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

PROTOCOL NO.: A3921079

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 82 study centers that took part in the study and enrolled subjects: Canada (15), Colombia (1), Germany (11), Hungary (3), Mexico (3), Poland (3), Puerto Rico (1), Serbia (1), Taiwan (4), Ukraine (5), and United States (35). In addition, there were 3 study centers that received study drug, but did not randomize subjects.

Study Initiation Date and Primary Completion or Final Completion Dates:
14 March 2011 to 24 April 2013

Phase of Development: Phase 3

Study Objective(s):

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

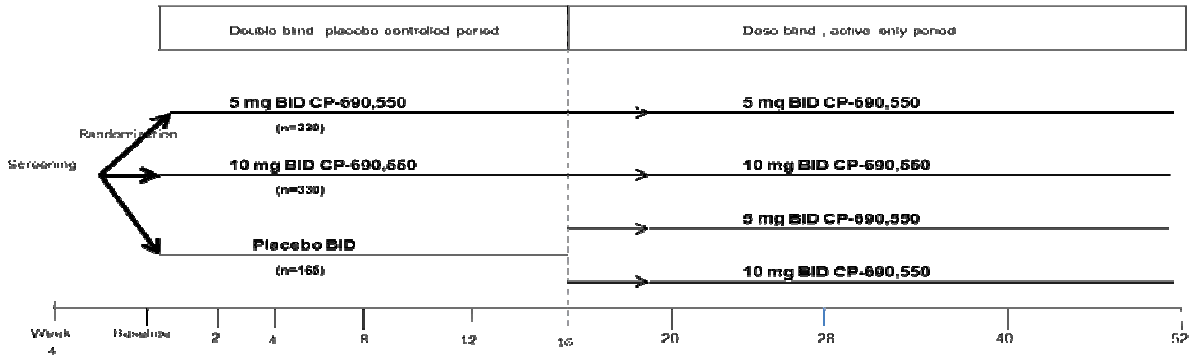
severe chronic plaque psoriasis who were candidates for systemic therapy or phototherapy;

- 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. The double-blind treatment period was 16 weeks. 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) through Week 16, at which point the primary efficacy endpoints were assessed. 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 (Figure 1). 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 active treatment remained blinded.

Figure 1. Study Design Schematic



Abbreviations: BID = twice daily, at approximately 12 hour-intervals.

Subjects who participated in this study were eligible to enter the long-term, open-label safety study, A3921061, provided Study A3921061 was conducted at the A3921079 study site. Subjects not achieving Psoriasis Area and Severity Index 75 (PASI75) (ie, 75% reduction in PASI from Baseline) or Physician's Global Assessment (PGA) of "clear" or "almost clear" response at Week 28 were withdrawn, with opportunity to transfer to Study A3921061. At time of study completion or discontinuation, if a subject did not transfer to Study A3921061, an off-treatment End of Study (EOS) visit was conducted 2 to 4 weeks after the subject's last dose.

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: 960 subjects were randomized to treatment. Of these, 959 subjects received at least 1 dose of study medication (safety analysis set): 382 subjects in the CP-690,550 5 mg BID group, 381 subjects in the CP-690,550 10 mg BID group, and 196 subjects in the placebo group. At Week 16, 152 subjects in the placebo group were re-randomized to active treatment (75 subjects to receive CP-690,550 5 mg BID and 77 subjects to receive CP-690,550 10 mg BID), while 331 subjects in the CP-690,550 5 mg BID group and 341 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, and 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 (except nail psoriasis), evidence of skin conditions, current drug-induced psoriasis, or 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) $<3.0 \times 10^9$/L ($<3000/mm^3$); absolute neutrophil count $<1.5 \times 10^9$/L ($<1500/mm^3$); platelet count $<100 \times 10^9$/L ($<100{,}000/mm^3$); 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 CP-690,550 5 mg BID or CP-690,550 10 mg BID or matching placebo tablets orally BID (once in the morning and once in the evening; approximately 12 hours apart).

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, 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 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 at 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 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 Type I error rate 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 are presented in separate reports.

*Safety Analysis: S*afety data were summarized according to the safety reporting standards.

For clinical laboratory parameters, data recorded prior to and on the date of the initial dose after re-randomization were tabulated in the Week 0 to Week 16 interval and data recorded after the date of the initial dose after re-randomization were tabulated in the Week 16 to Week 52 interval. For all other safety parameters, data recorded prior to the date of the initial dose after re-randomization were tabulated in the Week 0 to Week 16 interval and data recorded on and after the date of the initial dose after re-randomization were tabulated in the Week 16 to Week 52 interval.

RESULTS

Subject Disposition and Demography: Of 1409 subjects screened for entry into the study, 960 were randomized to treatment, and 959 subjects received at least 1 dose of study medication: 382 subjects in the CP-690,550 5 mg BID group, 381 subjects in the CP-690,550 10 mg BID group, and 196 subjects in the placebo group. Following the placebo-controlled 16-week treatment period, the 152 subjects in the placebo group were re-randomized to active treatment (75 subjects to receive CP-690,550 5 mg BID and 77 subjects to receive CP-690,550 10 mg BID), while 331 subjects in the CP-690,550 5 mg BID group and 341 subjects in the CP-690,550 10 mg BID group continued to receive their respective treatments through Week 52. 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				1409
Randomized	383[a]	381	196	960
Safety Analysis Set[b]	382 (100.0)	381 (100.0)	196 (100.0)	959 (100.0)
FAS[c]	376 (98.4)	374 (98.2)	193 (98.5)	943 (98.3)
PP Analysis Set[d]	367 (96.1)	363 (95.3)	185 (94.4)	915 (95.4)
Re-randomized[e]	331 (86.6)	341 (89.5)	152 (77.6)	824 (85.9)
Discontinued[f]	51 (13.4)	40 (10.5)	44 (22.4)	135 (14.1)
Primary reason for discontinuation:				
Subject died	1 (0.3)	0	1 (0.5)	-
Related to study drug	24 (6.3)	8 (2.1)	26 (13.3)	-
Adverse event[g]	9 (2.4)	6 (1.6)	2 (1.0)	-
Insufficient clinical response	15 (3.9)	2 (0.5)	24 (12.2)	-
Not related to study drug	26 (6.8)	32 (8.4)	17 (8.7)	-
Adverse event[g]	2 (0.5)	4 (1.0)	3 (1.5)	-
Lost to follow-up	7 (1.8)	8 (2.1)	3 (1.5)	-
No longer willing to participate in study	7 (1.8)	6 (1.6)	7 (3.6)	-
Other[h]	10 (2.6)	14 (3.7)	4 (2.0)	-

Abbreviations: BID = twice daily, FAS = Full Analysis Set, n = number of subjects meeting prespecified criteria, PP = Per Protocol, '-' = data not available.

[a] One subject 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, excluding site 1105 due to GCP compliance issues.

[d] Per Protocol Analysis Set - All FAS subjects who were considered not to have had any 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. Re-randomized is equivalent to 'completed' for this time period.

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

[g] Subjects marked as discontinued due to 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 During Week 16 to Week 52 (Subjects Re-randomized from Placebo to Active Treatment) by Treatment Sequence

	Week 0 – Week 52		Week 16 – Week 52	
	CP-690,550 5 mg BID n (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	Placebo to CP-690,550 5 mg BID n (%) (N=75)[a]	Placebo to CP-690,550 10 mg BID n (%) (N=77)[a]
Completed	198 (51.8)	238 (62.5)	41 (54.7)	44 (57.1)
Discontinued	184 (48.2)	143 (37.5)	34 (45.3)	33 (42.9)
Primary reason for discontinuation:				
Subject died	1 (0.3)	0	0	1 (1.3)
Related to study drug	134 (35.1)	88 (23.1)	28 (37.3)	23 (29.9)
Adverse event[b]	12 (3.1)	10 (2.6)	3 (4.0)	2 (2.6)
Insufficient clinical response	122 (31.9)	78 (20.5)	25 (33.3)	21 (27.3)
Not related to study drug	49 (12.8)	55 (14.4)	6 (8.0)	9 (11.7)
Adverse event[b]	6 (1.6)	7 (1.8)	3 (4.0)	3 (3.9)
Lost to follow-up	11 (2.9)	10 (2.6)	1 (1.3)	4 (5.2)
No longer willing to participate in study	12 (3.1)	12 (3.1)	0	2 (2.6)
Other[c]	20 (5.2)	26 (6.8)	2 (2.7)	0

Abbreviations: BID = twice daily, n = number of subjects meeting prespecified criteria, N = number of subjects in the Safety Analysis Set.
[a] Subjects who have been re-randomized and dosed in the second period.
[b] Subjects marked as discontinued due to adverse event are based on the subject withdrawal date.
[c] Category of Other included 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 (648 subjects, 67.6%) and white (799 subjects, 83.3%). The mean age of subjects was 45 years (range 18 years to 82 years). The mean weight of subjects was 89.2 kg (range 38.6 kg to 218.6 kg), and mean body mass index (BMI) was 30.2 kg/m^2 (range 15.8 kg/m^2 to 63.6 kg/m^2). Demographic characteristics were similar between treatment groups.

Efficacy, Pharmacokinetic, Pharmacodynamic, or Outcomes Research Results:

Primary Efficacy Results (PASI75 and PGA Responses):

The CP-690,550 5 mg BID and CP-690,550 10 mg BID both were superior to placebo for PASI75 and PGA "clear" or "almost clear" 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 (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	376	173 (46.01)	2.57	34.61	3.44	27.87, 41.36	9.06 (5.02, 16.45)	<0.0001
	CP-690,550 10 mg BID	374	223 (59.63)	2.54	48.23	3.42	41.53, 54.92	17.97 (9.00, 30.73)	<0.0001
	Placebo	193	22 (11.40)	2.29					
PGA									
	CP-690,550 5 mg BID	376	173 (46.01)	2.57	35.13	3.41	28.45, 41.81	10.20 (5.33, 17.68)	<0.0001
	CP-690,550 10 mg BID	374	221 (59.09)	2.54	48.21	3.39	41.57, 54.85	20.43 (8.99, 30.59)	<0.0001
	Placebo	193	21 (10.88)	2.24					

Test of homogeneity, p=0.6943 at Week 16 for 5 mg vs placebo.
Test of homogeneity, p=0.9058 at Week 16 for 10 mg vs placebo.
Test of homogeneity, p=0.8647 at Week 16 for 5 mg vs placebo.
Test of homogeneity, p=0.9962 at Week 16 for 10 mg vs placebo.
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, PGA = Physician Global Assessment, SE = standard error.
[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.

Key Secondary Efficacy Results:

Based on the step-down procedure for the hypothesis testing of key secondary endpoints, the CP-690,550 10 mg BID group achieved statistically significant difference from placebo for all of the key secondary efficacy endpoints. Statistically significant difference from placebo could not be claimed for the PASI75 response at Week 4, change from Baseline in DLQI total score at Week 4, and percent change from Baseline in NAPSI score at Week 16 in subjects with nail psoriasis at Baseline for the CP-690,550 5 mg BID group, since these endpoints did not meet the step-down testing criterion (Table 4).

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]	371	370	188
LS Mean (SE)	-16.79 (0.78)	-19.17 (0.78)	-3.20 (1.11)
LS Mean difference from placebo (SE)	-13.59 (1.36)	-15.97 (1.36)	
P-value	<0.0001*	<0.0001*	
PASI90 response at Week 16 (FAS, NRI)			
N	376	374	193
n (%)	92 (24.47)	145 (38.77)	10 (5.18)
Difference from placebo[b]	19.29	33.59	
P-value[c]	<0.0001*	<0.0001*	
Change from Baseline in DLQI total score at Week 16 (FAS, Observed Case)			
N[a]	372	368	188
LS Mean (SE)	-7.28 (0.30)	-8.92 (0.31)	-2.82 (0.44)
LS Mean difference from placebo (SE)	-4.46 (0.53)	-6.10 (0.53)	
P-value	<0.0001*	<0.0001*	
PGA response of "clear" or "almost clear" at Week 4 (FAS, NRI)			
N	376	374	193
n (%)	64 (17.02)	104 (27.81)	10 (5.18)
Difference from placebo[b]	11.84	22.63	
P-value[c]	<0.0001*	<0.0001*	
PASI75 response at Week 4 (FAS, NRI)			
N	376	374	193
n (%)	28 (7.45)	53 (14.17)	8 (4.15)
Difference from placebo[b]	3.30	10.03	
P-value[c]	0.1786	0.0003*	
Change from Baseline in DLQI total score at Week 4 (FAS, Observed Case)			
N[a]	372	368	188
LS Mean (SE)	-5.55 (0.24)	-6.88 (0.25)	-2.57 (0.35)
LS Mean difference from placebo (SE)	-2.97 (0.42)	-4.30 (0.42)	
P-value	<0.0001	<0.0001*	
Percent Change from Baseline in NAPSI score at Week 16 in subjects with nail psoriasis at Baseline (Observed Case)			
N[a]	227	216	109
LS Mean (SE)	-21.62 (7.65)	-25.97 (7.87)	15.82 (11.27)
LS Mean difference from placebo (SE)	-37.44 (13.62)	-41.79 (13.75)	
P-value	0.0062	0.0025*	

* Statistically significant based on step-down procedure for the hypothesis testing of key secondary endpoints

Abbreviations: BID = twice daily, BSA = body surface area, DLQI = Dermatology Life Quality Index, CI = confidence interval, 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] Normal approximation

[c] 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 74.38% and 78.99%, respectively, of maintaining a PASI90 response was 70.33% and 63.83%, respectively, and of maintaining PGA response of "clear' or "almost clear" was 63.55% and 71.71%, 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 response at Week 52			
CP-690,550 5 mg BID	171	74.38	(66.94, 80.39)
CP-690,550 10 mg BID	217	78.99	(72.80, 83.92)
PASI90 response at Week 52			
CP-690,550 5 mg BID	92	70.33	(59.79, 78.60)
CP-690,550 10 mg BID	140	63.83	(55.21, 71.23)
PGA response at Week 52			
CP-690,550 5 mg BID	171	63.55	(55.67, 70.40)
CP-690,550 10 mg BID	215	71.71	(65.12, 77.28)

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

Onset of action was observed by Week 4 for PASI75 response for both the CP-690,550 5 mg BID and 10 mg BID groups (Table 6). PASI75 responses continued to improve beyond Week 16 through Week 28. The efficacy responses were largely maintained through Week 52 for those subjects who remained on study after non-responders were discontinued at Week 28 as per protocol. CP-690,550 5 mg BID and 10 mg BID both were superior to placebo for PASI75 at Week 16. PASI75 response rates were higher for the CP-690,550 10 mg BID group than for the 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 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	376	374	74	76
n (%)	5 (1.33)	7 (1.87)	0 (0.00)	0 (0.00)
95% CI	0.17, 2.49	0.50, 3.25	0.00, 0.00	0.00, 0.00
Week 4				
N	376	374	74	76
n (%)	28 (7.45)	53 (14.17)	4 (5.41)	3 (3.95)
95% CI	4.79, 10.10	10.64, 17.71	0.25, 10.56	0.00, 8.33
Week 8				
N	376	374	74	76
n (%)	92 (24.47)	147 (39.30)	6 (8.11)	4 (5.26)
95% CI	20.12, 28.81	34.35, 44.25	1.89, 14.33	0.24, 10.28
Week 12				
N	376	374	74	76
n (%)	145 (38.56)	200 (53.48)	10 (13.51)	5 (6.58)
95% CI	33.64, 43.48	48.42, 58.53	5.72, 21.30	1.01, 12.15
Week 16				
N	376	374	74	76
n (%)	173 (46.01)	223 (59.63)	12 (16.22)	9 (11.84)
95% CI	40.97, 51.05	54.65, 64.60	7.82, 24.61	4.58, 19.11
Week 20				
N	376	374	74	76
n (%)	186 (49.47)	232 (62.03)	24 (32.43)	29 (38.16)
95% CI	44.41, 54.52	57.11, 66.95	21.77, 43.10	27.24, 49.08
Week 28				
N	376	374	74	76
n (%)	196 (52.13)	248 (66.31)	39 (52.70)	49 (64.47)
95% CI	47.08, 57.18	61.52, 71.10	41.33, 64.08	53.71, 75.23
Week 40				
N	376	374	74	76
n (%)	173 (46.01)	226 (60.43)	37 (50.00)	45 (59.21)
95% CI	40.97, 51.05	55.47, 65.38	38.61, 61.39	48.16, 70.26
Week 52				
N	376	374	74	76
n (%)	158 (42.02)	196 (52.41)	31 (41.89)	34 (44.74)
95% CI	37.03, 47.01	47.34, 57.47	30.65, 53.13	33.56, 55.92

