[redacted]

STATISTICAL ANALYSIS PLAN

A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study Comparing Tazarotene Cream 0.05% to TAZORAC® (tazarotene) Cream 0.05% and Both Active Treatments to a Vehicle Control in the Treatment of Stable Plaque Psoriasis

Protocol Number: 0453-01-01 / NCT02886702

[redacted]

Sponsor:
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Melville, New York, 11747

Contract Research Organization:

[redacted]

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STATISTICAL ANALYSIS PLAN

Tazarotene Cream 0.05% **Protocol / [redacted] 0453-01-01/[redacted]**

SAP FINAL VERSION APPROVALS

A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study Comparing Tazarotene Cream 0.05% to TAZORAC® (tazarotene) Cream 0.05% and Both Active Treatments to a Vehicle Control in the Treatment of Stable Plaque Psoriasis

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[redacted]

STATISTICAL ANALYSIS PLAN

Tazarotene Cream 0.05% **Protocol / [redacted] 0453-01-01/[redacted]**

Revision History

[redacted]

List of Abbreviations and Definition of Terms

ADaM	Analysis Data Model
AE	Adverse Event
ANOVA	Analysis of Variance
BSA	Body Surface Area
C	Celsius
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CRF	Case Report Form
CRO	Contract Research Organization
eCRF	Electronic Case Report Form
EOS	End of Study
ET	Early Termination
F	Fahrenheit
FDA	Food and Drug Administration
Hg	Mercury
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IGA	Investigator Global Assessment
IP	Investigational Product
LOCF	Last Observation Carried Forward
MedDRA	Medical Dictionary for Regulatory Activities
mITT	modified Intent-to-Treat Population
OGD	Office of Generic Drugs
PASI	Psoriasis Area Severity Index
PD	Protocol Deviation
PP	Per-Protocol
RLD	Reference Listed Drug
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SDTM	Study Data Tabulation Model

[redacted]

STATISTICAL ANALYSIS PLAN

Tazarotene Cream 0.05% **Protocol / [redacted] 0453-01-01/[redacted]**

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1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the final Clinical Study Protocol 0453-01-01 Rev. 2 dated 12/22/2016. The SAP provides details on the planned statistical methodology for the analysis of the study data. The SAP also outlines the statistical programming specifications for the tables, listings and figures.

This SAP describes the study endpoints, derived variables, anticipated data transformations and manipulations, and other details of the analyses not provided in the study protocol. This SAP therefore outlines in detail all other aspects pertaining to the planned analyses and presentations for this study.

The following documents were reviewed in preparation of this SAP:

- Final Clinical Study Protocol 0453-01-01 Rev. 2 dated 12/22/2016
- Final eCRF Version 1.0 for [redacted]

The reader of this SAP is encouraged to also read the clinical protocol for details on the conduct of this study, and the operational aspects of clinical assessments and timing for completing a subject in this study.

2. OBJECTIVES

The objectives of this study are to:

1. Evaluate the therapeutic equivalence of the Test product, Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.) to the Reference product, TAZORAC® (tazarotene) Cream 0.05% (Allergan, Inc.) in the treatment of stable plaque psoriasis.

2. Demonstrate the superiority of the efficacy of the Test and Reference (active) products over that of the Placebo in the treatment of stable plaque psoriasis.

3. Compare the safety of the Test, Reference and Placebo products in the treatment of stable plaque psoriasis.

3. OVERALL STUDY DESIGN

This multi-center, double-blind, randomized, vehicle-controlled, parallel-group, bioequivalence clinical study has been designed to evaluate the efficacy and safety of a

generic tazarotene cream 0.05% (Fougera Pharmaceuticals Inc.) compared to the FDA Reference Listed Drug (RLD) TAZORAC® (tazarotene) Cream 0.05% (Allergan) in subjects with a clinical diagnosis of stable plaque psoriasis of at least moderate severity. Additionally, both the Test product and Reference (i.e., the RLD) products will be tested for superiority to a Placebo. Subjects with confirmed stable plaque psoriasis will apply the investigational product (IP) once daily, in the evening, to psoriatic lesions for 84 ± 4 days (12 weeks).

Before any study-specific procedures are performed, all subjects will read and sign the IRB-approved ICF.

Each site will develop an individualized recruitment plan to collectively enroll approximately 855 eligible subjects, 18 years of age and older, with a clinical diagnosis of stable plaque psoriasis and meeting the inclusion/exclusion criteria. Subjects will be randomized to one of the three IPs as follows:

- Test: Tazarotene Cream, 0.05% (Fougera Pharmaceuticals Inc.)
- Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
- Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

Subjects will attend the following scheduled clinic visits:

- Visit 1 - Screening/Baseline: Day -14 to Day 1
- Visit 2 - Interim Visit: Day 28 ± 4 days
- Visit 3 - Interim Visit: Day 56 ± 4 days
- Visit 4 - End of Study: Day 85 ± 4 days

Subjects may attend unscheduled clinic visits:

- Visit 9999 – Unscheduled visit

At Visit 1, eligible subjects will be randomized to the Test, Reference or Placebo product in a 1:1:1 ratio using the [redacted] system, which is an interactive response technology (IRT) system provided by the IRT provider. Study subjects will be provided with [redacted] of IP. [redacted] may be dispensed to the subject at the discretion of the Investigator if the subject has a high BSA affected with plaque psoriasis at the time of dispensation that would warrant additional product. At Visit 2 and Visit 3, subjects who continue to be eligible for continuation in the study can be dispensed an additional [redacted] of IP, as needed based on the subject's current BSA affected and the amount of IP remaining from the tube(s) previously dispensed. Further, any empty tubes will be collected at these visits. At Visit 4, all tubes will be collected (used and unused). A subject may return for an Unscheduled Visit at any time, should they require a resupply of IP (i.e., tube lost; all IP used between visits). It is estimated that approximately [redacted], but up to [redacted] may be needed to dose a subject with

high BSA involvement (~20% BSA) for the treatment period (depending upon their treatment response over the 12 weeks). Subjects with less BSA involvement will need significantly less IP (approximately 2 to 4 tubes).

