0)	0	2 (3.1)
N (Total)	312	321	66	65

Table 19. Descriptive Statistics of Physician Global Assessment (PGA) During Period Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID n (%)	10 mg BID n (%)	5 mg BID n (%)	10 mg BID n (%)
Week 28				
0=Clear	70 (23.3)	105 (34.2)	9 (14.8)	18 (29.5)
1=Almost clear	107 (35.7)	119 (38.8)	35 (57.4)	25 (41.0)
2=Mild	77 (25.7)	54 (17.6)	14 (23.0)	12 (19.7)
3=Moderate	43 (14.3)	27 (8.8)	3 (4.9)	4 (6.6)
4=Severe	3 (1.0)	2 (<1.0)	0	2 (3.3)
N (Total)	300	307	61	61
Week 40				
0=Clear	72 (35.5)	111 (45.9)	10 (18.9)	26 (55.3)
1=Almost clear	83 (40.9)	80 (33.1)	25 (47.2)	16 (34.0)
2=Mild	37 (18.2)	37 (15.3)	14 (26.4)	4 (8.5)
3=Moderate	10 (4.9)	13 (5.4)	4 (7.5)	1 (2.1)
4=Severe	1 (<1.0)	1 (<1.0)	0	0
N (Total)	203	242	53	47
Week 52				
0=Clear	57 (31.7)	95 (43.4)	9 (19.1)	25 (54.3)
1=Almost clear	72 (40.0)	73 (33.3)	20 (42.6)	14 (30.4)
2=Mild	35 (19.4)	43 (19.6)	17 (36.2)	7 (15.2)
3=Moderate	16 (8.9)	8 (3.7)	1 (2.1)	0
4=Severe	0	0	0	0
N (Total)	180	219	47	46

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = Full Analysis Set, N = number of subjects, n = number of subjects meeting prespecified criteria, PGA = physician global assessment.

BSA:

The efficacy of both doses of CP-690,550 was consistently observed for actual and mean percent changes in the percent of total BSA involvement (Table 20 and Table 21).

Table 20. Descriptive Statistics of Total Psoriatic BSA (%) During Week 0 to Week 52 (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Baseline				
N	363	360	66	66
Mean (SE)	28.48 (0.86)	31.13 (0.93)	28.03 (2.09)	30.17 (2.01)
Median	24.00	26.50	20.25	27.40
Week 2				
N	358	358	66	64
Mean (SE)	27.08 (0.89)	27.86 (0.91)	28.21 (2.37)	30.32 (2.12)
Median	23.00	24.00	20.00	26.25
Week 4				
N	352	350	65	66
Mean (SE)	23.69 (0.88)	22.79 (0.94)	27.15 (2.49)	29.52 (2.09)
Median	19.50	18.75	19.00	25.50
Week 8				
N	347	350	65	66
Mean (SE)	18.99 (0.87)	16.49 (0.87)	26.82 (2.47)	29.43 (2.15)
Median	16.00	11.25	20.50	26.00
Week 12				
N	345	345	65	66
Mean (SE)	15.73 (0.86)	12.64 (0.81)	25.89 (2.54)	29.02 (2.16)
Median	11.50	7.00	19.00	26.50
Week 16				
N	323	335	66	66
Mean (SE)	13.08 (0.88)	9.48 (0.71)	25.89 (2.68)	29.14 (2.36)
Median	7.50	4.30	18.00	25.50
Week 20				
N	312	321	66	65
Mean (SE)	10.77 (0.81)	7.59 (0.64)	18.57 (2.52)	21.73 (2.17)
Median	5.00	3.00	12.00	18.00
Week 28				
N	300	307	61	61
Mean (SE)	8.92 (0.75)	6.05 (0.53)	9.54 (2.03)	9.96 (1.59)
Median	3.50	2.00	4.50	6.00
Week 40				
N	203	242	53	47
Mean (SE)	4.37 (0.53)	3.51 (0.39)	4.47 (0.96)	3.02 (0.61)
Median	1.50	1.00	3.00	0.90
Week 52				
N	180	219	47	46
Mean (SE)	4.42 (0.52)	2.94 (0.36)	3.79 (0.64)	2.09 (0.41)
Median	2.00	1.00	2.20	1.00

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, BSA = Total Psoriatic Body Surface Area, FAS = full analysis set, N = number of subjects, SE = standard error.

Table 21. Descriptive Statistics of Percent Change from Baseline Total Psoriatic BSA (%) During Week 0 to Week 52 (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Week 2				
N	358	358	66	64
Mean (SE)	-6.87 (0.92)	-10.40 (1.09)	-1.99 (1.94)	-1.03 (1.22)
Median	0.00	-0.39	0.00	0.00
Week 4				
N	352	350	65	66
Mean (SE)	-18.51 (1.58)	-26.77 (1.69)	-5.38 (3.04)	-1.80 (3.18)
Median	-9.95	-18.54	0.00	0.00
Week 8				
N	347	350	65	66
Mean (SE)	-34.76 (1.97)	-46.32 (1.96)	-7.24 (3.96)	-1.56 (4.26)
Median	-28.99	-48.50	0.00	0.00
Week 12				
N	345	345	65	66
Mean (SE)	-46.24 (2.16)	-59.40 (2.00)	-9.84 (4.31)	-0.83 (6.45)
Median	-47.83	-69.23	0.00	0.00
Week 16				
N	323	335	66	66
Mean (SE)	-54.77 (2.29)	-68.78 (1.90)	-11.29 (5.16)	2.04 (9.72)
Median	-65.60	-83.33	-4.30	-0.61
Week 20				
N	312	321	66	65
Mean (SE)	-62.54 (2.21)	-74.40 (1.85)	-37.73 (5.46)	-26.42 (7.46)
Median	-76.92	-89.36	-43.26	-29.22
Week 28				
N	300	307	61	61
Mean (SE)	-67.89 (2.77)	-79.71 (1.62)	-67.73 (4.12)	-69.00 (4.04)
Median	-83.89	-92.00	-79.49	-78.13
Week 40				
N	203	242	53	47
Mean (SE)	-86.47 (1.31)	-88.55 (1.25)	-81.99 (2.63)	-90.44 (1.84)
Median	-94.00	-96.00	-87.88	-96.15
Week 52				
N	180	219	47	46
Mean (SE)	-86.18 (1.31)	-90.58 (1.01)	-82.90 (2.54)	-93.22 (1.31)
Median	-91.70	-96.50	-88.00	-96.01

Abbreviations: BID = twice daily, BSA = Body Surface Area, FAS = full analysis set, N = number of subjects, SE = standard error.

NAPSI

CP-690,550 improved the severity of nail psoriasis as measured by NAPSI (Table 22 through Table 27).

Table 22. Descriptive Statistics of NAPSI Score During Week 0 to Week 52 Sequence (FAS Subjects with Baseline Nail Psoriasis, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Baseline				
N	247	250	34	46
Mean (SD)	26.64 (20.65)	28.24 (20.89)	26.76 (18.33)	23.91 (16.21)
Week 8				
N	236	242	33	46
Mean (SD)	24.32 (20.60)	22.47 (19.43)	25.55 (18.50)	24.61 (16.76)
Week 16				
N	215	233	34	46
Mean (SD)	20.09 (18.79)	16.53 (17.87)	27.82 (17.64)	25.46 (18.57)
Week 20				
N	210	227	34	45
Mean (SD)	16.53 (17.35)	12.96 (16.11)	23.97 (18.18)	21.18 (18.69)
Week 28				
N	202	213	30	44
Mean (SD)	13.42 (16.17)	9.49 (13.92)	16.77 (14.69)	14.77 (17.29)
Week 40				
N	125	167	24	33
Mean (SD)	7.36 (10.04)	7.19 (12.71)	5.67 (7.92)	8.85 (11.27)
Week 52				
N	110	148	21	32
Mean (SD)	6.94 (9.48)	6.73 (12.44)	5.90 (8.92)	6.66 (9.09)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, NAPSI = Nail Psoriasis Severity Index, SD = standard deviation.

Table 23. Descriptive Statistics of Change from Baseline NAPSI Score During Week 0 to Week 52 Sequence (FAS Subjects with Baseline Nail Psoriasis, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Week 8				
N	236	242	33	46
Mean (SD)	-2.58 (10.98)	-5.55 (12.64)	-0.82 (7.26)	0.70 (6.89)
Week 16				
N	215	233	34	46
Mean (SD)	-6.91 (13.93)	-11.70 (16.68)	1.06 (9.37)	1.54 (11.34)
Week 20				
N	210	227	34	45
Mean (SD)	-10.51 (15.17)	-15.16 (17.51)	-2.79 (11.83)	-2.53 (13.00)
Week 28				
N	202	213	30	44
Mean (SD)	-13.08 (16.53)	-19.07 (18.62)	-10.30 (13.90)	-8.50 (14.18)
Week 40				
N	125	167	24	33
Mean (SD)	-18.40 (17.47)	-21.63 (19.61)	-16.38 (15.34)	-13.21 (13.07)
Week 52				
N	110	148	21	32
Mean (SD)	-18.49 (17.03)	-22.28 (20.33)	-17.19 (14.32)	-15.97 (12.47)

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

Table 24. Descriptive Statistics of Number of Nails Affected During Week 0 to Week 52 Sequence (FAS Subjects with Baseline Nail Psoriasis, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Baseline				
N	247	250	34	46
Mean (SD)	7.21 (3.14)	7.43 (3.12)	7.71 (3.05)	7.24 (3.39)
Week 8				
N	234	242	32	46
Mean (SD)	6.87 (3.58)	6.65 (3.80)	8.00 (3.01)	7.48 (3.00)
Week 16				
N	215	233	33	45
Mean (SD)	6.25 (3.79)	5.44 (4.16)	8.27 (2.65)	7.56 (3.03)
Week 20				
N	209	227	33	44
Mean (SD)	5.53 (3.83)	4.65 (4.13)	7.48 (3.01)	6.43 (3.70)
Week 28				
N	202	213	30	44
Mean (SD)	4.77 (3.92)	3.76 (4.03)	6.63 (3.32)	5.09 (3.84)
Week 40				
N	125	167	24	33
Mean (SD)	3.49 (3.68)	2.91 (3.61)	3.13 (3.69)	3.94 (4.00)
Week 52				
N	110	148	21	32
Mean (SD)	3.44 (3.60)	2.64 (3.57)	3.10 (3.70)	3.25 (3.88)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, SD = standard deviation.

