SAFETY AND EFFICACY OF CD5024 0.3% CREAM IN SUBJECTS WITH ATOPIC DERMATITIS

STATISTICAL ANALYSIS PLAN
RD.03.SPR.109696

13 JULY 2017

This document is electronically approved and signed by: *Statistic Manager*

Name	Reason for Signing	Date
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DOCUMENT HISTORY

Version No.	Description of Edits	Justification	Date
Amendment 1	The analysis of the primary endpoint changes from the percent change in EASI score from baseline to week 6 to the Change in EASI score from baseline to week 6 adjusted on baseline. Change from baseline will be analyzed on ITT-LOCF, ITT-MI and PP. As a secondary endpoint Percentage change in EASI score from baseline to any scheduled visits will be analyzed via a Cochran Mantel Haenszel test stratified by analysis center, using RIDIT transformation and Row mean score statistics. Percent change from baseline will be analyzed on ITT-LOCF and PP	During dry run, one observation (percent change from baseline of 200%) appears to deviate markedly from others. This patient has a very low EASI at baseline (EASI=1).This outlier skews the distribution and for the intended analysis (ANOVA) increases the residual error and thus makes the statistical test less powerful and not appropriate.	13/07/2017

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1 STUDY OBJECTIVES

The primary objective of this study is to evaluate the local and systemic safety of CD5024 0.3% cream applied once daily over a 6-week treatment period in adults with chronic lesions of moderate atopic dermatitis (AD), compared to its vehicle.

The secondary objective is to evaluate the efficacy of CD5024 0.3 % cream versus its vehicle on chronic lesions of moderate AD.

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2 STUDY DESIGN

This is an exploratory, multi-center (approximately 5 sites in Canada), randomized, vehicle-controlled, investigator-blind, parallel group study, involving approximately 85 subjects screened to get approximately 60 randomized subjects with chronic lesions of AD meeting specific inclusion/non-inclusion criteria. The investigator and/or other evaluator(s) will not come into contact with the study materials. Subjects and the study staff do not have access to the correspondence between the kit number and the assigned treatment group.

Subjects who consent to be enrolled and fulfill study criteria will be allocated to one of the study treatment according to the randomization list, in a 1:1 ratio (for example Group A: N=30 subjects treated with CD5024 0.3% cream, and Group B: N=30 subjects treated with the vehicle).

Efficacy and safety assessments

	Screening period	Treatment Period													Early Termination	Unscheduled	Follow-up
	Week-5 to Week-1	Week 1		Week 2		Week 3		Week 4		Week 5		Week 6		Week 7			Week 9
	D-30 to D-3	D01	D02 to D07	D0 8	D09 to D14	D15	D16 to D21	D22	D23 to D28	D29	D30 to D35	D36	D37 to D42	D43			D54±2
Efficacy assessment																	
EASI Score		X		X		X		X		X		X		X (b)	X	X	
Investigator Global Assessment (IGA)	X	X		X		X		X		X		X		X (b)	X		
TSS		X		X		X		X		X		X		X (b)	X		
Modified-Objective SCORAD		X		X		X		X		X		X		X (b)	X		
Hand IGA when applicable		X		X		X		X		X		X		X (b)	X		
tBSA (Total Body Surface Area)	X																
BSA (i.e. affected by AD)	X	X		X		X		X		X		X		X (b)	X	X	
Patient-reported Outcome - Pruritus Numerical Rating Scale & DIARY	X	X	X	X	X	X	X	X	X	X	X	X	X	X (b)	X		
Patient-reported Outcome - Pruritus Verbal Rating Scale & DIARY		X												X (b)	X		
Safety assessment																	
Blood samplings (coagulation, hematology, biochemistry)	X							X						X	X		
Blood samplings (IgE & TARC)	X													X	X		
Physical examination	X	X				X				X				X	X		X
Vital signs	X	X				X				X				X	X		X
ECG	X	X												X	X		
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Other assessment																	
CCI																	
CCI																	

(b) All assessments are to be done before any procedures are performed.

3 EFFICACY AND SAFETY VARIABLES

3.1 Efficacy variables

3.1.1 Primary efficacy endpoints

The Primary efficacy endpoint is the change from Baseline to Week 6 of the EASI score.

3.1.2 Secondary efficacy endpoints

The change from Baseline of the EASI score at any other evaluation visit and the percent change from Baseline in EASI score at each evaluation visit.

Investigator Global Assessment in terms of distribution and in terms of success rate (success is defined as a subject with an IGA score of 0 [clear] or 1 [Almost clear]) at each evaluation visit.

Percent change from Baseline of the Total Sum Score (TSS) of the target plaque.

Change from Baseline of each individual score (Erythema, Induration/Papulation, Oozing/Crusting, Excoriation, Lichenification).

Percent Change from baseline of the Modified Objective SCORAD.

Pruritus (numerical rating scale [NRS], verbal rating scale [VRS]) and their changes from Baseline at each evaluation visit.

4 SAFETY AND OTHER VARIABLES

Physical examination, Vital signs (pulse rate and blood pressure)

Laboratory parameters

Adverse events

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5 POPULATIONS ANALYZED

5.1 Intent-to-treat (ITT) Efficacy analysis set

The ITT set is defined as any subjects who are randomized. Data from subjects included in the ITT population will be analyzed according to the treatment as randomized.

5.2 Per-protocol (PP) Efficacy analysis set

The PP set is defined as the ITT population, after exclusion of subjects deemed non-evaluable for efficacy due to major deviations from the protocol. Major deviations are divided into 4 categories:

- Entrance criteria deviations,
- Non-compliance,
- Concomitant therapies taken during the study and/or Concomitant illnesses, interfering with efficacy,
- Administrative errors such as unblinding or study drug dispensing errors.

Major deviations will be identified and categorized before database lock and unblinding, during a blind data review meeting.

5.3 Safety population

The Safety set is defined as comprising the ITT Population subjects who applied/were administered the study drug(s) at least once. In practice, only the subjects who return their study drug(s) unopened will be excluded from the Safety Population. All safety data will be summarized based on the Safety Population.

5.4 PK set

The PK set is defined as comprising all subjects from the safety set who have signed the ICF for PK samples and who provide at least one post-baseline evaluable drug concentration value. All PK data will be based on observed cases.

6 SAMPLE SIZE CONSIDERATION

In a previous Galderma R&D trial (SPR.18158) where a Vehicle was used in atopic dermatitis in subjects with involved BSA between 5% and 20%, the Vehicle percent change from Baseline at Week 4 of a modified EASI (No Head and Neck) was -40% and the standard deviation (SD) was 45%.

In studies evaluating Dupilumab versus placebo, the observed placebo EASI score percent changes from Baseline at Week 4 ranged from -17% to -25% with a SD around 40% (Beck 2014), and was - 18% at Week 16 with a standard deviation of 40% (Thaci 2016). In this last trial it was observed that these values were reached from week 4 onwards. Based on these historical data, the SD was set at 40%.

The magnitude of effect of Dupilumab reached 45% over placebo. However, systemic immunosuppressant drug for atopic dermatitis are generally more effective than topical treatments (Thaci 2016). Taking that into account, for CD5024 cream 0.3% applied once daily, an effect of 30% over its vehicle would be considered as clinically relevant. Consequently, the effect size (delta/sigma) has been set at 0.75 (30%/40%).