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	376	374	74	76
n (%)	35 (9.31)	46 (12.30)	2 (2.70)	5 (6.58)
95% CI	6.37, 12.25	8.97, 15.63	0.00, 6.40	1.01, 12.15
Week 4				
N	376	374	74	76
n (%)	106 (28.19)	155 (41.44)	7 (9.46)	9 (11.84)
95% CI	23.64, 32.74	36.45, 46.44	2.79, 16.13	4.58, 19.11
Week 8				
N	376	374	74	76
n (%)	194 (51.60)	250 (66.84)	14 (18.92)	11 (14.47)
95% CI	46.54, 56.65	62.07, 71.62	10.00, 27.84	6.56, 22.38
Week 12				
N	376	374	74	76
n (%)	230 (61.17)	273 (72.99)	19 (25.68)	12 (15.79)
95% CI	56.24, 66.10	68.49, 77.49	15.72, 35.63	7.59, 23.99
Week 16				
N	376	374	74	76
n (%)	238 (63.30)	278 (74.33)	22 (29.73)	18 (23.68)
95% CI	58.43, 68.17	69.90, 78.76	19.32, 40.14	14.13, 33.24
Week 20				
N	376	374	74	76
n (%)	254 (67.55)	293 (78.34)	42 (56.76)	48 (63.16)
95% CI	62.82, 72.29	74.17, 82.52	45.47, 68.04	52.31, 74.00
Week 28				
N	376	374	74	76
n (%)	259 (68.88)	289 (77.27)	52 (70.27)	58 (76.32)
95% CI	64.20, 73.56	73.03, 81.52	59.86, 80.68	66.76, 85.87
Week 40				
N	376	374	74	76
n (%)	201 (53.46)	253 (67.65)	42 (56.76)	53 (69.74)
95% CI	48.42, 58.50	62.91, 72.39	45.47, 68.04	59.41, 80.07
Week 52				
N	376	374	74	76
n (%)	183 (48.67)	232 (62.03)	36 (48.65)	40 (52.63)
95% CI	43.62, 53.72	57.11, 66.95	37.26, 60.04	41.41, 63.86

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]	371	370	188
Week 2	n events - n (%)	5 (1.35)	7 (1.89)	0 (0.00)
	N Remaining	362	359	184
Week 4	n events - n (%)	24 (6.63)	46 (12.81)	8 (4.35)
	N Remaining	329	308	172
Week 8	n events - n (%)	68 (20.67)	97 (31.49)	5 (2.91)
	N Remaining	254	206	161
Week 12	n events - n (%)	52 (20.47)	64 (31.07)	6 (3.73)
	N Remaining	193	137	140
Week 16	n events - n (%)	35 (18.13)	30 (21.90)	7 (5.00)
	N Remaining	0	0	0
Week 2	Probability of response % (95% CI)	1.35 (0.56, 3.21)	1.89 (0.91, 3.93)	0.00 (0.00, 0.00)
Week 4	Probability of response % (95% CI)	7.89 (5.55, 11.15)	14.46 (11.25, 18.50)	4.35 (2.20, 8.51)
Week 8	Probability of response % (95% CI)	26.93 (22.65, 31.83)	41.40 (36.52, 46.66)	7.13 (4.20, 11.96)
Week 12	Probability of response % (95% CI)	41.89 (36.94, 47.21)	59.61 (54.56, 64.72)	10.59 (6.89, 16.11)
Week 16	Probability of response % (95% CI)	52.43 (47.27, 57.78)	68.45 (63.55, 73.25)	15.06 (10.49, 21.36)
Total censored n (%)		187 (50.40)	126 (34.05)	162 (86.17)
Estimated median time to event (response) - weeks (95% CI)		16.0 (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.
[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]	371	370	188
Week 2	n events - n (%)	35 (9.43)	46 (12.43)	7 (3.72)
	N Remaining	332	320	177
Week 4	n events - n (%)	72 (21.69)	109 (34.06)	12 (6.78)
	N Remaining	251	210	161
Week 8	n events - n (%)	91 (36.25)	102 (48.57)	13 (8.07)
	N Remaining	154	103	143
Week 12	n events - n (%)	44 (28.57)	34 (33.01)	12 (8.39)
	N Remaining	102	67	117
Week 16	n events - n (%)	13 (12.75)	17 (25.37)	9 (7.69)
	N Remaining	0	0	0
Week 2	Probability of response % (95% CI)	9.43 (6.87, 12.89)	12.43 (9.46, 16.25)	3.72 (1.79, 7.65)
Week 4	Probability of response % (95% CI)	29.07 (24.72, 34.01)	42.26 (37.39, 47.49)	10.25 (6.66, 15.60)
Week 8	Probability of response % (95% CI)	54.79 (49.73, 60.00)	70.31 (65.56, 74.91)	17.50 (12.71, 23.83)
Week 12	Probability of response % (95% CI)	67.71 (62.79, 72.54)	80.11 (75.82, 84.07)	24.42 (18.78, 31.40)
Week 16	Probability of response % (95% CI)	71.82 (67.00, 76.47)	85.15 (81.22, 88.64)	30.23 (23.97, 37.69)
Total censored n (%)		116 (31.27)	62 (16.76)	135 (71.81)
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.
[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	376	374	74	76
n (%)	1 (0.27)	1 (0.27)	0 (0.00)	0 (0.00)
95% CI	0.00, 0.79	0.00, 0.79	0.00, 0.00	0.00, 0.00
Week 4				
N	376	374	74	76
n (%)	10 (2.66)	10 (2.67)	0 (0.00)	0 (0.00)
95% CI	1.03, 4.29	1.04, 4.31	0.00, 0.00	0.00, 0.00
Week 8				
N	376	374	74	76
n (%)	34 (9.04)	57 (15.24)	3 (4.05)	2 (2.63)
95% CI	6.14, 11.94	11.60, 18.88	0.00, 8.55	0.00, 6.23
Week 12				
N	376	374	74	76
n (%)	68 (18.09)	111 (29.68)	4 (5.41)	3 (3.95)
95% CI	14.19, 21.98	25.05, 34.31	0.25, 10.56	0.00, 8.33
Week 16				
N	376	374	74	76
n (%)	92 (24.47)	145 (38.77)	7 (9.46)	3 (3.95)
95% CI	20.12, 28.81	33.83, 43.71	2.79, 16.13	0.00, 8.33
Week 20				
N	376	374	74	76
n (%)	111 (29.52)	157 (41.98)	11 (14.86)	11 (14.47)
95% CI	24.91, 34.13	36.98, 46.98	6.76, 22.97	6.56, 22.38
Week 28				
N	376	374	74	76
n (%)	111 (29.52)	165 (44.12)	23 (31.08)	35 (46.05)
95% CI	24.91, 34.13	39.09, 49.15	20.54, 41.63	34.85, 57.26
Week 40				
N	376	374	74	76
n (%)	109 (28.99)	150 (40.11)	20 (27.03)	33 (43.42)
95% CI	24.40, 33.58	35.14, 45.07	16.91, 37.15	32.28, 54.56
Week 52				
N	376	374	74	76
n (%)	103 (27.39)	136 (36.36)	17 (22.97)	25 (32.89)
95% CI	22.89, 31.90	31.49, 41.24	13.39, 32.56	22.33, 43.46

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	369	367	73	76
n (%)	2 (0.54)	4 (1.09)	1 (1.37)	1 (1.32)
95% CI	0.00, 1.29	0.03, 2.15	0.00, 4.04	0.00, 3.88
Week 4				
N	363	366	74	75
n (%)	3 (0.83)	4 (1.09)	2 (2.70)	3 (4.00)
95% CI	0.00, 1.76	0.03, 2.16	0.00, 6.40	0.00, 8.43
Week 8				
N	354	356	74	76
n (%)	4 (1.13)	3 (0.84)	3 (4.05)	6 (7.89)
95% CI	0.03, 2.23	0.00, 1.79	0.00, 8.55	1.83, 13.96
Week 12				
N	347	348	74	76
n (%)	4 (1.15)	4 (1.15)	6 (8.11)	6 (7.89)
95% CI	0.03, 2.28	0.03, 2.27	1.89, 14.33	1.83, 13.96
Week 16				
N	340	345	74	76
n (%)	5 (1.47)	4 (1.16)	8 (10.81)	7 (9.21)
95% CI	0.19, 2.75	0.03, 2.29	3.74, 17.89	2.71, 15.71
Week 20				
N	327	338	74	76
n (%)	2 (0.61)	1 (0.30)	3 (4.05)	1 (1.32)
95% CI	0.00, 1.46	0.00, 0.87	0.00, 8.55	0.00, 3.88
Week 28				
N	305	327	69	72
n (%)	2 (0.66)	1 (0.31)	2 (2.90)	0 (0.00)
95% CI	0.00, 1.56	0.00, 0.90	0.00, 6.86	0.00, 0.00
Week 40				
N	213	263	46	55
n (%)	0 (0.00)	2 (0.76)	1 (2.17)	0 (0.00)
95% CI	0.00, 0.00	0.00, 1.81	0.00, 6.39	0.00, 0.00
Week 52				
N	194	239	38	42
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	371	370	74	76
n (%)	12 (3.23)	13 (3.51)	11 (14.86)	10 (13.16)
95% CI	1.43, 5.03	1.64, 5.39	6.76, 22.97	5.56, 20.76

Normal approximation

Overall n indicates the total number of subjects with PASI Score ≥125% of Baseline at least once during Weeks 1 to 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	376	374	74	76
Mean (SD)	22.96 (8.80)	21.88 (8.41)	22.58 (8.62)	22.36 (8.43)
Week 2				
N	369	367	73	76
Mean (SD)	18.62 (8.47)	17.19 (8.94)	21.46 (8.88)	19.53 (7.72)
Week 4				
N	363	366	74	75
Mean (SD)	14.84 (8.27)	12.60 (8.44)	19.43 (9.35)	18.87 (7.86)
Week 8				
N	354	356	74	76
Mean (SD)	10.98 (8.23)	8.39 (7.65)	17.42 (9.42)	18.16 (9.04)
Week 12				
N	347	348	74	76
Mean (SD)	9.22 (8.58)	6.39 (7.22)	17.07 (10.27)	17.29 (8.44)
Week 16				
N	340	345	74	76
Mean (SD)	8.16 (8.77)	5.36 (6.71)	16.59 (10.83)	16.59 (8.67)
Week 20				
N	327	338	74	76
Mean (SD)	6.76 (7.71)	4.46 (5.83)	10.62 (8.71)	9.28 (8.20)
Week 28				
N	305	327	69	72
Mean (SD)	5.62 (6.56)	4.15 (6.13)	6.71 (7.41)	5.38 (8.35)
Week 40				
N	213	263	46	55
Mean (SD)	3.33 (4.65)	2.74 (4.66)	4.21 (6.19)	2.90 (3.92)
Week 52				
N	194	239	38	42
Mean (SD)	3.24 (4.16)	2.60 (3.89)	3.49 (4.13)	2.88 (3.56)

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	376	2.35 (0.97)	374	2.30 (1.04)	74	2.36 (0.92)	76	2.29 (0.86)
Week 2	369	1.86 (1.05)	367	1.76 (1.07)	73	2.30 (0.89)	76	2.07 (0.93)
Week 4	363	1.49 (1.04)	366	1.31 (1.09)	74	2.11 (0.90)	75	2.05 (0.97)
Week 8	354	1.24 (1.04)	356	0.96 (1.02)	74	1.85 (1.02)	76	1.79 (1.04)
Week 12	347	1.10 (1.05)	348	0.78 (0.96)	74	1.86 (1.09)	76	1.93 (1.04)
Week 16	340	1.06 (1.08)	345	0.74 (0.95)	74	1.91 (1.12)	76	1.75 (1.05)
Week 20	327	0.93 (1.00)	338	0.68 (0.91)	74	1.34 (1.06)	76	1.11 (1.04)
Week 28	305	0.88 (0.95)	327	0.65 (0.93)	69	0.90 (1.06)	72	0.76 (0.96)
Week 40	213	0.67 (0.85)	263	0.48 (0.75)	46	0.72 (1.07)	55	0.51 (0.72)
Week 52	194	0.70 (0.90)	239	0.48 (0.77)	38	0.68 (0.96)	42	0.48 (0.77)
Erythema (upper limbs)								
Baseline	376	2.89 (0.66)	374	2.90 (0.61)	74	2.82 (0.65)	76	2.86 (0.71)
Week 2	369	2.41 (0.82)	367	2.27 (0.82)	73	2.70 (0.74)	76	2.57 (0.87)
Week 4	363	2.00 (0.86)	366	1.82 (0.89)	74	2.53 (0.81)	75	2.53 (0.89)
Week 8	354	1.70 (0.92)	356	1.40 (0.91)	74	2.28 (0.82)	76	2.47 (0.93)
Week 12	347	1.49 (0.97)	348	1.19 (0.92)	74	2.18 (0.88)	76	2.29 (0.98)
Week 16	340	1.37 (1.04)	345	1.08 (0.97)	74	2.09 (1.02)	76	2.28 (0.89)
Week 20	327	1.23 (1.01)	338	0.98 (0.92)	74	1.59 (0.96)	76	1.55 (0.91)
Week 28	305	1.17 (0.97)	327	0.96 (0.98)	69	1.26 (1.01)	72	1.15 (0.96)
Week 40	213	0.85 (0.87)	263	0.76 (0.85)	46	0.98 (1.00)	55	0.78 (0.88)
Week 52	194	0.91 (0.93)	239	0.77 (0.88)	38	1.05 (0.93)	42	0.88 (1.04)
Erythema (trunk)								
Baseline	376	2.92 (0.70)	374	2.93 (0.70)	74	2.96 (0.71)	76	2.80 (0.80)
Week 2	369	2.45 (0.85)	367	2.35 (0.89)	73	2.82 (0.73)	76	2.55 (0.90)
Week 4	363	2.07 (0.93)	366	1.89 (0.95)	74	2.50 (0.95)	75	2.49 (0.92)
Week 8	354	1.75 (1.05)	356	1.37 (1.02)	74	2.27 (0.96)	76	2.46 (0.97)
Week 12	347	1.52 (1.13)	348	1.11 (1.03)	74	2.24 (1.00)	76	2.38 (0.94)
Week 16	340	1.34 (1.16)	345	0.94 (1.06)	74	2.08 (1.11)	76	2.30 (1.03)
Week 20	327	1.14 (1.11)	338	0.81 (0.99)	74	1.59 (1.12)	76	1.59 (0.98)
Week 28	305	1.00 (1.07)	327	0.81 (1.06)	69	1.09 (1.20)	72	0.88 (1.05)