Table 25. Least-Square Mean of Percent Change from Baseline NAPSI Score - Testing from the Longitudinal Model During Week 0 to Week 52 Sequence (FAS Subjects with Baseline Nail Psoriasis, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Week 8				
N	238	242	34	46
LS Mean (SE)	2.58 (6.46)	-19.37 (6.40)	16.91 (17.18)	36.22 (14.67)
Week 16				
N	238	242	34	46
LS Mean (SE)	-14.13 (9.39)	-42.26 (9.16)	78.80 (24.22)	50.19 (20.82)
Week 20				
N	238	242	34	46
LS Mean (SE)	-32.74 (9.20)	-52.62 (8.93)	43.82 (23.46)	38.66 (20.24)
Week 28				
N	238	242	34	46
LS Mean (SE)	-43.52 (7.22)	-65.20 (7.06)	12.39 (18.71)	-18.71 (15.95)
Week 40				
N	238	242	34	46
LS Mean (SD)	-64.55 (4.05)	-75.41 (3.57)	-57.01 (9.38)	-54.83 (8.02)
Week 52				
N	238	242	34	46
LS Mean (SE)	-58.27 (5.98)	-73.56 (5.54)	-45.67 (14.67)	-72.42 (12.31)

Least Square means and corresponding standard error are derived from mixed model with fixed effects for treatment, visit, treatment-by-visit interaction and baseline value, repeated measures for visit (nested within subject) were included, unstructured covariance matrix was used.
Abbreviations: BID = twice daily, FAS = full analysis set, LS = least squares, N = total number of unique subjects in the longitudinal model, NAPSI = Nail Psoriasis Severity Index, SE = standard error

Table 26. Proportion of Subjects Achieving NAPSI75 Response During Week 0 to Week 52 (FAS Subjects with Baseline Nail Psoriasis, NRI)

	Response			
	N	n (%)	SE	95% CI
Week 8				
CP-690,550 5 mg BID	247	24 (9.72)	1.88	6.02, 13.41
CP-690,550 10 mg BID	250	36 (14.40)	2.22	10.05, 18.75
Placebo to CP-690,550 5 mg BID	34	3 (8.82)	4.86	0.00, 18.36
Placebo to CP-690,550 10 mg BID	46	2 (4.35)	3.01	0.00, 10.24
Week 16				
CP-690,550 5 mg BID	247	37 (14.98)	2.27	10.53, 19.43
CP-690,550 10 mg BID	250	73 (29.20)	2.88	23.56, 34.84
Placebo to CP-690,550 5 mg BID	34	2 (5.88)	4.04	0.00, 13.79
Placebo to CP-690,550 10 mg BID	46	3 (6.52)	3.64	0.00, 13.66
Week 20				
CP-690,550 5 mg BID	247	52 (21.05)	2.59	15.97, 26.14
CP-690,550 10 mg BID	250	98 (39.20)	3.09	33.15, 45.25
Placebo to CP-690,550 5 mg BID	34	3 (8.82)	4.86	0.00, 18.36
Placebo to CP-690,550 10 mg BID	46	11 (23.91)	6.29	11.59, 36.24
Week 28				
CP-690,550 5 mg BID	247	77 (31.17)	2.95	25.40, 36.95
CP-690,550 10 mg BID	250	123 (49.20)	3.16	43.00, 55.40
Placebo to CP-690,550 5 mg BID	34	6 (17.65)	6.54	4.83, 30.46
Placebo to CP-690,550 10 mg BID	46	13 (28.26)	6.64	15.25, 41.27
Week 40				
CP-690,550 5 mg BID	247	70 (28.34)	2.87	22.72, 33.96
CP-690,550 10 mg BID	250	122 (48.80)	3.16	42.60, 55.00
Placebo to CP-690,550 5 mg BID	34	14 (41.18)	8.44	24.63, 57.72
Placebo to CP-690,550 10 mg BID	46	17 (36.96)	7.12	23.01, 50.91
Week 52				
CP-690,550 5 mg BID	247	63 (25.51)	2.77	20.07, 30.94
CP-690,550 10 mg BID	250	103 (41.20)	3.11	35.10, 47.30
Placebo to CP-690,550 5 mg BID	34	12 (35.29)	8.20	19.23, 51.36
Placebo to CP-690,550 10 mg BID	46	20 (43.48)	7.31	29.15, 57.80

NRI (Non-responder Imputation): Setting missing values to be non-responsive.
Normal approximation
Abbreviations: BID = twice daily, CI = confidence interval, FAS = Full Analysis Set, N = number of subjects, n = number of subjects meeting prespecified criteria, NAPSI = Nail Psoriasis Severity Index, NRI = non-responder imputation, SE = standard error.

Table 27. Proportion of Subjects Achieving NAPSI100 Response During Week 0 to Week 52 (FAS Subjects with Baseline Nail Psoriasis, NRI)

	Response			
	N	n (%)	SE	95% CI
Week 8				
CP-690,550 5 mg BID	247	20 (8.10)	1.74	4.70, 11.50
CP-690,550 10 mg BID	250	31 (12.40)	2.08	8.31, 16.49
Placebo to CP-690,550 5 mg BID	34	2 (5.88)	4.04	0.00, 13.79
Placebo to CP-690,550 10 mg BID	46	2 (4.35)	3.01	0.00, 10.24
Week 16				
CP-690,550 5 mg BID	247	25 (10.12)	1.92	6.36, 13.88
CP-690,550 10 mg BID	250	50 (20.00)	2.53	15.04, 24.96
Placebo to CP-690,550 5 mg BID	34	2 (5.88)	4.04	0.00, 13.79
Placebo to CP-690,550 10 mg BID	46	2 (4.35)	3.01	0.00, 10.24
Week 20				
CP-690,550 5 mg BID	247	34 (13.77)	2.19	9.47, 18.06
CP-690,550 10 mg BID	250	68 (27.20)	2.81	21.68, 32.72
Placebo to CP-690,550 5 mg BID	34	3 (8.82)	4.86	0.00, 18.36
Placebo to CP-690,550 10 mg BID	46	6 (13.04)	4.97	3.31, 22.78
Week 28				
CP-690,550 5 mg BID	247	48 (19.43)	2.52	14.50, 24.37
CP-690,550 10 mg BID	250	80 (32.00)	2.95	26.22, 37.78
Placebo to CP-690,550 5 mg BID	34	2 (5.88)	4.04	0.00, 13.79
Placebo to CP-690,550 10 mg BID	46	8 (17.39)	5.59	6.44, 28.34
Week 40				
CP-690,550 5 mg BID	247	45 (18.22)	2.46	13.40, 23.03
CP-690,550 10 mg BID	250	76 (30.40)	2.91	24.70, 36.10
Placebo to CP-690,550 5 mg BID	34	10 (29.41)	7.81	14.10, 44.73
Placebo to CP-690,550 10 mg BID	46	12 (26.09)	6.47	13.40, 38.78
Week 52				
CP-690,550 5 mg BID	247	39 (15.79)	2.32	11.24, 20.34
CP-690,550 10 mg BID	250	72 (28.80)	2.86	23.19, 34.41
Placebo to CP-690,550 5 mg BID	34	10 (29.41)	7.81	14.10, 44.73
Placebo to CP-690,550 10 mg BID	46	13 (28.26)	6.64	15.25, 41.27

NRI (Non-responder Imputation): Setting missing values to be non-responsive.
Normal approximation
Abbreviations: BID = twice daily, CI = confidence interval, FAS = Full Analysis Set, N = number of subjects, n = number of subjects meeting prespecified criteria, NAPSI = Nail Psoriasis Severity Index, NRI = non-responder imputation, SE = standard error.

Itch Severity Item (ISI)

Improvement in itch was rapid for both CP-690,550 5 mg BID and 10 mg BID and was maintained through Week 52 (Table 28 and Table 29).

