2. SYNOPSIS

Name of Sponsor/Company: Celgene Corporation **Name of Finished Product:** CC-10004 20 mg capsules **Name of Active Ingredient:** CC-10004	Individual Study Table Referring to Part of the Dossier Volume: Page:	(For National Authority Use Only)

Title of Study:

A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Comparison Study of CC-10004 in Subjects With Moderate-To-Severe Plaque-Type Psoriasis

Principal Investigator: [redacted] was the coordinating investigator for Canada; [redacted] was the coordinating investigator for Germany; and [redacted] was the coordinating investigator for the Czech Republic.

Investigators: Refer to Appendix 16.1.4.

Study center(s):

This study included 34 active sites in Canada, Germany, and Czech Republic. Of those, 28 sites randomized subjects, 2 sites screened but did not randomize any subjects, and 4 sites did not screen or randomize any subjects.

Publications (reference):

Not applicable

Studied period (years): **Date first patient enrolled:** 23 April 2006 **Date last patient completed:** 07 February 2007	**Phase of development:** 2

Objectives:

Primary:

- To compare the clinical efficacy of 2 oral (PO) doses of CC-10004 (20 mg once daily [QD] and 20 mg twice daily [BID]) with placebo when taken for 12 weeks in subjects with moderate-to-severe plaque-type psoriasis

Secondary:

- To evaluate the safety of CC-10004 (20 mg QD and 20 mg BID PO) compared with placebo in subjects with moderate-to-severe plaque-type psoriasis
- To evaluate the effects of CC-10004 (20 mg QD and 20 mg BID PO) compared with placebo on the quality of life in subjects with moderate-to-severe plaque-type psoriasis

Methodology:

This was a phase 2, multicenter, randomized, double-blind, placebo-controlled, parallel group, dose-comparison efficacy and safety study in subjects with moderate-to-severe plaque-type psoriasis who were candidates for systemic therapy. The study included 3 phases: a pre-randomization phase for up to 4 weeks, followed by a 12-week treatment phase, and a 4-week observational follow-up phase (to

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monitor relapse and flare rates off study medication). Subjects meeting eligibility criteria at the baseline visit (Visit 2) were randomized to 1 of 3 oral treatments: CC-10004 20 mg QD, CC-10004 20 mg BID, or identical matching placebo. Subjects who were considered treatment failures during the treatment phase or subjects who prematurely discontinued study treatment for other reasons were asked to continue to participate in the observational follow-up phase of the study.

Subjects were to have a ≥ 6-month history of moderate-to-severe plaque-type psoriasis immediately prior to enrollment to qualify for this study. In addition the subjects were to have a Psoriasis Area and Severity Index (PASI) score ≥ 10 and body surface area (BSA) involvement ≥ 10% at screening. Randomized subjects received their first dose of CC-10004 or placebo at baseline (Visit 2) and had scheduled visits weekly up through Day 14 (Visit 4), then every 2 weeks thereafter to assess safety and the temporal onset of response.

Efficacy and safety assessments performed during the study are outlined in the Schedule of Study Assessments in Table 3.

While safety data was monitored on an ongoing basis, an interim analysis was planned to evaluate safety when 50% of enrolled subjects had either completed the 12-week treatment or prematurely discontinued from the study. The interim analysis was conducted by a Data Monitoring Committee (DMC) that was independent of the study personnel.

Number of patients (planned and analyzed):

Planned: Approximately 255

Analyzed: 260 in the intent-to-treat population;

259 in the safety population (1 subject was randomized in error but did not receive study medication, and therefore was excluded from the safety population)

Diagnosis and main criteria for inclusion:

- Must understand and voluntarily sign an informed consent form
- Must be a male or female of any ethnic origin or race, aged 18 years or older at time of consent
- Must be in good health as judged by the investigator, based on medical history, physical examination, 12-lead ECG, serum chemistry, hematology, and urinalysis
- Must be able to adhere to the study visit schedule and other protocol requirements
- Must have a ≥ 6-month history of moderate-to-severe plaque-type psoriasis immediately prior to enrollment. Note that the severity must have been moderate-to-severe during the entire 6-month period before screening.
- Must have a PASI score ≥ 10 and BSA ≥ 10%
- Must meet the following laboratory criteria:
  - White blood cell count ≥3000/mm^3 (≥ 3.0 X 10^9/L) and < 20,000/mm^3 (< 20 X 10^9/L)
  - Platelet count ≥ 100,000/µL (≥ 100 X 10^9/L)
  - Serum creatinine ≤ 1.5 mg/dl (≤ 132.6 µmol/L)

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- AST (SGOT) and ALT (SGPT) ≤ 1.5 X upper limit of normal (ULN)
- Must be a candidate for photo/systemic therapy (a subject is considered a candidate for photo/systemic therapy if, in the judgment of a clinician, the subject requires any systemic therapy, e.g., ultraviolet light A [UVA], ultraviolet light B [UVB], psoralens and long-wave ultraviolet radiation [PUVA], cyclosporine, corticosteroids, methotrexate, oral retinoids, mycophenolate mofetil, thioguanine, hydroxyurea, sirolimus, tacrolimus, azathioprine, or biological agents to control psoriasis whether or not that subject has a history of receiving systemic therapy).
- Women of childbearing potential (WCBP) must have a negative urine pregnancy test at screening (Visit 1). In addition, sexually active WCBP must agree to use two of the following adequate forms of contraception methods (such as oral, injectable, or implantable hormonal contraception; tubal ligation; intrauterine device; barrier contraceptive with spermicide; vasectomized partner) while on study. A WCBP must agree to have pregnancy tests every 4 weeks while on study medication.
- Males (including those who have had a vasectomy) must agree to use barrier contraception (latex condoms) when engaging in reproductive sexual activity with WCBP while on study medication and for 4 weeks after taking the last dose of study medication

Test product, dose and mode of administration, batch number:

CC-10004 was supplied as 20-mg capsules. Identically appearing placebo capsules were provided for blinding purposes.

CC-10004 20-mg capsules or placebo capsules were administered orally as follows:

- Subjects randomized to Treatment A (20 mg QD) took 1 X 20-mg CC-10004 capsule in the AM and 1 identical-appearing placebo capsule in the PM
- Subjects randomized to Treatment B (20 mg BID) took 1 X 20-mg CC-10004 capsule in the AM and 1 X 20-mg CC-10004 capsule in the PM
- Subjects randomized to Treatment C (placebo) took 1 placebo capsule in the AM and 1 placebo capsule in the PM

Study medication capsules were to be taken at approximately the same time every day, once in the morning and once in the evening, approximately 12 hours apart. Morning doses were taken orally between 7 and 9 AM fasted; PM doses are taken orally 12 hours later (± 30 minutes), >1 hour after the evening meal.

Batch number: CC-10004 20 mg capsules - 06B0001

Duration of treatment:

84-day treatment phase (ie, 12 weeks)

Reference therapy, dose and mode of administration, batch number:

CC-10004 20 mg placebo capsules taken orally – Batch number: 05B0007

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Criteria for evaluation:

Efficacy:

- Psoriasis area and severity index (PASI)
- Static Physician Global Assessment (sPGA)
- Body surface area (BSA) of involved skin
- Proportion of subjects achieving PASI-50, PASI-75, and PASI-90
- Time to achieve PASI-50, PASI-75, and PASI-90
- Time to relapse during the follow-up phase
- Photography (selected clinical sites)

Safety:

- Adverse events
- Complete physical examinations including, height (at Visit 1 only), weight (at Visits 1 and 9 only), skin, nasal cavities, eyes, ears, respiratory, cardiovascular, gastrointestinal, neurological, lymphatic, and musculoskeletal systems
- Vital signs, including blood pressure, pulse and temperature
- Clinical laboratory evaluations, eg, serum chemistry, hematology (including absolute white blood cell count, erythrocyte sedimentation rate, and fibrinogen), urinalysis, C-reactive protein, antinuclear antibody, serum antineutrophilic cytoplasmic antibody, quantitative assessment of serum immunoglobulins (immunoglobulin A [IgA], immunoglobulin M [IgM], and immunoglobulin G [IgG]), CD3+, CD4+, CD8+ lymphocyte subsets (flow cytometry)
- Centralized manual 12-lead ECG over-reading by external cardiologist
- Assessment of flare as defined as a sudden intensification of psoriasis or a diagnosis of erythrodermic, guttate, or pustular psoriasis.
- To determine a worsening of disease state, a retrospective analysis was done to calculate the proportion of subjects who achieved PASI-125 or greater during the study. PASI-125 was defined as a ≥25% worsening of PASI in reference to the baseline.

Other:

- Dermatology Life Quality Index (DLQI) and Medical Outcome Study Short Form 36-Item Health Survey (SF-36), Version 2

Statistical methods:

The primary goal of this study was to investigate the efficacy and safety of 2 doses of CC-10004 relative to placebo in subjects with moderate-to-severe plaque-type psoriasis. A 25% difference between active and placebo treatment in the proportions of subjects who showed at least a 75% improvement (reduction) from baseline on the PASI (PASI-75) at Day 84 (Week 12/Final Visit) was considered to be relevant based on a review of the current literature. Sample size estimates were based on a response rate of 10% for the subjects in the placebo group and 35% for the subjects in an active treatment group. A

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two group continuity corrected chi-square test with a 0.025, 2-sided significance level (using the Bonferroni procedure to adjust for the two active group comparisons to placebo to preserve an overall error rate at 0.05 2-sided) had 90% power to detect a 25% difference between an active treatment group and placebo when the sample size in each group is 68. Approximately 85 subjects were enrolled in each treatment group for a total of approximately 255 subjects to allow for an estimated 20% dropout rate.

Primary Endpoint:

- Proportion of subjects treated with CC 10004 (20 mg QD and 20 mg BID PO) who achieve a Psoriasis Area and Severity Index reduction of ≥ 75% (PASI-75) at Day 84 (Visit 9/Final Treatment Visit) in reference to the baseline visit compared with placebo

Secondary Endpoints:

- Difference between CC-10004 (20 mg BID and 20 mg QD) and placebo in percent change from baseline PASI at Visit 9/Final Treatment Visit
- Difference between CC-10004 (20 mg BID and 20 mg QD) and placebo in percent change from baseline in percent of body surface area (BSA) affected at Visit 9/Final Treatment Visit
- Shift change from baseline (1 or more points on 0 to 5 point scale) in the static Physician Global Assessment (sPGA) at Visit 9/Final Treatment Visit
- Proportion of subjects treated with CC 10004 (20 mg BID and 20 mg QD PO) compared with placebo who achieve ≥ PASI-50 and ≥ PASI-90 scores at Visit 9/Final Treatment Visit
- Time to clinically relevant response (ie, time to achieve ≥ PASI-50) during treatment phase
- Time to achieve ≥ PASI-75 and ≥ PASI-90
- Time to relapse (50% loss of maximal PASI score decrease in subjects who achieved at least a PASI-50 during the treatment phase) during the follow-up phase
- Change from baseline at Weeks 4, 8, and 12 in the Dermatology Life Quality Index (DLQI) and in the 8 subscales of the Medical Outcome Study Short Form 36-Item Health Survey (SF-36), Version 2

Efficacy Analysis:

The primary efficacy variable was the proportion of subjects treated with CC 10004 (20 mg QD and 20 mg BID PO) who achieved a Psoriasis Area and Severity Index reduction of 75% (PASI-75) at Day 84 (Visit 9/Final Treatment Visit) in reference to the baseline visit compared with placebo. All efficacy analyses were performed by visit on the intent-to-treat (ITT) and modified intent-to-treat (MITT) populations. The ITT population included all randomized subjects. The MITT population included all randomized subjects who received at least 1 dose of study medication, and had a baseline and at least 1 posttreatment PASI evaluation. If a subject was withdrawn before study completion, the

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last observation before withdrawal was used.