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	213	0.65 (0.88)	263	0.62 (0.95)	46	0.72 (0.98)	55	0.45 (0.74)
Week 52	194	0.74 (1.01)	239	0.60 (0.91)	38	0.76 (0.88)	42	0.48 (0.71)
Erythema (lower limbs)								
Baseline	376	3.18 (0.63)	374	3.18 (0.60)	74	3.16 (0.50)	76	3.17 (0.64)
Week 2	369	2.78 (0.81)	367	2.63 (0.83)	73	3.07 (0.51)	76	2.91 (0.85)
Week 4	363	2.34 (0.90)	366	2.11 (0.90)	74	2.74 (0.76)	75	2.80 (0.93)
Week 8	354	1.92 (1.04)	356	1.60 (0.99)	74	2.55 (0.88)	76	2.72 (0.83)
Week 12	347	1.72 (1.09)	348	1.32 (1.05)	74	2.50 (0.93)	76	2.61 (1.05)
Week 16	340	1.51 (1.13)	345	1.17 (1.07)	74	2.42 (1.05)	76	2.46 (1.04)
Week 20	327	1.34 (1.05)	338	1.02 (1.05)	74	1.82 (1.16)	76	1.78 (0.96)
Week 28	305	1.20 (1.02)	327	0.96 (1.11)	69	1.39 (1.05)	72	0.99 (1.04)
Week 40	213	0.82 (0.93)	263	0.72 (0.94)	46	1.00 (1.03)	55	0.69 (0.81)
Week 52	194	0.87 (1.01)	239	0.76 (0.97)	38	0.84 (1.03)	42	0.79 (1.05)
Induration (head\neck)								
Baseline	376	2.11 (1.05)	374	2.02 (1.03)	74	2.24 (0.90)	76	2.00 (0.95)
Week 2	369	1.73 (1.10)	367	1.53 (1.07)	73	2.11 (0.86)	76	1.86 (0.96)
Week 4	363	1.30 (1.05)	366	1.08 (1.00)	74	1.86 (0.91)	75	1.72 (0.99)
Week 8	354	1.05 (1.04)	356	0.78 (0.94)	74	1.62 (1.00)	76	1.64 (1.07)
Week 12	347	0.93 (1.05)	348	0.63 (0.90)	74	1.61 (1.04)	76	1.66 (1.01)
Week 16	340	0.89 (1.04)	345	0.58 (0.86)	74	1.66 (1.06)	76	1.53 (1.00)
Week 20	327	0.77 (0.93)	338	0.48 (0.76)	74	1.11 (0.92)	76	0.89 (0.93)
Week 28	305	0.71 (0.90)	327	0.47 (0.75)	69	0.78 (0.97)	72	0.60 (0.88)
Week 40	213	0.48 (0.76)	263	0.36 (0.64)	46	0.54 (0.91)	55	0.38 (0.73)
Week 52	194	0.49 (0.76)	239	0.33 (0.60)	38	0.53 (0.80)	42	0.33 (0.65)
Induration (upper limbs)								
Baseline	376	2.79 (0.69)	374	2.74 (0.70)	74	2.66 (0.63)	76	2.86 (0.74)
Week 2	369	2.36 (0.82)	367	2.20 (0.85)	73	2.53 (0.71)	76	2.53 (0.84)
Week 4	363	1.91 (0.86)	366	1.67 (0.91)	74	2.41 (0.77)	75	2.40 (0.89)
Week 8	354	1.59 (0.97)	356	1.29 (0.96)	74	2.14 (0.85)	76	2.33 (0.87)
Week 12	347	1.37 (1.02)	348	1.13 (0.99)	74	2.09 (0.94)	76	2.21 (0.91)
Week 16	340	1.28 (1.11)	345	1.05 (1.02)	74	2.07 (1.09)	76	2.16 (0.90)

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	327	1.14 (1.06)	338	0.96 (1.00)	74	1.43 (0.92)	76	1.37 (0.86)
Week 28	305	1.10 (1.05)	327	0.95 (1.02)	69	1.10 (0.93)	72	0.94 (0.99)
Week 40	213	0.78 (0.91)	263	0.73 (0.92)	46	0.89 (1.04)	55	0.85 (1.01)
Week 52	194	0.79 (0.93)	239	0.69 (0.87)	38	0.95 (0.93)	42	0.76 (0.88)
Induration (trunk)								
Baseline	376	2.69 (0.76)	374	2.72 (0.77)	74	2.69 (0.68)	76	2.64 (0.96)
Week 2	369	2.33 (0.87)	367	2.22 (0.91)	73	2.52 (0.71)	76	2.38 (0.92)
Week 4	363	1.89 (0.94)	366	1.72 (0.99)	74	2.27 (0.91)	75	2.36 (0.90)
Week 8	354	1.54 (1.05)	356	1.21 (1.03)	74	2.09 (0.97)	76	2.26 (0.91)
Week 12	347	1.30 (1.11)	348	0.96 (1.02)	74	2.11 (1.08)	76	2.21 (0.93)
Week 16	340	1.16 (1.15)	345	0.79 (1.02)	74	2.01 (1.19)	76	2.11 (1.01)
Week 20	327	0.98 (1.08)	338	0.71 (0.96)	74	1.41 (1.06)	76	1.26 (0.88)
Week 28	305	0.90 (1.04)	327	0.67 (0.94)	69	0.94 (1.08)	72	0.76 (1.01)
Week 40	213	0.52 (0.82)	263	0.51 (0.89)	46	0.57 (0.93)	55	0.45 (0.77)
Week 52	194	0.55 (0.85)	239	0.46 (0.74)	38	0.61 (0.82)	42	0.50 (0.77)
Induration (lower limbs)								
Baseline	376	2.95 (0.69)	374	2.99 (0.70)	74	2.86 (0.63)	76	2.92 (0.74)
Week 2	369	2.60 (0.81)	367	2.48 (0.83)	73	2.73 (0.71)	76	2.66 (0.79)
Week 4	363	2.16 (0.93)	366	1.93 (0.95)	74	2.55 (0.80)	75	2.51 (0.84)
Week 8	354	1.71 (1.03)	356	1.40 (1.00)	74	2.42 (0.92)	76	2.51 (0.82)
Week 12	347	1.50 (1.11)	348	1.12 (1.04)	74	2.36 (0.97)	76	2.42 (0.91)
Week 16	340	1.34 (1.14)	345	1.01 (1.06)	74	2.31 (1.03)	76	2.33 (0.89)
Week 20	327	1.20 (1.06)	338	0.87 (1.00)	74	1.68 (0.99)	76	1.46 (0.94)
Week 28	305	1.08 (1.04)	327	0.80 (1.04)	69	1.29 (1.03)	72	0.89 (1.08)
Week 40	213	0.70 (0.89)	263	0.62 (0.91)	46	0.85 (0.99)	55	0.62 (0.80)
Week 52	194	0.69 (0.92)	239	0.64 (0.89)	38	0.76 (0.97)	42	0.69 (1.00)
Scaling (head\neck)								
Baseline	376	2.33 (1.09)	374	2.32 (1.10)	74	2.47 (1.05)	76	2.30 (1.03)
Week 2	369	1.80 (1.19)	367	1.69 (1.15)	73	2.33 (1.04)	76	2.11 (1.03)
Week 4	363	1.42 (1.16)	366	1.20 (1.11)	74	2.00 (1.07)	75	1.95 (1.09)
Week 8	354	1.13 (1.10)	356	0.89 (1.05)	74	1.82 (1.06)	76	1.79 (1.10)

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	347	0.99 (1.10)	348	0.74 (1.01)	74	1.77 (1.10)	76	1.78 (1.08)
Week 16	340	1.00 (1.15)	345	0.68 (0.99)	74	1.74 (1.15)	76	1.68 (1.16)
Week 20	327	0.84 (1.01)	338	0.63 (0.96)	74	1.11 (0.99)	76	1.03 (1.06)
Week 28	305	0.81 (0.97)	327	0.60 (0.92)	69	0.80 (1.02)	72	0.68 (0.96)
Week 40	213	0.67 (0.95)	263	0.46 (0.81)	46	0.67 (1.01)	55	0.58 (0.96)
Week 52	194	0.63 (0.87)	239	0.45 (0.78)	38	0.58 (0.83)	42	0.43 (0.77)
Scaling (upper limbs)								
Baseline	376	2.77 (0.73)	374	2.77 (0.73)	74	2.78 (0.73)	76	2.79 (0.81)
Week 2	369	2.25 (0.92)	367	2.16 (0.92)	73	2.56 (0.90)	76	2.36 (0.80)
Week 4	363	1.85 (0.92)	366	1.64 (0.97)	74	2.31 (0.94)	75	2.25 (0.89)
Week 8	354	1.53 (1.00)	356	1.29 (1.01)	74	2.18 (0.93)	76	2.20 (0.91)
Week 12	347	1.38 (1.09)	348	1.11 (1.01)	74	2.04 (1.01)	76	2.09 (0.87)
Week 16	340	1.31 (1.17)	345	1.03 (1.06)	74	2.04 (1.15)	76	2.11 (0.86)
Week 20	327	1.14 (1.07)	338	1.00 (1.05)	74	1.41 (1.05)	76	1.37 (0.89)
Week 28	305	1.07 (1.07)	327	0.96 (1.08)	69	1.20 (1.04)	72	1.10 (1.02)
Week 40	213	0.84 (1.03)	263	0.74 (0.96)	46	0.89 (1.06)	55	0.89 (1.03)
Week 52	194	0.84 (0.97)	239	0.70 (0.92)	38	0.95 (0.93)	42	0.81 (0.97)
Scaling (trunk)								
Baseline	376	2.69 (0.77)	374	2.68 (0.77)	74	2.77 (0.79)	76	2.61 (0.95)
Week 2	369	2.18 (0.92)	367	2.12 (0.95)	73	2.44 (0.96)	76	2.29 (0.86)
Week 4	363	1.83 (0.97)	366	1.61 (1.00)	74	2.23 (1.08)	75	2.17 (0.79)
Week 8	354	1.42 (1.07)	356	1.11 (1.05)	74	2.03 (1.06)	76	2.14 (0.96)
Week 12	347	1.22 (1.12)	348	0.88 (1.01)	74	1.97 (1.15)	76	2.11 (1.01)
Week 16	340	1.08 (1.15)	345	0.75 (1.00)	74	1.84 (1.19)	76	1.95 (1.08)
Week 20	327	0.89 (1.06)	338	0.66 (0.93)	74	1.31 (1.08)	76	1.21 (1.02)
Week 28	305	0.81 (1.00)	327	0.63 (0.96)	69	0.96 (1.17)	72	0.79 (1.01)
Week 40	213	0.56 (0.91)	263	0.47 (0.84)	46	0.57 (0.98)	55	0.47 (0.84)
Week 52	194	0.58 (0.88)	239	0.45 (0.75)	38	0.66 (0.94)	42	0.45 (0.74)
Scaling (lower limbs)								
Baseline	376	3.02 (0.74)	374	3.04 (0.66)	74	3.03 (0.62)	76	3.03 (0.80)
Week 2	369	2.53 (0.91)	367	2.48 (0.90)	73	2.71 (0.84)	76	2.67 (0.81)

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	363	2.13 (1.00)	366	1.95 (1.00)	74	2.57 (0.88)	75	2.45 (0.90)
Week 8	354	1.68 (1.11)	356	1.36 (1.08)	74	2.34 (0.98)	76	2.41 (0.88)
Week 12	347	1.50 (1.16)	348	1.07 (1.05)	74	2.30 (1.03)	76	2.30 (0.99)
Week 16	340	1.38 (1.17)	345	1.00 (1.07)	74	2.16 (1.12)	76	2.34 (1.04)
Week 20	327	1.17 (1.10)	338	0.89 (1.08)	74	1.43 (0.99)	76	1.50 (1.09)
Week 28	305	1.05 (1.07)	327	0.84 (1.11)	69	1.22 (1.04)	72	0.90 (1.05)
Week 40	213	0.74 (0.95)	263	0.63 (0.96)	46	0.93 (1.12)	55	0.71 (0.90)
Week 52	194	0.72 (0.95)	239	0.64 (0.92)	38	0.89 (1.13)	42	0.74 (0.99)

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	369	-0.48 (0.76)	367	-0.56 (0.77)	73	-0.05 (0.50)	76	-0.22 (0.53)
Week 4	363	-0.85 (0.97)	366	-1.01 (1.04)	74	-0.26 (0.70)	75	-0.25 (0.70)
Week 8	354	-1.09 (1.07)	356	-1.35 (1.12)	74	-0.51 (0.95)	76	-0.50 (0.82)
Week 12	347	-1.25 (1.17)	348	-1.54 (1.16)	74	-0.50 (1.01)	76	-0.36 (0.89)
Week 16	340	-1.27 (1.17)	345	-1.57 (1.17)	74	-0.46 (1.15)	76	-0.54 (0.90)
Week 20	327	-1.39 (1.16)	338	-1.62 (1.17)	74	-1.03 (1.06)	76	-1.18 (1.14)
Week 28	305	-1.46 (1.10)	327	-1.64 (1.18)	69	-1.42 (1.14)	72	-1.56 (1.10)
Week 40	213	-1.69 (1.05)	263	-1.79 (1.14)	46	-1.67 (1.21)	55	-1.78 (0.96)
Week 52	194	-1.64 (1.06)	239	-1.82 (1.11)	38	-1.66 (1.19)	42	-1.95 (1.06)
Erythema (upper limbs)								
Week 2	369	-0.48 (0.71)	367	-0.63 (0.68)	73	-0.12 (0.47)	76	-0.29 (0.63)
Week 4	363	-0.89 (0.86)	366	-1.08 (0.90)	74	-0.30 (0.70)	75	-0.32 (0.70)
Week 8	354	-1.18 (0.98)	356	-1.51 (1.01)	74	-0.54 (0.88)	76	-0.38 (0.80)
Week 12	347	-1.40 (1.08)	348	-1.71 (1.05)	74	-0.65 (1.05)	76	-0.57 (0.88)
Week 16	340	-1.53 (1.16)	345	-1.81 (1.13)	74	-0.73 (1.19)	76	-0.58 (0.93)
Week 20	327	-1.66 (1.17)	338	-1.91 (1.11)	74	-1.23 (1.15)	76	-1.30 (1.06)
Week 28	305	-1.72 (1.13)	327	-1.92 (1.16)	69	-1.57 (1.23)	72	-1.72 (1.22)
Week 40	213	-2.05 (1.04)	263	-2.15 (1.00)	46	-1.96 (1.07)	55	-2.11 (1.18)
Week 52	194	-1.99 (1.07)	239	-2.15 (1.04)	38	-1.92 (1.08)	42	-2.07 (1.28)
Erythema (trunk)								
Week 2	369	-0.47 (0.69)	367	-0.59 (0.70)	73	-0.14 (0.58)	76	-0.25 (0.66)
Week 4	363	-0.86 (0.90)	366	-1.04 (0.90)	74	-0.46 (0.91)	75	-0.31 (0.88)
Week 8	354	-1.18 (1.09)	356	-1.56 (1.07)	74	-0.69 (1.05)	76	-0.34 (1.01)
Week 12	347	-1.41 (1.19)	348	-1.82 (1.10)	74	-0.72 (1.08)	76	-0.42 (1.02)
Week 16	340	-1.58 (1.25)	345	-1.99 (1.17)	74	-0.88 (1.17)	76	-0.50 (1.09)
Week 20	327	-1.80 (1.25)	338	-2.12 (1.12)	74	-1.36 (1.18)	76	-1.21 (1.16)
Week 28	305	-1.94 (1.20)	327	-2.12 (1.17)	69	-1.88 (1.28)	72	-1.94 (1.32)
Week 40	213	-2.26 (1.04)	263	-2.31 (1.12)	46	-2.28 (1.11)	55	-2.45 (1.12)
Week 52	194	-2.19 (1.13)	239	-2.36 (1.03)	38	-2.29 (1.18)	42	-2.48 (1.06)
Erythema (lower limbs)								

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)
Week 2	369	-0.40 (0.66)	367	-0.55 (0.68)	73	-0.10 (0.48)	76	-0.26 (0.62)
Week 4	363	-0.84 (0.85)	366	-1.07 (0.87)	74	-0.42 (0.72)	75	-0.36 (0.80)
Week 8	354	-1.25 (1.05)	356	-1.57 (1.04)	74	-0.61 (0.89)	76	-0.45 (0.87)
Week 12	347	-1.46 (1.12)	348	-1.85 (1.12)	74	-0.66 (0.95)	76	-0.57 (1.10)
Week 16	340	-1.68 (1.20)	345	-2.00 (1.18)	74	-0.74 (1.07)	76	-0.71 (1.13)
Week 20	327	-1.84 (1.18)	338	-2.15 (1.16)	74	-1.34 (1.20)	76	-1.39 (1.06)
Week 28	305	-1.98 (1.18)	327	-2.21 (1.22)	69	-1.80 (1.18)	72	-2.19 (1.15)
Week 40	213	-2.38 (1.05)	263	-2.46 (1.08)	46	-2.17 (1.18)	55	-2.55 (1.09)
Week 52	194	-2.32 (1.12)	239	-2.44 (1.09)	38	-2.39 (1.17)	42	-2.52 (1.17)
Induration (head\neck)								
Week 2	369	-0.36 (0.72)	367	-0.51 (0.76)	73	-0.12 (0.55)	76	-0.14 (0.51)
Week 4	363	-0.81 (0.96)	366	-0.97 (0.97)	74	-0.38 (0.81)	75	-0.29 (0.71)
Week 8	354	-1.05 (1.12)	356	-1.27 (1.10)	74	-0.62 (1.02)	76	-0.36 (0.87)
Week 12	347	-1.18 (1.21)	348	-1.42 (1.15)	74	-0.64 (1.07)	76	-0.34 (0.93)
Week 16	340	-1.20 (1.20)	345	-1.45 (1.17)	74	-0.58 (1.09)	76	-0.47 (0.97)
Week 20	327	-1.33 (1.17)	338	-1.54 (1.13)	74	-1.14 (1.00)	76	-1.11 (1.04)
Week 28	305	-1.41 (1.14)	327	-1.55 (1.14)	69	-1.41 (1.15)	72	-1.44 (1.12)
Week 40	213	-1.67 (1.12)	263	-1.66 (1.15)	46	-1.78 (1.11)	55	-1.73 (1.03)
Week 52	194	-1.64 (1.12)	239	-1.72 (1.09)	38	-1.74 (1.16)	42	-1.83 (1.08)
Induration (upper limbs)								
Week 2	369	-0.42 (0.65)	367	-0.54 (0.70)	73	-0.12 (0.47)	76	-0.33 (0.62)
Week 4	363	-0.87 (0.85)	366	-1.07 (0.93)	74	-0.26 (0.74)	75	-0.44 (0.66)
Week 8	354	-1.18 (1.01)	356	-1.46 (1.12)	74	-0.53 (0.89)	76	-0.53 (0.66)
Week 12	347	-1.42 (1.09)	348	-1.61 (1.14)	74	-0.57 (0.98)	76	-0.64 (0.86)
Week 16	340	-1.51 (1.19)	345	-1.68 (1.20)	74	-0.59 (1.19)	76	-0.70 (0.91)
Week 20	327	-1.64 (1.17)	338	-1.79 (1.20)	74	-1.23 (1.10)	76	-1.49 (1.14)
Week 28	305	-1.69 (1.13)	327	-1.79 (1.23)	69	-1.55 (1.18)	72	-1.94 (1.24)
Week 40	213	-2.04 (1.06)	263	-2.05 (1.09)	46	-1.91 (1.15)	55	-2.20 (1.11)
Week 52	194	-2.00 (1.09)	239	-2.10 (1.02)	38	-1.87 (1.09)	42	-2.29 (1.13)
Induration (trunk)								
Week 2	369	-0.36 (0.64)	367	-0.50 (0.70)	73	-0.16 (0.47)	76	-0.26 (0.60)