The day that the subject administers their first dose of IP will be considered Day 1. [redacted] For all other subjects, the first dose (Day 1) of IP will be applied on the evening of Visit 1.

The subject will be instructed to apply enough cream (2 mg/cm^2) to cover only the psoriatic lesions with a thin film (2 mg/cm^2) once daily, in the evening, until the evening before Visit 4 (Day 85 ± 4 days).There will be no application of the product on the day of the End of Study visit.

Efficacy evaluations will be based on dermatological assessments in the clinic. The primary statistical analysis of interest is the (1) proportion of subjects with treatment success (defined as none, minimal or mild disease, a score of 0, 1 or 2, within the treatment area) on the Investigator's Global Assessment (IGA) at the Week 12 visit. The secondary analyses are (1) proportion of subjects with disease severity at the Week 12 visit consistent with none or minimal, a score of 0 or 1, within the treatment area on the IGA, and (2) proportion of subjects with target site plaque elevation, scaling, and erythema scores of less than or equal to one on the PASI at the Week 12 visit. PASI is the sum of the three individual component scores.

Study Schematic

PROCEDURE	VISIT 1 (Day -14 to 1) Screening/ Baseline	VISIT 2 (Day 28 ± 4 Days) Interim Visit	VISIT 3 (Day 56 ± 4 Days) Interim Visit	VISIT 4 (Day 85 ± 4 Days)* End of Study/ Early Termination
Informed Consent	X‡			
Medical History/ Demographics	X‡			
Pregnancy Test†	X‡	X	X	X
Vital Signs	X‡			X
Dermatologic Assessment	X‡			
IGA	X‡	X	X	X
PASI Assessment	X‡	X	X	X
Application Site Reactions	X	X	X	X
Inclusion/Exclusion Criteria Review	X‡			
Concomitant Medication	X‡	X	X	X
Randomization	X			
Dispense IP	X	X**	X**	
Return of IP		X**	X**	X
Dispense Subject Diary/Supplies	X	X	X	
Collect/Review Subject Diary		X	X	X
Adverse Events		X	X	X
Discharge from Study				X

* Dosing regimen is once daily in the evening for 84 days (Day 1 to Day 84) through the evening before Visit 4 (Day 85 ± 4)

** If applicable, based on use of previously dispensed product.

† For females of childbearing potential

‡ Procedures performed as part of the screening assessment, before randomization

4. RANDOMIZATION AND BLINDING

The IP will be randomized, packaged and blinded by an [redacted]. The randomization code will be generated using a validated computer program. [redacted] Each site will receive multiple, full blocks of IP in each delivery. The quantity received may vary.

Randomization will be pre-planned according to a computer-generated randomization scheme. The randomization code will be retained within [redacted] which is maintained by [redacted]. [redacted] will also retain the kit boxes numbers supplied to each site and the kit boxes numbers that have been selected for retention and are therefore unavailable for dispensing to subjects.

Upon confirmation of subject eligibility, the subject's information (i.e., subject's initials, date of birth, etc.) will be entered into [redacted], and the system will assign a [redacted] randomization number to the subject based upon [redacted]. [redacted] will then assign the subject a [redacted] kit box number in a blinded fashion at Visit 1. This kit box number will correspond to a specific treatment group within [redacted]; however the treatment group will be unknown to the Investigator, the CRO, the sponsor and the subject. The site will record the randomization number and the kit box number in the subject's source documentation and drug dispensing log. The [redacted] will then dispense [redacted] from the kit box. The [redacted] will record the tube number of the [redacted] dispensed to the subject in the subject's source documentation and drug dispensing log. At Visits 2, 3 and/or Unscheduled Visit, additional IP may be dispensed to the subject, as needed. The [redacted] will select an additional unused tube from the subject's previously assigned kit box, dispense it to the subject and record the tube number. [redacted] Each subject will maintain the same treatment assignment throughout the study.

5. SAMPLE SIZE

Sample size calculations were performed using [redacted]. For the primary endpoint analysis, the rate of treatment success for the Reference treatment after 12 weeks of treatment is expected to be approximately [redacted] in the PP population. Assuming that the rates of treatment success for Test and Reference treatments are the same, a sample size of [redacted] subjects in each active group in the PP population will provide approximately [redacted] power to demonstrate therapeutic equivalence (i.e., the 90% confidence interval (Yates' continuity-corrected) of the absolute difference between the Test and Reference rates of treatment success is within a defined equivalence range [-20% to + 20%]).

The rates of treatment success for the Placebo and active treatment groups after 12 weeks of treatment are assumed to be approximately [redacted] and at least [redacted] respectively, in the mITT population. Using a 1:1 (active: placebo) randomization scheme, and assuming the conversion rate from mITT to PP population will be about [redacted] subjects in each treatment group (Test, Reference and Placebo) of the mITT population will provide at least [redacted] power to demonstrate superiority of active over Placebo at the 5% significance level ($p < 0.05$, two-sided continuity-corrected Z-Tests and a pooled response rate for the standard error of the difference in proportions).

Under the above assumptions, the overall study power to demonstrate therapeutic equivalence and superiority is estimated to be at least [redacted]. To allow for approximately [redacted] of subjects who may drop out from the study or are otherwise non-evaluable, up to 855 subjects may be randomized to obtain [redacted] subjects in the mITT population (i.e., [redacted] per treatment arm).

6. ANALYSIS POPULATION

Per-Protocol Population

The PP population will include subjects that comply with the protocol as follows:

- All randomized subjects who meet all inclusion and exclusion criteria.
- Make the final study visit (Visit 4) within the protocol window of Day 85 ± 4 days with no PDs that would affect the integrity of the data.
- Comply with study restrictions including concomitant medications.
- Apply the IP appropriately and are within [redacted] compliant with dosing during the 12 weeks (Day 85 ± 4) of treatment.
- Do not miss the scheduled applications for more than [redacted]

[redacted]

Modified Intent-to-Treat Population (mITT) Population

The mITT population will include all subjects in the PP population plus all randomized subjects who meet all inclusion/exclusion criteria, apply at least one dose of assigned product, and return for at least one post-Baseline evaluation.