Table 28. Descriptive Statistics of Itch Severity Item (ISI) During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Baseline				
N	343	341	62	58
Mean (SD)	5.49 (2.81)	5.59 (2.72)	5.64 (2.65)	5.94 (2.94)
Week 2				
N	357	358	66	64
Mean (SD)	3.74 (2.51)	3.32 (2.56)	5.45 (2.87)	5.61 (3.04)
Week 4				
N	351	350	64	66
Mean (SD)	2.89 (2.44)	2.41 (2.28)	5.36 (2.86)	5.56 (3.05)
Week 8				
N	347	348	65	66
Mean (SD)	2.56 (2.60)	1.87 (2.20)	5.51 (2.94)	5.50 (3.35)
Week 12				
N	343	344	65	66
Mean (SD)	2.38 (2.66)	1.62 (2.18)	4.83 (3.11)	5.42 (3.30)
Week 16				
N	322	335	66	66
Mean (SD)	2.44 (2.70)	1.48 (2.14)	4.82 (3.11)	5.83 (3.27)
Week 20				
N	312	319	66	65
Mean (SD)	1.94 (2.20)	1.43 (2.23)	2.48 (2.27)	2.48 (2.63)
Week 28				
N	293	306	61	61
Mean (SD)	1.96 (2.41)	1.41 (2.11)	2.02 (2.31)	1.62 (2.09)
Week 40				
N	202	242	53	47
Mean (SD)	1.47 (2.15)	1.01 (1.77)	1.43 (2.03)	0.83 (1.54)
Week 52				
N	179	218	47	46
Mean (SD)	1.35 (2.00)	0.83 (1.53)	1.60 (2.09)	0.93 (1.44)

Baseline ISI is average of prior 7 day scores from diary
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, SD = standard deviation

Table 29. Least-Square Mean of Change from Baseline Itch Severity Item (ISI) from the Longitudinal Model During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Week 2				
N	340	339	62	58
LS Mean (SE)	-1.76 (0.10)	-2.25 (0.11)	-0.13 (0.25)	-0.06 (0.26)
Week 4				
N	340	339	62	58
LS Mean (SE)	-2.62 (0.11)	-3.16 (0.11)	-0.27 (0.26)	-0.11 (0.27)
Week 8				
N	340	339	62	58
LS Mean (SE)	-2.95 (0.13)	-3.72 (0.13)	-0.01 (0.29)	-0.18 (0.30)
Week 12				
N	340	339	62	58
LS Mean (SE)	-3.02 (0.13)	-3.91 (0.13)	-0.79 (0.30)	-0.25 (0.31)
Week 16				
N	340	339	62	58
LS Mean (SE)	-2.85 (0.14)	-3.97 (0.14)	-0.77 (0.31)	0.17 (0.32)
Week 20				
N	340	339	62	58
LS Mean (SE)	-3.31 (0.13)	-3.98 (0.13)	-3.11 (0.29)	-3.16 (0.30)
Week 28				
N	340	339	62	58
LS Mean (SE)	-3.25 (0.14)	-3.94 (0.13)	-3.59 (0.30)	-4.16 (0.32)
Week 40				
N	340	339	62	58
LS Mean (SD)	-3.07 (0.15)	-3.88 (0.14)	-3.84 (0.32)	-4.40 (0.34)
Week 52				
N	340	339	62	58
LS Mean (SE)	-3.05 (0.15)	-3.89 (0.14)	-3.50 (0.32)	-4.17 (0.33)

Least Square means and corresponding standard error are derived from mixed model with fixed effects for treatment, visit, treatment-by-visit interaction and baseline value, repeated measures for visit (nested within subject) were included, unstructured covariance matrix was used.
Baseline ISI is average of prior 7 day scores from diary.
Abbreviations: BID = twice daily, FAS = full analysis set, LS = least squares, N = number of subjects, SE = standard error.

Dermatology Life Quality Index (DLQI)

Substantial improvement in health-related quality of life as measured by the DLQI was seen by Week 2 for both CP-690,550 5 mg BID and CP-690,550 10 mg BID, and was maintained through Week 52 (Table 30 and Table 31).

Table 30. Descriptive Statistics of Dermatology Life Quality Index (DLQI) During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	**10 mg BID**	**5 mg BID**	**10 mg BID**
Baseline				
N	363	359	66	66
Mean (SD)	12.46 (6.89)	12.87 (6.91)	13.83 (6.97)	14.68 (6.80)
Week 2				
N	356	357	66	64
Mean (SD)	8.65 (6.11)	8.32 (6.45)	11.44 (7.02)	12.67 (7.06)
Week 4				
N	351	349	65	66
Mean (SD)	6.98 (5.97)	6.50 (5.94)	11.45 (6.87)	13.05 (7.14)
Week 8				
N	345	347	65	66
Mean (SD)	5.88 (6.00)	4.95 (5.58)	10.89 (6.23)	13.05 (7.49)
Week 12				
N	340	344	65	66
Mean (SD)	5.36 (6.06)	4.17 (5.10)	10.29 (6.82)	13.06 (7.58)
Week 16				
N	319	331	66	66
Mean (SD)	5.45 (6.07)	3.85 (5.17)	10.05 (6.23)	12.83 (7.80)
Week 20				
N	310	319	66	65
Mean (SD)	4.28 (5.18)	3.26 (4.67)	5.89 (4.88)	7.17 (6.69)
Week 28				
N	289	303	61	61
Mean (SD)	3.94 (5.05)	3.24 (4.83)	4.34 (4.88)	3.46 (4.27)
Week 40				
N	200	239	53	46
Mean (SD)	2.53 (4.11)	2.11 (3.79)	3.25 (4.43)	1.63 (2.17)
Week 52				
N	177	216	47	46
Mean (SD)	2.86 (4.35)	1.91 (3.72)	3.40 (4.43)	1.78 (2.44)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, SD = standard deviation

Table 31. Least-Square Mean of Change from Baseline Dermatology Life Quality Index (DLQI) Statistical Testing from the Longitudinal Model During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Week 2				
N	358	357	66	66
LS Mean (SE)	-4.02 (0.23)	-4.56 (0.23)	-1.94 (0.54)	-1.07 (0.54)
Week 4				
N	358	357	66	66
LS Mean (SE)	-5.65 (0.25)	-6.41 (0.25)	-1.90 (0.57)	-0.77 (0.57)
Week 8				
N	358	357	66	66
LS Mean (SE)	-6.68 (0.27)	-7.95 (0.27)	-2.45 (0.61)	-0.77 (0.61)
Week 12				
N	358	357	66	66
LS Mean (SE)	-7.09 (0.27)	-8.70 (0.27)	-3.08 (0.63)	-0.75 (0.63)
Week 16				
N	358	357	66	66
LS Mean (SE)	-6.97 (0.29)	-8.90 (0.28)	-3.33 (0.65)	-0.98 (0.65)
Week 20				
N	358	357	66	66
LS Mean (SE)	-8.01 (0.27)	-9.42 (0.27)	-7.48 (0.61)	-6.48 (0.61)
Week 28				
N	358	357	66	66
LS Mean (SE)	-8.25 (0.28)	-9.36 (0.28)	-9.02 (0.62)	-9.72 (0.62)
Week 40				
N	358	357	66	66
LS Mean (SD)	-8.50 (0.30)	-9.51 (0.29)	-9.26 (0.63)	-10.89 (0.65)
Week 52				
N	358	357	66	66
LS Mean (SE)	-8.26 (0.31)	-9.56 (0.30)	-9.23 (0.65)	-10.90 (0.66)

Least Square means and corresponding standard error are derived from mixed model with fixed effects for treatment, visit, treatment-by-visit interaction and baseline value, repeated measures for visit (nested within subject) were included, unstructured covariance matrix was used.
Abbreviations: BID = twice daily, FAS = full analysis set, LS = least square, , N = number of subjects, SE = standard error

Other Patient Reported Outcomes:

- At Baseline, 35% and 61% of subjects reported their disease as “moderate” or “severe” on the Patient Global Assessment (PtGA), respectively. By Week 16, 32% and 49% of subjects in the 5 mg BID and 10 mg BID groups, respectively, reported their overall skin disease had improved to “clear” or “almost clear” as measured by the PtGA, with similar response rates observed at Week 52.

- Significant improvement in the physical and mental component summary scores of the Short Form 36 (SF-36), as well as all 9 domains, was seen at the first post-baseline assessment (Week 16) for both CP-690,550 5 mg BID and 10 mg BID and was maintained through Week 52.

- Symptoms of depression and anxiety, as measured by the Hospital Anxiety and Depression Scale (HADS), significantly improved compared to placebo by Week 16 for both CP-690,550 5 mg BID and 10 mg BID.

- Most subjects were satisfied with their treatment as measured by Patient Satisfaction with Study Medication (PSSM) for CP-690,550 5 mg BID and 10 mg BID.

- Work productivity improved with the CP-690,550 10 mg BID (but not the 5 mg BID) group at Week 16 as measured by the Work Limitation Questionnaire (WLQ).

- There was a significant reduction in joint pain versus placebo as measured by the Joint Pain Assessment (JPA) by Week 16 for both CP-690,550 5 mg BID and 10 mg BID; response was maintained through Week 52.

- All treatment groups demonstrated improvements on the Euro-Qol 5 Dimensions (EQ-5D) Utility score at Week 52.

Data for these patient reported outcomes over the 52-week treatment period are summarized in Table 32 through Table 38.