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)
Week 4	363	-0.79 (0.89)	366	-1.01 (0.94)	74	-0.42 (0.91)	75	-0.28 (0.81)
Week 8	354	-1.15 (1.11)	356	-1.54 (1.10)	74	-0.59 (1.06)	76	-0.38 (0.92)
Week 12	347	-1.40 (1.20)	348	-1.79 (1.17)	74	-0.58 (1.16)	76	-0.43 (1.04)
Week 16	340	-1.52 (1.31)	345	-1.94 (1.19)	74	-0.68 (1.26)	76	-0.54 (1.10)
Week 20	327	-1.72 (1.28)	338	-2.04 (1.14)	74	-1.28 (1.21)	76	-1.38 (1.13)
Week 28	305	-1.83 (1.21)	327	-2.07 (1.16)	69	-1.74 (1.29)	72	-1.94 (1.28)
Week 40	213	-2.20 (1.09)	263	-2.25 (1.13)	46	-2.22 (1.15)	55	-2.29 (1.12)
Week 52	194	-2.17 (1.15)	239	-2.32 (1.03)	38	-2.18 (1.14)	42	-2.24 (1.19)
Induration (lower limbs)								
Week 2	369	-0.35 (0.65)	367	-0.51 (0.70)	73	-0.14 (0.54)	76	-0.26 (0.53)
Week 4	363	-0.80 (0.88)	366	-1.06 (0.96)	74	-0.31 (0.76)	75	-0.40 (0.75)
Week 8	354	-1.23 (1.09)	356	-1.59 (1.15)	74	-0.45 (0.98)	76	-0.41 (0.73)
Week 12	347	-1.46 (1.17)	348	-1.86 (1.20)	74	-0.50 (1.10)	76	-0.50 (0.95)
Week 16	340	-1.63 (1.26)	345	-1.97 (1.25)	74	-0.55 (1.21)	76	-0.59 (0.98)
Week 20	327	-1.76 (1.23)	338	-2.12 (1.21)	74	-1.19 (1.24)	76	-1.46 (1.00)
Week 28	305	-1.87 (1.22)	327	-2.19 (1.27)	69	-1.58 (1.39)	72	-2.07 (1.20)
Week 40	213	-2.31 (1.10)	263	-2.43 (1.09)	46	-2.15 (1.23)	55	-2.40 (0.97)
Week 52	194	-2.30 (1.17)	239	-2.40 (1.08)	38	-2.26 (1.25)	42	-2.29 (1.22)
Scaling (head\neck)								
Week 2	369	-0.53 (0.86)	367	-0.65 (0.83)	73	-0.14 (0.61)	76	-0.20 (0.63)
Week 4	363	-0.92 (1.07)	366	-1.13 (1.05)	74	-0.47 (0.95)	75	-0.36 (0.82)
Week 8	354	-1.20 (1.17)	356	-1.44 (1.18)	74	-0.65 (1.05)	76	-0.51 (0.96)
Week 12	347	-1.37 (1.25)	348	-1.60 (1.22)	74	-0.70 (1.07)	76	-0.53 (1.06)
Week 16	340	-1.34 (1.29)	345	-1.66 (1.22)	74	-0.73 (1.24)	76	-0.62 (1.23)
Week 20	327	-1.49 (1.21)	338	-1.69 (1.23)	74	-1.36 (1.14)	76	-1.28 (1.24)
Week 28	305	-1.54 (1.17)	327	-1.70 (1.20)	69	-1.62 (1.26)	72	-1.64 (1.19)
Week 40	213	-1.70 (1.21)	263	-1.83 (1.20)	46	-1.93 (1.32)	55	-1.76 (1.29)
Week 52	194	-1.71 (1.11)	239	-1.86 (1.19)	38	-2.00 (1.21)	42	-2.00 (1.23)
Scaling (upper limbs)								
Week 2	369	-0.51 (0.79)	367	-0.60 (0.73)	73	-0.22 (0.58)	76	-0.43 (0.62)
Week 4	363	-0.92 (0.92)	366	-1.12 (0.98)	74	-0.47 (0.85)	75	-0.52 (0.81)

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)
Week 8	354	-1.23 (1.07)	356	-1.47 (1.13)	74	-0.61 (0.90)	76	-0.59 (0.88)
Week 12	347	-1.39 (1.19)	348	-1.65 (1.18)	74	-0.74 (1.02)	76	-0.70 (0.91)
Week 16	340	-1.47 (1.26)	345	-1.73 (1.24)	74	-0.74 (1.23)	76	-0.68 (1.00)
Week 20	327	-1.63 (1.19)	338	-1.76 (1.23)	74	-1.38 (1.18)	76	-1.42 (1.00)
Week 28	305	-1.69 (1.22)	327	-1.82 (1.30)	69	-1.57 (1.25)	72	-1.71 (1.24)
Week 40	213	-1.93 (1.25)	263	-2.07 (1.18)	46	-2.02 (1.24)	55	-1.95 (1.24)
Week 52	194	-1.92 (1.21)	239	-2.13 (1.14)	38	-1.95 (1.16)	42	-1.95 (1.27)
Scaling (trunk)								
Week 2	369	-0.50 (0.75)	367	-0.57 (0.78)	73	-0.33 (0.60)	76	-0.32 (0.66)
Week 4	363	-0.85 (0.97)	366	-1.08 (0.99)	74	-0.54 (0.97)	75	-0.43 (0.96)
Week 8	354	-1.27 (1.15)	356	-1.59 (1.17)	74	-0.74 (1.11)	76	-0.46 (0.99)
Week 12	347	-1.48 (1.23)	348	-1.81 (1.18)	74	-0.80 (1.16)	76	-0.50 (1.03)
Week 16	340	-1.61 (1.28)	345	-1.95 (1.16)	74	-0.93 (1.24)	76	-0.66 (1.09)
Week 20	327	-1.81 (1.26)	338	-2.04 (1.12)	74	-1.46 (1.21)	76	-1.39 (1.16)
Week 28	305	-1.92 (1.18)	327	-2.07 (1.19)	69	-1.80 (1.37)	72	-1.88 (1.29)
Week 40	213	-2.15 (1.20)	263	-2.25 (1.10)	46	-2.33 (1.16)	55	-2.18 (1.20)
Week 52	194	-2.13 (1.20)	239	-2.30 (1.03)	38	-2.18 (1.11)	42	-2.14 (1.18)
Scaling (lower limbs)								
Week 2	369	-0.49 (0.74)	367	-0.56 (0.75)	73	-0.32 (0.66)	76	-0.36 (0.69)
Week 4	363	-0.88 (0.97)	366	-1.10 (1.01)	74	-0.46 (0.83)	75	-0.56 (0.84)
Week 8	354	-1.34 (1.15)	356	-1.69 (1.19)	74	-0.69 (0.99)	76	-0.62 (0.92)
Week 12	347	-1.52 (1.23)	348	-1.97 (1.20)	74	-0.73 (1.08)	76	-0.72 (1.11)
Week 16	340	-1.64 (1.28)	345	-2.05 (1.28)	74	-0.86 (1.20)	76	-0.68 (1.19)
Week 20	327	-1.84 (1.26)	338	-2.16 (1.29)	74	-1.59 (1.12)	76	-1.53 (1.23)
Week 28	305	-1.96 (1.27)	327	-2.22 (1.33)	69	-1.81 (1.26)	72	-2.15 (1.26)
Week 40	213	-2.31 (1.21)	263	-2.48 (1.16)	46	-2.22 (1.26)	55	-2.38 (1.24)
Week 52	194	-2.31 (1.23)	239	-2.49 (1.12)	38	-2.29 (1.27)	42	-2.33 (1.32)

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 – 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	371	370	74	76
LS Mean (SE)	-4.09 (0.28)	-4.94 (0.28)	-1.04 (0.62)	-2.87 (0.61)
Week 4				
N	371	370	74	76
LS Mean (SE)	-7.87 (0.34)	-9.47 (0.34)	-3.09 (0.76)	-3.65 (0.75)
Week 8				
N	371	370	74	76
LS Mean (SE)	-11.68 (0.40)	-13.70 (0.40)	-5.11 (0.89)	-4.23 (0.87)
Week 12				
N	371	370	74	76
LS Mean (SE)	-13.35 (0.42)	-15.56 (0.42)	-5.46 (0.92)	-5.10 (0.91)
Week 16				
N	371	370	74	76
LS Mean (SE)	-14.23 (0.44)	-16.44 (0.44)	-5.94 (0.96)	-5.80 (0.95)
Week 20				
N	371	370	74	76
LS Mean (SE)	-15.54 (0.41)	-17.36 (0.40)	-11.90 (0.88)	-13.12 (0.87)
Week 28				
N	371	370	74	76
LS Mean (SE)	-16.50 (0.41)	-17.65 (0.41)	-15.08 (0.89)	-17.14 (0.88)
Week 40				
N	371	370	74	76
Mean (SD)	-15.84 (0.46)	-16.98 (0.45)	-14.33 (0.98)	-16.42 (0.96)
Week 52				
N	371	370	74	76
LS Mean (SE)	-15.40 (0.47)	-16.42 (0.45)	-13.92 (1.02)	-16.16 (0.99)

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 - 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	371	370	74	76
LS Mean (SE)	-18.21 (1.10)	-22.15 (1.10)	-5.07 (2.46)	-11.41 (2.42)
Week 4				
N	371	370	74	76
LS Mean (SE)	-34.62 (1.44)	-42.21 (1.44)	-14.25 (3.20)	-14.41 (3.17)
Week 8				
N	371	370	74	76
LS Mean (SE)	-50.36 (1.64)	-61.31 (1.64)	-22.18 (3.64)	-17.40 (3.59)
Week 12				
N	371	370	74	76
LS Mean (SE)	-57.96 (1.73)	-69.63 (1.73)	-24.39 (3.82)	-19.37 (3.77)
Week 16				
N	371	370	74	76
LS Mean (SE)	-62.06 (1.81)	-73.21 (1.80)	-25.91 (3.97)	-22.50 (3.92)
Week 20				
N	371	370	74	76
LS Mean (SE)	-67.66 (1.60)	-77.82 (1.59)	-51.51 (3.48)	-57.68 (3.44)
Week 28				
N	371	370	74	76
LS Mean (SE)	-71.71 (1.59)	-79.17 (1.56)	-65.89 (3.40)	-76.28 (3.36)
Week 40				
N	371	370	74	76
Mean (SD)	-67.88 (1.90)	-75.71 (1.83)	-60.94 (4.06)	-72.19 (3.95)
Week 52				
N	371	370	74	76
LS Mean (SE)	-63.98 (2.10)	-71.82 (2.02)	-56.64 (4.54)	-69.52 (4.42)

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

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

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	376	374	74	76
n (%)	20 (5.32)	36 (9.63)	2 (2.70)	3 (3.95)
95% CI	3.05, 7.59	6.64, 12.61	0.00, 6.4	0.00, 8.33
Week 4				
N	376	374	74	76
n (%)	64 (17.02)	104 (27.81)	5 (6.76)	4 (5.26)
95% CI	13.22, 20.82	23.27, 32.35	1.04, 12.48	0.24, 10.28
Week 8				
N	376	374	74	76
n (%)	126 (33.51)	184 (49.20)	9 (12.16)	6 (7.89)
95% CI	28.74, 38.28	44.13, 54.26	4.72, 19.61	1.83, 13.96
Week 12				
N	376	374	74	76
n (%)	156 (41.49)	207 (55.35)	11 (14.86)	6 (7.89)
95% CI	36.51, 46.47	50.31, 60.39	6.76, 22.97	1.83, 13.96
Week 16				
N	376	374	74	76
n (%)	173 (46.01)	221 (59.09)	13 (17.57)	7 (9.21)
95% CI	40.97, 51.05	54.11, 64.07	8.90, 26.24	2.71, 15.71
Week 20				
N	376	374	74	76
n (%)	178 (47.34)	221 (59.09)	25 (33.78)	31 (40.79)
95% CI	42.29, 52.39	54.11, 64.07	23.01, 44.56	29.74, 51.84
Week 28				
N	376	374	74	76
n (%)	190 (50.53)	232 (62.03)	39 (52.70)	52 (68.42)
95% CI	45.48, 55.59	57.11, 66.95	41.33, 64.08	57.97, 78.87
Week 40				
N	376	374	74	76
n (%)	160 (42.55)	209 (55.88)	32 (43.24)	45 (59.21)
95% CI	37.56, 47.55	50.85, 60.91	31.96, 54.53	48.16, 70.26
Week 52				
N	376	374	74	76
n (%)	139 (36.97)	187 (50.00)	27 (36.49)	31 (40.79)
95% CI	32.09, 41.85	44.93, 55.07	25.52, 47.45	29.74, 51.84

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, SE = standard error.