[redacted]

Safety Population

All subjects who are randomized and received IP will be included in the analysis of safety.

7. STUDY EFFICACY VARIABLES

Primary Efficacy Endpoints

Proportion of subjects with treatment success (defined as none, minimal or mild disease, a score of 0, 1 or 2 within the treatment area) on the IGA at the Week 12 visit (Day 85 ± 4 days, End of Study).

Secondary Efficacy Endpoints

1. Proportion of subjects with disease severity at the Week 12 visit (Day 85 ± 4 days, End of Study) consistent with none or minimal, a score of 0 or 1, within the treatment area on the IGA

AND

2. Proportion of subjects with target site plaque elevation, scaling and erythema scores of less than or equal to 1 on the PASI at the Week 12 visit (Day 85 ± 4, End of Study).

8. STATISTICAL ANALYSIS METHODS

If not otherwise specified, statistical significance is defined as $p<0.05$ and is two-tailed. Data will be summarized with respect to demographic and baseline characteristics, efficacy variables and safety variables.

For categorical variables, the number and percent of each category within a parameter will be

calculated for non-missing data. For continuous variables with non-missing values, statistics will include number of observations, mean, standard deviation, median, minimum and maximum values.

All statistical analyses will be conducted using SAS®, Version 9.4 or higher. Datasets will be prepared using headings from Clinical Data Interchange Consortium (CDISC) Study Data Tabulation Model (SDTM) implementation for human clinical trials and ADaM (Analysis Dataset Model).

8.1 Baseline Characteristics

8.1.1 Demographics Comparability of Treatment Groups

Baseline characteristics will be evaluated separately for the PP, mITT and Safety populations.

Demographic information collected at baseline includes the following:

- Age (years)
- Sex (Male/Female)
- Ethnicity (Hispanic/non Hispanic)
- Race (White, Black/African American, Native Hawaiian or Other Pacific Islander, Asian, American Indian or Alaska Native, Other)
- Baseline total BSA affected with Psoriasis
- Baseline percent BSA affected with Psoriasis
- Baseline PASI Score (the sum of the three individual component scores)
- Baseline Scores for Individual Components (Erythema, Scaling and Plaque Elevation)
- Baseline IGA Score
- Treatment location
- Treatment area size (area)
- Target lesion size (area)

Summary tables by treatment group will be presented. Continuous variables will be summarized using descriptive statistics (number of observations, median, minimum, maximum, mean and standard deviation). Categorical variables will be summarized using frequencies and percentage. Baseline treatment comparisons will be presented using Chi-Square test for the categorical variables, and Analysis of Variance (ANOVA) for the continuous variables.

All data will be listed by treatment and subject.

8.1.2 Medical History

At Visit 1 subjects will be questioned about their personal medical history, including psoriasis history. The medical history will include a complete review of all current diseases and their respective durations and treatments.

Medical history data will be listed by treatment and subject.

8.1.3 Concomitant Medications

At Visit 1, subjects will be questioned about current and prior concomitant medication use over the 6 months. Subjects will also be questioned about ongoing or new concomitant medication use during the treatment period at Visits 2, 3 and 4.

All prior and concomitant medications taken since screening until the end of the study will be listed by treatment and subject.

8.1.4 Pregnancy Test

All females of childbearing potential will have a urine pregnancy test performed at each Scheduled visit. All females of childbearing potential will have a urine pregnancy test performed at Visit 1 (Baseline), Visit 2, Visit 3, and Visit 4 (or early termination).

Pregnancy test results will be listed by treatment and subject.

8.2 Primary and Secondary Endpoint Analyses

Therapeutic Bioequivalence Analysis

Therapeutic equivalence will be evaluated for both primary and secondary endpoints using the PP population, with results in the mITT population being supportive.

Based on the usual method used in OGD for binary outcomes, the 90% confidence interval for the difference in success proportions between test and reference treatment should be contained within [-0.20, +0.20] in order to establish equivalence.

The compound hypothesis to be tested is:

$H_0: \ P_T - P_R < -.20 \ or \ P_T - P_R > .20$ versus

$H_A : -.20 \leq P_T - P_R \leq .20$

where P_T = success rate of test treatment
P_R = success rate of reference treatment.

Let

n_T = sample size of test treatment group
cn_T= number of patients considered as Treatment Success in test treatment group
n_R = sample size of reference treatment group
cn_R= number of patients considered as Treatment Success in reference treatment group
$\hat{P}_T = cn_T/n_T$ $\hat{P}_R = cn_R/n_R$, and

$$se = (\hat{P}_T(1-\hat{P}_T)/n_T + (\hat{P}_R(1-\hat{P}_R)/n_R)^{1/2}$$

The 90% confidence interval for the difference in proportions between test and reference will be calculated as follows, using Yates' correction:

$$L = (\hat{P}_T - \hat{P}_R) - 1.645\, se - (1/n_T + 1/n_R)/2$$

$$U = (\hat{P}_T - \hat{P}_R) + 1.645\, se + (1/n_T + 1/n_R)/2$$

For the proportion of Treatment Success, if the 90% confidence interval (with Yates' Correction Factor) of the difference between the proportion of subjects considered a "treatment success" in the Test and the Reference treatment groups at Week 12 is contained within the pre-defined equivalence limits [-20%, +20%], then therapeutic equivalence will be considered to have been supported for the endpoint. The same statistical approach will be conducted for analysis of the two dichotomized secondary endpoints in the PP and mITT populations.

To declare therapeutic equivalence of the Test product to the Reference product, therapeutic equivalence must be demonstrated for only the primary endpoint in the PP population.

Superiority to Placebo Analysis

The primary measure of superiority will be evaluated using the mITT population and LOCF for missing efficacy values. The results in the PP population will be considered supportive.