Table 32. Descriptive Statistics of Patient Global Assessment (PtGA) During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
	n (%)	n (%)	n (%)	n (%)
Baseline				
Clear	0	0	0	0
Almost clear	0	0	0	0
Mild	7 (1.9)	13 (3.6)	2 (3.0)	1 (1.5)
Moderate	127 (35.3)	128 (35.7)	21 (31.8)	23 (34.8)
Severe	226 (62.8)	218 (60.7)	43 (65.2)	42 (63.6)
N (Total)	360	359	66	66
Week 2				
Clear	0	1 (<1.0)	0	0
Almost clear	4 (1.1)	14 (3.9)	0	0
Mild	53 (14.8)	63 (17.6)	5 (7.6)	4 (6.3)
Moderate	182 (51.0)	172 (48.0)	25 (37.9)	26 (40.6)
Severe	118 (33.1)	108 (30.2)	36 (54.5)	34 (53.1)
N (Total)	357	358	66	64
Week 4				
Clear	0	3 (<1.0)	0	0
Almost clear	35 (10.0)	42 (12.1)	1 (1.5)	0
Mild	86 (24.6)	104 (29.9)	5 (7.7)	3 (4.6)
Moderate	150 (42.9)	141 (40.5)	30 (46.2)	24 (36.9)
Severe	79 (22.6)	58 (16.7)	29 (44.6)	38 (58.5)
N (Total)	350	348	65	65
Week 8				
Clear	6 (1.7)	13 (3.8)	0	0
Almost clear	68 (19.7)	96 (27.7)	1 (1.5)	1 (1.5)
Mild	101 (29.3)	100 (28.9)	8 (12.3)	4 (6.1)
Moderate	104 (30.1)	94 (27.2)	28 (43.1)	26 (39.4)
Severe	66 (19.1)	43 (12.4)	28 (43.1)	35 (53.0)
N (Total)	345	346	65	66
Week 12				
Clear	13 (3.8)	30 (8.7)	0	0
Almost clear	85 (24.9)	121 (35.2)	2 (3.1)	2 (3.1)
Mild	101 (29.6)	96 (27.9)	15 (23.1)	5 (7.7)
Moderate	83 (24.3)	67 (19.5)	21 (32.3)	22 (33.8)
Severe	59 (17.3)	30 (8.7)	27 (41.5)	36 (55.4)
N (Total)	341	344	65	65
Week 16				
Clear	11 (3.4)	36 (10.9)	0	0
Almost clear	91 (28.4)	125 (37.8)	4 (6.1)	2 (3.0)
Mild	98 (30.6)	82 (24.8)	10 (15.2)	7 (10.6)
Moderate	72 (22.5)	63 (19.0)	28 (42.4)	17 (25.8)
Severe	48 (15.0)	25 (7.6)	24 (36.4)	40 (60.6)
N (Total)	320	331	66	66
Week 20				
Clear	19 (6.1)	52 (16.3)	0	1 (1.6)
Almost clear	106 (34.1)	114 (35.7)	15 (23.1)	13 (20.3)
Mild	89 (28.6)	87 (27.3)	17 (26.2)	13 (20.3)
Moderate	73 (23.5)	43 (13.5)	30 (46.2)	23 (35.9)
Severe	24 (7.7)	23 (7.2)	3 (4.6)	14 (21.9)
N (Total)	311	319	65	64

Table 32. Descriptive Statistics of Patient Global Assessment (PtGA) During Week 0 to Week 52 Sequence (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
	n (%)	n (%)	n (%)	n (%)
Week 28				
Clear	34 (11.7)	63 (20.8)	4 (6.6)	9 (14.8)
Almost clear	107 (36.9)	123 (40.6)	20 (32.8)	24 (39.3)
Mild	56 (19.3)	53 (17.5)	24 (39.3)	18 (29.5)
Moderate	73 (25.2)	48 (15.8)	12 (19.7)	7 (11.5)
Severe	20 (6.9)	16 (5.3)	1 (1.6)	3 (4.9)
N (Total)	290	303	61	61
Week 40				
Clear	37 (18.5)	73 (30.5)	6 (11.3)	13 (28.3)
Almost clear	88 (44.0)	99 (41.4)	27 (50.9)	26 (56.5)
Mild	37 (18.5)	37 (15.5)	11 (20.8)	7 (15.2)
Moderate	32 (16.0)	27 (11.3)	8 (15.1)	0
Severe	6 (3.0)	3 (1.3)	1 (1.9)	0
N (Total)	200	239	53	46
Week 52				
Clear	25 (14.1)	71 (32.9)	9 (19.1)	16 (34.8)
Almost clear	81 (45.8)	86 (39.8)	15 (31.9)	21 (45.7)
Mild	31 (17.5)	33 (15.3)	11 (23.4)	6 (13.0)
Moderate	29 (16.4)	20 (9.3)	10 (21.3)	3 (6.5)
Severe	11 (6.2)	6 (2.8)	2 (4.3)	0
N (Total)	177	216	47	46

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, n = number of subjects meeting prespecified criteria

Table 33. Descriptive Statistics of Short Form 36 (SF-36) Physical and Mental Health Scores at Baseline and Weeks 16, 28, and 52 (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Physical Health Score								
Baseline	358	47.36 (9.10)	355	47.02 (9.05)	66	47.12 (8.95)	66	44.86 (9.12)
Week 16	318	49.83 (8.34)	329	50.99 (8.63)	65	48.04 (8.75)	65	45.60 (8.87)
Week 28	286	51.01 (7.67)	303	51.92 (7.86)	60	51.11 (8.08)	61	49.63 (8.52)
Week 52	177	51.98 (7.10)	216	52.42 (7.93)	46	50.90 (8.75)	46	52.12 (7.64)
Mental Health Score								
Baseline	358	42.98 (12.53)	355	43.35 (11.57)	66	42.53 (11.77)	66	42.97 (11.44)
Week 16	318	47.23 (10.93)	329	49.06 (9.50)	65	44.47 (10.77)	65	43.07 (12.34)
Week 28	286	48.59 (10.47)	303	49.64 (9.35)	60	48.63 (9.57)	61	49.69 (9.71)
Week 52	177	49.05 (10.33)	216	50.73 (8.38)	46	50.77 (9.43)	46	49.58 (9.67)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, SD = standard deviation

Table 34. Descriptive Statistics of Hospital Anxiety and Depression Scale (HADS): 2 Subscale Scores at Baseline, Weeks 4, 16, 28, and 52 (FAS, Observed Case)

	CP-690,550				Placebo to CP-690,550			
	5 mg BID		10 mg BID		5 mg BID		10 mg BID	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Anxiety Subscale								
Baseline	362	6.58 (4.21)	358	6.21 (4.08)	66	6.94 (4.21)	66	7.06 (4.02)
Week 4	350	5.66 (3.96)	349	5.30 (3.90)	65	6.82 (4.11)	66	6.70 (4.12)
Week 16	317	5.50 (4.18)	333	4.74 (3.76)	65	6.20 (4.39)	66	6.85 (4.50)
Week 28	286	4.98 (4.04)	304	4.47 (4.00)	60	4.60 (3.89)	61	4.82 (3.88)
Week 52	177	3.97 (3.65)	215	3.84 (3.88)	46	4.33 (4.21)	46	4.00 (3.81)
Depression Subscale								
Baseline	362	5.20 (4.27)	358	5.09 (4.09)	66	5.61 (3.98)	66	5.68 (3.93)
Week 4	350	4.34 (3.59)	349	4.23 (3.75)	65	5.28 (4.06)	66	5.26 (4.12)
Week 16	317	3.97 (3.87)	333	3.51 (3.71)	65	4.92 (3.65)	66	5.50 (4.07)
Week 28	286	3.63 (3.64)	304	3.21 (3.65)	60	3.65 (3.66)	61	3.59 (3.25)
Week 52	177	3.05 (3.48)	215	2.80 (3.49)	46	3.11 (3.16)	46	3.09 (3.03)

Baseline is the latest predose measurement
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, SD = standard deviation

Table 35. Descriptive Statistics of Patient Satisfaction with Study Medication (PSSM) Score at Weeks 16, 28, and 52 (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
	n (%)	n (%)	n (%)	n (%)
Week 16				
Very dissatisfied	17 (5.4)	14 (4.2)	19 (29.2)	22 (33.3)
Somewhat dissatisfied	19 (6.0)	10 (3.0)	6 (9.2)	12 (18.2)
Slightly dissatisfied	10 (3.2)	5 (1.5)	6 (9.2)	5 (7.6)
Neither satisfied nor dissatisfied	19 (6.0)	21 (6.3)	8 (12.3)	9 (13.6)
Slightly satisfied	25 (7.9)	23 (6.9)	6 (9.2)	8 (12.1)
Somewhat satisfied	70 (22.1)	76 (22.9)	11 (16.9)	5 (7.6)
Very satisfied	157 (49.5)	183 (55.1)	9 (13.8)	5 (7.6)
N (Total)	317	332	65	66
Week 28				
Very dissatisfied	7 (2.5)	11 (3.6)	0	0
Somewhat dissatisfied	11 (3.9)	2 (<1.0)	0	1 (1.6)
Slightly dissatisfied	13 (4.6)	10 (3.3)	1 (1.7)	1 (1.6)
Neither satisfied nor dissatisfied	6 (2.1)	12 (4.0)	1 (1.7)	2 (3.3)
Slightly satisfied	30 (10.5)	21 (6.9)	7 (11.7)	2 (3.3)
Somewhat satisfied	77 (27.0)	79 (26.1)	24 (40.0)	19 (31.1)
Very satisfied	141 (49.5)	168 (55.4)	27 (45.0)	36 (59.0)
N (Total)	285	303	60	61
Week 52				
Very dissatisfied	0	2 (<1.0)	0	0
Somewhat dissatisfied	4 (2.3)	2 (<1.0)	1 (2.2)	0
Slightly dissatisfied	2 (1.1)	2 (<1.0)	1 (2.2)	0
Neither satisfied nor dissatisfied	5 (2.8)	2 (<1.0)	0	0
Slightly satisfied	9 (5.1)	12 (5.5)	6 (13.0)	0
Somewhat satisfied	59 (33.5)	55 (25.3)	16 (34.8)	13 (28.3)
Very satisfied	97 (55.1)	142 (65.4)	22 (47.8)	33 (71.7)
N (Total)	176	217	46	46

Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects

Table 36. Descriptive Statistics of Work Limitation Questionnaire (WLQ) Index Score at Baseline, Weeks 4, 16, 28, and 52 (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Baseline				
N	309	305	55	56
Mean (SD)	7.40 (6.38)	7.90 (6.51)	7.16 (5.84)	8.40 (6.01)
Week 4				
N	291	298	53	55
Mean (SD)	6.92 (6.68)	6.64 (6.42)	6.67 (6.41)	9.66 (6.55)
Week 16				
N	273	279	51	55
Mean (SD)	6.68 (6.37)	5.72 (5.93)	6.53 (5.97)	7.13 (5.69)
Week 28				
N	241	254	51	53
Mean (SD)	6.12 (6.37)	5.77 (6.29)	6.03 (6.29)	6.24 (6.36)
Week 52				
N	148	183	41	41
Mean (SD)	6.02 (6.26)	5.95 (6.65)	6.73 (6.54)	5.29 (6.49)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, SD = standard deviation

Table 37. Descriptive Statistics of Joint Pain Assessment (JPA) Score at Baseline, Weeks 4, 16, 28, and 52 (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Baseline				
N	363	359	66	65
Mean (SD)	3.42 (3.21)	2.96 (2.99)	3.00 (2.94)	3.69 (3.15)
Week 4				
N	351	349	64	66
Mean (SD)	2.24 (2.57)	2.13 (2.56)	3.13 (2.68)	3.18 (3.19)
Week 16				
N	319	333	65	66
Mean (SD)	2.41 (2.76)	1.89 (2.59)	3.20 (3.07)	3.45 (3.22)
Week 28				
N	287	304	60	60
Mean (SD)	2.08 (2.53)	1.71 (2.46)	1.93 (2.18)	1.93 (2.36)
Week 52				
N	176	215	46	46
Mean (SD)	1.60 (2.25)	1.38 (2.25)	1.46 (2.24)	1.50 (2.41)

Baseline is the latest predose measurement
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, SD = standard deviation

Table 38. Descriptive Statistics of Euro-Qol 5 Dimensions (EQ-5D) Utility Score at Baseline and Weeks 16, 28, 40, and 52 (FAS, Observed Case)

	CP-690,550		Placebo to CP-690,550	
	5 mg BID	10 mg BID	5 mg BID	10 mg BID
Baseline				
N	363	360	66	66
Mean (SD)	0.77 (0.19)	0.77 (0.19)	0.78 (0.17)	0.74 (0.19)
Week 16				
N	319	333	65	65
Mean (SD)	0.86 (0.16)	0.88 (0.15)	0.81 (0.18)	0.76 (0.19)
Week 28				
N	288	303	60	61
Mean (SD)	0.86 (0.15)	0.89 (0.14)	0.89 (0.14)	0.88 (0.13)
Week 40				
N	201	239	53	46
Mean (SD)	0.91 (0.13)	0.91 (0.15)	0.92 (0.14)	0.90 (0.16)
Week 52				
N	176	217	47	46
Mean (SD)	0.89 (0.12)	0.90 (0.14)	0.89 (0.14)	0.90 (0.13)

Baseline is the latest predose measurement
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, SD = standard deviation

Safety Results:

Treatment-Emergent Adverse Events:

- The incidence of non-serious treatment-emergent adverse events (TEAEs) was similar for CP-690,550 5 mg BID, CP-690,550 10 mg BID, and placebo groups (26.7%, 35.3%, and 27.1%, respectively) during the 16-week treatment period (Table 39) and similar for CP-690,550 5 mg BID and CP-690,550 10 mg BID groups (46.0% and 56.4%, respectively) during Week 0 to Week 52 (Table 40). Most AEs were mild to moderate. The most common non-serious TEAEs by preferred term reported across all treatment groups during Week 0 to Week 16, during Week 0 to Week 52, and during Week 16 to Week 52 were nasopharyngitis, upper respiratory tract infection, blood creatine phosphokinase increased, and headache and the incidences were similar in subjects receiving CP-690,550 5 mg BID and CP-690,550 10 mg BID.

- The incidence of treatment related non-serious TEAEs was also similar for CP-690,550 5 mg BID, CP-690,550 10 mg BID, and placebo groups during the 16-week treatment period (9.9%, 15.6%, and 9.6%, respectively) and similar for CP-690,550 5 mg BID and CP-690,550 10 mg BID groups during Week 0 to Week 52 (20.7% and 26.7%, respectively). The most common treatment related non-serious TEAEs by PT reported across all treatment groups included upper respiratory tract infection and blood creatine phosphokinase increased (Table 41 and Table 42).

- The incidence of treatment-emergent SAEs was low and comparable across all treatment groups in the placebo controlled period (2.2% in the CP-690,550 5 mg BID group, 2.8% each in the CP-690,550 10 mg BID group and placebo groups) and was similar for

CP-690,550 5 mg BID and CP-690,550 10 mg BID groups throughout the study (6.6% and 5.3%, respectively). All SAEs, by preferred terms, were reported only in 1 subject during Week 0 to Week 16, during Week 0 to Week 52, and during Week 16 to Week 52 except for appendicitis, herpes zoster, pneumonia, and pustular psoriasis that was reported by 2 subjects each (Table 43 and Table 44).

- The incidence of treatment-emergent, treatment related SAEs was low and comparable across all treatment groups in the placebo controlled period (0.3% in the CP-690,550 5 mg BID group, 0.6% each in the CP-690,550 10 mg BID group and placebo groups) and was similar for CP-690,550 5 mg BID and CP-690,550 10 mg BID groups throughout the study (1.1% and 1.4%, respectively).

- Incidence of AEs leading to discontinuation was low and comparable across all treatment groups and there was no pattern of events causing discontinuation. The incidence of AEs resulting in withdrawal in the placebo controlled period was 3.0% in the CP-690,550 5 mg BID group, 3.3% in the CP-690,550 10 mg BID group, and 6.2% in the placebo group and 5.8% of subjects each in CP-690,550 5 mg BID and CP-690,550 10 mg BID groups led to discontinuation throughout the study.

- During the placebo controlled period, psoriasis (4 subjects in the CP-690,550 5 mg BID group) and blood creatine phosphokinase (increased) (3 subjects in the CP-690,550 10 mg BID group) were the only AEs that led to permanent discontinuation which occurred in more than 1 subject in the active treatment group and in the placebo group, psoriasis (7 subjects) was the most common AEs by preferred term leading to withdrawal from the study. During Week 0 to Week 52, the only AEs that led to permanent discontinuation in more than 1 subject were psoriasis (4 subjects in the CP-690,550 5 mg BID group), blood creatine phosphokinase increased (5 subjects in the CP-690,550 10 mg BID group), and pneumonia (2 subjects in the CP-690,550 10 mg BID group). During Week 16 to Week 52, no AEs that led to permanent discontinuation occurred in more than 1 subject across all treatment sequences. For AEs leading to withdrawal, AE and SAE results are not separated.

- Three deaths occurred during the study, all 3 subjects were in the CP-690,550 5 mg BID group: 1 due to esophageal carcinoma, 1 due to myocardial infarction, and 1 due to lung neoplasm.

- The incidence of malignancies (excluding non-melanoma skin cancer [NMSC]) was higher in the CP-690,550 5 mg BID group (6 subjects; malignancies reported were prostate cancer, esophageal cancer, lung cancer, renal cell carcinoma, malignant melanoma, and preexisting malignant melanoma) than in the CP-690,550 10 mg BID group (1 subject; malignancy reported was prostate cancer).

- There were 2 cases of squamous cell carcinoma in the CP-690,550 10 mg BID group and none in the CP-690,550 5 mg BID group.

- Serious infections were reported during the Week 0 to Week 52 period for 3 subjects in the CP-690,550 5 mg BID and for 7 subjects in the CP-690,550 10 mg BID treatment

group. Additionally, from Week 16 to Week 52, 2 subjects in the placebo to CP-690,550 10 mg BID treatment sequence experienced serious infections.

- During the study, 14 subjects experienced an adverse event of herpes zoster: 4 subjects in the CP-690,550 5 mg BID and 10 subjects in the CP-690,550 10 mg BID group.

- Overall, adjudicated major adverse cardiovascular events (MACE) were reported for 2 subjects, 1 subject in the CP-690,550 5 mg BID group (myocardial infarction) and 1 subject in the CP-690,550 10 mg BID group (cerebrovascular accident).