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]	372	370	188
Week 2	n events - n (%)	21 (5.65)	36 (9.73)	5 (2.66)
	N Remaining	346	330	179
Week 4	n events - n (%)	45 (13.01)	71 (21.52)	6 (3.35)
	N Remaining	292	255	169
Week 8	n events - n (%)	70 (23.97)	90 (35.29)	8 (4.73)
	N Remaining	216	160	156
Week 12	n events - n (%)	47 (21.76)	35 (21.88)	6 (3.85)
	N Remaining	160	120	135
Week 16	n events - n (%)	20 (12.50)	27 (22.50)	5 (3.70)
	N Remaining	0	0	0
Week 2	Probability of response % (95% CI)	5.65 (3.72, 8.53)	9.73 (7.12, 13.23)	2.66 (1.12, 6.27)
Week 4	Probability of response % (95% CI)	17.92 (14.36, 22.23)	29.15 (24.79, 34.09)	5.92 (3.32, 10.44)
Week 8	Probability of response % (95% CI)	37.59 (32.82, 42.82)	54.16 (49.12, 59.36)	10.38 (6.75, 15.79)
Week 12	Probability of response % (95% CI)	51.17 (46.09, 56.48)	64.19 (59.22, 69.13)	13.82 (9.55, 19.78)
Week 16	Probability of response % (95% CI)	57.28 (52.15, 62.51)	72.24 (67.48, 76.83)	17.01 (12.20, 23.46)
Total censored n (%)		169 (45.43)	111 (30.00)	158 (84.04)
Estimated median time to event (response) - weeks (95% CI)		12.0 (12.0,16.0)	8.0 (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 meeting prespecified criteria, PGA = physician global assessment.
[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 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 (%)
Baseline				
0=Clear	0	0	0	0
1=Almost clear	0	0	0	0
2=Mild	0	0	0	0
3=Moderate	310 (82.4)	305 (81.6)	65 (87.8)	64 (84.2)
4=Severe	66 (17.6)	69 (18.4)	9 (12.2)	12 (15.8)
N (Total)	376	374	74	76
Week 2				
0=Clear	1 (<1.0)	1 (<1.0)	0	0
1=Almost clear	19 (5.1)	35 (9.5)	2 (2.7)	3 (3.9)
2=Mild	113 (30.5)	114 (31.1)	6 (8.2)	12 (15.8)
3=Moderate	205 (55.4)	189 (51.5)	54 (74.0)	54 (71.1)
4=Severe	32 (8.6)	28 (7.6)	11 (15.1)	7 (9.2)
N (Total)	370	367	73	76
Week 4				
0=Clear	6 (1.7)	8 (2.2)	0	0
1=Almost clear	58 (16.0)	96 (26.2)	5 (6.8)	4 (5.3)
2=Mild	146 (40.3)	143 (39.1)	13 (17.6)	21 (28.0)
3=Moderate	139 (38.4)	106 (29.0)	49 (66.2)	46 (61.3)
4=Severe	13 (3.6)	13 (3.6)	7 (9.5)	4 (5.3)
N (Total)	362	366	74	75
Week 8				
0=Clear	25 (7.1)	36 (10.1)	2 (2.7)	2 (2.6)
1=Almost clear	101 (28.5)	148 (41.6)	7 (9.5)	4 (5.3)
2=Mild	123 (34.7)	108 (30.3)	20 (27.0)	25 (32.9)
3=Moderate	94 (26.6)	59 (16.6)	38 (51.4)	40 (52.6)
4=Severe	11 (3.1)	5 (1.4)	7 (9.5)	5 (6.6)
N (Total)	354	356	74	76
Week 12				
0=Clear	40 (11.5)	70 (20.1)	4 (5.4)	2 (2.6)
1=Almost clear	116 (33.4)	137 (39.4)	7 (9.5)	4 (5.3)
2=Mild	113 (32.6)	92 (26.4)	22 (29.7)	29 (38.2)
3=Moderate	66 (19.0)	44 (12.6)	35 (47.3)	35 (46.1)
4=Severe	12 (3.5)	5 (1.4)	6 (8.1)	6 (7.9)
N (Total)	347	348	74	76
Week 16				
0=Clear	56 (16.5)	93 (27.0)	5 (6.8)	2 (2.6)
1=Almost clear	117 (34.4)	128 (37.1)	8 (10.8)	5 (6.6)
2=Mild	93 (27.4)	83 (24.1)	19 (25.7)	29 (38.2)
3=Moderate	65 (19.1)	33 (9.6)	37 (50.0)	36 (47.4)
4=Severe	9 (2.6)	8 (2.3)	5 (6.8)	4 (5.3)
N (Total)	340	345	74	76
Week 20				
0=Clear	63 (19.3)	102 (30.2)	8 (10.8)	4 (5.3)
1=Almost clear	115 (35.2)	119 (35.2)	17 (23.0)	27 (35.5)
2=Mild	96 (29.4)	81 (24.0)	31 (41.9)	31 (40.8)
3=Moderate	50 (15.3)	33 (9.8)	18 (24.3)	14 (18.4)
4=Severe	3 (<1.0)	3 (<1.0)	0	0

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

	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 (%)
N (Total)	327	338	74	76
Week 28				
0=Clear	69 (22.6)	101 (30.8)	14 (20.3)	22 (30.6)
1=Almost clear	121 (39.7)	131 (39.9)	25 (36.2)	30 (41.7)
2=Mild	79 (25.9)	63 (19.2)	16 (23.2)	13 (18.1)
3=Moderate	33 (10.8)	26 (7.9)	14 (20.3)	7 (9.7)
4=Severe	3 (<1.0)	7 (2.1)	0	0
N (Total)	305	328	69	72
Week 40				
0=Clear	73 (34.3)	93 (35.4)	15 (32.6)	21 (38.2)
1=Almost clear	87 (40.8)	116 (44.1)	17 (37.0)	24 (43.6)
2=Mild	40 (18.8)	36 (13.7)	10 (21.7)	9 (16.4)
3=Moderate	11 (5.2)	15 (5.7)	3 (6.5)	1 (1.8)
4=Severe	2 (<1.0)	3 (1.1)	1 (2.2)	0
N (Total)	213	263	46	55
Week 52				
0=Clear	70 (36.1)	94 (39.3)	13 (34.2)	17 (40.5)
1=Almost clear	69 (35.6)	93 (38.9)	14 (36.8)	14 (33.3)
2=Mild	44 (22.7)	38 (15.9)	8 (21.1)	9 (21.4)
3=Moderate	11 (5.7)	13 (5.4)	3 (7.9)	2 (4.8)
4=Severe	0	1 (<1.0)	0	0
N (Total)	194	239	38	42

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = Full Analysis Set, n = number of subjects meeting prespecified criteria, N = number of subjects, 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 Body Surface Area (BSA) (%) 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	376	374	74	76
Mean (SE)	30.94 (0.93)	28.49 (0.84)	30.10 (2.09)	30.27 (2.06)
Median	26.00	24.00	24.00	26.50
Week 2				
N	369	367	73	76
Mean (SE)	28.25 (0.90)	26.40 (0.85)	30.63 (2.15)	29.59 (2.00)
Median	24.00	21.50	25.00	26.00
Week 4				
N	363	366	74	75
Mean (SE)	25.09 (0.91)	21.98 (0.86)	29.46 (2.15)	29.48 (2.02)
Median	21.00	16.75	25.00	27.50
Week 8				
N	354	356	74	76
Mean (SE)	19.03 (0.83)	15.63 (0.82)	26.95 (2.07)	28.07 (2.08)
Median	15.75	11.25	23.25	27.00
Week 12				
N	347	348	74	76
Mean (SE)	15.54 (0.85)	11.46 (0.76)	25.67 (2.15)	26.80 (2.06)
Median	11.00	6.50	22.00	27.50
Week 16				
N	340	345	74	76
Mean (SE)	13.40 (0.88)	9.11 (0.68)	24.95 (2.24)	26.04 (2.03)
Median	7.00	4.00	20.50	26.50
Week 20				
N	327	338	74	76
Mean (SE)	11.56 (0.86)	7.16 (0.60)	18.71 (1.96)	17.65 (1.93)
Median	6.00	2.70	14.00	12.00
Week 28				
N	305	327	69	72
Mean (SE)	9.24 (0.76)	6.04 (0.59)	11.23 (1.59)	9.53 (1.81)
Median	4.00	2.00	5.00	3.25
Week 40				
N	213	263	46	55
Mean (SE)	5.24 (0.66)	3.66 (0.47)	6.91 (2.00)	4.52 (1.15)
Median	1.90	1.20	2.40	1.00
Week 52				
N	194	239	38	42
Mean (SE)	4.37 (0.55)	3.32 (0.47)	4.91 (1.21)	3.32 (0.87)
Median	2.00	1.00	2.55	0.95

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

Table 21. Descriptive Statistics of Percent Change from Baseline Total Psoriatic BSA (%) 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	369	367	73	76
Mean (SE)	-7.69 (0.90)	-7.78 (0.97)	1.70 (1.78)	-1.14 (1.71)
Median	0.00	0.00	0.00	0.00
Week 4				
N	363	366	74	75
Mean (SE)	-18.97 (1.40)	-23.74 (1.53)	-2.53 (3.47)	-1.46 (2.47)
Median	-10.00	-15.59	0.00	0.00
Week 8				
N	354	356	74	76
Mean (SE)	-36.93 (1.89)	-46.65 (1.92)	-10.58 (4.21)	-4.59 (3.45)
Median	-34.55	-46.06	-1.85	0.00
Week 12				
N	347	348	74	76
Mean (SE)	-49.03 (2.05)	-61.14 (1.94)	-15.28 (5.01)	-7.57 (4.14)
Median	-53.85	-68.23	-7.91	0.00
Week 16				
N	340	345	74	76
Mean (SE)	-56.91(2.13)	-67.98 (1.97)	-18.32 (4.83)	-8.14 (4.84)
Median	-71.32	-83.90	-6.63	0.00
Week 20				
N	327	338	74	76
Mean (SE)	-64.26 (2.04)	-74.96 (1.74)	-37.34 (5.58)	-38.95 (4.54)
Median	-79.31	-87.32	-30.79	-32.46
Week 28				
N	305	327	69	72
Mean (SE)	-71.57 (1.76)	-79.23 (1.60)	-59.53 (5.54)	-67.91 (4.72)
Median	-82.14	-91.67	-75.00	-89.74
Week 40				
N	213	263	46	55
Mean (SE)	-83.65 (1.51)	-86.99 (1.27)	-79.76 (3.88)	-85.21 (3.47)
Median	-92.31	-94.62	-88.58	-96.55
Week 52				
N	194	239	38	42
Mean (SE)	-85.64 (1.47)	-88.03 (1.20)	-85.03 (2.81)	-91.25 (2.08)
Median	-92.21	-94.74	-92.95	-96.57

Baseline is the latest predose measurement.
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, Table 23, Table 24, Table 25, Table 26, and 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	240	226	43	55
Mean (SD)	27.31 (20.45)	26.22 (20.35)	25.40 (17.60)	26.78 (18.67)
Week 8				
N	226	214	43	55
Mean (SD)	22.36 (19.83)	21.88 (19.29)	21.86 (17.24)	25.75 (18.29)
Week 16				
N	218	205	43	55
Mean (SD)	17.17 (16.86)	16.58 (18.13)	22.53 (18.96)	25.69 (18.37)
Week 20				
N	208	206	43	55
Mean (SD)	15.03 (16.97)	14.02 (16.70)	21.44 (18.32)	24.29 (17.30)
Week 28				
N	193	197	40	53
Mean (SD)	11.77 (15.29)	11.78 (15.90)	15.93 (16.06)	17.77 (15.90)
Week 40				
N	118	148	26	39
Mean (SD)	10.11 (15.71)	7.95 (13.57)	7.73 (11.80)	11.31 (13.41)
Week 52				
N	108	137	21	30
Mean (SD)	9.06 (13.43)	7.92 (14.32)	5.29 (7.12)	7.53 (9.35)

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	226	214	43	55
Mean (SD)	-4.33 (11.30)	-4.21 (10.80)	-3.53 (10.35)	-1.04 (8.54)
Week 16				
N	218	205	43	55
Mean (SD)	-8.74 (14.02)	-9.36 (13.60)	-2.86 (12.72)	-1.09 (11.07)
Week 20				
N	208	206	43	55
Mean (SD)	-10.61 (15.48)	-11.50 (14.74)	-3.95 (14.31)	-2.49 (10.63)
Week 28				
N	193	197	40	53
Mean (SD)	-13.86 (14.96)	-14.30 (14.75)	-9.45 (17.63)	-8.91 (12.90)
Week 40				
N	118	148	26	39
Mean (SD)	-16.45 (14.80)	-18.11 (15.84)	-21.50 (17.28)	-15.33 (12.60)
Week 52				
N	108	137	21	30
Mean (SD)	-17.08 (15.36)	-18.13 (15.27)	-23.29 (19.97)	-19.17 (13.88)

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	240	226	43	55
Mean (SD)	7.45 (3.03)	7.23 (3.20)	7.21 (2.77)	7.36 (3.08)
Week 8				
N	226	214	43	55
Mean (SD)	6.50 (3.51)	6.65 (3.61)	6.98 (3.11)	7.56 (2.99)
Week 16				
N	218	204	43	55
Mean (SD)	5.83 (3.58)	5.37 (3.91)	6.79 (3.53)	7.56 (3.02)
Week 20				
N	207	206	43	55
Mean (SD)	5.19 (3.66)	4.86 (3.89)	6.44 (3.80)	7.42 (2.99)
Week 28				
N	193	197	40	53
Mean (SD)	4.42 (3.74)	4.23 (3.85)	5.38 (4.11)	6.40 (3.62)
Week 40				
N	118	148	26	39
Mean (SD)	3.79 (3.75)	3.03 (3.53)	3.12 (3.56)	4.41 (3.89)
Week 52				
N	108	137	21	30
Mean (SD)	3.63 (3.70)	2.85 (3.73)	2.86 (3.45)	3.67 (3.74)

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	227	217	43	55
LS Mean (SE)	-11.95 (6.56)	0.55 (6.73)	-14.70 (15.06)	11.37 (13.31)
Week 16				
N	227	217	43	55
LS Mean (SE)	-21.56 (7.65)	-25.87 (7.83)	-10.70 (17.32)	31.51 (15.32)
Week 20				
N	227	217	43	55
LS Mean (SE)	-24.02 (9.50)	-35.56 (9.65)	-12.19 (21.30)	37.72 (18.83)
Week 28				
N	227	217	43	55
LS Mean (SE)	-46.40 (6.80)	-53.80 (6.85)	-31.97 (15.17)	5.38 (13.34)
Week 40				
N	227	217	43	55
Mean (SD)	-54.22 (5.70)	-60.39 (5.39)	-67.71 (12.43)	-51.65 (10.52)
Week 52				
N	227	217	43	55
LS Mean (SE)	-56.38 (5.55)	-65.06 (5.17)	-69.87 (12.46)	-72.94 (10.57)

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 Sequence (FAS Subjects with Baseline Nail Psoriasis, NRI)

	Response			
	N	n (%)	SE	95% CI
Week 8				
CP-690,550 5 mg BID	240	26 (10.83)	2.01	6.90, 14.77
CP-690,550 10 mg BID	226	27 (11.95)	2.16	7.72, 16.18
Placebo to CP-690,550 5 mg BID	43	3 (6.98)	3.88	0.00, 14.59
Placebo to CP-690,550 10 mg BID	55	1 (1.82)	1.80	0.00, 5.35
Week 16				
CP-690,550 5 mg BID	240	45 (18.75)	2.52	13.81, 23.69
CP-690,550 10 mg BID	226	61 (26.99)	2.95	21.20, 32.78
Placebo to CP-690,550 5 mg BID	43	7 (16.28)	5.63	5.24, 27.31
Placebo to CP-690,550 10 mg BID	55	3 (5.45)	3.06	0.00, 11.46
Week 20				
CP-690,550 5 mg BID	240	58 (24.17)	2.76	18.75, 29.58
CP-690,550 10 mg BID	226	75 (33.19)	3.13	27.05, 39.33
Placebo to CP-690,550 5 mg BID	43	10 (23.26)	6.44	10.63, 35.88
Placebo to CP-690,550 10 mg BID	55	4 (7.27)	3.50	0.41, 14.14
Week 28				
CP-690,550 5 mg BID	240	83 (34.58)	3.07	28.57, 40.60
CP-690,550 10 mg BID	226	90 (39.82)	3.26	33.44, 46.21
Placebo to CP-690,550 5 mg BID	43	14 (32.56)	7.15	18.55, 46.56
Placebo to CP-690,550 10 mg BID	55	10 (18.18)	5.20	7.99, 28.38
Week 40				
CP-690,550 5 mg BID	240	59 (24.58)	2.78	19.14, 30.03
CP-690,550 10 mg BID	226	92 (40.71)	3.27	34.30, 47.11
Placebo to CP-690,550 5 mg BID	43	19 (44.19)	7.57	29.34, 59.03
Placebo to CP-690,550 10 mg BID	55	21 (38.18)	6.55	25.34, 51.02
Week 52				
CP-690,550 5 mg BID	240	57 (23.75)	2.75	18.37, 29.13
CP-690,550 10 mg BID	226	92 (40.71)	3.27	34.30, 47.11
Placebo to CP-690,550 5 mg BID	43	17 (39.53)	7.46	24.92, 54.15
Placebo to CP-690,550 10 mg BID	55	16 (29.09)	6.12	17.09, 41.09

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 Sequence (FAS Subjects with Baseline Nail Psoriasis, NRI)