The superiority of the Test and Reference products over Placebo will be concluded for the primary endpoint if the proportion of treatment success at Week 12 is statistically superior to Placebo ($p < 0.05$, two-sided a Cochran-Mantel-Haenszel exact test stratified by clinical site) using the mITT population and LOCF. The same statistical approach will be conducted for analysis of the two dichotomized secondary endpoints in the mITT and PP populations.

.

To declare superiority of the Test and Reference products over Placebo, their superiority must be demonstrated for only the primary endpoint in the mITT population.

A summary table with frequency and percentage of the proportion of Treatment Success by treatment group will be presented.

Treatment-by-Site Interaction and Pooling of Clinical Sites

As this is a multiple-site study, the interaction of treatment-by-site may be evaluated by the Cochran-Mantel-Haenszel test (stratified by site) at the 5% significance level ($p < 0.05$, 2-sided) for the primary efficacy endpoint in both the PP population (for equivalence testing) and mITT population (for superiority testing).. [redacted]

If the treatment-by-site interaction is found to be statistically significant ($p < 0.05$) then the interaction will also be assessed for clinical relevance before pooling the data across sites. This will include examination of responder rates at each site where sample sizes per treatment may be influential in the assessment of the interaction.

8.3 Safety Analysis

All safety analyses will be based on the Safety Population.

8.3.1 Adverse Events

All the adverse events (AEs) reported throughout the study will be coded and classified according to the MedDRA (Medical Dictionary for Regulatory Activities) coding dictionary (Version 18.1 or higher). Each adverse event is to be evaluated for date of start and end, seriousness, severity, relationship to the IP, action taken and outcome.

In each of the following categories, the total number and percentage of subjects with 1) at least one AE, 2) discontinued study drug due to AEs, 3) AE severity and AEs related to the IP, 4) serious AEs and death will be summarized separately by treatment groups.

A summary table of the number and percent of subjects with AEs by system organ class, preferred term, and treatment group will be presented. Each subject will be counted only once within each preferred term.

A frequency summary table of the number of AEs by system organ class, preferred term, severity, and treatment group will be presented. Severity will be classified as "Mild", "Moderate", or "Severe".

Similarly, a frequency summary table of the number of AEs by system organ class, preferred term, and relationship to the IP, and treatment group will be presented. Relationship to a study drug will be classified as "Suspected" or "Not Suspected".

Should sufficient data exist, adverse event frequencies will be compared between treatments using Fisher's exact test.

8.3.2 Application Site Reactions

At Visits 1, 2, 3 and 4 the Investigator will evaluate the subject for local application site reactions.

Signs and Symptoms recorded at each visit will be compared between treatment groups. Descriptive summaries (number of observations, mean, standard deviation, minimum, median and maximum) comparing the application site reactions for each treatment group will be presented by visit.

A frequency summary table comparing the application site reactions for each treatment group will be presented by visit.

8.3.3 Vital Signs

The subject's vital signs (pulse, blood pressure, temperature and respiration rate) will be recorded at Visit 1 and Visit 4.

Descriptive summaries (number of observations, mean, standard deviation, minimum, median and maximum) will be provided by treatment and visit for non-missing values.

All data will be listed by treatment and subject.

8.4 Multiple Comparisons

No multiple comparison adjustment will be made in this study.

8.5 Methods for Handling Missing Data

For demographic and baseline characteristics, each variable will be analyzed using all available

data. Subjects with missing data will be excluded only from analyses for which data are not available, including denominators.

Subjects who discontinue early for reasons besides lack of treatment effect or worsening of condition should be excluded from the PP population, but included in the modified Intent-to-Treat (mITT) population using the last observation carried forward (LOCF), provided they administered at least one dose of randomized IP and completed at least one post-dose evaluation.

8.6 Interim Analyses

There is no interim analysis planned in this study.

9. TABLE, LISTING AND FIGURE SHELLS

The following shells are provided in order to provide a framework for the display of data from this study. These shells may not be reflective of every aspect of this study but are intended to show the general layout of the Tables, Listings and Figures that will be included in the final clinical study report. Tables, Listings and Figures are numbered following the ICH structure. Table headers, variables names and footnotes will be modified as needed following data analyses. All descriptive and inferential statistical analyses will be performed using SAS® statistical software Version 9.4 or higher, unless otherwise noted.

TABLE, LISTING AND FIGURE SHELLS

T16.1.9.1 Summary of Discontinued Subjects (Safety Population)

Subjects	Test	Reference	Placebo	Total
Randomized	xxx	xxx	xxx	xxx
Completed Study	xxx	xxx	xxx	xxx
Terminated Early	xxx	xxx	xxx	xxx
Early Termination Reason				
Administrative reasons	xxx	xxx	xxx	xxx
Lack of efficacy	xxx	xxx	xxx	xxx
Lost to Follow-Up	xxx	xxx	xxx	xxx
etc.				

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.2 Summary of Protocol Deviations (Safety Population)

	Test	Reference	Placebo	Total
Total Subjects with Protocol Deviations	xxx	xxx	xxx	xxx
Total Deviations	xxx	xxx	xxx	xxx
Lost to follow up	xxx	xxx	xxx	xxx
Outside visit window	xxx	xxx	xxx	xxx
Missed Visit	xxx	xxx	xxx	xxx
Restricted Medication	xxx	xxx	xxx	xxx
etc	xxx	xxx	xxx	xxx
Other	xxx	xxx	xxx	xxx

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.3.1 Summary of Subjects Excluded from Efficacy Analysis (Population Determination)

		Test	Reference	Placebo	Total
Randomized	Total	xxx	xxx	xxx	xxx
Safety Population	Total	xxx	xxx	xxx	xxx
Excluded from Safety	Did not received study product	xxx	xxx	xxx	xxx
	etc.				
mITT Population	Total	xxx	xxx	xxx	xxx
Excluded from mITT	Did not received study product	xxx	xxx	xxx	xxx
	etc.				
PP Population	Total	xxx	xxx	xxx	xxx
Excluded from Excluded from PP	Restricted Medication	xxx	xxx	xxx	xxx
	etc.				