Table 39. Treatment-Emergent Non Serious Adverse Events Reported by 2% or More Subjects by System Organ Class and Preferred Term (All Causalities) During Week 0 to Week 16

	CP-690,550		
System Organ Class Preferred Term	**5 mg BID n (%) (N=363)**	**10 mg BID n (%) (N=360)**	**Placebo n (%) (N=177)**
Any AEs	97 (26.7)	127 (35.3)	48 (27.1)
Gastrointestinal Disorders	16 (4.4)	16 (4.4)	6 (3.4)
Diarrhoea	9 (2.5)	8 (2.2)	3 (1.7)
Nausea	10 (2.8)	9 (2.5)	4 (2.3)
Infections and Infestations	36 (9.9)	54 (15.0)	25 (14.1)
Nasopharyngitis	20 (5.5)	31 (8.6)	20 (11.3)
Upper respiratory tract infection	17 (4.7)	24 (6.7)	5 (2.8)
Investigations	20 (5.5)	33 (9.2)	4 (2.3)
Blood cholesterol increased	7 (1.9)	8 (2.2)	0
Blood creatine phosphokinase increased	13 (3.6)	26 (7.2)	4 (2.3)
Metabolism and nutrition disorders	15 (4.1)	22 (6.1)	3 (1.7)
Hypercholesterolaemia	9 (2.5)	9 (2.5)	1 (0.6)
Hyperlipidaemia	7 (1.9)	13 (3.6)	2 (1.1)
Musculoskeletal and connective tissue disorders	6 (1.7)	5 (1.4)	5 (2.8)
Arthralgia	6 (1.7)	5 (1.4)	5 (2.8)
Nervous system disorders	25 (6.9)	24 (6.7)	5 (2.8)
Headache	25 (6.9)	24 (6.7)	5 (2.8)
Skin and subcutaneous tissue disorders	6 (1.7)	4 (1.1)	14 (7.9)
Pruritus	1 (0.3)	1 (0.3)	5 (2.8)
Psoriasis	6 (1.7)	3 (0.8)	11 (6.2)

MedDRA coding dictionary v16.1.
Subjects are only counted once per treatment for each row.
Abbreviations: AEs = adverse events, BID = twice daily, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects, n = number of subjects meeting prespecified criteria.

Table 40. Treatment-Emergent Non Serious Adverse Events Reported by 2% or More Subjects by System Organ Class and Preferred Term (All Causalities) During Week 0 to Week 52 and During Week 16 to Week 52

	Week 0 to Week 52		Week 16 to Week 52			
System Organ Class Preferred Term	CP-690,550 5 mg BID N=363 n (%)	CP-690,550 10 mg BID N=360 n (%)	CP-690,550 5 mg BID to 5 mg BID N=363 n (%)	CP-690,550 10 mg BID to 10 mg BID N=360 n (%)	Placebo to CP-690,550 5 mg BID N=66 n (%)	Placebo to CP-690,550 10 mg BID N=66 n (%)
Any AEs	167 (46.0)	203 (56.4)	89 (24.5)	99 (27.5)	29 (43.9)	25 (37.9)
Blood and lymphatic system disorders	-	-	3 (0.8)	1 (0.3)	2 (3.0)	1 (1.5)
Lymphadenopathy	-	-	3 (0.8)	1 (0.3)	2 (3.0)	1 (1.5)
Gastrointestinal Disorders	31 (8.5)	33 (9.2)	8 (2.2)	13 (3.6)	2 (3.0)	5 (7.6)
Abdominal pain	-	-	3 (0.8)	0	0	2 (3.0)
Abdominal pain upper	8 (2.2)	2 (0.6)	-	-	-	-
Diarrhoea	12 (3.3)	13 (3.6)	3 (0.8)	7 (1.9)	2 (3.0)	1 (1.5)
Nausea	12 (3.3)	13 (3.6)	2 (0.6)	7 (1.9)	0	3 (4.5)
Toothache	4 (1.1)	9 (2.5)	-	-	-	-
General disorders and administration site conditions	8 (2.2)	6 (1.7)	-	-	-	-
Fatigue	8 (2.2)	6 (1.7)	-	-	-	-
Infections and Infestations	83 (22.9)	117 (32.5)	50 (13.8)	62 (17.2)	14 (21.2)	11 (16.7)
Folliculitis	2 (0.6)	8 (2.2)	1 (0.3)	5 (1.4)	1 (1.5)	2 (3.0)
Gastroenteritis	2 (0.6)	9 (2.5)	2 (0.6)	2 (0.6)	2 (3.0)	0
Gastroenteritis viral	-	-	1 (0.3)	2 (0.6)	2 (3.0)	1 (1.5)
Herpes zoster	4 (1.1)	8 (2.2)	-	-	-	-
Influenza	3 (0.8)	11 (3.1)	-	-	-	-
Nasopharyngitis	38 (10.5)	55 (15.3)	23 (6.3)	32 (8.9)	3 (4.5)	4 (6.1)
Pharyngitis	-	-	1 (0.3)	1 (0.3)	3 (4.5)	2 (3.0)
Respiratory tract infection viral	-	-	0	1 (0.3)	2 (3.0)	1 (1.5)
Upper respiratory tract infection	33 (9.1)	35 (9.7)	20 (5.5)	15 (4.2)	1 (1.5)	2 (3.0)
Urinary tract infection	12 (3.3)	12 (3.3)	7 (1.9)	8 (2.2)	3 (4.5)	0
Investigations	37 (10.2)	52 (14.4)	21 (5.8)	25 (6.9)	8 (12.1)	11 (16.7)
Bacterial test positive	-	-	0	0	2 (3.0)	0
Blood cholesterol increased	9 (2.5)	13 (3.6)	3 (0.8)	6 (1.7)	2 (3.0)	1 (1.5)
Blood creatine phosphokinase increased	26 (7.2)	38 (10.6)	14 (3.9)	16 (4.4)	2 (3.0)	6 (9.1)
Gamma-glutamyltransferase increased	8 (2.2)	9 (2.5)	4 (1.1)	6 (1.7)	0	3 (4.5)
Haemoglobin decreased	-	-	1 (0.3)	0	2 (3.0)	0
Low density lipoprotein increased	10 (2.8)	10 (2.8)	5 (1.4)	4 (1.1)	1 (1.5)	2 (3.0)
Metabolism and nutrition disorders	24 (6.6)	35 (9.7)	10 (2.8)	9 (2.5)	1 (1.5)	2 (3.0)

Table 40. Treatment-Emergent Non Serious Adverse Events Reported by 2% or More Subjects by System Organ Class and Preferred Term (All Causalities) During Week 0 to Week 52 and During Week 16 to Week 52

	Week 0 to Week 52		Week 16 to Week 52			
System Organ Class Preferred Term	**CP-690,550 5 mg BID N=363 n (%)**	**CP-690,550 10 mg BID N=360 n (%)**	**CP-690,550 5 mg BID to 5 mg BID N=363 n (%)**	**CP-690,550 10 mg BID to 10 mg BID N=360 n (%)**	**Placebo to CP-690,550 5 mg BID N=66 n (%)**	**Placebo to CP-690,550 10 mg BID N=66 n (%)**
Hypercholesterolaemia	15 (4.1)	17 (4.7)	10 (2.8)	9 (2.5)	1 (1.5)	2 (3.0)
Hyperlipidaemia	10 (2.8)	18 (5.0)	-	-	-	-
Musculoskeletal and connective tissue disorders	30 (8.3)	21 (5.8)	6 (1.7)	2 (0.6)	0	2 (3.0)
Arthralgia	12 (3.3)	11 (3.1)	-	-	-	-
Back pain	11 (3.0)	6 (1.7)	6 (1.7)	2 (0.6)	0	2 (3.0)
Myalgia	8 (2.2)	4 (1.1)	-	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-	-	0	3 (0.8)	2 (3.0)	0
Skin papilloma	-	-	0	3 (0.8)	2 (3.0)	0
Nervous system disorders	28 (7.7)	28 (7.8)	7 (1.9)	8 (2.2)	4 (6.1)	1 (1.5)
Dizziness	-	-	2 (0.6)	1 (0.3)	2 (3.0)	0
Headache	28 (7.7)	28 (7.8)	5 (1.4)	7 (1.9)	2 (3.0)	1 (1.5)
Respiratory, thoracic and mediastinal disorders	8 (2.2)	7 (1.9)	-	-	-	-
Cough	8 (2.2)	7 (1.9)	-	-	-	-
Skin and subcutaneous tissue disorders	13 (3.6)	12 (3.3)	1 (0.3)	0	2 (3.0)	0
Acne	5 (1.4)	9 (2.5)	-	-	-	-
Psoriasis	9 (2.5)	4 (1.1)	-	-	-	-
Pruritus	-	-	1 (0.3)	0	2 (3.0)	0

MedDRA coding dictionary v16.1.
Subjects are only counted once per treatment for each row.
Abbreviations: AEs = adverse events, BID = twice daily, incl = including, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects, n = number of subjects meeting prespecified criteria.
'-' = event not observed in this group

Table 41. Treatment-Emergent, Treatment Related Non Serious Adverse Events Reported by 2% or More Subjects by System Organ Class and Preferred Term (All Causalities) During Week 0 to Week 16

System Organ Class Preferred Term	CP-690,550 5 mg BID n (%) (N=363)	CP-690,550 10 mg BID n (%) (N=360)	Placebo n (%) (N=177)
Any AEs	36 (9.9)	56 (15.6)	17 (9.6)
Infections and Infestations	16 (4.4)	20 (5.6)	11 (6.2)
Nasopharyngitis	5 (1.4)	8 (2.2)	8 (4.5)
Upper respiratory tract infection	11 (3.0)	12 (3.3)	3 (1.7)
Investigations	7 (1.9)	22 (6.1)	3 (1.7)
Blood creatine phosphokinase increased	7 (1.9)	22 (6.1)	3 (1.7)
Metabolism and nutrition disorders	6 (1.7)	11 (3.1)	1 (0.6)
Hyperlipidaemia	6 (1.7)	11 (3.1)	1 (0.6)
Nervous system disorders	10 (2.8)	9 (2.5)	3 (1.7)
Headache	10 (2.8)	9 (2.5)	3 (1.7)

MedDRA coding dictionary v16.1.
Subjects are only counted once per treatment for each row.
Abbreviations: AEs = adverse events, BID = twice daily, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects, n = number of subjects meeting prespecified criteria.