	Response			
	N	n (%)	SE	95% CI
Week 8				
CP-690,550 5 mg BID	240	19 (7.92)	1.74	4.50, 11.33
CP-690,550 10 mg BID	226	17 (7.52)	1.75	4.08, 10.96
Placebo to CP-690,550 5 mg BID	43	1 (2.33)	2.30	0.00, 6.83
Placebo to CP-690,550 10 mg BID	55	1 (1.82)	1.80	0.00, 5.35
Week 16				
CP-690,550 5 mg BID	240	25 (10.42)	1.97	6.55, 14.28
CP-690,550 10 mg BID	226	37 (16.37)	2.46	11.55, 21.20
Placebo to CP-690,550 5 mg BID	43	5 (11.63)	4.89	2.05, 21.21
Placebo to CP-690,550 10 mg BID	55	3 (5.45)	3.06	0.00, 11.46
Week 20				
CP-690,550 5 mg BID	240	34 (14.17)	2.25	9.75, 18.58
CP-690,550 10 mg BID	226	49 (21.68)	2.74	16.31, 27.05
Placebo to CP-690,550 5 mg BID	43	7 (16.28)	5.63	5.24, 27.31
Placebo to CP-690,550 10 mg BID	55	2 (3.64)	2.52	0.00, 8.58
Week 28				
CP-690,550 5 mg BID	240	45 (18.75)	2.52	13.81, 23.69
CP-690,550 10 mg BID	226	57 (25.22)	2.89	19.56, 30.88
Placebo to CP-690,550 5 mg BID	43	10 (23.26)	6.44	10.63, 35.88
Placebo to CP-690,550 10 mg BID	55	7 (12.73)	4.49	3.92, 21.54
Week 40				
CP-690,550 5 mg BID	240	41 (17.08)	2.43	12.32, 21.84
CP-690,550 10 mg BID	226	58 (25.66)	2.91	19.97, 31.36
Placebo to CP-690,550 5 mg BID	43	10 (23.26)	6.44	10.63, 35.88
Placebo to CP-690,550 10 mg BID	55	11 (20.00)	5.39	9.43, 30.57
Week 52				
CP-690,550 5 mg BID	240	41 (17.08)	2.43	12.32, 21.84
CP-690,550 10 mg BID	226	67 (29.65)	3.04	23.69, 35.60
Placebo to CP-690,550 5 mg BID	43	9 (20.93)	6.20	8.77, 33.09
Placebo to CP-690,550 10 mg BID	55	11 (20.00)	5.39	9.43, 30.57

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 (as early as Week 2) and statistically significant for 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	364	361	74	71
Mean (SD)	5.70 (2.65)	5.51 (2.64)	5.32 (2.66)	5.08 (2.58)
Week 2				
N	369	367	73	76
Mean (SD)	3.88 (2.66)	3.47 (2.61)	5.01 (2.72)	4.66 (2.50)
Week 4				
N	364	365	74	75
Mean (SD)	3.22 (2.61)	2.45 (2.36)	4.64 (3.05)	4.83 (2.64)
Week 8				
N	354	354	74	76
Mean (SD)	2.79 (2.68)	1.89 (2.33)	4.77 (2.96)	4.95 (2.79)
Week 12				
N	347	349	74	76
Mean (SD)	2.55 (2.75)	1.77 (2.38)	4.46 (2.94)	5.01 (2.95)
Week 16				
N	340	345	74	76
Mean (SD)	2.31 (2.59)	1.68 (2.38)	4.84 (3.19)	5.17 (3.07)
Week 20				
N	327	338	74	76
Mean (SD)	2.06 (2.52)	1.44 (2.16)	2.28 (2.47)	2.42 (2.43)
Week 28				
N	304	326	68	72
Mean (SD)	2.05 (2.53)	1.52 (2.21)	1.93 (2.51)	1.51 (2.42)
Week 40				
N	212	262	46	55
Mean (SD)	1.58 (2.30)	1.34 (2.01)	1.89 (2.64)	1.15 (2.09)
Week 52				
N	194	238	38	42
Mean (SD)	1.62 (2.31)	1.15 (1.80)	1.82 (2.55)	1.19 (1.99)

Baseline ISI is average of prior 7 day scores from diary.
Abbreviations: BID = twice daily, FAS = full analysis set, ISI= Itch Severity Item, 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	361	359	74	71
LS Mean (SE)	-1.72 (0.11)	-2.05 (0.11)	-0.44 (0.24)	-0.63 (0.25)
Week 4				
N	361	359	74	71
LS Mean (SE)	-2.39 (0.12)	-3.05 (0.12)	-0.78 (0.26)	-0.43 (0.26)
Week 8				
N	361	359	74	71
LS Mean (SE)	-2.84 (0.13)	-3.63 (0.13)	-0.64 (0.27)	-0.31 (0.28)
Week 12				
N	361	359	74	71
LS Mean (SE)	-2.99 (0.13)	-3.68 (0.13)	-0.95 (0.28)	-0.21 (0.29)
Week 16				
N	361	359	74	71
LS Mean (SE)	-3.15 (0.13)	-3.78 (0.13)	-0.58 (0.29)	-0.00 (0.30)
Week 20				
N	361	359	74	71
LS Mean (SE)	-3.37 (0.13)	-3.97 (0.13)	-3.13 (0.27)	-2.87 (0.28)
Week 28				
N	361	359	74	71
LS Mean (SE)	-3.35 (0.13)	-3.88 (0.13)	-3.32 (0.28)	-3.79 (0.29)
Week 40				
N	361	359	74	71
Mean (SD)	-3.23 (0.15)	-3.59 (0.15)	-2.97 (0.33)	-3.69 (0.32)
Week 52				
N	361	359	74	71
LS Mean (SE)	-3.03 (0.16)	-3.62 (0.15)	-2.71 (0.36)	-3.14 (0.36)

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, ISI= Itch Severity Item, LS = least squares, N = total number of unique subjects in the longitudinal model, SE = standard error.

DLQI

Substantial improvement in health-related quality of life as measured by the DLQI was seen by Week 2 with 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	376	371	74	76
Mean (SD)	13.22 (7.21)	12.69 (7.18)	13.05 (7.09)	12.12 (7.01)
Week 2				
N	369	367	73	76
Mean (SD)	9.07 (6.51)	8.02 (6.25)	10.37 (7.09)	9.51 (5.86)
Week 4				
N	362	365	74	75
Mean (SD)	7.54 (6.40)	5.70 (5.48)	9.61 (7.42)	9.47 (6.45)
Week 8				
N	352	354	74	76
Mean (SD)	6.44 (6.35)	4.50 (5.37)	8.99 (6.91)	9.68 (6.45)
Week 12				
N	346	346	74	76
Mean (SD)	5.91 (6.29)	3.72 (5.03)	8.28 (6.74)	10.25 (6.91)
Week 16				
N	338	342	74	76
Mean (SD)	5.53 (5.93)	3.55 (4.93)	8.95 (8.12)	10.03 (7.33)
Week 20				
N	327	338	74	76
Mean (SD)	4.82 (5.46)	3.29 (4.80)	4.91(5.33)	5.97 (6.07)
Week 28				
N	301	324	68	70
Mean (SD)	4.50 (5.19)	2.97 (4.65)	3.78 (5.22)	4.29 (6.20)
Week 40				
N	210	256	46	54
Mean (SD)	3.27 (4.71)	2.32 (4.00)	4.30 (6.50)	2.94 (4.85)
Week 52				
N	194	238	38	42
Mean (SD)	3.25 (4.48)	2.21 (3.87)	4.32 (5.85)	2.95 (5.07)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, DLQI = dermatology life quality index, 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	372	368	74	76
LS Mean (SE)	-3.98 (0.22)	-4.70 (0.22)	-2.56 (0.50)	-2.95 (0.49)
Week 4				
N	372	368	74	76
LS Mean (SE)	-5.50 (0.24)	-6.89 (0.24)	-3.35 (0.53)	-3.00 (0.53)
Week 8				
N	372	368	74	76
LS Mean (SE)	-6.63 (0.27)	-8.08 (0.27)	-3.97 (0.59)	-2.78 (0.58)
Week 12				
N	372	368	74	76
LS Mean (SE)	-7.03 (0.28)	-8.73 (0.28)	-4.67 (0.61)	-2.21 (0.61)
Week 16				
N	372	368	74	76
LS Mean (SE)	-7.24 (0.29)	-8.95 (0.30)	-4.01 (0.64)	-2.44 (0.64)
Week 20				
N	372	368	74	76
LS Mean (SE)	-7.93 (0.28)	-9.21 (0.27)	-8.05 (0.60)	-6.49 (0.59)
Week 28				
N	372	368	74	76
LS Mean (SE)	-8.20 (0.29)	-9.44 (0.29)	-8.80 (0.63)	-8.07 (0.62)
Week 40				
N	372	368	74	76
LS Mean (SE)	-8.23 (0.31)	-9.38 (0.30)	-7.75 (0.67)	-8.31 (0.65)
Week 52				
N	372	368	74	76
LS Mean (SE)	-8.18 (0.32)	-9.43 (0.30)	-7.30 (0.70)	-8.01 (0.67)

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, DLQI = dermatology life quality index, N = total number of unique subjects in the longitudinal model, SE = standard error.

Other Patient Reported Outcomes

- By Week 16, 33% and 51% of subjects in the CP-690,550 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 Patient Global Assessment (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 for 6 of the 9 domain scores, 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, but not 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, and a greater improvement was observed in the 10 mg BID group.

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

- No significant effect was observed for overall work productivity at Week 16 as measured by the Work Limitation Questionnaire (WLQ).

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

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

- The mean Family Dermatology Life Quality Index (FDLQI) scores at Baseline, which were similar in all groups, indicated a moderate burden of skin disease on family members of the subjects.

Descriptive statistics for these patient reported outcomes over the 52-week treatment period are summarized in Table 32 through Table 39.

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

	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 (%)
Baseline				
Clear	0	0	0	0
Almost clear	2 (<1.0)	0	0	0
Mild	16 (4.3)	11 (3.0)	2 (2.7)	2 (2.6)
Moderate	125 (33.2)	122 (32.8)	31 (41.9)	26 (34.2)
Severe	233 (62.0)	239 (64.2)	41 (55.4)	48 (63.2)
N (Total)	376	372	74	76
Week 2				
Clear	0	0	0	0
Almost clear	8 (2.2)	8 (2.2)	1 (1.4)	0
Mild	50 (13.6)	77 (21.0)	9 (12.3)	6 (7.9)
Moderate	184 (49.9)	166 (45.4)	30 (41.1)	32 (42.1)
Severe	127 (34.4)	115 (31.4)	33 (45.2)	38 (50.0)
N (Total)	369	366	73	76
Week 4				
Clear	2 (<1.0)	1 (<1.0)	0	0
Almost clear	27 (7.4)	50 (13.7)	4 (5.4)	0
Mild	81 (22.3)	129 (35.3)	8 (10.8)	9 (12.0)
Moderate	168 (46.3)	122 (33.4)	34 (45.9)	31 (41.3)
Severe	85 (23.4)	63 (17.3)	28 (37.8)	35 (46.7)
N (Total)	363	365	74	75
Week 8				
Clear	6 (1.7)	15 (4.2)	3 (4.1)	0
Almost clear	70 (19.9)	115 (32.5)	1 (1.4)	0
Mild	104 (29.5)	109 (30.8)	12 (16.2)	8 (10.5)
Moderate	113 (32.1)	80 (22.6)	35 (47.3)	31 (40.8)
Severe	59 (16.8)	35 (9.9)	23 (31.1)	37 (48.7)
N (Total)	352	354	74	76
Week 12				
Clear	15 (4.3)	38 (11.0)	2 (2.7)	0
Almost clear	104 (30.1)	151 (43.8)	6 (8.1)	2 (2.6)
Mild	86 (24.9)	68 (19.7)	15 (20.3)	6 (7.9)
Moderate	93 (26.9)	63 (18.3)	28 (37.8)	33 (43.4)
Severe	48 (13.9)	25 (7.2)	23 (31.1)	35 (46.1)
N (Total)	346	345	74	76
Week 16				
Clear	21 (6.2)	48 (14.0)	5 (6.8)	0
Almost clear	104 (30.9)	143 (41.8)	2 (2.7)	2 (2.7)
Mild	94 (27.9)	75 (21.9)	15 (20.3)	11 (14.7)
Moderate	72 (21.4)	57 (16.7)	29 (39.2)	26 (34.7)
Severe	46 (13.6)	19 (5.6)	23 (31.1)	36 (48.0)
N (Total)	337	342	74	75

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

	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 (%)
Week 20				
Clear	29 (8.9)	53 (15.7)	7 (9.6)	1 (1.3)
Almost clear	110 (33.6)	148 (43.8)	10 (13.7)	14 (18.4)
Mild	83 (25.4)	72 (21.3)	29 (39.7)	26 (34.2)
Moderate	77 (23.5)	43 (12.7)	21 (28.8)	23 (30.3)
Severe	28 (8.6)	22 (6.5)	6 (8.2)	12 (15.8)
N (Total)	327	338	73	76
Week 28				
Clear	34 (11.3)	69 (21.3)	13 (19.1)	9 (12.5)
Almost clear	103 (34.3)	141 (43.5)	25 (36.8)	31 (43.1)
Mild	79 (26.3)	57 (17.6)	12 (17.6)	13 (18.1)
Moderate	66 (22.0)	39 (12.0)	12 (17.6)	13 (18.1)
Severe	18 (6.0)	18 (5.6)	6 (8.8)	6 (8.3)
N (Total)	300	324	68	72
Week 40				
Clear	44 (21.0)	67 (26.3)	10 (21.7)	11 (20.4)
Almost clear	84 (40.0)	117 (45.9)	17 (37.0)	27 (50.0)
Mild	48 (22.9)	43 (16.9)	9 (19.6)	7 (13.0)
Moderate	27 (12.9)	22 (8.6)	6 (13.0)	5 (9.3)
Severe	7 (3.3)	6 (2.4)	4 (8.7)	4 (7.4)
N (Total)	210	255	46	54
Week 52				
Clear	28 (14.4)	64 (26.9)	10 (26.3)	9 (21.4)
Almost clear	87 (44.8)	108 (45.4)	10 (26.3)	22 (52.4)
Mild	47 (24.2)	40 (16.8)	11 (28.9)	5 (11.9)
Moderate	25 (12.9)	21 (8.8)	5 (13.2)	3 (7.1)
Severe	7 (3.6)	5 (2.1)	2 (5.3)	3 (7.1)
N (Total)	194	238	38	42

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, PtGA = Patient Global Assessment.

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	375	46.80 (9.59)	371	47.25 (9.05)	74	47.39 (9.42)	76	47.90 (9.57)
Week 16	337	51.11 (8.12)	337	51.40 (8.45)	74	50.03 (9.56)	76	48.39 (10.29)
Week 28	300	51.85 (7.81)	322	51.79 (8.70)	68	52.27 (8.18)	72	50.34 (9.58)
Week 52	194	52.38 (7.25)	237	52.94 (7.92)	38	53.00 (7.66)	42	51.48 (8.71)
Mental Health Score								
Baseline	375	43.24 (12.04)	371	43.40 (12.54)	74	42.98 (12.43)	76	43.30 (12.57)
Week 16	337	47.32 (10.61)	337	49.07 (9.72)	74	45.96 (11.56)	76	44.65 (11.62)
Week 28	300	47.81 (10.83)	322	49.52 (10.29)	68	48.06 (9.17)	72	46.67 (10.86)
Week 52	194	49.46 (10.18)	237	49.99 (9.45)	38	46.44 (9.84)	42	50.87 (8.31)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, SD = standard deviation, SF-36 = Short Form 36.