Using a randomization ratio of 1:1 for CD5024 cream 0.3% QD and vehicle, a sample size of 30 randomized subjects in each treatment group can ensure an 80% power to detect a difference of 30 % between CD5024 and its vehicle on EASI score mean percent change from Baseline.

7 STATISTICAL METHODS AND DATA CONSIDERATIONS

For statistical analyses purpose, baseline is defined as the last measurement prior to the first application of the study drug. This is true for all variables except NRS, for which baseline is the mean of the values collected from Day -3 to Day -1.

7.1 Study subjects

7.1.1 Disposition of subjects

Reasons for early discontinuation, and normal completions, will be summarized using frequency distribution (n, %).

7.1.2 Protocol deviations

Major protocol deviations will be summarized overall using frequency distribution (n, %).

7.2 Efficacy analysis

7.2.1 Data sets analyzed

Number of subjects included in each efficacy analyses (ITT, PP) and number of subjects included in the safety analysis will be presented by treatment.

7.2.2 Demographic and baseline characteristics

The subject demographics and baseline characteristics will be summarized by descriptive statistics.

- Frequency distribution (n, %), for qualitative criteria,
- Usual statistics (n, mean, standard deviation, median, min, max), for quantitative criteria,
- Both frequency distribution and usual statistics for ordinal criteria.

7.2.3 Medical history, previous and concomitant therapies and previous and concomitant procedures

Frequency distribution of subjects with at least one previous or/and concomitant disease at inclusion will be given.

Previous and Concomitant therapies will be descriptively summarized on the safety population. Previous and concomitant procedures will be summarized in the same way using MedDRA dictionary v19.0.

Therapies and procedures ongoing at the baseline visit or starting after the baseline visit will be summarized in concomitant therapies /procedures and those ending at baseline or before will be summarized in previous therapies / procedures.

7.2.4 Compliance

Non-Compliance is defined as subjects who have a deviation of more than 20% from the planned 42 applications (i.e. less than 34 applications or more than 50 applications).

7.2.5 Statistical analysis for efficacy

A type I error of 0.05 (two-sided test) will be used to declare statistical significance.

All efficacy variables will be summarized by treatment at each visit. The categorical variables (e.g. IGA), and their changes from Baseline will be summarized by frequency and percentage for each response category (N, %). The continuous variables (EASI, objective SCORAD, TSS, and their change or percent changes, Pruritus [weekly average NRS and the VRS] and their changes from Baseline) will be summarized using means, medians, Q1, Q3, minimum, maximum, and standard deviations.

The Primary efficacy endpoint, the change from Baseline to Week 6 of the EASI score, will be analyzed using an analysis of covariance (ANCOVA) with the Treatment group as factor and Analysis center as a cofactor and EASI score at baseline as a covariate. The p-value for the treatment comparison, estimate of the Least Square means (LSmeans) treatment difference (CD5024 – Vehicle), will be generated from the ANCOVA model.

The change from Baseline in EASI score at any other evaluation visit, will be analyzed using analysis of covariance with the Treatment group as factor, Analysis center as a cofactor and EASI score at baseline as a covariate. The p- value for the treatment comparison, estimate of the LSmeans treatment difference (CD5024 – Vehicle), will be generated from the ANCOVA model.

Percent change from Baseline in EASI score at each evaluation visit will be analyzed by a CMH test stratified by analysis center with the ridit transformation and the row mean score difference statistic (FREQ procedure from SAS).

Modified objective SCORAD and TSS least square mean percent change from Baseline at each evaluation visit, will be analyzed individually using analysis of variance with the Treatment group as factor and analysis center as a cofactor.

Distribution of individual scores and their changes from Baseline, will be analyzed at each evaluation visit using the Cochran-Mantel-Haenszel (CMH) test stratified by analysis center with the ridit transformation and the row mean score difference statistic (FREQ procedure from SAS).

Proportion of subjects achieving success (IGA=0 [clear] or IGA=1 [Almost clear]) will be analyzed at each evaluation visit using the CMH test stratified by analysis center with the ridit transformation and the general association statistic (FREQ procedure from SAS).

Change in Pruritus (Weekly average NRS based on at least 4 daily scores and the VRS) will be separately analyzed at each evaluation visit by the CMH test stratified by analysis center with the ridit transformation and the row mean difference statistic (FREQ procedure from SAS).

7.2.6 Statistical and analytical issues

7.2.6.1 Adjustment for covariates

NA.

7.2.6.2 Handling of dropouts or missing data

For the primary endpoint (change from Baseline in EASI score) several sensitivity analyses will be conducted in ITT population:

- The primary imputation method will use the LOCF (Last observation carried forward) approach.
- For sensitivity purpose, the method of imputation for missing data will be MI (Multiple Imputation) using the Missing At Random (MAR) assumption. The MI procedure of the SAS system will be used to generate five sets of data with missing values imputed from observed data. It is expected that the pattern of missing data will be monotonic, with slight deviations being corrected by the Markov Chain Monte Carlo (MCMC) method of the MI procedure. Linear regression will be employed to model the missing EASI score, with the following covariates included in the imputation model: treatment and non-missing data from earlier timepoints. The imputed datasets will be analyzed using the methodology described for change from Baseline in EASI score. The results from the analysis of the multiple imputed datasets will be combined by the MIANALYZE procedure of the SAS system. The seed number to be used will be the protocol number (109696).

For secondary endpoints the LOCF method will be used.

7.2.6.3 Interim analyses and data monitoring

NA

7.2.6.4 Multicenter studies

Analysis center will be defined during the blind review meeting and will be included as a cofactor in the inferential analyses of primary and secondary endpoints.

7.2.6.5 Multiple comparison/multiplicity

The primary purpose is to compare CD5024 cream 0.3% QD daily to its vehicle in terms of EASI score. P-values for secondary criteria will be given for indicative purposes, so no adjustment will be made. All tests will be two-sided and significance will be declared at a 5% two-sided level.

7.2.6.6 Use of a subset of patients

The protocol deviations will be identified during the blind review, and some of them will lead to the exclusion of the subjects from the PP analyses. PP analyses will be performed on primary and secondary endpoints.

7.2.6.7 Active-Control studies intended to show equivalence

NA.

7.2.6.8 Examination of Subgroups

Subgroup analyses will be explored by IgE on the primary endpoint. A threshold will be defined during the blind review.

7.3 Safety analysis

7.3.1 Extent of exposure

7.3.1.1 Treatment duration

Treatment duration will be calculated as the difference in days between the date of last application of medication and the date of first use + 1 during Period A. Date of last visit under treatment will be used if the date of last use is not available.

7.3.1.2 Quantity of product used

All collected and weighed packaging of product will be used to determine the quantity of product used per subject. Total Medication usage (g) and Daily medication usage (g/day) will be summarized by descriptive statistics. The variables will be derived by the following:

- Total medication used = total dispensed weight (g) - total returned weight (g)
- Daily medication used = total medication used (g) / treatment duration (day)

As the subject will be instructed by a member of the staff on how to measure the prescribed dose using fingertip units (FTU), FTU will be summarized the same way as the medication used, Total and Daily FTU.

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7.3.3 Laboratory parameters

For each parameter, shift tables presenting: pre-treatment (the value obtained closest and prior to the first application, in case of retest) versus Day 22 and Day 43/Early termination (last post-baseline value on treatment) will be generated. The number and percentage of subjects below, within, and above the laboratory reference ranges will be summarized. The percentage will be based on the number of subjects with data available for both pre-treatment and post-treatment.