Continuity corrected chi-square tests were used to compare each of the two active treatment groups with the placebo group in a pair wise manner for categorical responses.

Continuous measures, ie, changes from baseline in PASI and BSA, were examined using 1-way analyses of variance/covariance (ANOVA/ANCOVA) followed by pairwise comparisons. A shift table was provided for change in sPGA. Trend analyses were performed to explore dose by response relationships. The Kaplan-Meier procedures were used to characterize time to achieve PASI-50 (ie, minimal clinical response), PASI-75 and PASI-90 during the treatment phase and the time to loss of 50% of maximal PASI score improvement (ie, time to relapse) for responders during the follow-up phase.

To allow for multiple comparisons, Bonferroni's procedure was employed when making the comparisons of each active group to placebo group.

Safety Analysis:

All subjects who took at least 1 dose of study medication were included in the safety analyses. Adverse events, clinical laboratory assessments, and vital sign measurements were tabulated and summarized by treatment group. Results of the ECG evaluation were reported separately. Adverse events occurring during the treatment phase and the follow-up phase were tabulated separately. All adverse events were summarized by frequency, severity, and relationship to study drug. Study drug-related adverse events, serious adverse events, and events leading to discontinuation or death were listed separately.

By-subject listings were provided for all relevant safety data.

Interim Analysis:

While safety data was monitored on an ongoing basis, an interim analysis was planned to evaluate safety at Day 84 (Week 12/Final Visit) when 50% of enrolled subjects had either completed the 12-week treatment or withdrawn early.

SUMMARY – CONCLUSIONS

EFFICACY RESULTS:

The study results demonstrate that a statistically significantly greater ($p = 0.023$) proportion of subjects in the 20 mg BID group (21/86 [24.4%] subjects) had a ≥75% reduction from baseline in PASI score compared with the placebo group (9/87 [10.3%] subjects). This was the primary efficacy measure of the study. The same proportion of subjects in the 20 mg QD and placebo groups had a ≥75% reduction from baseline in PASI score (9/87 [10.3%] subjects in each group).

Among the PASI-50, PASI-75, and PASI-90 responders at Visit 9/Week 12, there was a trend towards a dose response.

In addition, the secondary endpoints were met. More subjects showed improvement in sPGA score and psoriasis BSA by the end of treatment at Visit 9 in the 20 mg BID group compared with the placebo group (sPGA: 1.3 score reduction in the 20 mg BID group versus 0.7 score reduction in the placebo group, $p<0.001$; BSA: 30.8 % reduction in the 20 mg BID group versus 3.2% reduction in the placebo group, $p<0.001$). At Visit 9/Week 12/final treatment visit, there was a statistically significantly greater reduction from baseline in the percent change from PASI score in the 20 mg BID group compared with

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placebo (52.1% in the 20 mg BID group versus 17.4% in the placebo group; p≤0.001). The proportion of subjects who achieved PASI-50 at Visit 9/Week 12/final treatment visit was statistically significantly greater in the 20 mg BID group compared with the placebo group (49/86 [57.0%] subjects versus 20/87 [23.0%] subjects, respectively; p<0.001). The proportion of subjects who achieved PASI-90 at Visit 9/Week 12/final treatment visit was clinically significantly greater in the 20 mg BID group compared with the placebo group (12/86 [14%] subjects versus 5/87 [6%] subjects, respectively). All of these endpoints showed progressive improvement throughout the treatment phase. In addition, the differences between the 20 mg BID and placebo groups in these endpoints were observed as early as Visit 4/Week 2 or Visit 5/Week 4. Most of the effects observed in the 20 mg BID group were not sustained when subjects entered the 4-week observational follow-up phase and were no longer receiving study medication.

