Clinical Study Protocol

IDP-118

Protocol V01-118A-303

A Phase 3, Multicenter, Open Label Study to Evaluate the Long-Term Safety of IDP-118 Lotion in the Treatment of Plaque Psoriasis

Developmental phase of study:	3
Study design	Open label, multicenter, long-term safety study
Date: Initial	27 May 2015
Amendment 1	02 November 2015
Sponsor	Dow Pharmaceutical Sciences, a Division of Valeant Pharmaceuticals North America, LLC 1330 Redwood Way Petaluma, CA 94954 [redacted]

CONFIDENTIAL

Nothing herein is to be disclosed without prior approval of the sponsor.

VALEANT
Research & Development

Protocol Review and Approvals

A Phase 3, Multicenter, Open Label Study to Evaluate the Long-Term Safety of IDP-118 Lotion in the Treatment of Plaque Psoriasis

Reviewed and approved:

Signature Date

[redacted]
Valeant Pharmaceuticals North America, LLC

Signature Date

[redacted]
Valeant Pharmaceuticals North America, LLC

Signature Date

[redacted]
Valeant Pharmaceuticals North America, LLC

Personnel Responsible for Conducting the Study

A Phase 3, Multicenter, Open Label Study to Evaluate the Long-Term Safety of IDP-118 Lotion in the Treatment of Plaque Psoriasis

Contract Research Organization

[redacted]

Cu-Tech, LLC
333 Route 46 West
Mountain Lakes, NJ 07046

[redacted]

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Principal Investigator Protocol Agreement Page

I agree:

- To assume responsibility for the proper conduct of this clinical study at this site and to conduct the study in compliance with this protocol, any future amendments, and with any other study conduct procedures provided by the sponsor.
- That I am aware of, and will comply with, the internationally recognized code of Good Clinical Practices (GCP) and all other applicable regulatory requirements to obtain written and dated approval from the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) for the study protocol, written informed consent, consent form updates, subject-recruitment procedures (e.g., advertisements), and any other written information to be provided to the subjects, before initiating this clinical study.
- Not to implement any changes to, or deviations from the protocol without prior agreement from the sponsor and review and documented approval from the IRB/IEC, except to eliminate an immediate hazard to the study subjects, or when change(s) involves only logistical or administrative aspects of the clinical study.
- To permit direct monitoring and auditing by the sponsor or sponsor's representatives and inspection by the appropriate regulatory authority(ies).
- That I am thoroughly familiar with the appropriate use of the investigational products(s), as described in this protocol, and any other information provided by the sponsor or designee, including, but not limited to, the current Investigator Brochure or equivalent document and approved product label (if applicable).
- To provide sufficient time, and adequate numbers of qualified staff and facilities for the foreseen duration of the clinical study to conduct the study properly, ethically, and safely.
- To ensure that all persons assisting in this study are adequately informed about the protocol, investigational product(s), and their clinical study-related duties and functions.

_____

Principal Investigator (print name)

_____ _____

Principal Investigator (signature) Date

2 Synopsis

Name of Sponsor/Company: Dow Pharmaceutical Sciences, a division of Valeant Pharmaceuticals North America, LLC
Name of Investigational Product: IDP-118 Lotion
Name of Active Ingredients: Tazarotene 0.045% w/w and halobetasol propionate 0.01% w/w
Title of Study: A Phase 3, Multicenter, Open Label Study to Evaluate the Long-Term Safety of IDP-118 Lotion in the Treatment of Plaque Psoriasis
Number of clinical centers: Multicenter, approximately 45-50 investigational centers in North America
Objective: The objective of this study is to evaluate the long-term safety of IDP-118 Lotion following once daily, 8-week treatment courses in subjects with plaque psoriasis followed by intermittent as needed treatment for up to 1 year. Subjects will receive treatment courses as needed during the year to manage their plaque psoriasis with the following safety endpoint evaluations being conducted: • The percentage of subjects who experience a local skin reaction (itching, dryness, and burning/stinging) graded at a level of 3 at any point in the study following the first application of study drug • Changes from baseline in all safety laboratory values and vital sign measurements as summarized using descriptive statistics by treatment group and study visit • Occurrences of new and ongoing adverse events (AEs). Descriptions of AEs will include the dates of onset and resolution (if resolved), maximum severity, seriousness, action taken regarding the study drug, corrective treatment, outcome, and investigator's assessment of causality • The number of treatment courses administered over the year of observation

Methodology:

This is a multicenter, open label study of the long-term safety of IDP-118 Lotion in subjects with plaque psoriasis. To be eligible for the study, subjects must be at least 18 years of age and have a clinical diagnosis of moderate to severe plaque psoriasis (defined as IGA score of 3 or 4).

Approximately 500 subjects who meet the study entry criteria will be entered into the study with the intent that at least 300 subjects will be followed for 6 months and at least 100 subjects will be followed for up to 1 year. All enrolled subjects will receive IDP-118 Lotion to be applied once daily for 8 weeks and then as needed once daily as assessed in 4-week periods for up to 1 year.

Two containers of the IDP-118 Lotion will be dispensed to each subject at baseline. The study drug will be applied topically to the affected areas (as determined by the investigator at baseline) with the initial application being made by the subject per instruction from the study staff. Subjects will apply their treatments at home once daily as explained by the study coordinator or designee at each investigational center. All subjects will be instructed to avoid exposure to direct sunlight, artificial ultraviolet light sources and to use protective clothing to prevent sunburn.

Following the initial 8-week treatment period, subjects will be evaluated for treatment success, defined as a score of 0 or 1 on the IGA. Subjects who achieve a treatment success at Week 8 will receive no further treatment and will be re-evaluated 4 weeks later at Week 12. Subjects who do not achieve a treatment success at Week 8 will receive an additional 4 weeks of once daily therapy and will also be re-evaluated at Week 12. At Week 12, the subject should have at least a 1 grade improvement from baseline to continue in the study. This 4-week evaluation/treatment cycle may continue for up to 1 year (ie, subjects will be evaluated every 4 weeks and subjects who achieve treatment success will receive no treatment until the next 4-week evaluation visit and subjects who do not achieve treatment success will receive once daily treatment until the next 4-week evaluation visit). If a subject remains on treatment after Week 12 by meeting the criteria of at least a 1 grade improvement, then at Week 24, if continuous treatment was received, they must have an IGA score equating to “Clear” or Almost Clear” to continue on study or they will be considered a failed treatment. Subjects who achieve a treatment success at any visit may not achieve a treatment success at a subsequent visit, and may therefore undergo periods of treatment and periods of nontreatment. The minimum continuous treatment exposure will be (the first) 8 weeks and the maximum continuous treatment exposure may be up to but no more than 24 weeks. Subjects who continue after Week 24 will be monitored to ensure treatment exposure does not exceed 24 consecutive weeks.

The subjects will be evaluated at Screening (Day -35 to Day -1), Baseline (Day 0), and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, and 52. The IGA will be performed at every study visit.

The study coordinator or designee will dispense new containers of study drug to the subject at appropriate (requiring treatment) study visit (ie, at Week 2, Week 4, and any subsequent study visit at which the subject did not achieve treatment success). At all postbaseline study visits (Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, and 52) the subjects will be asked to return their containers of study drug and have their treatment compliance evaluated if applicable. During the study, subjects will be allowed to use investigator approved non-medicated cleansers, moisturizers and suncreens; no other skin care products will be permitted on the treatment areas.

The investigator will assess the BSA affected by psoriasis for each subject at every study visit.

Local skin reactions will be evaluated and potential AEs will be assessed at every study visit. An abbreviated physical examination will be performed every 8 weeks during the study (ie, at Baseline and Weeks 8, 16, 24, 32, 40, 48, and 52). Blood samples will be collected for complete blood count with differential (CBC/Diff) and serum chemistry at Screening and Weeks 4, 8, 16, 24, 32, 40, 48, and 52. Female subjects of childbearing potential, will undergo urine and serum pregnancy testing at screening, and urine pregnancy testing will be performed at baseline prior to randomization and at all study visits other than Week 2.

Subjects who discontinue study participation early will be asked to complete all Week 52 assessments, as appropriate, prior to commencement of any alternative therapy for psoriasis (if possible). Subjects who discontinue from the study during the treatment period will not be replaced.

Subjects who discontinue from the study due to clinically significant laboratory abnormalities or other AEs will be instructed to follow up with their primary care physician, if indicated. If any subject has an AE during the study, the subject will be follow by the investigator until resolution (return to normal or to the baseline state) or stabilization, as determined by the investigator.

In addition to the above, application of study drug may be delayed or halted at any time if ongoing safety data evaluations (including reports of local skin reactions, such as skin atrophy, or severe AEs) raise concern for subject safety. If subject participation is suspended, all of the subject's safety data will be reviewed by the Medical Monitor in conjunction with the investigator to determine a course of action.

Number of subjects planned:

Approximately 500 subjects in order to retain at least 300 subjects for 6 months and 100 subjects for 1 year.

Inclusion criteria:

1. Male or female, of any race, at least 18 years of age.
2. Freely provides both verbal and written informed consent.
3. Has an area of plaque psoriasis appropriate for topical treatment that covers a BSA of at least 3%, but no more than 12%. The face, scalp, palms, soles, axillae, and intertriginous areas are to be excluded from this calculation.
4. Is willing and able to avoid prolonged exposure of the treatment area to ultraviolet radiation (natural and artificial) for the duration of the study.
5. Has a clinical diagnosis of psoriasis at the Baseline visit with an IGA score of 3 or 4. (The face, scalp, palms, soles, axillae and intertriginous areas are to be excluded in this assessment.)
6. Is in good general health based on the subject's medical history and a physical examination, with screening hematology and serum chemistry laboratory values within normal range or not clinically significant as determined by the investigator.
7. If female and of childbearing potential, must have negative urine and serum pregnancy tests at the Screening visit and a negative urine pregnancy test at the Baseline visit.

8. If female, is either not of childbearing potential, defined as postmenopausal for at least 12 months or surgically sterile (bilateral tubal ligation, bilateral oophorectomy, or hysterectomy), or is of childbearing potential and practicing one of the following methods of birth control throughout the study and for 30 days after the last dose of the study drug:
    - Condom with spermicide, diaphragm with spermicide, intrauterine device, or abstinence
    - Stable use of a hormonal contraceptive (oral, implant, insertable, injection, or transdermal patch) for at least 3 months prior to the Baseline visit
9. Subject is willing to comply with study instructions and return to the clinic for required visits.