Descriptive statistics (n, mean, min, max and median) will be performed for pre-treatment value, Day 22 and Day 43/Early termination. Change from baseline to Day 22 and to Day 43/Early termination value will also be summarized.

The maximal value will be imputed for any laboratory values below the limit of quantification (e.g. "X" will be used for "<X").

In case a parameter would a value '>X' no imputation will be made and no mean and standard deviation will be output as for IgE and Creatinine Clearance. For Creatinine Clearance the analysis will be summarized in categories:

Creatinine Clearance
> 90 mL/min/1.73m²
60-89 mL/min/1.73m²
30-59 mL/min/1.73m²
15-29 mL/min/1.73m²
<15 mL/min/1.73m²

7.3.4 Vital signs, physical findings and other observations related to safety

Vital signs, physical examination and ECG will be descriptively summarized.

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7.5 Analysis visit definition

If multiple measurements are taken in the same interval, the one closest to the target study day will be used for the analysis. If two measurements are taken with equal differences in timing compared with the target date, the nominal visit number (recorded on the CRF page) will be used. Analysis visit will apply to the summaries and analyses of all efficacy variables.

Analysis Visit	Analysis Visit number	Target Study Day	Visit Window (Study Day)
Baseline	Baseline	1	[≤ 1]
Week 1	Week 1	8	[2 – 11]
Week 2	Week 2	15	[12 – 18]
Week 3	Week 3	22	[19 – 25]
Week 4	Week 4	29	[26 – 32]
Week 5	Week 5	36	[33 – 39]
Week 6	Week 6	43	[40 - 46]

8 CHANGES FROM THE PROTOCOL ANALYSIS PLAN

The initial analysis plan was to perform an ANOVA on the percent change from baseline to week 6 in EASI score, but one observation appears to deviate markedly from others (200% increase of the EASI score). This outlier skews the distribution and for the intended analysis (ANOVA) increases the residual error and thus makes the statistical test less powerful and less appropriate.

Then, the change from Baseline in EASI score at Week 6 will be the primary endpoint and will be analyzed via an ANCOVA with treatment as factor, analysis center as a cofactor and EASI at Baseline as covariate. This analysis will be conducted on ITT-LOCF, ITT-MI and PP population.

Percent change from baseline at any scheduled visits will be secondary and will be analyzed via a CMH test using RIDIT transformation and row mean score statistics. This analysis will be conducted on ITT-LOCF and PP population.

9 TABLES, FIGURES, AND GRAPHS

9.1 Study subject

Table 9.1.1 Enrolment by country and investigator

	CD5024	Vehicle
Overall	xx	xx
5xxx-PR. XXX	xx	xx
5yyy-PR. YYY	xx	xx
….		

Table 9.1.2 Reason for discontinuation

	CD5024	Vehicle
N (%)	xx	xx
Normal Completion	xx (x.xx%)	xx (x.xx%)
Adverse Event	xx (x.xx%)	xx (x.xx%)
Subject's Request	xx (x.xx%)	xx (x.xx%)
Lost to Follow-up	xx (x.xx%)	xx (x.xx%)
Other	xx (x.xx%)	xx (x.xx%)
…		

Table 9.1.3 Demographic data

		CD5024	Vehicle
N		xx	xx
Gender	Female	xx(xx.x%)	xx(xx.x%)
	Male	xx(xx.x%)	xx(xx.x%)
Race	White	xx(xx.x%)	xx(xx.x%)
	…	xx(xx.x%)	xx(xx.x%)
Age (in Years)	Mean±SD	xx.x (xx.x)	xx.x (xx.x)
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx

Table 9.1.4 Baseline disease characteristics

		CD5024	Vehicle
IGA	**N**	xx	xx
	0-Clear	xx (xx.x%)	xx(xx.x%)
	1-Almost Clear	xx (xx.x%)	xx(xx.x%)
	2-Mild	xx (xx.x%)	xx(xx.x%)
	3-Moderate	xx (xx.x%)	xx(xx.x%)
	4-Severe	xx (xx.x%)	xx(xx.x%)
Hand IGA	**N**	xx	xx
	0-Clear	xx (xx.x%)	xx(xx.x%)
	1-Almost Clear	xx (xx.x%)	xx(xx.x%)
	2-Mild	xx (xx.x%)	xx(xx.x%)
	3-Moderate	xx (xx.x%)	xx(xx.x%)
	4-Severe	xx (xx.x%)	xx(xx.x%)
tBSA	**N**	xx	xx
	Mean±SD	xx.x (xx.x)	xx.x (xx.x)
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx
BSA affected	**N**	xx	xx
	Mean±SD	xx.x (xx.x)	xx.x (xx.x)
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx
EASI	**N**	xx	xx
	Mean±SD	xx.x (xx.x)	xx.x (xx.x)
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx

		CD5024	Vehicle
Modified SCORAD	**N**	xx	xx
	Mean±SD	xx.x (xx.x)	xx.x (xx.x)
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx
VRS	**N**	xx	xx
	Mean±SD	xx.x (xx.x)	xx.x (xx.x)
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx
NRS	**N**	xx	xx
	Mean±SD	xx.x (xx.x)	xx.x (xx.x)
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx
TSS	**N**	xx	xx
	Mean±SD	xx.x (xx.x)	xx.x (xx.x)
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx
Erythema	**N**	xx	xx
	0-Clear	xx (xx.x%)	xx (xx.x%)
	1-Almost Clear	xx (xx.x%)	xx (xx.x%)
	2-Mild	xx (xx.x%)	xx (xx.x%)
	3-Moderate	xx (xx.x%)	xx (xx.x%)
	4-Severe	xx (xx.x%)	xx (xx.x%)
Induration / Papulation	**N**	xx	xx
	0-Clear	xx (xx.x%)	xx (xx.x%)
	1-Almost Clear	xx (xx.x%)	xx (xx.x%)
	2-Mild	xx (xx.x%)	xx (xx.x%)
	3-Moderate	xx (xx.x%)	xx (xx.x%)
	4-Severe	xx (xx.x%)	xx (xx.x%)
Oozing / Crusting	**N**	xx	xx
	0-Clear	xx (xx.x%)	xx (xx.x%)
	1-Almost Clear	xx (xx.x%)	xx (xx.x%)
	2-Mild	xx (xx.x%)	xx (xx.x%)
	3-Moderate	xx (xx.x%)	xx (xx.x%)
	4-Severe	xx (xx.x%)	xx (xx.x%)
Excoriation	**N**	xx	xx
	0-Clear	xx (xx.x%)	xx (xx.x%)
	1-Almost Clear	xx (xx.x%)	xx (xx.x%)
	2-Mild	xx (xx.x%)	xx (xx.x%)
	3-Moderate	xx (xx.x%)	xx (xx.x%)
	4-Severe	xx (xx.x%)	xx (xx.x%)

		CD5024	Vehicle
Lichenification	**N**	xx	xx
	0-Clear	xx (xx.x%)	xx (xx.x%)
	1-Almost Clear	xx (xx.x%)	xx (xx.x%)
	2-Mild	xx (xx.x%)	xx (xx.x%)
	3-Moderate	xx (xx.x%)	xx (xx.x%)
	4-Severe	xx (xx.x%)	xx (xx.x%)