Table 42. Treatment-Emergent, Treatment Related Non Serious Adverse Events Reported by 2% or More Subjects by System Organ Class and Preferred Term (All Causalities) During Week 0 to Week 52 and During Week 16 to Week 52

	Week 0 to Week 52		Week 16 to Week 52			
System Organ Class Preferred Term	**CP-690,550 5 mg BID N=363 n (%)**	**CP-690,550 10 mg BID N=360 n (%)**	**CP-690,550 5 mg BID to 5 mg BID N=363 n (%)**	**CP-690,550 10 mg BID to 10 mg BID N=360 n (%)**	**Placebo to CP-690,550 5 mg BID N=66 n (%)**	**Placebo to CP-690,550 10 mg BID N=66 n (%)**
Any AEs	75 (20.7)	96 (26.7)	42 (11.6)	48 (13.3)	16 (24.2)	16 (24.2)
Blood and lymphatic system disorders	-	-	2 (0.6)	1 (0.3)	2 (3.0)	1 (1.5)
Lymphadenopathy	-	-	2 (0.6)	1 (0.3)	2 (3.0)	1 (1.5)
Gastrointestinal Disorders	8 (2.2)	10 (2.8)	-	-	-	-
Nausea	8 (2.2)	10 (2.8)	-	-	-	-
Infections and Infestations	35 (9.6)	35 (9.7)	22 (6.1)	20 (5.6)	4 (6.1)	3 (4.5)
Nasopharyngitis	16 (4.4)	17 (4.7)	11 (3.0)	11 (3.1)	0	2 (3.0)
Pharyngitis	-	-	0	0	2 (3.0)	0
Respiratory tract infection viral	-	-	0	0	2 (3.0)	1 (1.5)
Upper respiratory tract infection	20 (5.5)	18 (5.0)	12 (3.3)	9 (2.5)	1 (1.5)	0
Investigations	23 (6.3)	38 (10.6)	12 (3.3)	20 (5.6)	4 (6.1)	10 (15.2)
Blood cholesterol increased	9 (2.5)	11 (3.1)	3 (0.8)	5 (1.4)	2 (3.0)	1 (1.5)
Blood creatine phosphokinase increased	14 (3.9)	31 (8.6)	7 (1.9)	13 (3.6)	2 (3.0)	5 (7.6)
Gamma-glutamyltransferase increased	-	-	2 (0.6)	5 (1.4)	0	3 (4.5)
Low density lipoprotein increased	10 (2.8)	7 (1.9)	5 (1.4)	2 (0.6)	1 (1.5)	2 (3.0)
Metabolism and nutrition disorders	17 (4.7)	24 (6.7)	7 (1.9)	6 (1.7)	1 (1.5)	2 (3.0)
Hypercholesterolaemia	11 (3.0)	10 (2.8)	7 (1.9)	6 (1.7)	1 (1.5)	2 (3.0)
Hyperlipidaemia	6 (1.7)	14 (3.9)	-	-	-	-
Musculoskeletal and connective tissue disorders	-	-	1 (0.3)	0	0	2 (3.0)
Back pain	-	-	1 (0.3)	0	0	2 (3.0)
Nervous system disorders	12 (3.3)	10 (2.8)	4 (1.1)	3 (0.8)	4 (6.1)	1 (1.5)
Dizziness	-	-	2 (0.6)	1 (0.3)	2 (3.0)	0
Headache	12 (3.3)	10 (2.8)	2 (0.6)	2 (0.6)	2 (3.0)	1 (1.5)
Skin and subcutaneous tissue disorders	-	-	0	0	2 (3.0)	0
Pruritus	-	-	0	0	2 (3.0)	0

MedDRA coding dictionary v16.1. Subjects are only counted once per treatment for each row.
Abbreviations: AEs = adverse events, BID = twice daily, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects, n = number of subjects meeting prespecified criteria, '-' = event not observed in this group

Table 43. Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (All Causalities) During Week 0 to Week 16

System Organ Class Preferred Term	CP-690,550 5 mg BID n (%) (N=363)	CP-690,550 10 mg BID n (%) (N=360)	Placebo n (%) (N=177)
Any AEs	8 (2.2)	10 (2.8)	5 (2.8)
Blood and lymphatic system disorders	0	1 (0.3)	0
Lymphocytosis	0	1 (0.3)	0
Neutropenia	0	1 (0.3)	0
Cardiac disorders	1 (0.3)	1 (0.3)	0
Atrial flutter	0	1 (0.3)	0
Myocarditis	1 (0.3)	0	0
Gastrointestinal Disorders	1 (0.3)	1 (0.3)	0
Oesophageal ulcer	0	1 (0.3)	0
Umbilical hernia, obstructive	1 (0.3)	0	0
General disorders and administration site conditions	1 (0.3)	0	0
Non-cardiac chest pain	1 (0.3)	0	0
Infections and Infestations	0	2 (0.6)	2 (1.1)
Appendicitis	0	1 (0.3)	0
Burn infection	0	0	1 (0.6)
Meningitis aseptic	0	0	1 (0.6)
Pneumonia	0	1 (0.3)	0
Pyelonephritis	0	1 (0.3)	0
Injury, poisoning and procedural complications	0	1 (0.3)	1 (0.6)
Arthropod sting	0	1 (0.3)	0
Rib fracture	0	0	1 (0.6)
Thermal burn	0	0	1 (0.6)
Investigations	0	0	1 (0.6)
Mycobacterium test positive	0	0	1 (0.6)
Musculoskeletal and connective tissue disorders	0	0	1 (0.6)
Intervertebral disc protrusion	0	0	1 (0.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.8)	1 (0.3)	0
Malignant melanoma	1 (0.3)	0	0
Malignant melanoma in situ	1 (0.3)	0	0
Oesophageal carcinoma	1 (0.3)	0	0
Prostate cancer	0	1 (0.3)	0
Nervous system disorders	0	1 (0.3)	0
Cerebral infarction	0	1 (0.3)	0
Psychiatric disorders	1 (0.3)	0	1 (0.6)
Alcohol abuse	0	0	1 (0.6)
Obsessive-compulsive disorder	1 (0.3)	0	0
Respiratory, thoracic and mediastinal disorders	1 (0.3)	1 (0.3)	0
Chronic obstructive pulmonary disease	1 (0.3)	1 (0.3)	0
Skin and subcutaneous tissue disorders	0	1 (0.3)	0
Urticaria	0	1 (0.3)	0
Vascular disorders	0	1 (0.3)	0
Peripheral arterial occlusive disease	0	1 (0.3)	0

MedDRA coding dictionary v16.1.
Subjects are only counted once per treatment for each row.
Abbreviations: AEs = adverse events, BID = twice daily, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects, n = number of subjects meeting prespecified criteria.

Table 44. Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (All Causalities) During Week 0 to Week 52 and During Week 16 to Week 52

	Week 0 to Week 52		Week 16 to Week 52			
System Organ Class Preferred Term	**CP-690,550 5 mg BID N=363 n (%)**	**CP-690,550 10 mg BID N=360 n (%)**	**CP-690,550 5 mg BID to 5 mg BID N=363 n (%)**	**CP-690,550 10 mg BID to 10 mg BID N=360 n (%)**	**Placebo to CP-690,550 5 mg BID N=66 n (%)**	**Placebo to CP-690,550 10 mg BID N=66 n (%)**
Any AEs	24 (6.6)	19 (5.3)	16 (4.4)	9 (2.5)	0	4 (6.1)
Blood and lymphatic system disorders	0	1 (0.3)	-	-	-	-
Lymphocytosis	0	1 (0.3)	-	-	-	-
Neutropenia	0	1 (0.3)	-	-	-	-
Cardiac disorders	3 (0.8)	1 (0.3)	2 (0.6)	0	0	1 (1.5)
Atrial fibrillation	-	-	0	0	0	1 (1.5)
Atrial flutter	0	1 (0.3)	-	-	-	-
Myocardial infarction	1 (0.3)	0	1 (0.3)	0	0	0
Myocardial ischaemia	1 (0.3)	0	1 (0.3)	0	0	0
Myocarditis	1 (0.3)	0	-	-	-	-
Gastrointestinal Disorders	2 (0.6)	3 (0.8)	1 (0.3)	2 (0.6)	0	0
Haemorrhoids	0	1 (0.3)	0	1 (0.3)	0	0
Oesophageal ulcer	0	1 (0.3)	-	-	-	-
Tooth disorder	0	1 (0.3)	0	1 (0.3)	0	0
Umbilical hernia	1 (0.3)	0	1 (0.3)	0	0	0
Umbilical hernia, obstructive	1 (0.3)	0	-	-	-	-
General disorders and administration site conditions	2 (0.6)	1 (0.3)	1 (0.3)	1 (0.3)	0	0
Chest pain	1 (0.3)	0	1 (0.3)	0	0	0
Non-cardiac chest pain	1 (0.3)	0	-	-	-	-
Pelvic mass	0	1 (0.3)	0	1 (0.3)	0	0
Hepatobiliary disorders	1 (0.3)	0	1 (0.3)	0	0	1 (1.5)
Cholecystitis acute	1 (0.3)	0	1 (0.3)	0	0	0
Hepatic failure	-	-	0	0	0	1 (1.5)
Immune system disorders	1 (0.3)	0	1 (0.3)	0	0	0
Anaphylactic reaction	1 (0.3)	0	1 (0.3)	0	0	0
Infections and Infestations	3 (0.8)	7 (1.9)	3 (0.8)	5 (1.4)	0	2 (3.0)
Appendicitis	0	2 (0.6)	0	1 (0.3)	0	0
Bronchitis	1 (0.3)	0	1 (0.3)	0	0	0
Diverticulitis	1 (0.3)	0	1 (0.3)	0	0	0
Herpes zoster	0	2 (0.6)	0	2 (0.6)	0	0