Exclusion criteria:

1. Has spontaneously improving or rapidly deteriorating plaque psoriasis or pustular psoriasis, as determined by the investigator.
2. Presents with psoriasis that was treated with prescription medication and failed to respond to treatment, even partially or temporarily, as determined by the investigator.
3. Presents with any concurrent skin condition that could interfere with the evaluation of the treatment areas, as determined by the investigator.
4. Is pregnant, nursing an infant, or planning a pregnancy during the study period.
5. Has received treatment with any investigational drug or device within 60 days or 5 drug half-lives (whichever is longer) prior to the Baseline visit, or is concurrently participating in another clinical study with an investigational drug or device.
6. Received treatment with any topical antipsoriatic drug product within 14 days prior to the Baseline visit.
7. Has used any phototherapy (including laser), photochemotherapy, or non-biologic systemic psoriasis therapy (such as newer oral Psoriasis medications (eg Otezla), systemic corticosteroids, methotrexate, retinoids, or cyclosporine) within 4 weeks prior to the Baseline visit.
8. Has used immunomodulatory therapy (biologics) known to affect psoriasis within 3 months of the Baseline visit.
9. Has had prolonged exposure to natural or artificial sources of ultraviolet radiation within 4 weeks prior to the Baseline visit or is intending to have exposure during the study thought likely by the investigator to modify the subject's psoriasis.
10. Is currently using lithium or Plaquenil.
11. Has a history of hypersensitivity or allergic reaction to any of the study drug constituents.
12. Is unable to be compliant with study procedures, study drug administration requirements, study visit schedules, and prohibitions regarding the use of concomitant medications/therapies.
13. Is unable to communicate or cooperate with the investigator.
14. Has any underlying disease that the investigator deems uncontrolled that poses a concern for the subject's safety while participating on the study.
15. Has a history of drug or alcohol abuse as determined by the investigator.
16. Is considered by the investigator, for any other reason, to be an unsuitable candidate for the study.

Investigational product, dosage and mode of administration:

IDP-118 Lotion, applied topically, once daily for 8 weeks and then as needed up to 1 year.

Duration of treatment:

8 weeks for all subjects, and then intermittent treatment up to 1 year; the minimum continuous treatment exposure will be (the first) 8 weeks and the maximum continuous treatment exposure may be up to but no more than 24 weeks.

Reference therapy, dosage and mode of administration:

None

Criteria for evaluation:

Efficacy:

- IGA, assessed at every study visit

Safety:

- AEs, assessed at every study visit
- Clinical laboratory parameters (chemistry and hematology), assessed at Screening and Weeks 4, 8, 16, 24, 32, 40, 48, and 52
- Abbreviated physical examination findings, evaluated at baseline, and Weeks 8, 16, 24, 32, 40, 48, and 52
- Local skin reactions, assessed at baseline and all subsequent study visits

Statistical methods:

All subjects who receive at least 1 confirmed dose of study drug, and have at least 1 postbaseline safety assessment will be included in the safety analysis set. All analyses will be made using the safety analysis set.

Descriptive statistics will be used to present the data. Summaries of continuous variables will include the sample size, mean, median, standard deviation, minimum, and maximum. Summaries of categorical variables will include the sample size, frequency count, and percentage.

Investigator's Global Assessment

Descriptive statistics will be used to summarize the assessment of efficacy. The number and percentage of subjects who achieve treatment success at the Week 8 study visit will be tabulated.

Adverse Events

The AE analysis will be tabulated in a manner which provides information about the incidence of AE's for the entire treatment period as well as information by quarter to understand the evolution of AE's over time. Thus, in addition to the AE analysis over the entire 12-month treatment time, results will be presented for the first, second, and third 12-week period, which approximates a quarterly analysis. The analysis for the remaining period will be approximately 4 weeks longer than the first three quarters.

All AEs occurring during the study will be recorded and classified using terminology from the Medical Dictionary for Regulatory Activities (MedDRA). All reported treatment-emergent adverse events (TEAEs), defined as any AE with an onset on or after the date of first study drug application, will be summarized by the number of subjects reporting TEAEs, system organ class, preferred term, severity, and relationship to study drug. When summarizing TEAEs by severity or relationship to study drug, each subject will be counted only once within a system organ class or a preferred term using the event with the greatest severity or causality, respectively, within each category. All reported serious adverse events (SAEs) will be summarized by the number of subjects reporting the event, system organ class, preferred term, severity, and relationship to study drug.

All information pertaining to AEs noted during the study will be listed by subject and will include a verbatim description of the event as reported by the investigator, as well as the preferred term, system organ class, start date, stop date (if stopped), seriousness, severity, action taken regarding the study drug, corrective treatment, outcome, and relationship to the study drug. In addition, a listing of subjects who prematurely discontinue from the study due to AEs will be provided as well as a listing of subjects who reported an SAE.

Local Skin Reactions

The frequency of local skin reactions including itching, dryness, burning /stinging, skin atrophy, striae, telangiectasia, and folliculitis will be summarized by visit. Additionally, the percent of subjects who experience a local skin reaction (itching, dryness, and burning /stinging) graded at a score of 3 at any point in the study following the first application of study drug will be tabulated.

Safety Laboratory Values Changes from baseline in safety laboratory values will be summarized with descriptive statistics at all applicable study visits. Shift tables will be presented for changes in safety laboratory values. Normal ranges established by the central laboratory will be used to determine the shifts. A listing of all out-of-range laboratory test results at any assessment time point will also be provided. Determination of clinical significance for all out-of-range laboratory values will be made by each investigator and included in the listing. In addition, a listing of all clinically significant laboratory test results will be provided. *Concomitant Medications* All previous therapies and concomitant medications will be classified based on terminology from the World Health Organization (WHO) Drug Dictionary. Previous therapies and concomitant medications data will be presented in data listings.
Sample size calculations: The sample size selected for this study is expected to provide sufficient data for a long-term safety evaluation of IDP-118 Lotion when used by adult subjects with plaque psoriasis.

This study will be performed in compliance with GCP including the archiving of essential study documents. This protocol follows guidelines outlined by the International Conference on Harmonization (ICH). All data furnished to the investigator and his/her staff, and all data obtained through this stud, will be regarded as confidential and proprietary in nature and will not be disclosed to any third party, except for the United States Food and Drug Administration or other regulatory body, without written consent from the sponsor.

3 Table of Contents

LIST OF TABLES

4 List of Abbreviations and Definitions of Terms

Abbreviation or Specialist Term	Definition or Explanation
AE	Adverse event
BSA	Body surface area
CBC/Diff	Complete blood count with differential
CRF	Case Report Form
DPS	Dow Pharmaceutical Sciences, Inc.
ET	Early termination
FDA	United States Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Conference on Harmonization
IEC	Independent Ethics Committee
IGA	Investigator's Global Assessment
IRB	Institutional Review Board
MedDRA	Medical Dictionary for Regulatory Activities
SAE	Serious adverse event
TEAE	Treatment-emergent adverse event

In this protocol, "sponsor duties" refer to responsibilities that will be performed by the sponsor, the sponsor's designee, or the sponsor's designated contract research organization. In this protocol, "investigator" refers to the principal investigator or his/her designee, who is responsible for performing the study procedures and assessments.

5 Introduction

Psoriasis is a chronic, immune mediated disease, and varies widely in its clinical expression. Disease severity ranges from mild (limited number of plaques) to very severe. Characteristic features of psoriasis include hyperproliferation of epidermal cells associated with dermal/epidermal inflammation, resulting in sharply demarcated red plaques, which may be covered by silvery scales affecting the skin and scalp.

There are presently no curative treatments for psoriasis. Treatment options focus on relieving symptoms, reducing inflammation, induration, and scaling, and controlling the extent of the disease. Patient age, severity of disease, and the type and extent of body surface area (BSA) involvement are considerations in selecting therapy.

Topical therapies are used in all disease severities, but may be impractical when psoriasis involves a large BSA. The mainstay of psoriasis treatment is topical corticosteroids, which range in potency from superpotent to low potency (Class I to VII, respectively). Generally, the more potent corticosteroids are required for effective management of psoriasis.

IDP-118 (tazarotene 0.045% and halobetasol propionate 0.01%) Lotion is being developed for once daily treatment of plaque psoriasis. The current study is designed to obtain long-term safety data for IDP-118 Lotion when used over the course of a 1-year period

6 Study Objectives and Purpose

The objective of this study is to evaluate the long-term safety of IDP-118 Lotion following once daily, 8-week treatment courses in subjects with plaque psoriasis followed for up to 1 year. Subjects will receive treatment courses as needed during the year to manage their plaque psoriasis with the following safety endpoint evaluations being conducted:

- The percentage of subjects who experience a local skin reaction (itching, dryness, and burning/stinging) graded at a level of 3 at any point in the study following the first application of study drug
- Changes from baseline in all safety laboratory values and vital sign measurements as summarized using descriptive statistics by treatment group and study visit
- Occurrences of new and ongoing adverse events (AEs). Descriptions of AEs will include the dates of onset and resolution (if resolved), maximum severity, seriousness, action taken regarding the study drug, corrective treatment, outcome, and investigator's assessment of causality
- The number of treatment courses administered over the year of observation

7 Investigational Plan

7.1 Overall Study Design and Plan: Description

This is a multicenter, open label study of the long-term safety of IDP-118 Lotion in subjects with plaque psoriasis. To be eligible for the study, subjects must be at least 18 years of age and have a clinical diagnosis of moderate to severe plaque psoriasis (defined as an Investigator's Global Assessment [IGA] score of 3 or 4).

Approximately 500 subjects who meet the study entry criteria will be entered into the study with the intent that at least 300 subjects will be followed for 6 months and at least 100 subjects will be followed for up to 1 year. All enrolled subjects will receive IDP-118 Lotion to be applied once daily for 8 weeks and then as needed once daily as assessed in 4-week periods for up to 1 year.

Two containers of the IDP-118 Lotion will be dispensed to each subject at baseline. The study drug will be applied topically to the affected areas (as determined by the investigator at baseline) with the initial application being made by the subject per instruction from the study staff. Subjects will apply their treatments at home once daily as explained by the study coordinator or designee at each investigational center. All subjects will be instructed to avoid exposure to direct sunlight, artificial ultraviolet light sources, and to wear protective clothing to prevent sunburn.

Following the initial 8-week treatment period, subjects will be evaluated for treatment success, defined as a score of 0 or 1 on the IGA. Subjects who achieve a treatment success at Week 8 will receive no further treatment and will be re-evaluated 4 weeks later at Week 12. Subjects who do not achieve a treatment success at Week 8 will receive an additional 4 weeks of once daily therapy and will also be re-evaluated at Week 12. At Week 12, the subject should have at least a 1 grade improvement from baseline to continue in the study. This 4-week evaluation/treatment cycle may continue for up to 1 year (ie, subjects will be evaluated every 4 weeks and subjects who achieve treatment success will receive no treatment until the next 4-week evaluation visit and subjects who do not achieve treatment success will receive once daily treatment until the next evaluation visit). If a subject remains on treatment after Week 12 by meeting the criteria of at least a 1 grade improvement, then at Week 24, after continuous treatment, they must have an IGA score equating to "Clear" or Almost Clear" to continue on study or they will be considered a failed treatment. Subjects who achieve a treatment success at any visit may undergo periods of non-treatment. The minimum continuous treatment exposure will be (the first) 8 weeks and the maximum continuous treatment exposure may be up to but no more than 24 weeks. Subjects who continue past the Week 24 visit will be monitored to ensure treatment exposure does not exceed 24 consecutive weeks.

The subjects will be evaluated at Screening (Day -35 to Day -1), Baseline (Day 0), and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, and 52. The IGA and percent of body surface area involvement (BSA) will be performed at every study visit.

At all post-baseline study visits (Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, and 52) the subjects will be asked to return their containers of study drug and will have their treatment compliance evaluated as applicable. The study coordinator or designee at each investigational center will dispense new containers of study drug to the subject at each post-baseline study visit (ie, at Week 2, Week 4, and any subsequent study visit at which the subject did not achieve treatment success). During the study, subjects will be allowed to use investigator approved non-medicated cleansers, moisturizers and sunscreens; no other skin care products will be permitted on the treatment areas.