Table 9.1.5 Dataset analyzed

	CD5024	Vehicle	Total
Screened subjects	-	-	xx
ITT population	xx (x.xx%)	xx (x.xx%)	xx (x.xx%)
PP population	xx (x.xx%)	xx (x.xx%)	xx (x.xx%)
Safety population	xx (x.xx%)	xx (x.xx%)	xx (x.xx%)
PK set	xx (x.xx%)	xx (x.xx%)	xx (x.xx%)

Table 9.1.6 Medical history

		CD5024	Vehicle
Medical History	**N (%)**	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)

Table 9.1.7 Previous therapies

	CD5024			Vehicle		
	n therapies	n subjects	% subj.	n therapies	n subjects	% subj.
Subjects with at least one previous therapy*	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
ATC Text#1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
ATC Text#2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
ATC Text#3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
ATC Text#x…..	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
…..	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

*Multiple reports by each subject are possible

Table 9.1.8 Concomitant therapies

	CD5024			Vehicle		
	n therapies	n subjects	% subj.	n therapies	n subjects	% subj.
Subjects with at least one concomitant therapy*	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
ATC Text#1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
ATC Text#2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
ATC Text#3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
ATC Text#x…..	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
…..	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

*Multiple reports by each subject are possible

Table 9.1.9 Summary of Previous Procedures and Non-Drug Therapies

	CD5024			Vehicle		
	n procedures	n subjects	% subj.	n procedures	n subjects	% subj.
Subjects with at least one previous procedures and non drug therapy*	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SOC#1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SOC#2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SOC#3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SOC #x…..	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
…..	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

*Multiple reports by each subject are possible

Table 9.1.10 Summary of concomitant Procedures and Non-Drug Therapies

	CD5024			Vehicle		
	n procedures	n subjects	% subj.	n procedures	n subjects	% subj.
Subjects with at least one concomitant procedures and non drug therapy*	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SOC#1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SOC#2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SOC#3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #1	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #2	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Preferred term #3	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SOC #x…..	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
…..	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

*Multiple reports by each subject are possible

Table 9.1.11 Subject with major protocol deviations

	CD5024		Vehicle	
	N subj.*	% subj	N subj.*	% subj
AT LEAST ONE MAJOR DEVIATION*	xx	xx.x	xx	xx.x
entrance criteria deviations (at baseline)	x	x.x	x	x.x
concomitant therapies taken during the study	x	x.x	x	x.x
….	x	x.x	x	x.x

* Subjects with at least one major deviation
Numbers in columns cannot be added because a given subject may have reported more than one deviation

Table 9.1.12 Compliance

	CD5024		Vehicle	
	N subj.*	% subj	N subj.*	% subj
<34 applications	x	x.x	x	x.x
34 to 50 applications	x	x.x	x	x.x
>50 applications	x	x.x	x	x.x

9.2 Efficacy analysis

9.2.1 Primary efficacy endpoint

Table 9.2.1.1 Descriptive results of the change from baseline in EASI score at each timepoint – ITT-LOCF

		CD5024		Vehicle	
		Raw Data	Change from baseline	Raw Data	Change from baseline
Baseline	N	xx		xx	
	Mean±SD	xx.x ±xx		xx.x ±xx	
	Median	xx		xx	
	Min;Max	xx ; xx		xx ; xx	
	Q1;Q3	xx ; xx		xx ; xx	
Day 8-LOCF	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 15-LOCF	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 22-LOCF	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 29-LOCF	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx

		CD5024		Vehicle	
		Raw Data	Change from baseline	Raw Data	Change from baseline
Day 36-LOCF	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 43-LOCF	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx

Table 9.2.1.2 Statistical analysis of the change from baseline in score EASI at each timepoint – ITT-LOCF

		CD5024	Vehicle	CD5024- Vehicle
Baseline	N	xx	xx	-
	Mean	xx	xx	xx
	SD	xx	xx	xx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 8-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 15-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 22-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx

		CD5024	Vehicle	CD5024- Vehicle
Day 29-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 36-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 43-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx

(1) p-values from the ANCOVA model include treatment, analysis center and baseline EASI scores

Table 9.2.1.3 Statistical analysis of the change from baseline in score EASI at each timepoint – ITT-MI

		CD5024	Vehicle	CD5024- Vehicle
Baseline	N	xx	xx	-
	Mean	xx	xx	xx
	SD	xx	xx	xx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 8-MI	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 15-MI	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx

		CD5024	Vehicle	CD5024- Vehicle
Day 22-MI	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 29-MI	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 36-MI	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 43-MI	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx

(1) p-values from the ANCOVA model include treatment, analysis center and baselineEASI scores

Table 9.2.1.4 Descriptive results of the change from baseline in EASI score at each timepoint – PP population

		CD5024		Vehicle	
		Raw Data	Change from baseline	Raw Data	Change from baseline
Baseline	N	xx		xx	
	Mean±SD	xx.x ±xx		xx.x ±xx	
	Median	xx		xx	
	Min;Max	xx ; xx		xx ; xx	
	Q1;Q3	xx ; xx		xx ; xx	
Day 8-PP	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 15-PP	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 22-PP	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 29-PP	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 36-PP	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 43-LOCF	N	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx

Table 9.2.1.5 Statistical analysis of the change from baseline EASI at each timepoint – PP population

		CD5024	Vehicle	CD5024- Vehicle
Baseline	N	xx	xx	-
	Mean	xx	xx	xx
	SD	xx	xx	xx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 8-PP	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 15-PP	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 22-PP	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 29-PP	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx

		CD5024	Vehicle	CD5024- Vehicle
Day 36-PP	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 43-PP	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx

(1) p-values from the ANCOVA model include treatment, analysis center and baseline EASI scores

Table 9.2.1.6 Statistical Analysis of the percent change from baseline in EASI score at each timepoint – ITT-LOCF

		CD5024		Vehicle		p-value
		Raw Data	Percent change from baseline	Raw Data	Change from baseline	
Baseline	N	xx		xx		
	Mean±SD	xx.x ±xx		xx.x ±xx		
	Median	xx		xx		-
	Min;Max	xx ; xx		xx ; xx		
	Q1;Q3	xx ; xx		xx ; xx		
Day 8-LOCF	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Day 15-LOCF	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Day 22-LOCF	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	

		CD5024		Vehicle		p-value
		Raw Data	Percent change from baseline	Raw Data	Change from baseline	
Day 29-LOCF	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Day 36-LOCF	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Day 43-LOCF	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	

(1) p-values based on CMH test stratified by analysis center

Table 9.2.1.7 Statistical Analysis results of the percent change from baseline in EASI score at each timepoint – PP

		CD5024		Vehicle		p-value
		Raw Data	Percent change from baseline	Raw Data	Change from baseline	
Baseline	N	xx		xx		
	Mean±SD	xx.x ±xx		xx.x ±xx		
	Median	xx		xx		-
	Min;Max	xx ; xx		xx ; xx		
	Q1;Q3	xx ; xx		xx ; xx		
Day 8-PP	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Day 15-PP	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	

		CD5024		Vehicle		p-value
		Raw Data	Percent change from baseline	Raw Data	Change from baseline	
Day 22-PP	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Day 29-PP	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Day 36-PP	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Day 43-PP	N	xx	xx	xx	xx	
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	0.xxx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	