Quality of life was measured using the DLQI scores and SF-36 instrument. There was statistically significant reduction of DLQI scores in the 20 mg BID group compared with the placebo group at Visit 5/Week 4 (4.9 versus 1.4 score reduction, respectively; p<0.001) Visit 7/Week 8 (6.5 versus 2.2 score reduction, respectively; p<0.001), and Visit 9/Week 12 (7.0 versus 2.7 score reduction, respectively; p<0.001). A score change of 5 or more in the DLQI scale represents a change which is of importance to patients. The quality of life measured using the SF-36 instrument showed that in the 20 mg BID group, there was a statistically significant increase in score for social functioning compared with placebo at Visit 9/Week 12 (p=0.047). At the end of the treatment phase, the 20 mg BID group had a greater percentage of subjects that showed improvement in the SF-36 subscales (except mental health) compared with placebo. The 20 mg BID group demonstrated statistically significant improvement in summary physical score compared with placebo (p=0.045). Furthermore, the 20 mg BID group had a greater improvement compared with placebo in summary mental (48.8% subjects versus 39.1% subjects, respectively) and summary physical (52.3% subjects versus 29.2% subjects, respectively) components at Visit 9/Week 12.

In general, there were no significant differences observed between the 20 mg QD and placebo groups with regard to most of the secondary endpoints (ie, mean percent change from baseline in BSA; shift change in sPGA; proportion of subjects who achieved at least PASI-50 and PASI-90; time to achieve at least PASI-50, PASI-75 and PASI-90; and time to relapse). However, as shown with the 20 mg BID group, there was a statistically significant greater percent reduction in the PASI score at Visit 9/Week 12/final treatment visit in the 20 mg QD group compared with the placebo group (30.3% reduction versus 17.4% reduction, respectively; p=0.021). In addition, as observed with the 20 mg BID group, there were statistically significant differences observed between the 20 mg QD and placebo groups in the improvement of DLQI during the treatment phase at Visit 5/Week 4 (3.9 versus 1.4 score reduction, respectively; p=0.002), Visit 7/Week 8 (4.9 versus 2.2 score reduction, respectively; p=0.003), and Visit 9/Week 12 (4.8 versus 2.7 score reduction, respectively; p=0.027). There were greater percentages of subjects in the 20 mg QD group compared with the placebo group who showed improvement in the summary mental (42.5% versus 39.1%, respectively) and summary physical (37.9% versus 29.9%, respectively) components of the SF-36 at Visit 9/Week 12.

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SAFETY RESULTS:

Overall, CC-10004 was safe and well tolerated in subjects with moderate-to-severe plaque-type psoriasis in this study. The percentage of subjects who reported at least 1 AE was 54% subjects in the 20 mg BID group, 68% subjects in the 20 mg QD group, and 60% in the placebo group. There were no deaths reported in this study. The number and percentage of subjects with SAEs was 1 (1.2%) in the 20 mg BID group (psoriasis aggravated), 1 (1.1%) in the 20 mg QD group (knee ligament repair and meniscus lesion), and 5 (5.7%) in the placebo group (alcoholism, panic attack, psoriasis aggravated, rehabilitation therapy, and positive pregnancy test in 1 subject each). None of the subjects in either the 20 mg BID or the 20 mg QD groups experienced SAEs that were suspected to be related to study medication, as judged by the investigator.

The most common AEs reported were headache (11 [12.9%] subjects in the 20 mg BID group, 16 [18.4%] subjects in the 20 mg QD group, and 9 [10.3%] subjects in the placebo group), nasopharyngitis (12 [14.1%] subjects in the 20 mg BID group, 12 [13.8%] subjects in the 20 mg QD group, and 12 [13.8%] subjects in the placebo group), and diarrhea (5 [5.9%] subjects in the 20 mg BID group, 9 [10.3%] subjects in the 20 mg QD group, and 2 [2.3%] subjects in the placebo group).