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.3.2 Summary of Subjects Included in Analysis Population by Study Center

Site No.	Name	Total Randomized	PP				mITT				Safety			
			Test	Ref	Placebo	Total	Test	Ref	Placebo	Total	Test	Ref	Placebo	Total
xx	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xx	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.4.1 Summary of Demographic Data (Safety Population)

		Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)	P-value
Age (years)	n	xxx	xxx	xxx	x.xxxx
	Mean ± SD	xx.x ± xx.x	xx.x ± xx.x	xx.x ± xx.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x	
Race	White	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xxxx
	Black/African American	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Native Hawaiian or other Pacific Islander	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Asian	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	American Indian or Alaska Native	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Other	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Sex	Female	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xxxx
	Male	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Ethnicity	Hispanic or Latino	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xxxx
	Not Hispanic or Latino	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	

N= number of subjects in the treatment group; n= number of subjects with data available; % is based on N

P-values are from Chi-squre test for categorical variables and ANOVA for the continuous variables.

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

T16.1.9.4.2 Summary of Baseline Parameters (Safety Population)

		Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)	P-value
Total BSA affected with Psoriasis	n	xxx	xxx	xxx	x.xxxx
	Mean ± SD	xx.x ± xx.x	xx.x ± xx.x	xx.x ± xx.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x	
Total percent BSA affected with Psoriasis	n	xxx	xxx	xxx	x.xxxx
	Mean ± SD	xx.x ± xx.x	xx.x ± xx.x	xx.x ± xx.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x	
Baseline IGA Score	n	xxx	xxx	xxx	x.xxxx
	Mean ± SD	xx.x ± xx.x	xx.x ± xx.x	xx.x ± xx.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x	
Baseline PASI Score	n	xxx	xxx	xxx	x.xxxx
	Mean ± SD	xx.x ± xx.x	xx.x ± xx.x	xx.x ± xx.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x	

Note: N= number of subjects in the treatment group; n= number of subjects with data available; % is based on N

P-values are from Chi-squre test for categorical variables and ANOVA for the continuous variables.

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.4.2 Summary of Baseline Parameters
(Safety Population)

		Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)	P-value
Erythema	Clear	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xxxx
	Almost clear	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Mild	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Moderate	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Severe	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Very severe	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Scaling	Clear	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xxxx
	Almost clear	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Mild	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Moderate	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Severe	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Very severe	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Plaque Elevation	Clear	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xxxx
	Almost clear	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Mild	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Moderate	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Severe	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Very severe	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	

Note: N= number of subjects in the treatment group; n= number of subjects with data available; % is based on N

P-values are from Chi-squre test for categorical variables and ANOVA for the continuous variables.

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.4.2 Summary of Baseline Parameters (Safety Population)

		Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)	P-value
Treatment area size (area)	n	xxx	xxx	xxx	x.xxxx
	Mean ± SD	xx.x ± xx.x	xx.x ± xx.x	xx.x ± xx.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x	
Target lesion size (area)	n	xxx	xxx	xxx	x.xxxx
	Mean ± SD	xx.x ± xx.x	xx.x ± xx.x	xx.x ± xx.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x	
Treatment location	Head front	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xxxx
	Head back	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Torso front	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Torso back	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	etc	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	

Note: N= number of subjects in the treatment group; n= number of subjects with data available; % is based on N

P-values are from Chi-squre test for categorical variables and ANOVA for the continuous variables.

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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Similar tables will be created for T16.1.9.5.1, T16.1.9.5.2, T16.1.9.6.1 and T16.1.9.6.2

T16.1.9.5.1 Summary of Demographic Data
(modified Intent-to-Treat Population)

T16.1.9.5.2 Summary of Baseline Parameters
(modified Intent-to-Treat Population)

T16.1.9.6.1 Summary of Demographic Data
(Per-Protocol Population)

T16.1.9.6.2 Summary of Baseline Parameters
(Per-Protocol Population)

T16.1.9.7.1 Summary of Analysis Results of Primary Efficacy Endpoint
Proportion of Treatment Successes on the IGA (a score of 0 or 1 or 2) at the Week 12 Visit

Equivalence: Per-Protocol Population

Treatment Group	Number of Subjects (N)	Number of Treatment Successes (n)	Proportion of Treatment Successes (%)	Difference Between Treatments	
				Difference	90% CI Evaluation
Test	xxx	xxx	xx.x%		
Reference	xxx	xxx	xx.x%	xx.x%	xx.x – xx.x

Superiority: modified Intent-to-Treat Population

Treatment Group	Number of Subjects (N)	Number of Treatment Successes (n)	Proportion of Treatment Successes (%)	P-value
Placebo	xxx	xxx	xx.x%	
Test	xxx	xxx	xx.x%	x.xxxx
Reference	xxx	xxx	xx.x%	x.xxxx

The 90% confidence interval for the difference in proportions between test and reference was calculated using Yates' correction.

Superiority of Active treatments over Placebo were tested using a two-sided Cochran-Mantel-Haenszel (CMH) exact test, stratified by clinical site, at the 5% significance level using last observation carried forward (LOCF).

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.7.2 Summary of Supportive Analysis Results of Primary Efficacy Endpoint
Proportion of Treatment Successes on the IGA (a score of 0 or 1 or 2) at the Week 12 Visit

Equivalence: modified Intent-to-Treat Population

				Difference Between Treatments	
Treatment Group	**Number of Subjects (N)**	**Number of Treatment Successes (n)**	**Proportion of Treatment Successes (%)**	**Difference**	**90% CI Evaluation**
Test	xxx	xxx	xx.x%		
Reference	xxx	xxx	xx.x%	xx.x%	xx.x – xx.x

Superiority: Per-Protocol Population

Treatment Group	**Number of Subjects (N)**	**Number of Treatment Successes (n)**	**Proportion of Treatment Successes (%)**	**P-value**
Placebo	xxx	xxx	xx.x%	
Test	xxx	xxx	xx.x%	x.xxxx
Reference	xxx	xxx	xx.x%	x.xxxx

The 90% confidence interval for the difference in proportions between test and reference was calculated using Yates' correction.