(1) p-values based on CMH test stratified by analysis center

9.2.2 Secondary efficacy endpoints

Table 9.2.2.1 Distribution of Investigator Global Assessment by visit –ITT LOCF

		CD5024	Vehicle	p-value
Baseline	N (%)	xx	xx	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
Day 8-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 15-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 22-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 29-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 36-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 43-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	

(1) p-values based on CMH test stratified by analysis center

Table 9.2.2.2 Distribution of Investigator Global Assessment by visit – PP

		CD5024	Vehicle	p-value
Baseline	N (%)	xx	xx	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
Day 8	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 15	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 22	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 29	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 36	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 43	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	

(1) p-values based on CMH test stratified by analysis center

Table 9.2.2.3 Summary of IGA Success - ITT LOCF

		CD5024	Vehicle	p-value
Baseline	N (%)	xx	xx	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
Day 8	N (%)	xx	xx	0.xxx
	Success	xx (xx.x%)	xx (xx.x%)	
	Failure	xx (xx.x%)	xx (xx.x%)	
Day 15	N (%)	xx	xx	0.xxx
	Success	xx (xx.x%)	xx (xx.x%)	
	Failure	xx (xx.x%)	xx (xx.x%)	
Day 22	N (%)	xx	xx	0.xxx
	Success	xx (xx.x%)	xx (xx.x%)	
	Failure	xx (xx.x%)	xx (xx.x%)	
Day 29	N (%)	xx	xx	0.xxx
	Success	xx (xx.x%)	xx (xx.x%)	
	Failure	xx (xx.x%)	xx (xx.x%)	
Day 36	N (%)	xx	xx	0.xxx
	Success	xx (xx.x%)	xx (xx.x%)	
	Failure	xx (xx.x%)	xx (xx.x%)	
Day 43	N (%)	xx	xx	0.xxx
	Success	xx (xx.x%)	xx (xx.x%)	
	Failure	xx (xx.x%)	xx (xx.x%)	

(1) p-values based on CMH test stratified by analysis center

Table 9.2.2.4 Summary of IGA Success - PP

Table 9.2.2.5 Distribution of the Hand Investigator Global Assessment by visit –ITT LOCF

Same as for IGA

Table 9.2.2.6 Distribution of the Hand Investigator Global Assessment by visit –PP

Same as for IGA

Table 9.2.2.7 Descriptive results of the TSS at each timepoint – ITT-LOCF

		CD5024			Vehicle		
		Raw Data	Change from baseline	Percent change from baseline	Raw Data	Change from baseline	Percent change from baseline
Baseline	N	xx			xx		
	Mean±SD	xx.x ±xx			xx.x ±xx		
	Median	xx			xx		
	Min;Max	xx ; xx			xx ; xx		
	Q1;Q3	xx ; xx			xx ; xx		
Day 8-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 15-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 22-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 29-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 36-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 43-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx

Table 9.2.2.8 Statistical analysis of the percent change from baseline of the TSS at each timepoint – ITT-LOCF

		CD5024	Vehicle	CD5024- Vehicle
Baseline	N	xx	xx	-
	Mean	xx	xx	xx
	SD	xx	xx	xx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 8-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 15-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 22-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 29-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 36-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx

		CD5024	Vehicle	CD5024- Vehicle
Day 43-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx

(1) p-values from the ANOVA model including treatment and analysis center effects

Table 9.2.2.9 Descriptive results of the TSS at each timepoint – PP population

Table 9.2.2.10 Statistical analysis of the percent change from baseline of the TSS at each timepoint – PP

Table 9.2.2.11 Descriptive results of the Modified Objective SCORAD at each timepoint – ITT population

		CD5024			Vehicle		
		Raw Data	Change from baseline	Percent change from baseline	Raw Data	Change from baseline	Percent change from baseline
Baseline	N	xx			xx		
	Mean±SD	xx.x ±xx			xx.x ±xx		
	Median	xx			xx		
	Min;Max	xx ; xx			xx ; xx		
	Q1;Q3	xx ; xx			xx ; xx		
Day 8-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 15-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 22-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx

		CD5024			Vehicle		
		Raw Data	Change from baseline	Percent change from baseline	Raw Data	Change from baseline	Percent change from baseline
Day 29-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 36-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 43-LOCF	N	xx	xx	xx	xx	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx

Table 9.2.2.12 Statistical analysis of the percent change from baseline of the Modified Objective SCORAD at each timepoint – ITT-LOCF

		CD5024	Vehicle	CD5024- Vehicle
Baseline	N	xx	xx	-
	Mean	xx	xx	xx
	SD	xx	xx	xx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 8-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 15-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx

		CD5024	Vehicle	CD5024- Vehicle
Day 22-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 29-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 36-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx
Day 43-LOCF	N	xx	xx	-
	LS-Mean	xx	xx	xx
	SE	xx	xx	xx
	p-value (1)	xx	xx	0.xxx
	Lower bound 95%CI	xx	xx	xx
	Upper bound 95%CI	xx	xx	xx

(1) p-values from the ANOVA model including treatment and analysis center effects

Table 9.2.2.13 Descriptive results of the Modified Objective SCORAD at each timepoint – PP population

Table 9.2.2.14 Statistical analysis of the percent change from baseline of the Modified Objective SCORAD at each timepoint – PP

Table 9.2.2.15 Distribution of Erythema score by visit –ITT LOCF

		CD5024	Vehicle	p-value
Baseline	N (%)	xx	xx	
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 8-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 15-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 22-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 29-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 36-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	
Day 43-LOCF	N (%)	xx	xx	0.xxx
	0-Clear	xx (xx.x%)	xx (xx.x%)	
	1-Almost clear	xx (xx.x%)	xx (xx.x%)	
	2-Mild	xx (xx.x%)	xx (xx.x%)	
	3-Moderate	xx (xx.x%)	xx (xx.x%)	
	4-Severe	xx (xx.x%)	xx (xx.x%)	

(1) p-values based on CMH test stratified by analysis center, for the change from baseline

Table 9.2.2.16 Distribution of Erythema score by visit – PP

Table 9.2.2.17 Distribution of Induration/Papulation score by visit – ITT LOCF

Table 9.2.2.18 Distribution of Induration/Papulation score by visit – PP

Table 9.2.2.19 Distribution of Oozing/Crusting score by visit – ITT LOCF

Table 9.2.2.20 Distribution of Oozing/Crusting score by visit – PP

Table 9.2.2.21 Distribution of Excoriation score by visit – ITT LOCF

Table 9.2.2.22 Distribution of Excoriation score by visit – PP

Table 9.2.2.23 Distribution of Lichenification score by visit – ITT LOCF

Table 9.2.2.24 Distribution of Lichenification score by visit – PP

Table 9.2.2.25 Descriptive results of the weekly average NRS at each timepoint – ITT population

		CD5024		Vehicle		p-value(1)
		Raw Data	Change from baseline	Raw Data	Change from baseline	
Baseline	N	xx		xx		
	Mean±SD	xx.x ±xx		xx.x ±xx		
	Median	xx		xx		
	Min;Max	xx ; xx		xx ; xx		
	Q1;Q3	xx ; xx		xx ; xx		
Week 1 - LOCF	N	xx	xx	xx	xx	0.xxx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Week 2-LOCF	N	xx	xx	xx	xx	0.xxx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Week 3 -LOCF	N	xx	xx	xx	xx	0.xxx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Week 4 -LOCF	N	xx	xx	xx	xx	0.xxx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Week 5 -LOCF	N	xx	xx	xx	xx	0.xxx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
Week 6 -LOCF	N	xx	xx	xx	xx	0.xxx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	