Local skin reactions will be evaluated and potential AEs will be assessed at every study visit. An abbreviated physical examination will be performed every 8 weeks during the study (ie, at Baseline and Weeks 8, 16, 24, 32, 40, 48, and 52). Blood samples will be collected for complete blood count with differential (CBC/Diff) and serum chemistry at Screening and Weeks 4, 8, 16, 24, 32, 40, 48, and 52. All female subjects of childbearing potential will undergo both urine and serum pregnancy testing at screening, and urine pregnancy testing will be performed at baseline and at all study visits other than Week 2.

Subjects who discontinue study participation early will be asked to complete all Week 52 assessments, as appropriate, prior to commencement of any alternative therapy for psoriasis (if possible). Subjects who discontinue from the study during the treatment period will not be replaced.

Subjects who discontinue from the study due to clinically significant laboratory abnormalities or AEs will be instructed to follow up with the investigator and/or their primary care physician, if indicated. If any subject has an AE during the treatment period, the subject will be followed-up by the investigator until resolution (return to normal or to the baseline state) or stabilization, as determined by the investigator.

In addition to the above, application of study drug may be delayed or halted at any time if ongoing safety data evaluations (including reports of local skin reactions, such as skin atrophy, or severe AEs) raise concern for subject safety. If subject participation is suspended, all of the subject's safety data will be reviewed by the Medical Monitor in conjunction with the investigator to determine a course of action.

Table 1: Study Design and Schedule of Assessments

PROCEDURES	Day -35 to Day -1 Screening	Day 0 Baseline	Week 2 (14 ± 3 days)	Week 4 (28 ± 3 days)	Week 8[a] (56 ± 5 days)	Week 12, 20, 28, 36, 44 (± 7 days)	Week 16, 24, 32, 40, 48 (± 7 days)	Week 52 /ET (± 7 days)
Informed consent	X							
Demographics	X							
Medical history [b]	X	X						
Previous psoriasis therapies [b]	X	X						
Inclusion/Exclusion criteria [b]	X	X						
Abbreviated physical examination [c]		X			X		X	X
Pregnancy testing [d]	X	X		X	X	X	X	X
Clinical laboratory tests [e]	X			X	X		X	X
Investigator's Global Assessment	X	X	X	X	X	X	X	X
Body surface area affected evaluation	X	X	X	X	X	X	X	X
Local skin reactions evaluation		X	X	X	X	X	X	X
Review study drug application instructions		X	X	X	X[f]	X[f]	X[f]	
Study drug weighed and dispensed		X	X	X	X[f]	X[f]	X[f]	
Study drug applied at investigational center		X			X[f]	X[f]	X[f]	
Study drug collected and weighed			X	X	X	X[g]	X[g]	X[g]
Study drug diary calendar dispensed		X	X	X	X[f]	X[f]	X[f]	
Review compliance with dosing / Diary			X	X	X	X[g]	X[g]	X[g]
Review adverse events		X	X	X	X	X	X	X
Review concomitant therapies	X	X	X	X	X	X	X	X
Study exit/end of study form								X

ET = early termination

[a] For subjects who discontinue early during the treatment period, all procedures outlined for the Week 52 visit should be completed at the time of discontinuation or within 2 weeks of discontinuation.

[b] Update at Visit 2 (baseline).

[c] Height will be measured at baseline only; weight measurements and examinations of other abbreviated physical parameters will be performed at baseline, Week 8, and Week 12.

[d] For females of childbearing potential, both urine and serum pregnancy testing will be conducted at the Screening visit. The urine pregnancy test must be completed at baseline and then as per the visit schedule. Subjects with a positive pregnancy test at any time during the study will be discontinued.

[e] Blood samples for laboratory tests will be collected at screening and prior to study drug application at Weeks 4, 8, 16, 24, 32, 40, 48, and 52. Clinically significant laboratory findings at Week 4 or Week 8 will be repeated at the discretion of the investigator, and the subject will be followed until resolution (return to normal or to the baseline state) or until clinically stable as determined by the investigator.

[f] For subjects with a score of 0 or 1, do not dispense further medication and re-evaluate at next visit.

[g] If applicable (i.e., if drug was dispensed at the previous study visit).

8 Selection and Withdrawal of Subjects

8.1 Subject Inclusion Criteria

Subjects meeting all of the following criteria will be eligible for study entry:

1. Male or female, of any race, at least 18 years of age.
2. Freely provides both verbal and written informed consent.
3. Has an area of plaque psoriasis appropriate for topical treatment that covers a BSA of at least 3%, but no more than 12%. The face, scalp, palms, soles, axillae, and intertriginous areas are to be excluded in this calculation.
4. Is willing and able to avoid prolonged exposure of the treatment area to ultraviolet radiation (natural and artificial) for the duration of the study.
5. Has a clinical diagnosis of psoriasis at the Baseline visit with an IGA score of 3 or 4. (The face, scalp, palms, soles, axillae, and intertriginous areas are to be excluded in this assessment.)
6. Is in good general health based on the subject's medical history and a physical examination, with screening hematology and serum chemistry laboratory values within normal range or not clinically significant as determined by the investigator.
7. If female and of childbearing potential, must have negative urine and serum pregnancy tests at the Screening visit and a negative urine pregnancy test at the Baseline visit.
8. If female, is either not of childbearing potential, defined as postmenopausal for at least 12 months or surgically sterile (bilateral tubal ligation, bilateral oophorectomy or hysterectomy), or is of childbearing potential and practicing one of the following methods of birth control throughout the study and for 30 days after the last dose of study drug:
    - Condom with spermicide, diaphragm with spermicide, intrauterine device, or abstinence
    - Stable use of a hormonal contraceptive (oral, implant, insertable, injection, or transdermal patch) for at least 3 months prior to the Baseline visit
9. Subject is willing to comply with study instructions and return to the clinic for required visits.

8.2 Subject Exclusion Criteria

Subjects meeting any one of the following criteria will be excluded from the study:

1. Has spontaneously improving or rapidly deteriorating plaque psoriasis or pustular psoriasis, as determined by the investigator.
2. Presents with psoriasis that was treated with prescription medication and failed to respond to treatment, even partially or temporarily, as determined by the investigator.
3. Presents with any concurrent skin condition that could interfere with the evaluation of the treatment areas, as determined by the investigator.
4. Is pregnant, nursing an infant, or planning a pregnancy during the study period.
5. Has received treatment with any investigational drug or device within 60 days or 5 drug half-lives (whichever is longer) prior to the Baseline visit, or is concurrently participating in another clinical study with an investigational drug or device.
6. Received treatment with any topical antipsoriatic drug product within 14 days prior to the Baseline visit.
7. Has used any phototherapy (including laser), photochemotherapy, or non-biologic systemic psoriasis therapy (such as newer oral psoriasis medications (eg Otezla), systemic corticosteroids, methotrexate, retinoids, or cyclosporine) within 4 weeks prior to the Baseline visit.
8. Has used immunomodulatory therapy (biologics) known to affect psoriasis within 3 months of the Baseline visit.
9. Has had prolonged exposure to natural or artificial sources of ultraviolet radiation within 4 weeks prior to the Baseline visit or is intending to have exposure during the study thought likely by the investigator to modify the subject's psoriasis.
10. Is currently using lithium or Plaquenil.
11. Has a history of hypersensitivity or allergic reaction to any of the study drug constituents.
12. Is unable to be compliant with study procedures, study drug administration requirements, study visit schedules, and prohibitions regarding the use of concomitant medications/therapies.
13. Is unable to communicate or cooperate with the investigator.
14. Has any underlying disease that the investigator deems uncontrolled that poses a concern for the subject's safety while participating on the study.

15. Has a history of drug or alcohol abuse as determined by the investigator.
16. Is considered by the investigator, for any other reason, to be an unsuitable candidate for the study.

8.3 Subject Withdrawal Criteria

Reasons for withdrawal may include, but are not limited to, the following:

- Psoriasis flare, as determined by the investigator, which requires treatment with a disallowed therapy.
- Local skin reactions that are known to be drug-related AEs, which could raise concern for subject safety, as per the investigator. If subject participation is suspended, all of the subject's safety data will be reviewed by the Medical Monitor in conjunction with the investigator to determine a course of action.
- Either at the investigator's request, for tolerability reasons (e.g., severe adverse reactions), or at the subject's request.
- When the requirements of the protocol are not followed.
- When a concomitant therapy likely to interfere with the results of the study is reported, or required by the subject (the investigators will report all such information on the source documents/case report forms and decide, in accordance with the sponsor, whether the subject is to be withdrawn).
- When a subject is lost to follow up, the investigators will try twice to reach the subject by telephone and will send a follow up letter by certified mail before considering that the subject is lost to follow up. These actions will be reported on the End of Study CRF and a copy of the follow up letter will be maintained in the investigator's file.

All premature discontinuations and their reasons must be carefully documented by the investigator on the final CRF, and, if need be, on the AE form. In any case, no subject who has been included and has a study number assigned can be replaced by another if they discontinue prematurely for whatever reason. All data gathered on the subject prior to termination will be made available to the sponsor.

Reasons for study completion/discontinuation as listed on the final report form are defined as follows:

Normal Study Completion – Subject completes the study as planned in the protocol

Adverse Event – Complete AE form

Subject Request – Consent withdrawal, subject moved, schedule conflicts

Protocol Violation – Contact the Sponsor or designee before making decision

Lost to Follow Up – Document with 2 phone calls and a certified letter

Pregnancy – Subject will discontinue study drug immediately, but will be followed to term. Complete pregnancy form

Worsening Condition – Subject requires alternate treatment for psoriasis before the end of the study and the investigator determines it is not due to lack of efficacy

Lack of Efficacy – Subject requires alternate treatment for psoriasis after at least 2 weeks of study drug treatment and the risk of continuing the subject in the study outweighs the benefit as determined by the investigator Subject is deemed a failed treatment; defined as either not having at least a 1 grade improvement at Week 12 or having received up to 24 weeks of continuous study drug treatment and not exhibiting an IGA score equating to "Clear" or "Almost Clear."

Other – Specify in comments section of final CRF

For subjects who discontinue early during the treatment period, all procedures outlined for the Early Termination (ET) visit (i.e., Week 52) should be completed at the time of discontinuation. The appropriate source document should be completed in addition to the End of Study CRF.

All subjects are free to withdraw from participating in this study at any time and for whatever reason, specified or unspecified, and without prejudice. No constraints will be placed on ordinary subject management, and subjects, when appropriate, will be placed on other conventional therapy upon request or whenever clinically necessary as determined by their physician.

9 Treatment Plan

9.1 Methods of Assigning Subjects to Treatment Groups

All subjects will receive open label IDP-118 Lotion. The study drug will be applied topically, once daily, for 8 weeks and then, as needed and assessed at 4-week visit intervals over the course of the 1-year study duration.

9.2 Randomization and Blinding

Not applicable. This is an open label study with 1 treatment group on active IDP-118 Lotion.

9.3 Concomitant Medications

Any concomitant therapy stopped for washout as indicated below is to be recorded. As noted in the exclusion criteria, concurrent use of lithium or Plaquenil during the study is prohibited. In addition, there are mandatory washout periods and restrictions during the study for the use of the following:

- Topical antipsoriatic drug product within 14 days prior to the Baseline visit
- Phototherapy (including laser), photochemotherapy, or non-biologic systemic psoriasis therapy (such as newer oral psoriasis medications (eg Otezla), systemic corticosteroids, methotrexate, retinoids, or cyclosporine) within 4 weeks prior to the Baseline visit
- Immunomodulatory therapy (biologics) known to affect psoriasis within 3 months of the Baseline visit
- Prolonged exposure to natural or artificial sources of ultraviolet radiation within 4 weeks prior to the Baseline visit

Any subjects using concomitant therapies that could interfere with the interpretation of study results during the course of the study (including but not limited to those listed above) should not be withdrawn, but the use of the product should be discontinued. Only investigator approved non-medicated cleansers, moisturizers and sunscreens are allowed in the treatment areas; no other skin care products will be permitted on the study.