Table 34. Descriptive Statistics of Hospital Anxiety and Depression Scale (HADS): 2 Subscale Scores at Baseline, Weeks 8, 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	376	7.05 (4.14)	371	6.94 (4.36)	74	7.72 (4.31)	76	6.38 (4.14)
Week 8	351	5.65 (4.00)	354	5.15 (3.59)	74	6.45 (3.81)	76	6.47 (4.06)
Week 16	337	5.43 (4.08)	340	5.18 (4.00)	74	5.43 (3.80)	76	5.55 (4.22)
Week 28	300	4.86 (3.92)	322	4.71 (3.85)	68	4.96 (4.26)	72	5.10 (4.11)
Week 52	194	4.36 (3.94)	237	4.32 (3.68)	38	4.89 (4.57)	42	4.10 (3.53)
Depression Subscale								
Baseline	376	6.00 (4.42)	371	5.64 (4.16)	74	5.85 (4.38)	76	5.51 (3.79)
Week 8	351	4.68 (3.91)	354	3.72 (3.35)	74	4.95 (4.02)	76	5.03 (3.75)
Week 16	337	4.36 (4.06)	340	3.50 (3.32)	74	4.49 (4.20)	76	5.21 (3.94)
Week 28	300	4.03 (3.97)	322	3.20 (3.29)	68	3.68 (3.91)	72	4.65 (3.82)
Week 52	194	3.62 (3.84)	237	3.14 (3.22)	38	3.29 (3.50)	42	2.95 (3.11)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, HADS = Hospital Anxiety and Depression Scale, 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	16 (4.7)	13 (3.8)	13 (17.6)	12 (15.8)
Somewhat dissatisfied				
Slightly dissatisfied				
Neither satisfied nor dissatisfied	11 (3.3)	5 (1.5)	5 (6.8)	3 (3.9)
Slightly satisfied	27 (8.0)	19 (5.6)	8 (10.8)	10 (13.2)
Somewhat satisfied	84 (24.9)	81 (23.9)	15 (20.3)	11 (14.5)
Very satisfied	163 (48.4)	205 (60.5)	8 (10.8)	13 (17.1)
N (Total)	337	339	74	76
Week 28				
Neither satisfied nor dissatisfied	9 (3.0)	8 (2.5)	3 (4.4)	3 (4.2)
Slightly dissatisfied	10 (3.3)	7 (2.2)	4 (5.9)	4 (5.6)
Slightly satisfied	33 (11.0)	18 (5.6)	8 (11.8)	7 (9.7)
Somewhat dissatisfied	8 (2.7)	9 (2.8)	2 (2.9)	2 (2.8)
Somewhat satisfied	84 (28.0)	84 (26.3)	17 (25.0)	14 (19.4)
Very dissatisfied	10 (3.3)	6 (1.9)	3 (4.4)	3 (4.2)
Very satisfied	146 (48.7)	188 (58.8)	31 (45.6)	39 (54.2)
N (Total)	300	320	68	72
Week 52				
Neither satisfied nor dissatisfied	3 (1.5)	3 (1.3)	1 (2.6)	1 (2.4)
Slightly dissatisfied	3 (1.5)	4 (1.7)	0	1 (2.4)
Slightly satisfied	12 (6.2)	11 (4.6)	4 (10.5)	2 (4.8)
Somewhat dissatisfied	5 (2.6)	2 (<1.0)	2 (5.3)	0
Somewhat satisfied	57 (29.4)	66 (27.8)	11 (28.9)	7 (16.7)
Very dissatisfied	2 (1.0)	2 (<1.0)	1 (2.6)	1 (2.4)
Very satisfied	112 (57.7)	149 (62.9)	19 (50)	30 (71.4)
N (Total)	194	237	38	42

Abbreviations: BID = twice daily, FAS = full analysis set, N = number of subjects, n = number of subjects meeting prespecified criteria, PSSM = Patient Satisfaction with Study Medication.

Table 36. Descriptive Statistics of Work Limitation Questionnaire (WLQ) Index Score at Baseline, Weeks 8, 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	324	318	66	68
Mean (SD)	7.77 (5.94)	8.26 (6.59)	7.63 (5.65)	7.78 (6.32)
Week 8				
N	293	302	63	61
Mean (SD)	6.89 (6.79)	6.99 (6.68)	7.04 (6.41)	8.53 (7.11)
Week 16				
N	278	292	64	61
Mean (SD)	6.28 (6.31)	6.44 (6.48)	7.27 (6.97)	7.14 (6.46)
Week 28				
N	249	277	56	61
Mean (SD)	5.93 (6.03)	5.71 (5.64)	6.11 (6.76)	7.45 (7.27)
Week 52				
N	164	205	31	38
Mean (SD)	5.86 (6.35)	5.79 (6.03)	6.48 (6.41)	5.23 (5.97)

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

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	376	372	74	76
Mean (SD)	3.79 (3.13)	3.44 (3.09)	3.45 (2.89)	2.96 (3.05)
Week 4				
N	351	354	74	76
Mean (SD)	2.50 (2.56)	2.22 (2.58)	2.86 (2.91)	3.14 (3.00)
Week 16				
N	336	340	74	76
Mean (SD)	2.24 (2.59)	1.95 (2.41)	2.88 (2.93)	3.21 (3.16)
Week 28				
N	300	320	68	72
Mean (SD)	2.25 (2.64)	1.78 (2.40)	2.15 (2.62)	2.26 (2.64)
Week 52				
N	193	235	38	42
Mean (SD)	1.88 (2.41)	1.74 (2.30)	2.00 (2.63)	1.64 (2.59)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, JPA = Joint Pain Assessment, 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	376	372	74	76
Mean (SD)	0.76 (0.20)	0.78 (0.18)	0.79 (0.15)	0.80 (0.19)
Week 16				
N	337	340	74	76
Mean (SD)	0.85 (0.16)	0.88 (0.14)	0.82 (0.17)	0.80 (0.20)
Week 28				
N	300	322	68	72
Mean (SD)	0.86 (0.16)	0.88 (0.15)	0.88 (0.15)	0.86 (0.16)
Week 40				
N	210	256	46	54
Mean (SD)	0.90 (0.13)	0.91 (0.12)	0.91 (0.10)	0.88 (0.18)
Week 52				
N	194	237	38	42
Mean (SD)	0.89 (0.12)	0.89 (0.14)	0.90 (0.10)	0.87 (0.17)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, EQ-5D = Euro-Qol 5 Dimensions, FAS = full analysis set, SD = standard deviation.

Table 39. Descriptive Statistics of Family Dermatology Life Quality Index (FDLQI) Score at Baseline, Weeks 16 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	41	47	14	11
Mean (SD)	9.20 (6.65)	9.57 (6.78)	8.07 (6.26)	6.27 (4.50)
Week 16				
N	36	32	11	9
Mean (SD)	4.17 (4.48)	2.84 (3.48)	6.09 (4.41)	7.33 (6.02)
Week 52				
N	13	12	4	4
Mean (SD)	3.08 (5.22)	2.33 (2.90)	1.75 (3.50)	2.00 (1.41)

Baseline is the latest predose measurement.
Abbreviations: BID = twice daily, FAS = full analysis set, FDLQI = Family Dermatology Life Quality Index, SD = standard deviation.

Safety Results:

Treatment-Emergent Adverse Events

- The incidence of non-serious treatment-emergent adverse events (TEAEs) was similar for the CP-690,550 5 mg BID, CP-690,550 10 mg BID, and placebo groups (29.3%, 30.7%, and 26.5%, respectively) during the 16-week treatment period (Table 40) and similar for the CP-690,550 5 mg BID and CP-690,550 10 mg BID treatment groups (51.3% and 53.0%, respectively) during Week 0 to Week 52 (Table 41). Most AEs were mild to moderate. Additionally, the overall incidence of all-causality TEAEs reported during Week 16 to Week 52 was similar among the placebo to CP-690,550 5 mg BID (33.3%) and placebo to CP-690,550 10 mg BID (44.2%) treatment sequences.

- 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, and hypercholesterolemia, and the incidences were similar in subjects receiving CP-690,550 5 mg BID and CP-690,550 10 mg BID.

- The overall incidence of treatment related non-serious TEAEs reported during the Week 0 to Week 16 period was slightly higher for the CP-690,550 5 mg BID, and CP-690,550 10 mg BID treatment groups (18.6% and 17.8%) compared with placebo (9.7%) (Table 42), and similar results were noted for CP-690,550 5 mg BID and CP-690,550 10 mg BID treatment groups during Week 0 to Week 52 (29.6% and 28.3%, respectively) (Table 43). The most frequent treatment related events reported across all treatment groups included nasopharyngitis, upper respiratory tract infection and hypercholesterolemia.

- The incidence of treatment-emergent serious adverse events (SAEs) was low and comparable across the treatment groups CP-690,550 5 mg BID (2.9%), CP-690,550 10 mg BID (1.3%), and placebo (1.0%) during the 16-week treatment period. The incidence of treatment-emergent SAEs was also comparable between treatment groups during the 52-week treatment period (Table 44 and Table 45).

- 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 of subjects during the 16-Week treatment period was 3.7% in the CP-690,550 5 mg BID group, 2.6% in the CP-690,550 10 mg BID group, and 3.1% in the placebo group. The incidence of AEs resulting in withdrawal of subjects was also comparable for placebo to CP-690,550 5 mg BID (8.0%) and placebo to CP-690,550 10 mg (7.8%) treatment sequences during Week 16 to Week 52.

- There were a total of 17 subjects with serious infections: 8 events in subjects receiving CP-690,550 5 mg BID group and 10 events in subjects receiving CP-690,550 10 mg BID; 1 subject had 2 serious infections (liver abscess and sepsis).

- During the study, 6 subjects had herpes zoster: 3 subjects in the CP-690,550 5 mg BID and 3 subjects in the CP-690,550 10 mg BID group. Of the 6 subjects, 1 subject (CP-690,550 5 mg group) reported an SAE of herpes zoster infection and the remaining cases were non-serious.

- There were 6 malignancies (excluding non-melanoma skin cancer [NMSC]) in 6 subjects: 2 breast cancers and 1 case of mycosis fungoides (cutaneous T-cell lymphoma) in the CP-690,550 5 mg BID group; 1 testicular cancer, 1 lymphoma (B-cell lymphoma), and 1 small intestinal cancer in the CP-690,550 10 mg BID group. There were no melanomas. There were more cases of squamous cell carcinoma in the CP-690,550 10 mg BID group (4 subjects) compared with the CP-690,550 5 mg BID group (1 subject).

- There were 3 adjudicated major adverse cardiovascular events (MACE): 2 subjects in the CP-690,550 5 mg BID group (1 subject with myocardial infarction with subsequent sudden cardiac death and 1 subject with stroke) and 1 subject in the placebo to CP-690,550 10 mg BID group with cardiac arrest.

- One subject treated with CP-690,550 10 mg BID and 1 subject treated with CP-690,550 5 mg BID (initially on placebo) experienced erythrodermic psoriasis during the Week 16 to Week 52 period.

- Three deaths occurred during the study: 2 during the Week 0 to Week 16 period (1 subject in the CP-690,550 5 mg BID group due to myocardial infarction followed by cardiac arrest and 1 subject in the placebo group due to a motor vehicle accident) and 1 during the Week 16 to Week 52 period (in the placebo to CP-690,550 10 mg BID group due to cardiac arrest).

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 16

System Organ Class Preferred Term	CP-690,550 5 mg BID n (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	Placebo n (%) (N=196)
Any AEs	112 (29.3)	117 (30.7)	52 (26.5)
Blood and lymphatic system disorders	3 (0.8)	8 (2.1)	4 (2.0)
Lymphadenopathy	3 (0.8)	8 (2.1)	4 (2.0)
Gastrointestinal Disorders	17 (4.5)	18 (4.7)	1 (0.5)
Constipation	0	8 (2.1)	1 (0.5)
Diarrhoea	17 (4.5)	10 (2.6)	0
Infections and Infestations	49 (12.8)	51 (13.4)	17 (8.7)
Nasopharyngitis	32 (8.4)	30 (7.9)	11 (5.6)
Upper respiratory tract infection	18 (4.7)	21 (5.5)	6 (3.1)
Investigations	7 (1.8)	15 (3.9)	5 (2.6)
Blood creatine phosphokinase increased	7 (1.8)	15 (3.9)	5 (2.6)
Metabolism and nutrition disorders	20 (5.2)	20 (5.2)	4 (2.0)
Hypercholesterolaemia	20 (5.2)	20 (5.2)	4 (2.0)
Musculoskeletal and connective tissue disorders	21 (5.5)	10 (2.6)	14 (7.1)
Arthralgia	10 (2.6)	8 (2.1)	6 (3.1)
Back pain	11 (2.9)	3 (0.8)	8 (4.1)
Nervous system disorders	16 (4.2)	18 (4.7)	6 (3.1)
Headache	16 (4.2)	18 (4.7)	6 (3.1)
Skin and subcutaneous tissue disorders	4 (1.0)	9 (2.4)	7 (3.6)
Acne	3 (0.8)	8 (2.1)	1 (0.5)
Psoriasis	1 (0.3)	1 (0.3)	6 (3.1)
Vascular disorders	8 (2.1)	3 (0.8)	3 (1.5)
Hypertension	8 (2.1)	3 (0.8)	3 (1.5)

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

Table 41. 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 (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	CP-690,550 5 mg BID n (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	Placebo to CP-690,550 5 mg BID n (%) (N=75)	Placebo to CP-690,550 10 mg BID n (%) (N=77)
Any AEs	196 (51.3)	202 (53.0)	90 (23.6)	106 (27.8)	25 (33.3)	34 (44.2)
Blood and lymphatic system disorders	9 (2.4)	10 (2.6)	-	-	-	-
Lymphadenopathy	9 (2.4)	10 (2.6)	-	-	-	-
Gastrointestinal Disorders	36 (9.4)	36 (9.4)	4 (1.0)	3 (0.8)	2 (2.7)	1 (1.3)
Abdominal pain	7 (1.8)	8 (2.1)	4 (1.0)	3 (0.8)	2 (2.7)	1 (1.3)
Constipation	2 (0.5)	8 (2.1)	-	-	-	-
Diarrhoea	22 (5.8)	16 (4.2)	-	-	-	-
Nausea	9 (2.4)	9 (2.4)	-	-	-	-
General disorders and administration site conditions	-	-	3 (0.8)	1 (0.3)	2 (2.7)	0
Chest pain	-	-	3 (0.8)	1 (0.3)	2 (2.7)	0
Infections and Infestations	107 (28.0)	123 (32.3)	43 (11.3)	52 (13.6)	11 (14.7)	16 (20.8)
Bronchitis	8 (2.1)	8 (2.1)	-	-	-	-
Gastroenteritis	8 (2.1)	8 (2.1)	-	-	-	-
Folliculitis	-	-	2 (0.5)	2 (0.5)	1 (1.3)	2 (2.6)
Influenza	5 (1.3)	12 (3.1)	4 (1.0)	6 (1.6)	1 (1.3)	2 (2.6)
Nasopharyngitis	48 (12.6)	53 (13.9)	23 (6.0)	31 (8.1)	5 (6.7)	4 (5.2)
Oral herpes	6 (1.6)	8 (2.1)	-	-	-	-
Pharyngitis	8 (2.1)	6 (1.6)	3 (0.8)	3 (0.8)	1 (1.3)	2 (2.6)
Tinea pedis	-	-	2 (0.5)	0	0	2 (2.6)
Sinusitis	6 (1.6)	8 (2.1)	-	-	-	-
Upper respiratory tract infection	29 (7.6)	30 (7.9)	13 (3.4)	12 (3.1)	3 (4.0)	6 (7.8)
Urinary tract infection	9 (2.4)	9 (2.4)	-	-	-	-
Investigations	45 (11.8)	65 (17.1)	28 (7.3)	39 (10.2)	6 (8.0)	15 (19.5)
Alanine aminotransferase increased	6 (1.6)	10 (2.6)	3 (0.8)	7 (1.8)	4 (5.3)	2 (2.6)
Aspartate aminotransferase increased	-	-	4 (1.0)	2 (0.5)	2 (2.7)	1 (1.3)
Blood cholesterol increased	9 (2.4)	6 (1.6)	3 (0.8)	5 (1.3)	1 (1.3)	3 (3.9)
Blood creatine phosphokinase increased	18 (4.7)	26 (6.8)	13 (3.4)	13 (3.4)	1 (1.3)	6 (7.8)
Blood triglycerides increased	10 (2.6)	7 (1.8)	5 (1.3)	2 (0.5)	1 (1.3)	2 (2.6)