(1) p-values based on CMH test stratified by analysis center Baseline is the mean of the values collected from Day -1 to Day -3

Table 9.2.2.26 Descriptive results of the weekly average NRS at each timepoint – PP population

Table 9.2.2.27 Descriptive results of the VRS at each timepoint – ITT population

		CD5024		Vehicle		p-value(1)
		Raw Data	Change from baseline	Raw Data	Change from baseline	
Baseline	N	xx		xx		
	Mean±SD	xx.x ±xx		xx.x ±xx		
	Median	xx		xx		
	Min;Max	xx ; xx		xx ; xx		
	Q1;Q3	xx ; xx		xx ; xx		
Day 43 -LOCF	N	xx	xx	xx	xx	0.xxx
	Mean±SD	xx.x ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx	
	Median	xx	xx	xx	xx	
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	

(1) p-values based on CMH test stratified by analysis center

Table 9.2.2.28 Descriptive results of the VRS at each timepoint – PP population

9.2.3 Subgroup analyses

Table 9.2.3.1 Descriptive results of EASI at each timepoint broken down by IgE– ITT population

		IgE<X						IgE>=X					
		CD5024			Vehicle			CD5024			Vehicle		
		Raw Data	Change from baseline	Percent change from baseline	Raw Data	Change from baseline	Percent change from baseline	Raw Data	Change from baseline	Percent change from baseline	Raw Data	Change from baseline	Percent change from baseline
Baseline	N	xx		xx							xx		
	Mean±SD	xx.x ±xx		xx.x ±xx							xx.x ±xx		
	Median	xx		xx							xx		
	Min;Max	xx ; xx		xx ; xx							xx ; xx		
	Q1;Q3	xx ; xx		xx ; xx							xx ; xx		
Day 8-LOCF	N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean±SD	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 ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 15-LOCF	N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean±SD	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 ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 22-LOCF	N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean±SD	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 ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx

		IgE<X						IgE>=X					
		CD5024			Vehicle			CD5024			Vehicle		
Day 29-LOCF	N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean±SD	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 ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ;	xx ; xx	xx ; xx	xx ;	xx ; xx	xx ; xx	xx ;	xx ; xx	xx ; xx	xx ;	xx ; xx	xx ; xx
		xx			xx			xx			xx		
Day 36-LOCF	N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean±SD	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 ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
Day 43-LOCF	N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Mean±SD	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 ±xx	xx.x ±xx	xx.x ±xx	xx.x ±xx
	Median	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Min;Max	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx
	Q1;Q3	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx	xx ; xx

9.3 Safety analysis

9.3.1 Extent of exposure

Table 9.3.1.1 Treatment applications- Safety population

		CD5024	Vehicle
Treatment duration (in days)	N	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx

Table 9.3.1.2 Quantity of product used (g)

		CD5024	Vehicle
Total medication used (g)	N	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx
Daily medication used (g/day)	N	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx

Table 9.3.1.3 Quantity of product applied in Fingertips unit (FTU)

		CD5024	Vehicle
Total number of fingertips (FTU)	N	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx
Daily fingertips (FTU/day)	N	xx	xx
	Mean±SD	xx.x ±xx	xx.x ±xx
	Median	xx	xx
	Min;Max	xx ; xx	xx ; xx

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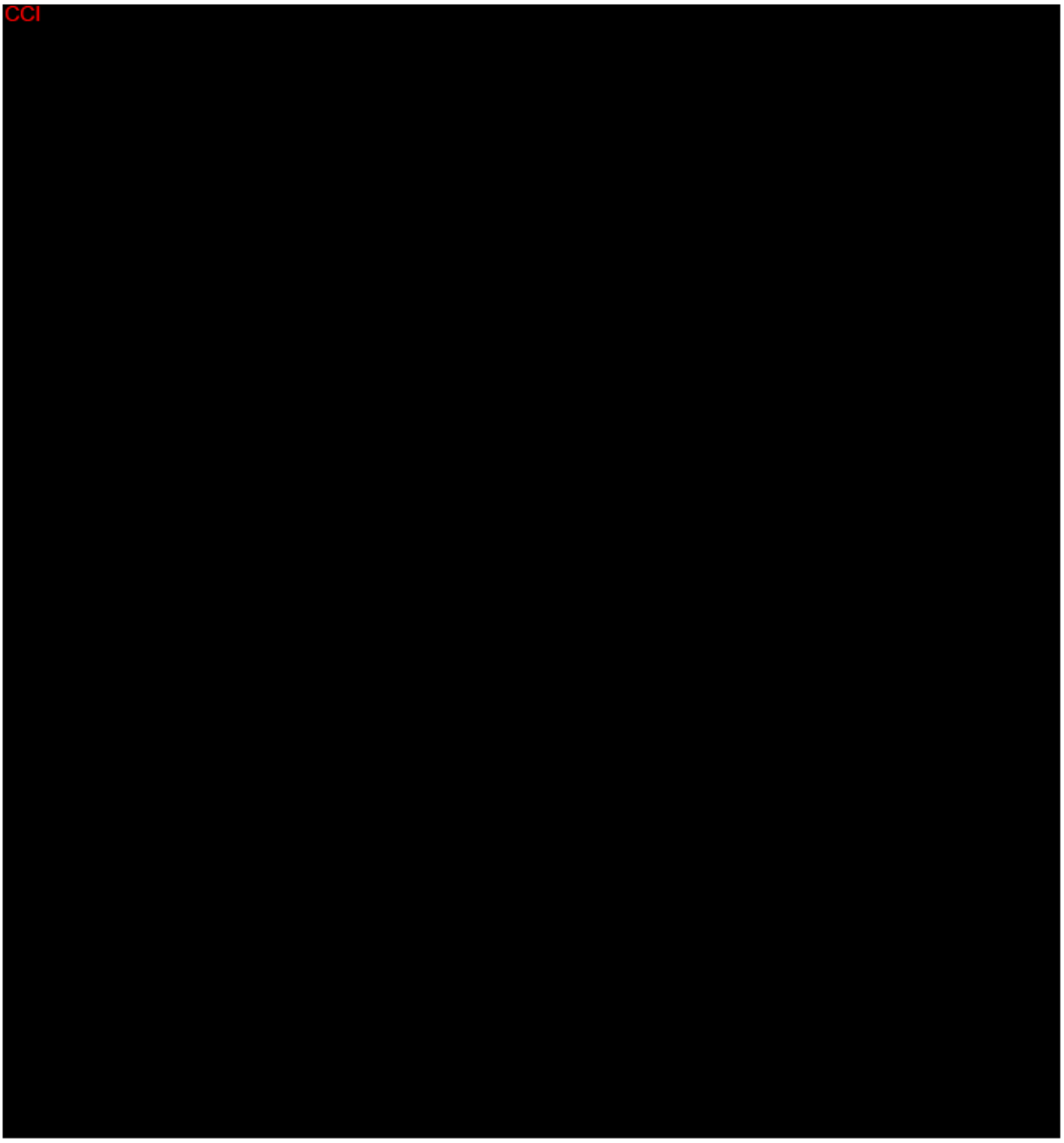