Table 44. Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (All Causalities) During Week 0 to Week 52 and During Week 16 to Week 52

	Week 0 to Week 52		Week 16 to Week 52			
System Organ Class Preferred Term	**CP-690,550 5 mg BID N=363 n (%)**	**CP-690,550 10 mg BID N=360 n (%)**	**CP-690,550 5 mg BID to 5 mg BID N=363 n (%)**	**CP-690,550 10 mg BID to 10 mg BID N=360 n (%)**	**Placebo to CP-690,550 5 mg BID N=66 n (%)**	**Placebo to CP-690,550 10 mg BID N=66 n (%)**
Lung infection	-	-	0	0	0	1 (1.5)
Pneumonia	0	2 (0.6)	0	1 (0.3)	0	0
Pyelonephritis	0	1 (0.3)	-	-	-	-
Skin infection	1 (0.3)	0	1 (0.3)	0	0	0
Staphylococcal skin infection	0	1 (0.3)	0	1 (0.3)	0	0
Subcutaneous abscess	0	1 (0.3)	0	1 (0.3)	0	0
Viral infection	-	-	0	0	0	1 (1.5)
Injury, poisoning and procedural complications	1 (0.3)	2 (0.6)	1 (0.3)	1 (0.3)	0	0
Arthropod sting	0	1 (0.3)	-	-	-	-
Contusion	1 (0.3)	0	1 (0.3)	0	0	0
Excoriation	1 (0.3)	0	1 (0.3)	0	0	0
Hand fracture	0	1 (0.3)	0	1 (0.3)	0	0
Joint dislocation	1 (0.3)	0	1 (0.3)	0	0	0
Road traffic accident	0	1 (0.3)	0	1 (0.3)	0	0
Tendon rupture	1 (0.3)	0	1 (0.3)	0	0	0
Musculoskeletal and connective tissue disorders	1 (0.3)	0	1 (0.3)	0	0	0
Bursitis	1 (0.3)	0	1 (0.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (1.7)	1 (0.3)	3 (0.8)	0	0	0
Lung neoplasm malignant	1 (0.3)	0	1 (0.3)	0	0	0
Malignant melanoma	1 (0.3)	0	-	-	-	-
Malignant melanoma in situ	1 (0.3)	0	-	-	-	-
Oesophageal carcinoma	1 (0.3)	0	-	-	-	-
Prostate cancer	0	1 (0.3)	-	-	-	-
Prostate cancer stage II	1 (0.3)	0	1 (0.3)	0	0	0
Renal cell carcinoma	1 (0.3)	0	1 (0.3)	0	0	0
Nervous system disorders	1 (0.3)	1 (0.3)	1 (0.3)	0	0	0
Cerebral infarction	0	1 (0.3)	-	-	-	-
Syncope	1 (0.3)	0	1 (0.3)	0	0	0

Table 44. Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (All Causalities) During Week 0 to Week 52 and During Week 16 to Week 52

	Week 0 to Week 52		Week 16 to Week 52			
System Organ Class Preferred Term	**CP-690,550 5 mg BID N=363 n (%)**	**CP-690,550 10 mg BID N=360 n (%)**	**CP-690,550 5 mg BID to 5 mg BID N=363 n (%)**	**CP-690,550 10 mg BID to 10 mg BID N=360 n (%)**	**Placebo to CP-690,550 5 mg BID N=66 n (%)**	**Placebo to CP-690,550 10 mg BID N=66 n (%)**
Psychiatric disorders	2 (0.6)	0	1 (0.3)	0	0	0
Depression	1 (0.3)	0	1 (0.3)	0	0	0
Obsessive-compulsive disorder	1 (0.3)	0	-	-	-	-
Renal and urinary disorders	-	-	0	0	0	1 (1.5)
Nephrolithiasis	-	-	0	0	0	1 (1.5)
Respiratory, thoracic and mediastinal disorders	1 (0.3)	1 (0.3)	-	-	-	-
Chronic obstructive pulmonary disease	1 (0.3)	1 (0.3)	-	-	-	-
Skin and subcutaneous tissue disorders	2 (0.6)	1 (0.3)	2 (0.6)	0	0	0
Pustular psoriasis	2 (0.6)	0	2 (0.6)	0	0	0
Urticaria	0	1 (0.3)	-	-	-	-
Vascular disorders	0	1 (0.3)	-	-	-	-
Peripheral arterial occlusive disease	0	1 (0.3)	-	-	-	-

MedDRA coding dictionary v16.1.
Subjects are only counted once per treatment for each row.
Abbreviations: AEs = adverse events, BID = twice daily, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects, n = number of subjects meeting prespecified criteria, '-' = event not observed in this group

Clinical Laboratory Evaluation

- Small dose-dependent initial decrease in mean neutrophil count was observed for the CP-690,550 groups followed by a plateau to Week 52. There were no confirmed cases of neutrophil levels <0.5 x $10^3/mm^3$.

- A small transient increase in mean lymphocyte count was observed for the CP-690,550 5 mg BID and CP-690,550 10 mg BID groups followed by a small gradual decrease over time. There were 2 confirmed cases (confirmed on 2 consecutive measurements or occurring at the final visit) of subjects with a lymphocyte count <$0.5\times10^3/mm^3$ with no associated serious infections (1 in the CP-690,550 5 mg BID group and 1 in the CP-690,550 10 mg BID group).

- A small dose-dependent decrease in hemoglobin, stable over time, was observed with the CP-690,550 groups. There were 2 confirmed cases (1 in the CP-690,550 5 mg BID group and 1 in the CP-690,550 10 mg BID group) of subjects with hemoglobin values <10 g/dL. In addition, there was 1 confirmed case in the placebo to CP-690,550 5 mg BID group of a subject with a hemoglobin value <10 g/dL after the subject began receiving active treatment.

- An increase in mean creatine phosphokinase (CPK) was observed within the first 4 weeks in the CP-690,550 5 mg group and thereafter values remained relatively constant through Week 52. No rhabdomyolysis events were reported in the study.

- The percentages of subjects with confirmed ≥3xULN elevations in AST or ALT, and ≥2 x ULN elevations in total bilirubin were low and similar among the groups. One subject in the CP-690,550 5 mg BID group had a confirmed ALT value ≥5 x ULN. No cases of Hy's law were reported during the study. One subject in the placebo to CP-690,550 10 mg BID group with alcoholic liver cirrhosis developed liver failure 2 months after discontinuation of study drug.

- There was an early dose-dependent increase in mean total cholesterol, high density lipoprotein (HDL) and low density lipoprotein (LDL) on active therapy that remained stable thereafter. The LDL/HDL ratio remained unchanged.

CONCLUSIONS:

- CP-690,550 5 mg BID and CP-690,550 10 mg BID both were superior to placebo for both PGA "clear" or "almost clear" and PASI75 at Week 16.

- Onset of action was observed by Week 4 as demonstrated by superiority of PGA response and PASI75 response versus placebo for both CP-690,550 5 and 10 mg BID.

- PASI75 and PGA responses continued to improve beyond Week 16 and sustained improvement through Week 28. The efficacy responses were maintained through Week 52 for those subjects who remained on study after non-responders were discontinued at Week 28 as per protocol.

- The observed efficacy response rates were generally higher for CP-690,550 5 mg BID and CP-690,550 10 mg BID compared with placebo for the secondary efficacy endpoints.

- Both the CP-690,550 5 mg BID and CP-690,550 10 mg BID doses were well tolerated and had an overall similar rate of AEs and discontinuations due to AEs.

- The rate of malignancies (excluding NMSC) was higher in the CP-690,550 5 mg BID group than in the CP-690,550 10 mg BID group.

- The rate of serious infections and herpes zoster was higher in the CP-690,550 10 mg BID group than in the CP-690,550 5 mg BID group.

- There were few cases of laboratory findings (low hemoglobin, low lymphocyte count and elevated AST/ALT) meeting pre-defined thresholds across the CP-690,550 5 mg BID and CP-690,550 10 mg BID groups.