Overall, the majority of AEs was judged by the investigator as mild or moderate, and most were not suspected to have a causal relationship to study medication in all 3 treatment groups. In the 20 mg BID group, there were 3 (3.5%) subjects with severe AEs (gastric ulcer, tooth abscess, and retinopathy), and 1 (1.2%) subject with a disabling (Grade 4) AE (migraine not otherwise specified). In the 20 mg QD group, there were 5 (5.7%) subjects with severe AEs (headache, upper respiratory infection not otherwise specified, aggravated psoriatic arthopathy, and pruritus in 1 subject each; and 1 subject with gravitational edema and deep vein thrombosis [follow-up information indicated that there was no evidence of deep vein thrombosis or Baker's cyst]). In the placebo group, there were 6 (6.9%) subjects with severe AEs (paresthesia, aggravated psoriasis, pruritus, urticaria, and alcoholism in 1 subject each; increased sweating, insomnia, and panic attack in 1 subject). In all 3 treatment groups, these severe and disabling AEs resolved without ongoing sequelae while the subject was on-study medication, or shortly after study medication was stopped.

Of the AEs reported in the system organ class, gastrointestinal disorders, the 4 most common AEs were diarrhea, not otherwise specified (5 [5.9%] subjects in the 20 mg BID group, 9 [10.3%] subjects in the 20 mg QD group, and 2 [2.3%] in the placebo group), nausea (5 [5.9%] subjects in the 20 mg BID group, 3 [3.4%] subjects in the 20 mg QD group, and none in the placebo group), upper abdominal pain (1 [1.2%] subjects in the 20 mg BID group, 2 [2.3%] subjects in the 20 mg QD group, and 1 [1.1%] in the placebo group), and vomiting, not otherwise specified (2 [2.4%] subjects in the 20 mg BID group, 2 [2.3%] subjects in the 20 mg QD group, and none in the placebo group). The most commonly reported gastrointestinal AEs with suspected relationship to study medication in the CC-10004 groups were nausea, diarrhea, dyspepsia, and vomiting. In the placebo group, the only gastrointestinal disorder with suspected relationship to study medication was glossodynia. Two out of three subjects in the 20 mg BID group, 3/7 subjects in the 20 mg QD group, and none of the subjects in the placebo group discontinued study medication due to diarrhea, nausea, vomiting, or headache. These AEs are typical of the PDE4 inhibitor drug class.

There was a low percentage of subjects who experienced any AEs in the system organ class of infections

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or infestations, and the percentage of subjects who reported any of these events was comparable across all 3 treatment groups (<2% subjects in the 20 mg BID group, <3% subjects in the 20 mg QD group, and <3% subjects in the placebo group).

Eleven subjects had clinically significant laboratory values that were reported as AEs. The majority of these AEs were rated by the investigator as mild in intensity and not having a suspected relationship to study medication. Overall, there were no differences between treatment groups in the number of subjects with improvement or worsening of ANA titers at the end of the treatment phase. None of the mean changes in the proinflammatory syndrome biomarker panel were considered to be clinically relevant, and no subject exhibited any clinical signs or symptoms of a proinflammatory syndrome. In addition, there were no notable findings in the immunology parameters, and there were no AEs associated with immunosuppression exhibited by any of the subjects treated with CC-10004.

There were no drug-related abnormalities in vital sign measurements or clinically significant changes in ECG findings compared with baseline.

A statistically significantly lower proportion of subjects in the 20 mg BID group had a 25% worsening of disease state (ie, PASI-125) compared with the placebo group. Furthermore, none of the subjects in the 20 mg BID group exhibited psoriasis flare symptoms throughout the treatment and observational follow-up phase.

CONCLUSION:

In this clinical study, CC-10004 at doses of 20 mg BID and 20 mg QD was shown to be well tolerated and safe in subjects with moderate-to-severe plaque-type psoriasis. There was no increase in AEs reported in the 20 mg BID group compared with the 20 mg QD group. The greater proportions of subjects treated with CC-10004, 20 mg BID that achieved 50%, 75%, and 90% improvement in PASI compared with those treated with placebo demonstrated the clinical activity of CC-10004 after 12 weeks of treatment. These results demonstrate a favorable benefit-risk profile for CC-10004 in subjects with moderate-to-severe plaque-type psoriasis.

Date of original report:

28 January 2008

Date of amended report:

10 November 2008