Information on concomitant therapies will be recorded in the Concomitant Therapy source document. Any therapy used by the subject will be considered concomitant medication or therapy (eg, aspirin, Tylenol, birth control pills, vitamins, moisturizers, sunscreens). Every attempt should be made to keep concomitant therapy dosing constant during the study. Any change to concomitant therapy should be noted on the Concomitant Therapy source document and CRF.

9.4 Treatment Compliance

Subjects will complete a diary to record treatment compliance and to specifically note any missed doses of study drug. All subjects will be instructed as to the proper treatment procedure, will receive their first application of study drug at the investigational center, and will be reminded at Weeks 2 and 4 during the initial 8-week application period to apply the study drug as instructed. As necessary throughout the study, the subjects will undergo subsequent 4-week visit intervals and will be assessed for additional treatment periods. The treatment application procedure will be reviewed during every study visit at which study drug is dispensed and treatment compliance will be recorded during every study visit at which study drug is collected. In all cases, the study drug will be weighed prior to dispensing

and will be re-weighed upon collection. Subjects will be instructed to bring all used and unused study drug containers to each applicable study visit.

9.5 Protocol Deviations and Violations

The investigators must read the protocol thoroughly and must follow the instructions exactly.

A deviation from the protocol is an unintended and/or unanticipated departure from the procedures and/or processes approved by the sponsor and the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) and agreed to by the investigator. Deviations usually have an impact on individual patients or a small group of patients and do not involve inclusion/exclusion or primary endpoint criteria.

A protocol violation occurs when there is non-adherence to the protocol that results in a significant, additional risk to the patient, when the patient or investigator has failed to adhere to significant protocol requirements (inclusion/exclusion criteria) and the patient was enrolled without prior sponsor approval, or when there is non-adherence to the United States Food and Drug Administration (FDA) regulations and/or the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guideline.

The investigator or designee must document and explain in the patients' source documentation any deviation from the approved protocol. The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard to study patients without prior IRB/IEC approval. As soon as possible after such an occurrence, the implemented deviation or change, the reasons for it, and any proposed protocol amendment(s) should be submitted to the IRB/IEC for review and approval, to the sponsor for agreement, and to the regulatory authorities, if required.

10 Study Drug Materials and Management

The study drug will be dispensed by an appropriately qualified member of the study staff assigned by the investigator to this task.

10.1 IDP-118 Lotion

The study drug contains the following ingredients: halobetasol propionate, tazarotene, diethyl sebacate, light mineral oil, sorbitan monooleate, sorbitol, disodium edetate, dihydrate, Pemulen TR 1, Carbopol 981, methylparaben, propylparaben, sodium hydroxide, and purified water.

10.1.1 Packaging and Labeling

IDP-118 Lotion will be packaged in a primary container and provided in study drug kits. Each kit will contain 2 containers, each containing 45 grams of study material. The subjects will be dispensed both containers at baseline and all subsequent study visits, as appropriate. Labels on the containers will contain the following information:

- Protocol number
- Subject number
- Space for entry of the subject initials
- Space for entry of date dispensed
- A statement reading, "For external use only. Avoid contact with eyes and lips"
- A statement reading, "Store at controlled room temperature 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C to 30°C (59°F to 86°F)"
- A statement indicating the sponsor, Dow Pharmaceutical Sciences, Inc. (DPS)
- A statement indicating the quantity of product (45 g)
- A statement reading, "Caution: New Drug Limited by Federal Law to Investigational Use"
- A statement reading, "Keep out of Reach of Children"

10.1.2 Storage, Handling, and Disposal of Study Drug

The study drug should be stored at controlled room temperature 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C to 30°C (59°F to 86°F).

10.1.3 Administration

The investigational center staff member will instruct the subject on the proper application procedure of the study drug to the affected treatment areas identified at the Baseline visit by the investigator. Subjects will be instructed to squeeze a small amount of study drug (about the size of a pea) onto a fingertip and then spread a thin layer of the study drug over the affected treatment area. If necessary, additional pea-sized amounts of study drug may be applied in increments to cover all affected treatment areas as designated by the investigator.

The study drug should be applied as a thin layer of study drug to the entire selected treatment area(s) (3%-12% BSA) as indicated on the body diagram. Subjects will be advised to avoid or minimize exposure to direct sunlight, and artificial ultraviolet light sources while in the study and to wash their hands before and after application of the study drug.

Following the initial 8-week treatment period, subjects will be evaluated for treatment success, defined as a score of 0 or 1 on the IGA. Subjects who achieve a treatment success at Week 8 will receive no further treatment and will be re-evaluated 4 weeks later at Week 12. Subjects who do not achieve a treatment success at Week 8 will receive an additional 4 weeks of once daily therapy and will also be re-evaluated at Week 12. This 4-week evaluation/treatment cycle may continue for up to 1 year, as applicable, based on achievement of treatment success.. Subjects who achieve a treatment success at a visit may not necessarily achieve a treatment success at a subsequent visit, and may undergo periods of non-treatment. The minimum continuous treatment exposure will be (the first) 8 weeks and the maximum continuous treatment exposure may be up to but no more than 24 weeks. Subjects who continue after Week 24 will be monitored to ensure continued treatment exposure is within the maximum allowable window.

Prior to dispensing study drug, each subject will receive both verbal and written instructions regarding proper dosing and study drug application technique. The study coordinator or designee will demonstrate the amount of drug to use daily and the method of application at the Baseline visit as described in Appendix 17.1. Subjects will apply their daily treatments at home, except on the day of the Baseline visit. At this visit, the study drug will be applied by the subject at the investigational center.

Subjects will be instructed on the importance of returning their study drug container at each subsequent study visit as applicable. Subjects who do not return their study drug containers will be instructed to do so as soon as possible. Upon return, the study coordinator or designee will weigh each container (with the cap on) and question the subject on the history of study drug use since the Baseline visit. The study coordinator or designee will assess the amount of remaining study drug relative to the application area in order to judge the subject's compliance with applying the study drug. Any missed applications of study drug will be noted in the appropriate source document.

10.2 Study Drug Accountability

Upon receipt of the study drug, the investigator is responsible for ensuring that the designated study coordinator or designee will conduct a complete inventory of study materials and assume responsibility for their storage and dispensing. In accordance with federal regulations, the investigators must agree to keep all study materials in a secure location with restricted access. The investigator will keep a record of the inventory and dispensing of all study drug. This record will be made available to the sponsor's monitor for the purpose of accounting for all clinical supplies. Any significant discrepancy and/or deficiency must be recorded with an explanation.

All supplies sent to the investigators will be accounted for and, in no case, used in any unauthorized situation. Each container will be weighed (with the cap on) before dispensing to and upon return by the subjects, and weights will be recorded on the required source documents, logs and appropriate CRF. All used and unused supplies will be returned to sponsor/designee for destruction at the conclusion of the study.

11 Study Procedures and Evaluations

11.1 Schedule of Evaluations and Procedures

11.1.1 Screening Visit (Day -35 to Day -1)

The following procedures will be conducted at this visit:

1. Obtain verbal and written informed consent from the subject prior to performing any study-related procedures. Give a signed copy to the subject.
2. Review and explain the nature of the study. Provide a visit schedule with the length of each visit to ensure subject can meet the requirements and has adequate transportation.
3. Assign the subject a 6-digit subject number, which will consist of the 3-digit site number (pre-assigned to your site) and the 3-digit chronological subject number, in screening order, starting with 001 (eg, 301001, 301002; in this example site number is 301).
4. Record the subject's demographic information.
5. Record the subject's medical history.
6. Record all previous medications for psoriasis used during the past 6 months under Prior and Concomitant Medications or Therapies. Include all medications used in the past 30 days and any therapy that required a washout prior to baseline.
7. Record any prescription or over the counter therapies that will be used concomitantly during the study under Prior and Concomitant Medications or Therapies. All medications taken within 30 days of the Screening visit should be recorded including any that may have ended prior to the Screening visit.
8. Record all previous cleansers, moisturizers, etc in the past 30 days under Prior and Concomitant Medications or Therapies. Inform subjects that only Investigator-approved non-medicated cleansers, moisturizers, and sunscreens are allowed.

9. The investigator will assess the extent of psoriasis involvement as a percentage of the subject's total BSA and determine the selected areas to be treated with study drug (3%-12% BSA; the face, scalp, palms, soles, axillae, and intertriginous areas will not be included in this calculation).
10. The investigator/evaluator will perform the IGA. The face, scalp, palms, soles, axillae, and intertriginous areas are to be excluded in this assessment. Every attempt should be made for the same sponsor-approved, qualified evaluator to perform the evaluations for the same subject.
11. For female subjects of childbearing potential collect a urine sample for a urine pregnancy test.
12. Verify that the subject meets the applicable inclusion/exclusion criteria as outlined in Sections 8.1 and 8.2.
13. Discuss the use of acceptable cleansers and moisturizers (only products approved by the investigator for this study will be allowed) with the subject.
14. Collect blood samples for routine laboratory analysis (CBC/Diff, serum chemistry and for female subjects of childbearing potential serum pregnancy).
15. Schedule subject to return for the Baseline/Day 0 visit. If the subject requires a washout, schedule the Baseline/Day 0 visit to occur after the washout is complete.

NOTE: At the Screening visit, serum pregnancy testing is **mandatory** for all females of childbearing potential. In addition, a urine pregnancy test must be completed at Screening and at the Baseline visit prior to randomization. The decision may be made by the investigator to do additional pregnancy tests during the course of the study.

11.1.2 Baseline Visit (Day 0)

The following procedures will be conducted at this visit:

1. Record any changes in medical history since screening.
2. Record changes in any previous psoriasis medications since the previous visit under Prior and Concomitant Medications or Therapies. Check for prohibited concomitant therapies and confirm any therapy that requires a washout prior to Baseline as per Section 9.3.
3. Record changes in any concomitant medications since the previous visit under Prior and Concomitant Medications or Therapies. Check for prior and concomitant therapies as per Section 9.3.