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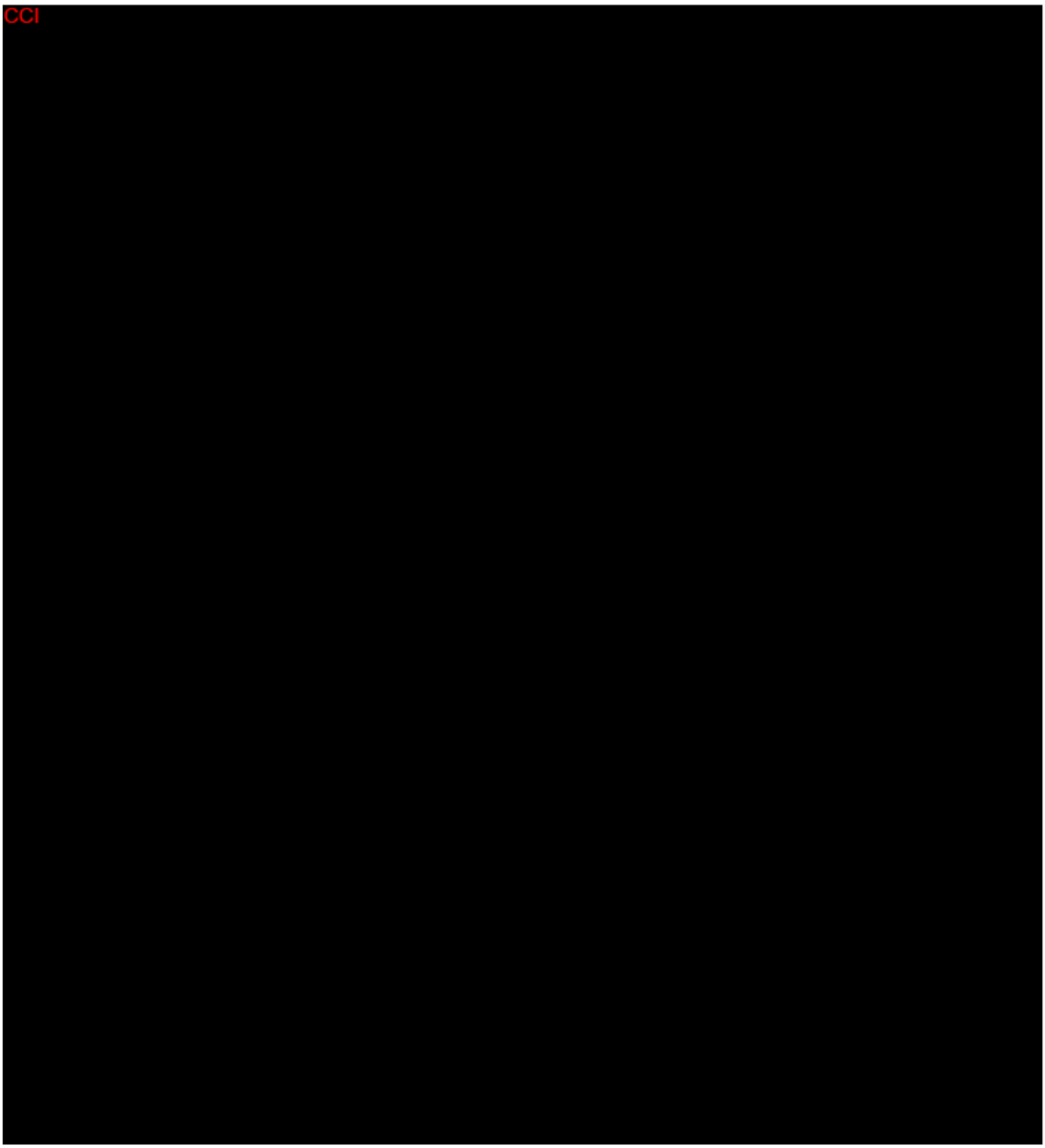

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9.3.3 Laboratory parameters

9.3.3.1 Blood chemistry

Table 9.3.3.1.1 Blood chemistry shift table

			Baseline							
			CD5024				Vehicle			
			Low	Normal	High	Missing	Low	Normal	High	Missing
Day 22	Parameter#1	Low	-	x (x.x)	-	-	-	-	-	-
		Normal	-	x (x.x)	-	-	-	x (x.x)	-	-
		High	-	x (x.x)	-	-	-	x (x.x)	-	-
		Missing	-	-	-	-	-	x (x.x)	-	-
	Parameter#2	Low	-	x (x.x)	-	-	-	x (x.x)	-	-
		Normal	-	x (x.x)	-	-	-	x (x.x)	-	-
		High	-	x (x.x)	-	-	-	x (x.x)	-	-
		Missing	-	-	-	-	-	-	-	-
	...	...								
Day 43/early Termination	Parameter#1	Low	-	-	-	-	-	-	-	-
		Normal	-	x (x.x)	-	-	-	x (x.x)	-	-
		High	-	x (x.x)	-	-	-	x (x.x)	-	-
		Missing	-	x (x.x)	-	-	-	x (x.x)	-	-
	Parameter#2	Low	-	x (x.x)	-	-	-	x (x.x)	-	-
		Normal	-	x (x.x)	-	-	-	x (x.x)	-	-
		High	-	x (x.x)	-	-	-	x (x.x)	-	-
		Missing	-	-	-	-	-	-	-	-
	...	...			-	-	-		-	-

Table 9.3.3.1.2 Blood chemistry parameter over time

			CD5024		Vehicle	
			Raw data	Change	Raw data	Change
Parameter# 1	Baseline	N	xx		xx	
		Mean±SD	x.xx±x.xx		x.xx±x.xx	
		Median	x.xx		x.xx	
		Min;Max	x.xx;x.xx		x.xx;x.xx	
	Day 22	N	xx	xx	xx	xx
		Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
		Median	x.xx	x.xx	x.xx	x.xx
		Min;Max	x.xx;x.xx	-x.xx;x.xx	x.xx;x.xx	-x.xx;x.xx
	Day 43 / Early Termination	N	xx	xx	xx	xx
		Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
		Median	x.xx	x.xx	x.xx	x.xx
		Min;Max	x.xx;x.xx	-x.xx;x.xx	x.xx;x.xx	-x.xx;x.xx
Parameter# 2	Baseline	N	xx		xx	
		Mean±SD	x.xx±x.xx		x.xx±x.xx	
		Median	x.xx		x.xx	
		Min;Max	x.xx;x.xx		x.xx;x.xx	
	Day 22	N	xx	xx	xx	xx
		Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
		Median	x.xx	x.xx	x.xx	x.xx
		Min;Max	x.xx;x.xx	-x.xx;x.xx	x.xx;x.xx	-x.xx;x.xx
	Day 43 / Early Termination	N	xx	xx	xx	xx
		Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
		Median	x.xx	x.xx	x.xx	x.xx
		Min;Max	x.xx;x.xx	-x.xx;x.xx	x.xx;x.xx	-x.xx;x.xx