Superiority of Active treatments over Placebo were tested using a two-sided Cochran-Mantel-Haenszel (CMH) exact test, stratified by clinical site, at the 5% significance level using last observation carried forward (LOCF).

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

T16.1.9.8.1 Summary of Analysis Results of Secondary Efficacy Endpoint
Proportion of Subjects with Disease Severity (a score of 0 or 1) on IGA at the Week 12 Visit

Equivalence: Per-Protocol Population

Treatment Group	Number of Subjects (N)	Number of Treatment Successes (n)	Proportion of Treatment Successes (%)	Difference Between Treatments	
				Difference	90% CI Evaluation
Test	xxx	xxx	xx.x%		
Reference	xxx	xxx	xx.x%	xx.x%	xx.x – xx.x

Superiority: modified Intent-to-Treat Population

Treatment Group	Number of Subjects (N)	Number of Treatment Successes (n)	Proportion of Treatment Successes (%)	P-value
Placebo	xxx	xxx	xx.x%	
Test	xxx	xxx	xx.x%	x.xxxx
Reference	xxx	xxx	xx.x%	x.xxxx

The 90% confidence interval for the difference in proportions between test and reference was calculated using Yates' correction.

Superiority of Active treatments over Placebo were tested using a two-sided Cochran-Mantel-Haenszel (CMH) exact test, stratified by clinical site, at the 5% significance level using last observation carried forward (LOCF).

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

T16.1.9.8.2 Summary of Supportive Analysis Results of Secondary Efficacy Endpoint Proportion of Subjects with Disease Severity (a score of 0 or 1) on IGA at the Week 12 Visit

Equivalence: modified Intent-to-Treat Population

Treatment Group	Number of Subjects (N)	Number of Treatment Successes (n)	Proportion of Treatment Successes (%)	Difference Between Treatments: Difference	Difference Between Treatments: 90% CI Evaluation
Test	xxx	xxx	xx.x%		
Reference	xxx	xxx	xx.x%	xx.x%	xx.x – xx.x

Superiority: Per-Protocol Population

Treatment Group	Number of Subjects (N)	Number of Treatment Successes (n)	Proportion of Treatment Successes (%)	P-value
Placebo	xxx	xxx	xx.x%	
Test	xxx	xxx	xx.x%	x.xxxx
Reference	xxx	xxx	xx.x%	x.xxxx

The 90% confidence interval for the difference in proportions between test and reference was calculated using Yates' correction.

Superiority of Active treatments over Placebo were tested using a two-sided Cochran-Mantel-Haenszel (CMH) exact test, stratified by clinical site, at the 5% significance level using last observation carried forward (LOCF).

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

T16.1.9.9.1 Summary of Analysis Results of Secondary Efficacy Endpoint
Proportion of Subjects with Target Site Plaque Elevation, Scaling and Erythema Scores of Less Than or Equal to 1 on the PASI at the Week 12 Visit

Equivalence: Per-Protocol Population

Treatment Group	Number of Subjects (N)	Number of Treatment Successes (n)	Proportion of Treatment Successes (%)	Difference Between Treatments: Difference	Difference Between Treatments: 90% CI Evaluation
Test	xxx	xxx	xx.x%		
Reference	xxx	xxx	xx.x%	xx.x%	xx.x – xx.x

Superiority: modified Intent-to-Treat Population

Treatment Group	Number of Subjects (N)	Number of Treatment Successes (n)	Proportion of Treatment Successes (%)	P-value
Placebo	xxx	xxx	xx.x%	
Test	xxx	xxx	xx.x%	x.xxxx
Reference	xxx	xxx	xx.x%	x.xxxx

The 90% confidence interval for the difference in proportions between test and reference was calculated using Yates' correction.

Superiority of Active treatments over Placebo were tested using a two-sided Cochran-Mantel-Haenszel (CMH) exact test, stratified by clinical site, at the 5% significance level using last observation carried forward (LOCF).

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

T16.1.9.9.2 Summary of Supportive Analysis Results of Secondary Efficacy Endpoint
Proportion of Subjects with Target Site Plaque Elevation, Scaling and Erythema Scores of Less Than or Equal to 1 on the PASI at the Week 12 Visit

Equivalence: modified Intent-to-Treat Population

				Difference Between Treatments	
Treatment Group	Number of Subjects (N)	Number of Treatment Successes (n)	Proportion of Treatment Successes (%)	Difference	90% CI Evaluation
Test	xxx	xxx	xx.x%		
Reference	xxx	xxx	xx.x%	xx.x%	xx.x – xx.x

Superiority: Per-Protocol Population

Treatment Group	Number of Subjects (N)	Number of Treatment Successes (n)	Proportion of Treatment Successes (%)	P-value
Placebo	xxx	xxx	xx.x%	
Test	xxx	xxx	xx.x%	x.xxxx
Reference	xxx	xxx	xx.x%	x.xxxx

The 90% confidence interval for the difference in proportions between test and reference was calculated using Yates' correction.

Superiority of Active treatments over Placebo were tested using a two-sided Cochran-Mantel-Haenszel (CMH) exact test, stratified by clinical site, at the 5% significance level using last observation carried forward (LOCF).

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

T16.1.9.10 Overall Summary of Adverse Events (Safety Population)

Description	Test N (%)	Reference N (%)	Placebo N (%)	Total N (%)
Subjects Randomized	xxx	xxx	xxx	xxx
Subjects with at least one AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Discontinued study drug due to above AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
AEs reported	xxx	xxx	xxx	xxx
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Serious AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.11 Summary of Frequency of All Adverse Events by Body System (Safety Population)

		Test (N = xxx)		Reference (N = xxx)		Placebo (N = xxx)		Fisher's
Body System	**MedDRA Term**	**Events**	**Subjects**	**Events**	**Subjects**	**Events**	**Subjects**	**P-value**
Subject with at least one AE	Total	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	x.xxxx
Ear and labyrinth disorders	Ear pain	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	x.xxxx
	etc.							
etc.								