4. Record changes in cleansers, moisturizers, and sunscreens since the previous visit under Prior and Concomitant Medications or Therapies. Remind subjects that only Investigator approved non-medicated cleansers, moisturizers and sunscreens are allowed.
5. Confirm that the subject meets all study inclusion/exclusion criteria as outlined in Sections 8.1 and 8.2
6. Perform a urine pregnancy test for female subjects of childbearing potential. Urine pregnancy test materials will be supplied by the central lab. The pregnancy test must be negative for the subject to be eligible for study drug treatment.
7. The investigator will perform an abbreviated physical examination, including height and weight and vital signs (blood pressure, heart rate, respiration rate, and oral temperature).
8. The investigator will assess the extent of psoriasis involvement as a percentage of the subject's total BSA and determine the selected areas to be treated with study drug (3%-12% BSA; the face, scalp, palms, soles, axillae, and intertriginous areas will not be included in this calculation).
9. The investigator/evaluator will perform the IGA. Every attempt should be made for the same sponsor-approved, qualified evaluator to perform the evaluations for the same subject throughout the course of the trial.
10. Record any new AEs reported spontaneously by the subject.
11. The investigator/evaluator will record local skin reactions (itching, burning/stinging, skin atrophy, striae, telangiectasia, and folliculitis as reported by the subject within the last 24 hours and dryness, as evaluated by the investigator).
12. Assign two containers of study medication to the subject.
13. The study coordinator or designee will weigh each of the 2 study drug containers prior to application and dispense them to the subject. A study drug diary calendar will also be dispensed.
14. The study coordinator or designee will explain the proper technique for application of the study drug. For the first application, the subject will apply the study drug in the clinic under the direction of the study coordinator or designee. The study drug should be applied **after** all clinical assessments. The subjects will be asked to avoid excessive exposure to direct sunlight and artificial ultraviolet light sources on the initial application day and thereafter. The study coordinator or designee will instruct the subjects to apply the study drug once daily at home.

15. Schedule the next clinic visit at Week 2 (Day 14 ± 3 days).

11.1.3 Week 2 (Day 14 ± 3 Days) Visit

The following procedures will be conducted at this visit:

1. Record changes in any concomitant medications since the previous visit under Concomitant Therapies.
2. Record any new AEs reported spontaneously by the subject or changes in any ongoing AEs.
3. The investigator/evaluator will determine the percent BSA affected by psoriasis.
4. The investigator/evaluator will perform the IGA. Every attempt should be made for the same sponsor-approved, qualified evaluator to perform the evaluations for the same subject.
5. The investigator/evaluator will record local skin reactions (itching, burning/stinging, skin atrophy, striae, telangiectasia, and folliculitis as reported by the subject within the last 24 hours and dryness, as evaluated by the investigator).
6. The study coordinator or designee will collect and weigh the previously dispensed study drug containers. The study coordinator or designee will then weigh and dispense 2 new study drug containers to the subject.
7. The study drug diary calendar will be collected and reviewed for compliance. Any missed doses should be reported. A new study drug diary calendar will be dispensed.
8. The study coordinator or designee will remind the subject of the proper technique for application of the study drug. Preferably, the subject can apply the study drug at the investigational center during the day under the direction of the study coordinator or designee to confirm proper technique. Any necessary retraining can be completed. The study drug should be applied **after** all clinical assessments.
9. Schedule the next clinic visit at Week 4 (Day 28 ± 3 days).

11.1.4 Week 4 (Day 28 ± 3 Days) Visit

The following procedures will be conducted at this visit:

1. Record changes in any concomitant medications since the previous visit under Concomitant Therapies.
2. Record any new AEs reported spontaneously by the subject or changes in any ongoing AEs.
3. Perform a urine pregnancy test for female subjects of childbearing potential.

4. The investigator/evaluator will determine the percent BSA affected by psoriasis.
5. The investigator/evaluator will perform the IGA. Every attempt should be made for the same sponsor-approved, qualified evaluator to perform the evaluations for the same subject.
6. The investigator/evaluator will record local skin reactions (itching, burning/stinging, skin atrophy, striae, telangiectasia, and folliculitis as reported by the subject within the last 24 hours and dryness, as evaluated by the investigator).
7. Collect blood samples for routine laboratory analysis (CBC/Diff and serum chemistry).
8. The study coordinator or designee will remind the subject of the proper technique for application of the study drug.
9. The study coordinator or designee will collect and weigh the previously dispensed study drug containers. The study coordinator or designee will then weigh and dispense 4 new study drug containers to the subject.
10. The study drug diary calendar will be collected and reviewed for compliance. Any missed doses should be reported. A new study drug diary calendar will be dispensed.
11. Schedule the next clinic visit at Week 8 (Day 56 ± 5 days).

11.1.5 Week 8 (Day 56 ± 5 Days) Visit

The following procedures will be conducted at this visit:

1. Record changes in any concomitant medications since the previous visit under Concomitant Therapies.
2. Record any new AEs reported spontaneously by the subject or changes in any ongoing AEs.
3. Perform a urine pregnancy test for female subjects of childbearing potential.
4. The investigator will perform an abbreviated physical examination, including weight.
5. The investigator/evaluator will determine the percent BSA affected by psoriasis.
6. The investigator/evaluator will perform the IGA. Every attempt should be made for the same sponsor-approved, qualified evaluator to perform the evaluations for the same subject.
7. The investigator/evaluator will record local skin reactions (itching, burning/stinging, skin atrophy, striae, telangiectasia, and folliculitis as reported by the subject within the last 24 hours and dryness, as evaluated by the investigator).

8. Collect blood samples for routine laboratory analysis (CBC/Diff and serum chemistry).
9. The study coordinator or designee will collect and weigh the previously dispensed study drug containers.
10. The study drug diary calendar will be collected and reviewed for compliance. Any missed doses should be reported.
11. If the IGA score is 2 or greater at this visit, the study coordinator or designee will weigh and dispense 4 new study drug containers to the subject. The study coordinator or designee will remind the subject of the proper technique for application of the study drug and will apply a dose at the investigational center. Any necessary retraining can be completed. A new study drug diary calendar will be dispensed.
12. Schedule the next clinic visit to occur in 4 weeks (± 7 days).

11.1.6 Weeks 12, 20, 28, 36, and 44 (± 7 Days) Visit

The following procedures will be conducted at this visit:

1. Record changes in any concomitant medications since the previous visit under Concomitant Therapies.
2. Record any new AEs reported spontaneously by the subject or changes in any ongoing AEs.
3. Perform a urine pregnancy test for female subjects of childbearing potential.
4. The investigator/evaluator will determine the percent BSA affected by psoriasis.
5. The investigator/evaluator will perform the IGA. Every attempt should be made for the same sponsor-approved, qualified evaluator to perform the evaluations for the same subject.
6. The investigator/evaluator will record local skin reactions (itching, burning/stinging, skin atrophy, striae, telangiectasia, and folliculitis as reported by the subject within the last 24 hours and dryness, as evaluated by the investigator).
7. The study coordinator or designee will collect and weigh the previously dispensed study drug containers, if study drug containers were dispensed.
8. The study drug diary calendar will be collected, reviewed for compliance, and any missed doses will be reported, if applicable.

9. If the IGA score is 2 or greater at this visit, the study coordinator or designee will weigh and dispense 4 new study drug containers to the subject. The study coordinator or designee will remind the subject of the proper technique for application of the study drug and will apply a dose at the investigational center. A new study drug diary calendar will be dispensed.
10. The investigator/evaluator will monitor the subject for length of continued treatment exposure and ensure treatment duration does not exceed 24 weeks.
11. **At Week 12**, Subject must have at least a 1 grade improvement from baseline to continue in the study. **Otherwise subject must be discontinued.**
12. **At Week 28, 36 and 44**, the investigator/evaluator will monitor the subject for length of continued treatment exposure and ensure treatment duration does not exceed 24 weeks. Subjects that do not reach "clear" or "almost clear" after 24 weeks of continuous treatment must be discontinued.

Schedule the next clinic visit to occur in 4 weeks (± 7 days).

11.1.7 Weeks 16, 24, 32, 40, and 48 (± 7 Days) Visit

The following procedures will be conducted at this visit:

1. Record changes in any concomitant medications since the previous visit under Concomitant Therapies.
2. Record any new AEs reported spontaneously by the subject or changes in any ongoing AEs.
3. Perform a urine pregnancy test for female subjects of childbearing potential.
4. The investigator will perform an abbreviated physical examination, including weight.
5. The investigator/evaluator will determine the percent BSA affected by psoriasis.
6. The investigator/evaluator will perform the IGA. Every attempt should be made for the same sponsor-approved, qualified evaluator to perform the evaluations for the same subject.
7. The investigator/evaluator will record local skin reactions (itching, burning/stinging, skin atrophy, striae, telangiectasia, and folliculitis as reported by the subject within the last 24 hours and dryness, as evaluated by the investigator).
8. Collect blood samples for routine laboratory analysis (CBC/Diff and serum chemistry).
9. The study coordinator or designee will collect and weigh the previously dispensed study drug containers, if study drug containers were dispensed.

10. The study drug diary calendar will be collected, reviewed for compliance, and any missed doses will be reported, if applicable.
11. If the IGA score is 2 or greater at this, the study coordinator or designee will weigh and dispense 4 new study drug containers to the subject. The study coordinator or designee will remind the subject of the proper technique for application of the study drug and will apply a dose at the investigational center. A new study drug diary calendar will be dispensed.
12. **At Week 24, 32, 40 and 48,** the investigator/evaluator will monitor the subject for length of continued treatment exposure and ensure treatment duration does not exceed 24 weeks. Subjects that do not reach "clear" or "almost clear" after 24 weeks of continuous treatment **must be discontinued.**

Schedule the next clinic visit to occur in 4 weeks (± 7 days).

11.1.8 Week 52 (± 7 Days) Visit/Early Termination

The following procedures will be conducted at this visit:

1. Record changes in any concomitant medications since the previous visit under Concomitant Therapies.
2. Record any new AEs reported spontaneously by the subject or changes in any ongoing AEs.
3. Perform a urine pregnancy test for female subjects of childbearing potential.
4. The investigator will perform an abbreviated physical examination, including weight.
5. The investigator/evaluator will determine the percent BSA affected by psoriasis.
6. The investigator/evaluator will perform the IGA. Every attempt should be made for the same sponsor-approved, qualified evaluator to perform the evaluations for the same subject.
7. The investigator/evaluator will record local skin reactions (itching, burning/stinging, skin atrophy, striae, telangiectasia, and folliculitis as reported by the subject within the last 24 hours and dryness, as evaluated by the investigator).
8. Collect blood samples for routine laboratory analysis (CBC/Diff and serum chemistry).
9. The study coordinator or designee will collect and weigh the previously dispensed study drug containers, if study drug containers were dispensed.
10. The study drug diary calendar will be collected, reviewed for compliance, and any missed doses will be reported, if applicable.

11. Exit the subject from the study.

11.2 Evaluation of Efficacy

This is study is not intended to assess efficacy, but rather the IGA is included to determine the need for treatment (in accordance with the entry criteria) and subsequent re-treatment after the initial 8-week course and any subsequent 4-week courses, if applicable. The IGA will be reported at every study visit.

The IGA is based on a 5-point scale ranging from 0 (clear) to 4 (severe), and will be assessed by the evaluator at each visit for the overall affected areas with plaque psoriasis. The face, scalp, palms, soles, axillae and intertriginous areas are to be excluded in this assessment. The scores shown in Table 2 will be used to describe the severity of overall psoriasis of the treatable areas.