Table 41. 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 (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	CP-690,550 5 mg BID n (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	Placebo to CP-690,550 5 mg BID n (%) (N=75)	Placebo to CP-690,550 10 mg BID n (%) (N=77)
Gamma-glutamyltransferase increased	7 (1.8)	8 (2.1)	2 (0.5)	2 (0.5)	4 (5.3)	4 (5.2)
Low density lipoprotein increased	12 (3.1)	9 (2.4)	9 (2.4)	9 (2.4)	0	2 (2.6)
Weight increased	10 (2.6)	17 (4.5)	7 (1.8)	11 (2.9)	0	0
Metabolism and nutrition disorders	31 (8.1)	34 (8.9)	9 (2.4)	17 (4.5)	2 (2.7)	6 (7.8)
Hypercholesterolaemia	24 (6.3)	25 (6.6)	9 (2.4)	17 (4.5)	2 (2.7)	6 (7.8)
Hyperlipidaemia	8 (2.1)	9 (2.4)	-	-	-	-
Musculoskeletal and connective tissue disorders	31 (8.1)	21 (5.5)	14 (3.7)	12 (3.1)	2 (2.7)	3 (3.9)
Arthralgia	16 (4.2)	18 (4.7)	8 (2.1)	10 (2.6)	1 (1.3)	2 (2.6)
Back pain	16 (4.2)	5 (1.3)	6 (1.6)	2 (0.5)	1 (1.3)	2 (2.6)
Nervous system disorders	22 (5.8)	25 (6.6)	14 (3.7)	15 (3.9)	4 (5.3)	1 (1.3)
Dizziness	-	-	5 (1.3)	3 (0.8)	2 (2.7)	1 (1.3)
Headache	22 (5.8)	25 (6.6)	10 (2.6)	12 (3.1)	3 (4.0)	1 (1.3)
Respiratory, thoracic and mediastinal disorders	18 (4.7)	28 (7.3)	4 (1.0)	11 (2.9)	1 (1.3)	0
Cough	9 (2.4)	17 (4.5)	4 (1.0)	11 (2.9)	1 (1.3)	0
Oropharyngeal pain	10 (2.6)	12 (3.1)	-	-	-	-
Skin and subcutaneous tissue disorders	11 (2.9)	15 (3.9)	0	2 (0.5)	0	2 (2.6)
Acne	3 (0.8)	10 (2.6)	0	2 (0.5)	0	2 (2.6)
Pruritus	8 (2.1)	5 (1.3)	-	-	-	-
Vascular disorders	13 (3.4)	7 (1.8)	-	-	-	-
Hypertension	13 (3.4)	7 (1.8)	-	-	-	-

Except for the Number of Adverse Events subjects are counted only once per treatment in each row.
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 During Week 0 to Week 16

System Organ Class Preferred Term	CP-690,550 5 mg BID n (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	Placebo n (%) (N=196)
Any AEs	71 (18.6)	68 (17.8)	19 (9.7)
Gastrointestinal Disorders	8 (2.1)	4 (1.0)	0
Diarrhoea	8 (2.1)	4 (1.0)	0
Infections and Infestations	36 (9.4)	30 (7.9)	8 (4.1)
Nasopharyngitis	25 (6.5)	20 (5.2)	5 (2.6)
Upper respiratory tract infection	12 (3.1)	10 (2.6)	3 (1.5)
Investigations	7 (1.8)	14 (3.7)	3 (1.5)
Blood creatine phosphokinase increased	7 (1.8)	14 (3.7)	3 (1.5)
Metabolism and nutrition disorders	19 (5.0)	20 (5.2)	4 (2.0)
Hypercholesterolaemia	19 (5.0)	20 (5.2)	4 (2.0)
Nervous system disorders	6 (1.6)	10 (2.6)	4 (2.0)
Headache	6 (1.6)	10 (2.6)	4 (2.0)
Vascular Disorders	8 (2.1)	2 (0.5)	1 (0.5)
Hypertension	8 (2.1)	2 (0.5)	1 (0.5)

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 43. Treatment-Emergent, Treatment Related Non Serious Adverse Events Reported by 2% or More Subjects by System Organ Class and Preferred Term 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 (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	CP-690,550 5 mg BID n (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	Placebo to CP-690,550 5 mg BID n (%) (N=75)	Placebo to CP-690,550 10 mg BID n (%) (N=77)
Any AEs	113 (29.6)	108 (28.3)	51 (13.4)	59 (15.5)	13 (17.3)	21 (27.3)
Blood and lymphatic system disorders	8 (2.1)	8 (2.1)	-	-	-	-
Lymphadenopathy	8 (2.1)	8 (2.1)	-	-	-	-
Gastrointestinal disorders	9 (2.4)	7 (1.8)	-	-	-	-
Diarrhoea	9 (2.4)	7 (1.8)	-	-	-	-
Investigations	36 (9.4)	43 (11.3)	19 (5.0)	25 (6.6)	5 (6.7)	11 (14.3)
Alanine aminotransferase increased	-	-	3 (0.8)	5 (1.3)	4 (5.3)	2 (2.6)
Aspartate aminotransferase increased	-	-	4 (1.0)	1 (0.3)	2 (2.7)	1 (1.3)
Blood cholesterol increased	9 (2.4)	5 (1.3)	3 (0.8)	4 (1.0)	1 (1.3)	3 (3.9)
Blood creatine phosphokinase increased	17 (4.5)	22 (5.8)	12 (3.1)	10 (2.6)	1 (1.3)	4 (5.2)
Blood triglycerides increased	9 (2.4)	6 (1.6)	-	-	-	-
Gamma-glutamyltransferase increased	-	-	2 (0.5)	2 (0.5)	3 (4.0)	4 (5.2)
Low density lipoprotein increased	12 (3.1)	9 (2.4)	9 (2.4)	9 (2.4)	0	2 (2.6)
Weight increased	8 (2.1)	12 (3.1)	-	-	-	-
General disorders and administration site conditions	-	-	2 (0.5)	1 (0.3)	2 (2.7)	0
Chest pain	-	-	2 (0.5)	1 (0.3)	2 (2.7)	0
Infections and infestations	52 (13.6)	52 (13.6)	25 (6.5)	29 (7.6)	5 (6.7)	9 (11.7)
Nasopharyngitis	34 (8.9)	34 (8.9)	16 (4.2)	19 (5.0)	3 (4.0)	4 (5.2)
Upper respiratory tract infection	20 (5.2)	19 (5.0)	9 (2.4)	11 (2.9)	2 (2.7)	5 (6.5)
Metabolism and nutrition disorders	22 (5.8)	25 (6.6)	8 (2.1)	17 (4.5)	2 (2.7)	5 (6.5)
Hypercholesterolaemia	22 (5.8)	25 (6.6)	8 (2.1)	17 (4.5)	2 (2.7)	5 (6.5)
Musculoskeletal and connective tissue disorders	6 (1.6)	8 (2.1)	-	-	-	-
Arthralgia	6 (1.6)	8 (2.1)	-	-	-	-

Table 43. Treatment-Emergent, Treatment Related Non Serious Adverse Events Reported by 2% or More Subjects by System Organ Class and Preferred Term 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 (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	CP-690,550 5 mg BID n (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	Placebo to CP-690,550 5 mg BID n (%) (N=75)	Placebo to CP-690,550 10 mg BID n (%) (N=77)
Nervous System Disorders	9 (2.4)	13 (3.4)	10 (2.6)	10 (2.6)	2 (2.7)	0
Dizziness	-	-	5 (1.3)	2 (0.5)	2 (2.7)	0
Headache	9 (2.4)	13 (3.4)	6 (1.6)	8 (2.1)	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders	5 (1.3)	10 (2.6)	-	-	-	-
Cough	5 (1.3)	10 (2.6)	-	-	-	-
Skin and subcutaneous tissue disorders	8 (2.1)	1 (0.3)	-	-	-	-
Pruritus	8 (2.1)	1 (0.3)	-	-	-	-
Vascular disorders	10 (2.6)	3 (0.8)	-	-	-	-
Hypertension	10 (2.6)	3 (0.8)	-	-	-	-

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.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 16

System Organ Class Preferred Term	CP-690,550 5 mg BID n (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	Placebo n (%) (N=196)
Any SAEs	11 (2.9)	5 (1.3)	2 (1.0)
Cardiac disorders	2 (0.5)	0	1 (0.5)
Atrial fibrillation	1 (0.3)	0	0
Atrial flutter	1 (0.3)	0	0
Myocardial infarction	1 (0.3)	0	0
Palpitations	0	0	1 (0.5)
Hepatobiliary disorders	0	1 (0.3)	0
Hepatobiliary disease	0	1 (0.3)	0
Infections and Infestations	3 (0.8)	0	0
Erysipelas	1 (0.3)	0	0
Herpes zoster	1 (0.3)	0	0
Pneumonia	1 (0.3)	0	0
Injury, poisoning and procedural complications	1 (0.3)	1 (0.3)	1 (0.5)
Brain contusion	0	1 (0.3)	0
Joint dislocation	1 (0.3)	0	0
Road traffic accident	0	0	1 (0.5)
Musculoskeletal and connective tissue disorders	2 (0.5)	0	0
Back pain	1 (0.3)	0	0
Intervertebral disc protrusion	1 (0.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (0.3)	0
Squamous cell carcinoma	0	1 (0.3)	0
Nervous system disorders	1 (0.3)	0	0
Cerebrovascular accident	1 (0.3)	0	0
Psychiatric disorders	1 (0.3)	1 (0.3)	0
Alcohol withdrawal syndrome	0	1 (0.3)	0
Schizophrenia	1 (0.3)	0	0
Reproductive system and breast disorders	1 (0.3)	0	0
Metrorrhagia	1 (0.3)	0	0
Skin and subcutaneous tissue disorders	0	1 (0.3)	0
Psoriasis	0	1 (0.3)	0

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

Table 45. 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 (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	CP-690,550 5 mg BID n (%) (N=382)	CP-690,550 10 mg n (%) (N=381)	Placebo to CP-690,550 5 mg BID n (%) (N=75)	Placebo to CP-690,550 10 mg BID n (%) (N=77)
Any SAEs	18 (4.7)	19 (5.0)	8 (2.1)	15 (3.9)	4 (5.3)	6 (7.8)
Cardiac disorders	2 (0.5)	0	0	0	0	1 (1.3)
Atrial fibrillation	1 (0.3)	0	-	-	-	-
Atrial flutter	1 (0.3)	0	-	-	-	-
Cardiac arrest	-	-	0	0	0	1 (1.3)
Myocardial infarction	1 (0.3)	0	-	-	-	-
Gastrointestinal Disorders	0	1 (0.3)	0	1 (0.3)	0	0
Pancreatitis	0	1 (0.3)	0	1 (0.3)	0	0
General disorders and administration site conditions	0	1 (0.3)	0	1 (0.3)	0	0
Drug withdrawal syndrome	0	1 (0.3)	0	1 (0.3)	0	0
Hepatobiliary disorders	0	2 (0.5)	0	1 (0.3)	0	0
Cholecystitis acute	0	1 (0.3)	0	1 (0.3)	0	0
Hepatobiliary disease	0	1 (0.3)	-	-	-	-
Infections and infestations	6 (1.6)	6 (1.6)	3 (0.8)	6 (1.6)	2 (2.7)	3 (3.9)
Acute sinusitis	0	1 (0.3)	0	1 (0.3)	0	0
Appendicitis	0	1 (0.3)	0	1 (0.3)	0	1 (1.3)
Chronic tonsillitis	-	-	0	0	0	1 (1.3)
Erysipelas	1 (0.3)	0	-	-	-	-
Herpes zoster	1 (0.3)	0	-	-	-	-
Influenza	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	0	0
Liver abscess	0	1 (0.3)	0	1 (0.3)	0	0
Localised infection	1 (0.3)	0	1 (0.3)	0	0	0
Pneumonia	2 (0.5)	1 (0.3)	1 (0.3)	1 (0.3)	0	0
Pneumonia cryptococcal	-	-	0	0	1 (1.3)	0
Sepsis	0	1 (0.3)	0	1 (0.3)	1 (1.3)	0
Staphylococcal sepsis	0	1 (0.3)	0	1 (0.3)	0	0
Tooth infection	-	-	0	0	0	1 (1.3)
Injury, poisoning and procedural complications	4 (1.0)	1 (0.3)	3 (0.8)	0	0	0
Ankle fracture	1 (0.3)	0	1 (0.3)	0	0	0

Table 45. 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 (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	CP-690,550 5 mg BID n (%) (N=382)	CP-690,550 10 mg n (%) (N=381)	Placebo to CP-690,550 5 mg BID n (%) (N=75)	Placebo to CP-690,550 10 mg BID n (%) (N=77)
Brain contusion	0	1 (0.3)	-	-	-	-
Joint dislocation	1 (0.3)	0	-	-	-	-
Post procedural haemorrhage	1 (0.3)	0	1 (0.3)	0	0	0
Thoracic vertebral fracture	1 (0.3)	0	1 (0.3)	0	0	0
Investigations	0	1 (0.3)	0	1 (0.3)	0	0
Hepatic enzyme increased	0	1 (0.3)	0	1 (0.3)	0	0
Metabolism and nutrition disorders	0	1 (0.3)	0	1 (0.3)	0	0
Type 2 diabetes mellitus	0	1 (0.3)	0	1 (0.3)	0	0
Musculoskeletal and connective tissue disorders	2 (0.5)	0	-	-	-	-
Back pain	1 (0.3)	0	-	-	-	-
Intervertebral disc protrusion	1 (0.3)	0	-	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	3 (0.8)	0	3 (0.8)	2 (2.7)	1 (1.3)
Breast cancer	-	-	0	0	1 (1.3)	0
Lymphoma	0	1 (0.3)	0	1 (0.3)	0	0
Mycosis fungoides	-	-	0	0	1 (1.3)	0
Small intestine carcinoma	-	-	0	0	0	1 (1.3)
Squamous cell carcinoma	0	1 (0.3)	0	1 (0.3)	0	0
Testis cancer	0	1 (0.3)	0	1 (0.3)	0	0
Nervous system disorders	1 (0.3)	0	-	-	-	-
Cerebrovascular accident	1 (0.3)	0	-	-	-	-
Psychiatric disorders	1 (0.3)	1 (0.3)	0	0	0	1 (1.3)
Alcohol withdrawal syndrome	0	1 (0.3)	-	-	-	-
Schizophrenia	1 (0.3)	0	-	-	-	-
Suicide attempt	-	-	0	0	0	1 (1.3)
Reproductive system and breast disorders	1 (0.3)	1 (0.3)	0	1 (0.3)	0	0
Menorrhagia	0	1 (0.3)	0	1 (0.3)	0	0

Table 45. 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 (%) (N=382)	CP-690,550 10 mg BID n (%) (N=381)	CP-690,550 5 mg BID n (%) (N=382)	CP-690,550 10 mg n (%) (N=381)	Placebo to CP-690,550 5 mg BID n (%) (N=75)	Placebo to CP-690,550 10 mg BID n (%) (N=77)
Metrorrhagia	1 (0.3)	0	-	-	-	-
Respiratory, thoracic and mediastinal disorders	0	2 (0.5)	0	2 (0.5)	0	0
Chronic obstructive pulmonary disease	0	2 (0.5)	0	2 (0.5)	0	0
Skin and subcutaneous tissue disorders	1 (0.3)	1 (0.3)	1 (0.3)	0	0	0
Psoriasis	1 (0.3)	1 (0.3)	1 (0.3)	0	0	0
Surgical and medical procedures	1 (0.3)	0	1 (0.3)	0	0	0
Jaw lesion excision	1 (0.3)	0	1 (0.3)	0	0	0
Vascular disorders	1 (0.3)	0	1 (0.3)	0	0	0
Hypertensive crisis	1 (0.3)	0	1 (0.3)	0	0	0

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

Clinical Laboratory Evaluation

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

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

- By Week 20, a small decrease was observed in hemoglobin with the CP-690,550 5 mg BID and 10 mg BID groups. Mean hemoglobin remained stable over time. There were 3 confirmed cases of subjects with hemoglobin values <10 g/dL in the higher dose group.

- A dose-dependent increase in mean CPK was observed in the CP-690,550 5 mg BID and 10 mg BID groups within the first 4 weeks and values remained stable after Week 16 through Week 52. No rhabdomyolysis events were reported in the study.

- The percentages of subjects with confirmed ≥3 × ULN elevations in AST or ALT, and ≥2 × ULN elevations in total bilirubin were low and similar among the CP 690,550 5 mg BID and 10 mg BID groups. No confirmed DILI events occurred. No cases of Hy's law were reported during the study.

- 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 10 mg BID were superior to placebo for PGA "clear" or "almost clear" and PASI75 at Week 16.

- PGA and PASI responses were noted as early as Week 4 and were maintained through Week 52 with both doses.

- CP-690,550 10 mg BID showed higher efficacy than CP-690,550 5 mg BID based on PASI75 and PGA response rates.

- CP-690,550 improved the severity of nail psoriasis as measured by NAPSI.

- Consistent, significant improvement was observed with both the 5 mg BID and 10 mg BID CP-690,550 doses for PROs including health-related quality of life and functioning, symptoms associated with psoriasis, and patient satisfaction with treatment.

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

- The rate of malignancies (excluding NMSC), serious infections, and herpes zoster was similar for the CP-690,550 5 mg BID and CP-690,550 10 mg BID treatments.

- Generally, abnormal laboratory findings meeting pre-defined criteria across the CP-690,550 5 mg BID and CP-690,550 10 mg BID groups were uncommon and not associated with clinical symptoms.

- No new unexpected safety findings were observed.