Comparison of treatment groups is with respect to the number of subjects with at least one occurrence of the AE.

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.12 Summary of Frequency for AEs Occurring in at Least 5% of Subjects by Body System (Safety Population)

T16.1.9.13 Summary of Frequency of All Adverse Events by Severity (Safety Population)

		Test # Events (N=xx)			Reference # Events (N=xx)			Placebo # Events (N=xx)		
Body System	**MedDRA Term**	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**
Total AEs	Total AEs	xx(xx.x%)	xx(xx.x%)	xx (xx.x%)	xx(xx.x%)	xx(xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ear and labyrinth disorders	Ear pain	xx(xx.x%)	xx(xx.x%)	xx (xx.x%)	xx(xx.x%)	xx(xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Hypoacusis	xx(xx.x%)	xx(xx.x%)	xx (xx.x%)	xx(xx.x%)	xx(xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

etc.

N = Total number of events in each treatment group; Percentage is based on total number of events.

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.14 Summary of Frequency of All Adverse Events by Relationship (Safety Population)

		Test # Events (N=xx)		Reference # Events (N=xx)		Placebo # Events (N=xx)	
Body System	**MedDRA Term**	**Suspected**	**Not Suspected**	**Suspected**	**Not Suspected**	**Suspected**	**Not Suspected**
Total AEs	Total AEs	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ear and labyrinth disorders	Ear pain	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Hypoacusis	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	etc.						
etc.							

N = Total number of events in each treatment group; Percentage is based on total number of events.

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.15 Summary of Frequency of Serious Adverse Events (Safety Population)

Body System	MedDRA Term	Test # Events	Reference # Events	Placebo # Events
Injury, poisoning and procedural complications	Alcohol poisoning	xx	xx	xx

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

T16.1.9.16 Summary of Application Site Reaction (Safety Population)

Signs and Symptoms	Visit	Statistic	Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)
Erythema	1	n	xxx	xxx	xxx
		Mean ± SD	xx.x ± xx.x	xx.x ± xx.x	xx.x ± xx.x
		Median	xx.x	xx.x	xx.x
		Range	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
	2				
	3				
	4/ET				
Dryness					
Burning/Stinging					
Erosion					
Edema					
Pain					
Itching					

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.17 Summary of Frequency of Application Site Reaction (Safety Population)

Signs and Symptoms	Visit	Statistic	Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)
Erythema	1	Absent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
		Mild	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
		Moderate	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
		Severe	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	2				
	3				
	4/ET				
Dryness					
Burning/Stinging					
Erosion					
Edema					
Pain					
Itching					

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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T16.1.9.18 Summary of Vital Signs
(Safety Population)

Vital Signs	Visit	Statistic	Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)
Systolic Blood Pressure (mmHg)	1	n	xxx	xxx	xxx
		Mean ± SD	xxx.x ± xx.x	xxx.x ± xx.x	xxx.x ± xx.x
		Median	xxx.x	xxx.x	xxx.x
		Range	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
	4/ET				
Diastolic Blood Pressure (mmHg)					
Pulse Rate (beats/min)					
Respiration Rate (breaths/min)					
Temperature (F)					

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

L16.2.1 Listing of Discontinued Subjects

Treatment Group	Subject Number	Discontinuation Reason	Population
Test	xx - xxxx	Withdrew Consent	Safety
	xx - xxxx	Lost to Follow-up	Safety
Reference			
Placebo			

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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L16.2.2 Listing of Protocol Deviations

Treatment Group	Subject Number	Protocol Deviation Summary	Population
Test	xx - xxxx	Outside Visit Window	Safety

Reference

Placebo

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

L16.2.3.1 Subjects Excluded from the Per-Protocol Population Data Set

Treatment Group	Subject Number	Exclusion Reason
Test	xx - xxxx	Subject did not meet IE criterion.
	xx - xxxx	Subject took prohibited medications
Reference		
Placebo		

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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L16.2.3.2 Subjects Excluded from the Modified Intent-to-Treat Data Set

Treatment Group	Subject Number	Exclusion Reason
Test	xx - xxxx	Subject did not have at least one post-randomization evaluation
	xx - xxxx	Subject did not have at least one post-randomization evaluation
Reference		
Placebo		

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

L16.2.4.1 Listing of Demographic Data

Treatment Group	Subject Number	Age	Sex	Ethnicity	Race
Test	xx - xxxx	30	Female	Not Hispanic or Latino	Black or African American

Reference

Placebo

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

L16.2.4.2 Listing of Medical History

Treatment Group	Subject Number	Category	Reported Term	Onset Date	End Date	Ongoing
Test	xx - xxxx	Gynecologic	Menopause	2003	2003	

Reference

Placebo

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

L16.2.4.3 Listing of Concomitant Medications

Test: Tazarotene Cream 0.05%

Subject Number	Medication/ Therapy Name	Dosage	Frequency	Route	Start/End Date	Indication
xx - xxxx	LISINOPRIL	20 MG	QD	PO	yyyy-mm-dd/	HYPERTENSION

Note to programmer: table will continue for reference and placebo group

L16.2.5.1 Listing of Visit Date Information

Treatment Group	Subject Number	Inform Consent Date	Visit 1	Visit 2	Visit 3	Visit 4 or Early Termination
Test	xx - xxxx	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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L16.2.5.2 Listing of Drug Administration

Treatment Group	Subject Number	Date of First Dose	Date of Last Dose	Total Doses Applied	Dosing Compliance (%)
Test	xx - xxxx	yyyy-mm-dd	yyyy-mm-dd	xx	xx.x
Reference					
Placebo					

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

L16.2.6.1 Listing of Investigator Global Assessment (IGA)

Treatment Group	Subject Number	Visit 1	Visit 2	Visit 3	Visit 4 or Early Termination	Treatment Success*	Treatment Success**
Test	xx - xxxx	4	4	3	0	Yes	Yes
	xx - xxxx	4	4	3	2	Yes	No
	xx - xxxx	4	4	3	3	No	No
Reference							
Placebo							