Table 2: Investigator's Global Assessment Scale

Grade	Score	Description
Clear	0	No evidence of scaling; No evidence of erythema; No evidence of plaque elevation above normal skin level
Almost Clear	1	Some plaques with fine scales; Faint pink/light red erythema on most plaques; Slight or barely perceptible elevation of plaques above normal skin level
Mild	2	Most to all plaques have some fine scales but are not fully covered, some plaques are completely covered with fine scale; Most to all plaques are pink/light red to bright red in color; Some plaques have definite elevation above normal skin level, typically with edges that are indistinct and sloped on some of the plaques
Moderate	3	Some plaques are at least partially covered with a coarse scale, most to all plaques are nearly covered with fine or course scale; Most to all plaques are bright red, some plaque may be dark red in color; Definite elevation of most to all plaques; rounded or sloped edges on most of the plaques
Severe	4	Most to all plaques are covered with coarse, thick scales; Most or all plaques are bright, dark or dusky red; Almost all plaques are raised and well-demarcated; sharp edges on virtually all plaques

At all study visits, the investigator will also assess the percent BSA affected by psoriasis for each subject at each visit. All areas affected by psoriasis (3%-12%, inclusive, of BSA) are to be treated with study drug. Affected areas of the face, scalp, palms, soles, axillae, and intertriginous areas will be excluded in the determination of total area affected by psoriasis, and these regions will not be included in the treatment areas.

11.3 Evaluation of Safety

11.3.1 Adverse Events

An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a medicinal product and which does not necessarily have a causal relationship with the study drug. AEs include any unfavorable and unintended illness, sign, symptom, clinically significant laboratory test abnormality, or disease temporally associated with the use of a medicinal product that has appeared or worsened during the course of the clinical trial, regardless of causal relationship to the study drug(s) under study. The collection of nonserious AEs and serious adverse events (SAEs) should begin following the subject's completion of the consent process to participate in the study.

The severity assigned to an AE should be determined by the maximum severity of the AE. The categories described below should be used to estimate the severity of AEs:

- Mild: Transient or mild discomfort; no limitation in activity; no medical intervention/therapy required
- Moderate: Mild to moderate limitation in activity; some assistance may be needed; no or minimal medical intervention/therapy required
- Severe: Marked limitation in activity; some assistance usually required; medical intervention/therapy required; hospitalization or prolongation of current hospitalization possible; may be incapacitating or life threatening

The investigator should assess the relationship of the AE, if any, to the study drug as either “Related” or “Not Related”. The following should be taken into account when assessing SAE causality:

- Positive temporal relationship to study drug, such as if the study drug was withdrawn and the SAE resolved or the event recurred after re introduction
- If there is a reasonable possibility that the AE is associated with an underlying or concomitant illness
- Possible association with previous or concomitant therapy
- No temporal relationship to the study drug and/or a more likely alternative etiology exists
- If the AE is directly related to study procedures or there is a lack of efficacy

11.3.1.1 Serious Adverse Events

All AEs will be assessed as either serious or nonserious. An SAE or serious adverse reaction is defined as any untoward medical occurrence that at any dose:

- Results in death
- Is immediately life threatening, (the term "life threatening" in the definition of "serious" refers to an event in which the subject is at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe)
- Requires in patient hospitalization or prolongation of existing hospitalization (hospitalization for elective surgery for a baseline condition is not considered an AE)
- Results in persistent or significant disability/incapacity (permanent or substantial disruption of a person's ability to conduct normal life functions)
- Is a congenital anomaly/birth defect
- Is a medically important event that may not be immediately life threatening or result in death or hospitalization, but may jeopardize the subject and may require medical or surgical intervention to prevent one of the above listed outcomes

Note: A spontaneous abortion will be considered an SAE, and must be reported to sponsor/designee within 24 hours of your awareness of the event.

11.3.1.2 Pregnancy

All female subjects of childbearing potential must use an effective method of birth control during the course of the study and for 30 days after the last dose of study drug, in a manner such that risk of contraceptive failure is minimized. Abstinence is allowed as a birth control method.

Before enrolling a female subject of childbearing potential in this clinical trial, the investigator must review the following information about study participation:

- Informed consent requirements
- Contraceptives in current use

Following review of this information and appropriate subject counseling, the investigator or designee and the subject must sign the informed consent before study enrollment.

During the study, all female subjects of childbearing potential should be instructed to contact the investigator immediately if they suspect they might be pregnant (eg, missed or late menstrual period).

If a subject or investigator suspects that the subject may be pregnant prior to study enrollment, the study drug must be withheld until the results of laboratory pregnancy testing are available. If pregnancy is confirmed, the subject must not receive study drug and must not be enrolled in the study. If pregnancy is suspected while the subject is receiving study treatment, the study drug must immediately be withheld until the result of pregnancy testing is known. If pregnancy is confirmed, the study drug will be permanently discontinued and the subject will be followed until the pregnancy comes to term. A Pregnancy Report form will be submitted to the sponsor/designee, initially and at the end of the pregnancy, which includes the outcome of the pregnancy and any complications occurring during the pregnancy or the delivery.

11.3.1.3 Procedures for Reporting Adverse Events and Serious Adverse Events

It is the responsibility of the investigator to document all AEs that occur during the course of the study. Adverse events should be documented as a single medical diagnosis. When this is not possible, the AE should be documented in terms of signs and/or symptoms observed by the investigator or reported by the subject at each study visit.

All AEs occurring after the subject signs the informed consent through the last study visit must be reported, regardless of whether or not the AEs are considered drug-related. All AEs, whether in response to a query, observed by the study site personnel, or reported spontaneously by the subject, will be recorded.

At each visit during the study, the subject will be assessed for the occurrence of new and ongoing AEs. Cutaneous tolerability signs and symptoms that result in the subject's requiring a concomitant therapy or discontinuation from the study will be reported as an AE. The following data will be collected on all AEs and recorded on the appropriate CRF:

- Event name (diagnosis preferred, if unknown, record the signs/symptoms)
- Onset date and end date
- Maximum intensity (severity)
- Seriousness
- Action taken regarding study drug
- Corrective treatment, if given
- Outcome

In addition, the investigator's assessment of causality will be recorded.

Adverse events classified as "serious" require expeditious handling and reporting to sponsor/designee within 24 hours of site notification to comply with regulatory requirements.

All SAEs, whether related or unrelated to study drug, must be immediately reported by telephone or confirmed facsimile transmission and must be submitted on a written SAE report form signed by the investigator within 24 hours of the investigator's awareness of the event.

The fax number for reporting an SAE is:

Investigators should not wait to receive additional information to fully document the event before notifying Sponsor/designee of an SAE. If only limited information is initially available, follow up reports are required. Additional relevant information such as hospital records and autopsy reports should be provided to Sponsor/designee as soon as they are available. Should the investigator become aware of an SAE (regardless of its relationship to investigational product) that occurs within 30 days after stopping the study drug, the SAE must be reported in accordance with procedures specified in this protocol.

The investigator should take all appropriate measures to ensure the safety of the subjects, notably he/she should follow a subject with an SAE until the event has resolved or the condition has stabilized. This may imply that follow up will continue after the subject has left the study, and that additional investigations may be requested by the sponsor.

An AE, whether serious or nonserious, is designated unexpected (unlabeled) if it is not reported in the clinical safety section of the Investigator Brochure or if the event is of greater frequency, specificity or severity.

Expedited SAE reports are those that are both unexpected based on the reference document (Investigator Brochure or Package Insert) and are related (ie, the relationship cannot be ruled out) to the study product. These expedited reports are subject to reporting timelines of 7 and/or 15 calendar days to the regulatory reporting agency(ies). Sponsor/designee will notify regulatory authorities of these AEs and all participating investigative sites in writing for investigator submission to the IRB/IEC. This notification will be in the form of a Safety Update to the Investigator Brochure (ie, "15 day letter").

Upon receiving such notices, the investigator must review and retain the notice with the Investigator Brochure and immediately submit a copy of this information to the responsible IRB/IEC according to local regulations. The investigator and IRB/IEC will determine if the informed consent requires revision. The investigator should also comply with the IRB/IEC procedures for reporting any other safety information.

11.3.2 Laboratory Tests

Clinical laboratory analyses (hematology and chemistry) will be conducted on blood samples collected from subjects at Screening and Weeks 4, 8, 16, 24, 32, 40, 48, and 52. All results will be reported, including results that are abnormal. Clinically significant results, in the opinion of the investigator, should be reported as AEs. If an AE should require laboratory testing, the results of the test must be obtained by the investigative site and filed in the subject's documentation.

11.3.3 Medical History and Abbreviated Physical Examination

A medical history will be taken at Screening, and confirmed and revised if needed, at Baseline. Medical histories having resolved 2 or more years before Baseline need not be collected unless considered relevant by the investigator.

An abbreviated physical examination including measurements of weight and vital signs (blood pressure, heart rate, respiration rate, and oral temperature) will be performed at Baseline, and Weeks 8, 16, 24, 32, 40, 48, and 52. Height will be measured at Baseline only. Any abnormal physical exam findings will be recorded.

11.3.4 Local Skin Reactions

Tolerability will be evaluated at baseline and all postbaseline study visits through assessments of selected local signs and symptoms (itching, dryness, burning/stinging). Additionally, at each study visit, the investigator will examine the treatment areas for the presence or absence of significant known drug-related AEs (skin atrophy, striae, telangiectasia, and folliculitis). Any local skin reaction that requires the use of a concomitant therapy or is a cause for study drug interruption or discontinuation should be reported as an AE. The scales to be used for assessing local skin reactions are presented in Table 3.

Table 3: Scales for Reporting Local Skin Reactions

Score	Grade	Description
Itching: as reported by the subject within the last 24 hours		
0	None	No itching
1	Mild	Slight itching, not really bothersome
2	Moderate	Definite itching that is somewhat bothersome
3	Severe	Intense itching that may interrupt daily activities and/or sleep
Dryness: as assessed by the investigator		
0	None	No dryness
1	Mild	Slight, but definite roughness
2	Moderate	Definite roughness
3	Severe	Marked roughness
Burning/Stinging: as reported by the subject within the last 24 hours		
0	None	No burning
1	Mild	Slight burning sensation; not really bothersome
2	Moderate	Definite warm, burning that is somewhat bothersome
3	Severe	Hot burning sensation that causes definite discomfort and may interrupt daily activities and/or sleep
All of the below will be assessed by the investigator as present or absent.		
Skin Atrophy:		
No		Skin atrophy not present
Yes		Skin atrophy present
Striae:		
No		Striae not present
Yes		Striae present
Telangiectasias:		
No		Telangiectasias not present
Yes		Telangiectasias present
Folliculitis:		
No		Folliculitis not present
Yes		Folliculitis present

12 Statistics

Descriptive statistics will be used to present the data. Summaries of continuous variables will include the sample size, mean, median, standard deviation, minimum, and maximum. Summaries of categorical variables will include the sample size, frequency count, and percentage.

12.1 Analysis of Efficacy

This is study is not intended to assess efficacy, but rather the IGA is included to determine the need for treatment (in accordance with the entry criteria) and subsequent re-treatment after the initial 8-week course and any subsequent 4-week courses, if applicable. Certain efficacy data and endpoints will, however, be summarized.

Descriptive statistics will be used to summarize the assessment of efficacy. The number and percentage of subjects who achieve treatment success at the Week 8 study visit will be tabulated.

Additionally, the number of weeks required for subjects to achieve their first score of clear or almost clear will be presented in a frequency table.

The number of weeks between times when the subject is not medicating will also be presented in a frequency table. This analysis assumes that a subject is not medicating because they achieved a satisfactory evaluation of their psoriasis. The number of weeks will first be averaged by subject and that score will be entered into the frequency tabulation. Appropriate tabulation brackets of time will be chosen, as appropriate.

12.2 Analysis of Safety

12.2.1 Adverse Events

The AE analysis will be tabulated in a manner which provides information about the incidence of AE's for the entire treatment period as well as information by quarter to understand the evolution of AE's over time. Thus, in addition to the AE analysis over the entire 12-month treatment time, results will be presented for the first, second, and third 12-week period, which approximates a quarterly analysis. The analysis for the remaining period will be approximately 4 weeks longer than the first three quarters.

All AEs occurring during the study will be recorded and classified using terminology from the Medical Dictionary for Regulatory Activities (MedDRA). All reported treatment-emergent adverse events (TEAEs), defined as any AE with an onset on or after the date of first study drug application, will be summarized by the number of subjects reporting TEAEs, system organ class, preferred term, severity, and relationship to study drug. When summarizing TEAEs by severity or relationship to study drug, each subject will be counted only once within a system organ class or a preferred term using the event with the greatest severity or causality, respectively, within each category. All reported SAEs will be summarized by the number of subjects reporting the event, system organ class, preferred term, severity, and relationship to study drug.

All information pertaining to AEs noted during the study will be listed by subject and will include a verbatim description of the event as reported by the investigator, as well as the preferred term, system organ class, start date, stop date (if stopped), seriousness, severity, action taken regarding the study drug, corrective treatment, outcome, and relationship to the study drug. In addition, a listing of subjects who prematurely discontinue from the study due to AEs will be provided as well as a listing of subjects who reported an SAE.

12.2.2 Laboratory Tests

Changes from baseline in safety laboratory values will be summarized with descriptive statistics at all applicable study visits. Shift tables will be presented for changes in safety laboratory values. Normal ranges established by the central laboratory will be used to determine the shifts. A listing of all out-of-range laboratory test results at any assessment time point will also be provided. Determination of clinical significance for all out-of-range laboratory values will be made by each investigator and included in the listing. In addition, a listing of all clinically significant laboratory test results will be provided.

12.2.3 Local Skin Reactions

The frequency of local skin reactions including itching, dryness, burning/stinging, skin atrophy, striae, telangiectasia, and folliculitis will be summarized by visit. Additionally, the percent of subjects who experience a local skin reaction (itching, dryness, and burning/stinging) graded at a score of 3 at any point in the study following the first application of study drug will be tabulated.

12.2.4 Concomitant Medications

All previous therapies and concomitant medications will be classified based on terminology from the World Health Organization (WHO) Drug Dictionary. Previous therapies and concomitant medications data will be presented in data listings.

12.3 Subject Disposition

A tabulation of subject disposition will be provided. The tabulation will include the numbers of subjects who enter the study, complete the study, complete 6 months and 12 months of the study, and discontinue the study. The reasons for discontinuation will be included.

12.4 Demographics and Baseline Characteristics

Subject demographic and baseline characteristics will be summarized using descriptive statistics for the safety analysis set as defined in Section 12.8.1.

12.5 Protocol Deviations

All protocol deviations will be reported to the sponsor and recorded throughout the study. A tabulation of protocol deviations will be included in the final study report.

12.6 Compliance

No formal evaluations of compliance are planned.

12.7 Interim Analyses

No interim analyses are planned.

12.8 Additional Statistical Considerations

12.8.1 Analysis Populations

Approximately 500 subjects who meet the study entry criteria will be entered into the study with the intent that at least 300 subjects will be followed for 6 months and at least 100 subjects will be followed for up to 1 year. All enrolled subjects will receive IDP-118 Lotion to be applied once daily for 8 weeks and then as needed once daily as assessed in 4 week periods for up to 1 year.

All subjects who receive at least 1 confirmed dose of study drug, and have at least 1 postbaseline safety assessment will be included in the safety analysis set. All analyses will be made using the safety analysis set.

12.8.2 Sample Size Determination

Approximately 500 subjects who meet the study entry criteria will be entered into the study with the intent that at least 300 subjects will be followed for 6 months and at least 100 subjects will be followed for up to 1 year. All enrolled subjects will receive IDP-118 Lotion to be applied once daily for 8 weeks and then as needed once daily as assessed in 4-week periods for up to 1 year.

The sample size selected for this study is expected to provide sufficient data for a long-term safety evaluation of IDP-118 Lotion when used by adult subjects with plaque psoriasis.

12.8.3 Handling of Missing Data

No imputations will be made for missing data.

12.8.4 Multicenter Issues

The study will be conducted at multiple investigational centers in North America with the intention of pooling the results for analysis.

12.8.5 Multiplicity Issues

Not applicable.

12.8.6 Windowing Rules

The timing of all study visits is relative to the Baseline (Day 0) visit. The Week 2 and 4 visits should occur within 3 days of the scheduled times, the Week 8 visit should occur within 5 days of the scheduled time, and all subsequent study visits should occur within 7 days of the scheduled times.

13 Quality Control and Quality Assurance

13.1 Study Monitoring

An Investigator Meeting or an initiation visit will be conducted with the principal investigator and study coordinators by the sponsor and/or its designee. During this meeting, an extensive review and discussion of the protocol, the role of the study coordinator or designee, all study procedures, source documents, and CRFs will be conducted. Evaluation scales will be reviewed extensively and documentation of training will be recorded for training of sponsor-approved evaluators.

The study monitors/clinical research associates will be trained prior to study initiation. Following this training, an overview of the study disease and study material background will be understood. Specific monitoring guidelines and procedures to be followed during monitoring visits will also be utilized. During the course of the study all data will be 100% source document verified by the monitors. All subject source records must be made available to the monitors.

The conduct of the study will be closely monitored by the sponsor or designated contract research organization (CRO) following GCP guidelines. The reports of these verifications will also be archived with the study report. In addition, inspections or on site audits may be carried out by local authorities or by the sponsor's Quality Assurance Department. The investigators will allow the sponsor's representatives and any regulatory agency to examine all study records, corresponding subject medical records, clinical dispensing records and storage area, and any other documents considered source documentation. The investigators agree to assist the representative, if required.

13.2 Audits and Inspections

The study will be conducted under the sponsorship of Valeant and in compliance with all appropriate local and federal regulations, as well as ICH guidelines. Interim and end of study audits of raw data, the study files, and the final report may be conducted by Valeant’s Quality Assurance Department or designee.

The sponsor is responsible for implementing and maintaining quality assurance and quality control systems to ensure that studies are conducted and data are generated, documented, and reported in compliance with the protocol, GCP, and applicable regulatory requirements. In addition, the sponsor will be responsible for securing agreement from all involved parties to ensure direct access to all study-related investigational centers, source data/documents, CRFs, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities.

13.3 Data Quality Assurance

All assessments performed will be accurately documented in the subject's source documents and CRFs. The investigator or designee will enter the information required by the protocol into the source documents and CRFs provided by the sponsor or designee. Subjects will be identified in the CRFs by their assigned subject number and initials only.

The investigators must read the protocol thoroughly and must follow the instructions exactly. Any deviations should be agreed to by prior discussion between the sponsor and the investigator, with appropriate written protocol amendments made prior to effecting the changes agreed upon. Any amendment containing major modifications (particularly if it may involve an increased risk to the subjects) will be approved by the IRB before it may be implemented. No change in the conduct of the study can be instituted without written approval from the sponsor.

14 Ethics and Administrative Issues

14.1 Ethical Conduct of the Study

This study will be conducted in accordance with the ethical principles originating from the Declaration of Helsinki, ICH guidelines, GCP, and in compliance with local regulatory requirements. The investigator agrees, when signing the protocol, to adhere to the instructions and procedures described in it and thereby to adhere to the principles of GCP.

14.2 Ethics Review

This protocol, proposed informed consent form and other information to subjects, and all appropriate amendments will be properly reviewed and approved by an IRB or IEC. A signed and dated notification of the IRB/IEC approval will be provided to the sponsor and investigator prior to study initiation. The name and occupation of the chairman and members of the IRB/IEC will be supplied to the sponsor. The investigator will provide required progress reports and report all SAEs to the IRB/IEC as required by the IRB/IEC.

14.3 Written Informed Consent

Written informed consent, in accordance with local clinical investigation regulations, must be obtained prior to participation in the study. The investigator or designee will discuss the purpose of the study with each subject, and provide a description of the study drug (including any potential and possible side effects) and the study procedures. Information must be given both in oral and written form. Subject information will be provided in a language understandable to the subject and may not include any language that appears to waive any of the subject‘s legal rights or appears to release the investigator, the sponsor or the institution from liability or negligence.

The investigator will provide the prospective subject sufficient time to consider whether or not to participate, minimizing the possibility of coercion or undue influence and will discuss any questions the subject may have. The investigator will explain to the subject that participation in the study is voluntary and that withdrawal from the study is possible at any time without detriment to care. The consent must include acknowledgment that medical records and medical data derived from the study may be forwarded to the sponsor or to responsible local or federal authorities.

No subject can enter the study or have any study-related procedures performed before his/her written informed consent has been obtained. The original signed and dated informed consent form will be retained with the study records, and a copy of the signed form will be given to the subject.

An informed consent template will be supplied by the sponsor. Any changes to the informed consent form must be agreed to by the sponsor or designee prior to submission to the IRB/IEC, and a copy of the approved version must be provided to the sponsor or designee after IRB/IEC approval.

14.4 Subject Data Protection

Subject data will be protected by ensuring that no captured data contain subject names, addresses, telephone numbers, email addresses, or other direct personally identifying information. It is acknowledged that subject initials, demographics (including birthdates), medical histories, and prior concomitant medication uses, along with the name and address of the enrolling investigator may allow for personal identification of study participants. Other than where necessary to meet regulatory requirements, all data collected in this study will be presented in tabulated (ie, aggregate) form and listings containing information that could be used to identify an individual subject will not be included in any public disclosures of the study data or the study results.

14.5 Data Monitoring Committee

Not applicable.

14.6 Financial Disclosure

Financial disclosures will be obtained from all investigators in order to document any potential conflicts of interest.

14.7 Investigator Obligations

The investigator agrees, when signing the protocol, to adhere to the instructions and procedures described within and thereby to adhere to the principles of GCP.

14.8 Changes to the Protocol

The investigators must read the protocol thoroughly and must follow the instructions exactly. Whenever possible, any planned deviations should be agreed to by prior discussion between the sponsor and the investigator, with appropriate documentation of sponsor approval prior to effecting the changes agreed upon. Any amendment to the protocol containing major modifications (particularly if it may involve an increased risk to the subjects) will be approved by the IRB/IEC before it may be implemented. No change in the conduct of the study can be instituted without written approval from the sponsor.

14.9 Confidentiality/Publication of the Study

All the data furnished to the investigator and his/her staff and all data obtained through this protocol will be regarded as confidential and proprietary in nature and will not be disclosed to any third party, except for the FDA or other regulatory body, without written consent from the sponsor.

14.10 Study Termination

The sponsor may choose to terminate the study after Week 24 depending on the number of subjects enrolled, the number of subjects completed to that point, and the average number of re-treatments required by subjects within the 24-week period.

15 Data Handling and Record Keeping

15.1 Inspection of Records

Investigators must maintain detailed records on all study subjects who are enrolled in the study or undergo screening. Data will be recorded in the subject's source documents and in applicable study logs provided by the sponsor. Source documents include subject medical records, hospital charts, clinic charts, investigator subject study files, as well as the results of diagnostic tests (eg, laboratory tests).

All required data should be completely recorded in the study documentation for prompt data review. Upon study completion or at any other time specified by the sponsor or designee, the appropriate study documents must be submitted.