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)
*Treatment Success: defined as none, minimal or mild disease, a score of 0, 1 or 2 within the treatment area on the IGA at the Week 12 visit (Day 85 ± 4 days, End of Study).
**Treatment Success: defined as subjects with disease severity at the Week 12 visit (Day 85 ± 4 days, End of Study) consistent with none or minimal, a score of 0 or 1, within the treatment area on the IGA

L16.2.6.2 Listing of Psoriasis Area Severity Index (PASI) at the Target Lesion Site

Treatment Group	Subject Number	Visit	Scaling	Erythema	Plaque Elevation	PASI Score	Clinical Success
Test	xx - xxxx	1	2	3	1	6	
		2	2	3	1	6	
		3	1	2	1	4	
		4/ET	1	1	0	2	Yes
	xx - xxxx	1	2	3	1	6	
		2	2	3	1	6	
		3	1	2	1	4	
		4/ET	1	2	0	3	No

Reference

Placebo

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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L16.2.6.3 Listing of Dermatological Examination

Treatment Group	Subject Number	Height (cm)	Weight (kg)	BSA (m^^2)	Location of the Target Lesion	Target Lesion Area (cm^^2)	% BSA Affected			
							V1	V2	V3	V4/ET
Test	xx - xxxx	xxx	xxx.x	xxx.x	Head front	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
Reference										
Placebo										

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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L16.2.7.1 Listing of Adverse Events by Treatment Group

Test: Tazarotene Cream 0.05%

Subject Number	Body System/ MedDRA Term/ AE Term	TX Area	Start /End Date	Severity	Relationship to Investigational Drug	Outcome	Action Taken with Investigational Drug / Other Action Taken	SAE?
xx - xxxx	Nervous system disorders/ headache/ Headache	No	yyyy-mm-dd / yyyy-mm-dd	Mild	Not Suspected	Recovered	Drug withdrawn/ None	No

Note to programmer: table will continue for reference and placebo group

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L16.2.7.2 Listing of Application Site Reactions

Treatment Group	Visit	Erythema	Dryness	Burning /Stinging	Erosion	Edema	Pain	Itching
Test	**1**	0	0	0	1	0	0	0
	2	0	1	0	0	0	0	0
	3	0	0	0	1	0	0	0
	4/ET	0	0	0	1	0	0	2
Reference								
Placebo								

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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L16.2.8.1 Listing of Pregnancy Test Results

Treatment Group	Subject Number	Visit 1	Visit 2	Visit 3	Visit 4 or Early Termination
Test	xx - xxxx	Negative	Negative	Negative	Negative
Reference					
Placebo					

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

L16.2.8.2 Listing of Vital Signs

Treatment Group	Subject Number	Visit	Systolic BP (mmHg)	Diastolic BP (mmHg)	Pulse Rate (beats/min)	Respiration Rate (breaths/min)	Temperature (F)
Test	xx - xxxx	1	120	70	84	18	98.6
		4/ET	140	80	74	18	97
	xx - xxxx						
Reference							
Placebo							

Test: Tazarotene Cream 0.05% (Fougera Pharmaceuticals Inc.)
Reference: TAZORAC® (tazarotene) Cream, 0.05% (Allergan, Inc.)
Placebo: Placebo (vehicle) Cream (Fougera Pharmaceuticals Inc.)

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APPENDIX A: Investigator's Global Assessment of Disease Severity

Score	Grade	Definition
0	None	No plaque elevation above normal skin level; may have residual non-erythematous discoloration; no psoriatic scale; no erythema
1	Minimal	Essentially flat with possible trace elevation; faint erythema; no psoriatic scale
2	Mild	Slight but definite elevation of plaque above normal skin level; may have up to moderate erythema (red coloration); fine scales with some lesions partially covered
3	Moderate	Moderate elevation with rounded or sloped edges to plaque; moderate erythema (red coloration); somewhat coarse scales with most lesions partially covered
4	Severe	Marked elevation with hard, sharp edges to plaque; severe erythema (very red coloration); coarse, thick scales with virtually all lesions covered and a rough surface
5	Very Severe	Very marked elevation with very hard, sharp edges to plaque; very severe erythema (extreme red coloration); very coarse, thick scales with all lesions covered and a very rough surface

To be eligible for participation in the study a subject must have a Baseline IGA score of 3, 4 or 5.

A subject shall be considered a "treatment success" if he/she has an IGA score of 0, 1 or 2 within the treatment area at the Week 12 visit.

APPENDIX B: Psoriasis Area Severity Index at the Target Lesion Site

Score	Grade	Erythema	Scaling	Plaque Elevation
0	Clear	No evidence of erythema	No evidence of scaling	No evidence of plaques above normal skin level
1	Almost Clear	Pink discoloration, minimal erythema	Occasional fine scales hardly noticeable	Slight, just discernible elevation above normal skin level
2	Mild	Light red coloration	Slight but definite roughness, fine scale present, no cracking	Discernible elevation above normal skin level upon examination, but not pronounced
3	Moderate	Moderate redness, but not dark	Moderate roughness, somewhat coarse scaling	Definite plaque formation with rounded/sloped edges to plaque
4	Severe	Dark red coloration	Marked roughness, coarse/thick scaling, cracking may be evident	Marked elevation with hard, distinct edges to plaque
5	Very Severe	Very dark red coloration with induration present	Very thick scales covering extensive area, severe cracking/fissures may be evident	Very marked elevation, very hard and sharp edges to plaque

To be eligible for participation in the study a subject must have a minimum plaque elevation of at least moderate severity (score ≥ 3) at the target lesion site. The most severe lesion at Baseline should be identified as the target lesion.

APPENDIX C: Application Site Reactions

The following application site reactions will be evaluated at each visit based on the scale provided below:

Signs and Symptoms:

Erythema

Dryness

Burning/Stinging

Erosion

Edema

Pain

Itching

Grading Scale:

Severity	**Grade**
Absent	0
Mild	1 (slight, barely perceptible)
Moderate	2 (distinct presence)
Severe	3 (marked, intense)