The investigator must keep accurate separate records (source documentation) of all subject visits, being sure to include all pertinent study-related information. At a minimum, this includes the following information:

- A statement indicating that the subject has been enrolled in the study and the subject number
- Date that informed consent was obtained
- Evidence that the subject meets study eligibility requirements (eg, medical history, screening evaluations)
- Dates of all study-related visits and results of any evaluations/procedures performed, including who performed each assessment at each visit
- Use of any concurrent medications during the study
- Documentation of study drug accountability
- Any and all side effects and AEs must be thoroughly documented to conclusion
- Results of any diagnostic tests conducted during the study
- The date the subject exited the study and a statement indicating that the subject completed the study or was discontinued early, including the reason for discontinuation

Telephone conversations and electronic mail with the subject, the sponsor or the sponsor's designee concerning the study must be recorded or kept on file. All source documents must be made available to the sponsor and the sponsor's designated monitor upon request.

15.2 Retention of Records

The investigator should properly store and maintain all study records in accordance with sponsor directives. All records relating to the conduct of this study are to be retained by the investigator until notified by the sponsor in writing that the records may be destroyed.

The investigator will allow representatives of the sponsor's monitoring team, the governing IRB/IEC, the FDA, and other applicable regulatory agencies to inspect all study records, CRFs, and corresponding portions of the subject's clinic and/or hospital medical records at regular intervals throughout the study. These inspections are for the purpose of verifying adherence to the protocol, completeness and accuracy of the data being entered onto the CRF, and compliance with FDA or other regulatory agency regulations.

16 References

Not applicable.

17 Appendices

17.1 Subject Instruction Sheet

A thin layer of study drug should be applied once daily at about the same time each day over the affected treatment areas indicated by the investigator. As a reminder, the face, scalp, axillae (armpit) and intertriginous (skinfold) areas will be excluded.

Specifically, subjects will squeeze a small amount of study drug (about the size of a pea) onto a fingertip and then spread a thin layer of the study drug over the affected treatment area. If necessary, additional pea-sized amounts of study drug may be applied in increments (one pea size gently rubbed over a treatment area at a time) to cover all affected treatment areas.

The amount of study drug used will be monitored by weighing each newly dispensed study drug container and weighing each returned study drug container at all applicable study visits.

Be sure to wash your hands after you apply the product (unless the study doctor has instructed you to treat your palms).

Reminders:

- On study visit days please wait until after your study assessments are completed before application of the study drug or any approved moisturizers. Any retraining can be provided by site staff, if needed.
- Avoid contact with the eyes, inside the nose, mouth and all mucous membranes.
- THE TEST MATERIAL SHOULD BE USED ONLY BY THE PERSON FOR WHOM IT WAS PRESCRIBED and it should be kept out of the reach of children or others of limited capacity to read or understand.

Store this at room temperature 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C to 30°C (59°F to 86°F).
Containers of test material must be returned to the study facility, even if they are empty.

Be sure to complete the study drug diary calendar each day to document applications and also note any missed doses; and bring the completed diary to each study visit.

Continue to use the same study doctor approved non-medicated cleansers, moisturizers and sunscreens throughout the study. Avoid or minimize unnecessary sun exposure. Also for additional ultraviolet protection, use protective clothing, such as long sleeved shirts and broad brimmed hats, as needed.

It is important that you inform the study site about any medications (ie, prescriptions, over-the-counter medications, street drugs, or herbal medications) that you have taken during the study.

If you have any questions or have a potential research-related side effect or injury you may contact _____ at _____.

17.2 Cleanser Moisturizer and Sunscreen Use Guidelines

Investigators may use their discretion on what cleansers and moisturizer products each subject may use in the treatment areas during the study. Subjects may only use investigatorapproved non-medicated products on the treatment areas. Information regarding products used should be captured in the source document and recorded on the Prior and Concomitant Medications or Therapies CRF.

Approved Cleansers:

- CeraVe cleanser
- Cetaphil daily cleaner and gentle cleansing bar
- Purpose gentle cleansing wash
- Investigator-approved nonmedicated cleanser

Approved Moisturizers:

- CeraVe Cream or Lotion
- Moisturel cream or lotion
- Nutraderm
- Cetaphil lotion or cream
- DML
- Eucerin lotion or cream
- Purpose

Subjects should avoid excessive sun exposure, but when this cannot be avoided, an investigator approved non-medicated sunscreen may be used. Also for further ultraviolet protection, use protective clothing, such as long-sleeved shirts and broad brimmed hats, as needed.

Approved Sunscreens:

- Banana Boat Sport Sunblock Lotion (SPF 15, 30+ or 50)
- Neutrogena UVA/UVB (SPF 30 or 45)
- Neutrogena Sensitive Skin Sunblock Lotion (SPF 17)
- Neutrogena Healthy Defense Oil-Free Sunblock Lotion (SPF 30 or 45)
- Coppertone Water Babies UVA/UVB Sunblock Lotion (SPF45)

17.3 Summary of Protocol Amendment 1 Changes

Section	*Original Protocol Previously Read:*	*Protocol Amendment 1 Currently Reads:*
2.0 Study Synopsis Methodology 7.1 Overall Study Design and Plan: Description 17.1 Subject Instruction Sheet	The subjects will be instructed to avoid exposure to direct sunlight to prevent sunburn.	The subjects will be instructed to avoid exposure to direct sunlight, artificial ultraviolet light sources and to use protective clothing to prevent sunburn.
2.0 Study Synopsis Methodology 11.1 Visit Descriptions 7.1 Overall Study Design and Plan: Description 17.1 Subject Instruction Sheet	During, the study, subjects will be allowed to use investigator approved non medicated cleansers and moisturizers; no sunscreens or other skin care products will be permitted on the treatment areas.	During the study, subjects will be allowed to use investigator approved non-medicated cleansers, moisturizers and sunscreens; no other skin care products will be permitted on the treatment areas.
2.0 Study Synopsis Methodology Key Exclusion Criteria 8.2 Subject Exclusion Criteria	7. Has used any phototherapy (including laser), photochemotherapy, or systemic psoriasis therapy (such as systemic corticosteroids, methotrexate, retinoids or cyclosporine) within 4 weeks prior to the Baseline visit.	7. Has used any phototherapy (including laser), photochemotherapy, or non-biologic systemic psoriasis therapy (such as systemic corticosteroids, methotrexate, retinoids or cyclosporine) within 4 weeks prior to the Baseline visit.
2.0 Study Synopsis Methodology Inferential Statistics Secondary Efficacy 12.1.2 Secondary Efficacy	N/A	• Percentage of subjects who show at least a 2 grade improvement and reach Clear to Almost Clear at Week 6 for IDP-118 Lotion versus IDP-118 Vehicle Lotion
9.4 Prior and Prohibited Concomitant Medication of Therapy	• Within 4 weeks prior to the Baseline visit, subjects must not have used any phototherapy (including laser), photochemotherapy, or systemic psoriasis therapy (such as systemic corticosteroids, methotrexate, retinoids or cyclosporine)	• Within 4 weeks prior to the Baseline visit, subjects must not have used any phototherapy (including laser), photochemotherapy, or non-biologic systemic psoriasis therapy (such as newer oral psoriasis medications (eg Otezla), systemic corticosteroids, methotrexate, retinoids or cyclosporine)
9.4 Prior and Prohibited Concomitant Medication of Therapy	Subjects are allowed only the use of investigator approved non-medicated cleansers and moisturizers in the treatment areas.	Subjects are allowed only the use of investigator approved non-medicated cleansers, moisturizers and sunscreens in the treatment areas.
17.1 Subject Instruction Sheet 17.2 Cleanser, moisturizer and sunscreen Use Guidelines	N/A	Also for further ultraviolet protection, use protective clothing such as long sleeves and broad brimmed hats, as needed.

Section	***Original Protocol Previously Read:***	***Protocol Amendment 1 Currently Reads:***
2.0 Study Synopsis Methodology	face, scalp, palms, soles, groin, axillae, and intertriginous areas.	face, scalp, palms, soles, axillae, and intertriginous areas.
2.0 Synopsis – Key Exclusion Criteria 8.2 Subject Exclusion Criteria	9. Has had prolonged exposure to natural or artificial sources of ultraviolet radiation within 4 weeks prior to the Screening visit or is intending to have exposure during the study thought likely by the investigator to modify the subject's psoriasis.	9. Has had prolonged exposure to natural or artificial sources of ultraviolet radiation within 4 weeks prior to the Baseline visit or is intending to have exposure during the study thought likely by the investigator to modify the subject's psoriasis.
2.0 Synopsis – Key Exclusion Criteria 8.2 Subject Exclusion Criteria	15. Has a history of drug or alcohol abuse.	15. Has a history of drug or alcohol abuse as determined by the investigator.
10. Study Drug Materials and Management Table of Contents	10. Study Dug Materials and Management	10. Study Drug Materials and Management
2.0 Synopsis – Methodology 7.1 Overall Study Design and Plan: Description 8.3 Subject withdrawal Criteria	N/A	At Week 12, the subject should have at least a 1 grade improvement from baseline to continue in the study. If a subject remains on treatment after Week 12 by meeting the criteria of at least a 1 grade improvement, then at Week 24, if continuous treatment was received, they must have an IGA score equating to "Clear" or Almost Clear" to continue on study or they will be considered a failed treatment.
2.0 Synopsis – Methodology; Treatment Duration 7.1 Overall Study Design and Plan: Description 10.1.3 Administration	The minimum possible treatment exposure will be 8 weeks and the maximum treatment exposure will be 52 weeks.	The minimum continuous treatment exposure will be (the first) 8 weeks and the maximum continuous treatment exposure may be up to but no more than 24 weeks. Subjects who continue after Week 24 will be monitored to ensure treatment exposure does not exceed 24 consecutive weeks.
2.0 Synopsis – Methodology; Inclusion Criteria 8.1 Inclusion Criteria 11.3.1.2 Pregnancy	8. If female, is either not of childbearing potential, defined as postmenopausal for at least 12 months or surgically sterile (bilateral tubal ligation, bilateral oophorectomy, or hysterectomy), or is of childbearing potential and practicing one of the following methods of birth control throughout the study	8. If female, is either not of childbearing potential, defined as postmenopausal for at least 12 months or surgically sterile (bilateral tubal ligation, bilateral oophorectomy, or hysterectomy), or is of childbearing potential and practicing one of the following methods of birth control throughout the study and for 30 days after the last dose of the study drug.

Section	*Original Protocol Previously Read:*	*Protocol Amendment 1 Currently Reads:*
11.1.6 Weeks 12, 20, 28, 36, and 44 (± 7 Days) Visit	N/A	10. The investigator/evaluator will monitor the subject for length of continued treatment exposure and ensure treatment duration does not exceed 24 weeks. 11. **At Week 12**, Subject must have at least a 1 grade improvement from baseline to continue in the study. **Otherwise subject must be discontinued.** **12. At Week 28, 36 and 44**, the investigator/evaluator will monitor the subject for length of continued treatment exposure and ensure treatment duration does not exceed 24 weeks. Subjects that do not reach "clear" or "almost clear" after 24 weeks of continuous treatment must be discontinued.
11.1.7 Weeks 16, 24, 32, 40, and 48 (± 7 Days) Visit	N/A	12. **At Week 24, 32, 40 and 48,** the investigator/evaluator will monitor the subject for length of continued treatment exposure and ensure treatment duration does not exceed 24 weeks. Subjects that do not reach "clear" or "almost clear" after 24 weeks of continuous treatment **must be discontinued.**