9.3.3.2 Hematology

Table 9.3.3.2.1 Hematology shift table

			Baseline							
			CD5024				Vehicle			
			Low	Normal	High	Missing	Low	Normal	High	Missing
Day 22	Parameter#1 (unit)	Low	-	x (x.x)	-	-	-	x (x.x)	-	-
		Normal	-	x (x.x)	-	-	-	x (x.x)	-	-
		High	-	x (x.x)	-	-	-	x (x.x)	-	-
		Missing	-	-	-	-	-		-	-
	Parameter#2 (unit)	Low	-	x (x.x)	-	-	-	x (x.x)	-	-
		Normal	-	x (x.x)	-	-	-	x (x.x)	-	-
		High	-	x (x.x)	-	-	-	x (x.x)	-	-
		Missing	-	-	-	-	-	-	-	-
	…	…								
Day 43/Early Termination	Parameter#1 (unit)	Low	-	-x (x.x)	-	-	-	x (x.x)	-	-
		Normal	-	x (x.x)	-	-	-	x (x.x)	-	-
		High	-	x (x.x)	-	-	-	x (x.x)	-	-
		Missing	-		-	-	-		-	-
	Parameter#2 (unit)	Low	-	x (x.x)	-	-	-	x (x.x)	-	-
		Normal	-	x (x.x)	-	-	-	x (x.x)	-	-
		High	-	x (x.x)	-	-	-	x (x.x)	-	-
		Missing	-	-	-	-	-	-	-	-
	…	…			-	-	-		-	-

Table 9.3.3.2.2 Descriptive analysis for Creatinine Clearance

		CD5024	Vehicle
Baseline	> 90 mL/min/1.73m²	x (x.x)	x (x.x)
	60-89 mL/min/1.73m²	x (x.x)	x (x.x)
	30-59 mL/min/1.73m²	x (x.x)	x (x.x)
	15-29 mL/min/1.73m²	x (x.x)	x (x.x)
	<15 mL/min/1.73m²	x (x.x)	x (x.x)
Day 22	> 90 mL/min/1.73m²	x (x.x)	x (x.x)
	60-89 mL/min/1.73m²	x (x.x)	x (x.x)
	30-59 mL/min/1.73m²	x (x.x)	x (x.x)
	15-29 mL/min/1.73m²	x (x.x)	x (x.x)
	<15 mL/min/1.73m²	x (x.x)	x (x.x)
Day 43/Early Termination	> 90 mL/min/1.73m²	x (x.x)	x (x.x)
	60-89 mL/min/1.73m²	x (x.x)	x (x.x)
	…		

Table 9.3.3.2.3 Hematology parameter over time

			CD5024		Vehicle	
			Raw data	Change	Raw data	Change
Parameter#1	Baseline	N	xx		xx	
		Mean±SD	x.xx±x.xx		x.xx±x.xx	
		Median	x.xx		x.xx	
		Min;Max	x.xx;x.xx		x.xx;x.xx	
	Day 22	N	xx	xx	xx	xx
		Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
		Median	x.xx	x.xx	x.xx	x.xx
		Min;Max	x.xx;x.xx	-x.xx;x.xx	x.xx;x.xx	-x.xx;x.xx
	Day 43 / Early Termination	N	xx	xx	xx	xx
		Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
		Median	x.xx	x.xx	x.xx	x.xx
		Min;Max	x.xx;x.xx	-x.xx;x.xx	x.xx;x.xx	-x.xx;x.xx

			CD5024		Vehicle	
			Raw data	Change	Raw data	Change
Parameter#2	Baseline	N	xx		xx	
		Mean±SD	x.xx±x.xx		x.xx±x.xx	
		Median	x.xx		x.xx	
		Min;Max	x.xx;x.xx		x.xx;x.xx	
	Day 22	N	xx	xx	xx	xx
		Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
		Median	x.xx	x.xx	x.xx	x.xx
		Min;Max	x.xx;x.xx	-x.xx;x.xx	x.xx;x.xx	-x.xx;x.xx
	Day 43 / Early Termination	N	xx	xx	xx	xx
		Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
		Median	x.xx	x.xx	x.xx	x.xx
		Min;Max	x.xx;x.xx	-x.xx;x.xx	x.xx;x.xx	-x.xx;x.xx

9.3.3.3 Coagulation

Table 9.3.3.3.1 Coagulation shift table

			Baseline							
			CD5024				Vehicle			
			Low	Normal	High	Missing	Low	Normal	High	Missing
Day 22	Prothrombin Ratio	Low	-	x (x.x)	-	-	-	x (x.x)	-	-
		Normal	-	x (x.x)	-	-	-	x (x.x)	-	-
		High	-	x (x.x)	-	-	-	x (x.x)	-	-
		Missing	-	-	-	-	-			-
Day 43/Early Termination	Prothrombin Ratio	Low	-	x (x.x)-	-	-	-	x (x.x)	-	-
		Normal	-	x (x.x)	-	-	-	x (x.x)	-	-
		High	-	x (x.x)	-	-	-	x (x.x)	-	-
		Missing	-		-	-	-		-	-

Table 9.3.3.3.2 Coagulation parameter over time

			CD5024		Vehicle	
			Raw data	Change	Raw data	Change
Prothrombin Ratio	Baseline	N	xx		xx	
		Mean±SD	x.xx±x.xx		x.xx±x.xx	
		Median	x.xx		x.xx	
		Min;Max	x.xx;x.xx		x.xx;x.xx	
	Day 22	N	xx	xx	xx	xx
		Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
		Median	x.xx	x.xx	x.xx	x.xx
		Min;Max	x.xx;x.xx	-x.xx;x.xx	x.xx;x.xx	-x.xx;x.xx
	Day 43 / Early Termination	N	xx	xx	xx	xx
		Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
		Median	x.xx	x.xx	x.xx	x.xx
		Min;Max	x.xx;x.xx	-x.xx;x.xx	x.xx;x.xx	-x.xx;x.xx

9.3.4 Vital Sign and physical examination and other information related to safety

Table 9.3.4.1 Descriptive results of vital signs

		CD5024			Vehicle		
		Systolic blood pressure (mmHg)	Diastolic blood pressure (mmHg)	Pulse rate (bpm)	Systolic blood pressure (mmHg)	Diastolic blood pressure (mmHg)	Pulse rate (bpm)
Baseline	N	xx	xx	xx	xx	xx	xx
	Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
	Median	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Min;Max	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx
….	N	xx	xx	xx	xx	xx	xx
	Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
	Median	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Min;Max	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx
Day 54/Early termination	N	xx	xx	xx	xx	xx	xx
	Mean±SD	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx	x.xx±x.xx
	Median	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Min;Max	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx	x.xx;x.xx

Table 9.3.4.2 Descriptive results of physical examination

		CD5024	Vehicle
Baseline	N (%)	xx	xx
	Normal Physical Examination	xx (xx.x)	xx (xx.x)
Day 15	N (%)	xx	xx
	Normal Physical Examination	xx (xx.x)	xx (xx.x)
	Ex #1 Neurological Function	x (x.x)	x (x.x)
	Ex #2 Skin	x (x.x)	x (x.x)
	…		
Day 29	N (%)	xx	xx
	Normal Physical Examination	xx (xx.x)	xx (xx.x)
	Ex #1 Neurological Function	x (x.x)	x (x.x)
	Ex #2 Skin		
	…	x (x.x)	x (x.x)
Day 43	N (%)	xx	xx
	Normal Physical Examination	xx (xx.x)	xx (xx.x)
	Ex #1 Neurological Function	x (x.x)	x (x.x)
	Ex #2 Skin	x (x.x)	x (x.x)
	…		
Day 54/Early termination	N (%)	xx	xx
	Normal Physical Examination	xx (xx.x)	xx (xx.x)
	Ex #1 Neurological Function	x (x.x)	x (x.x)
	Ex #2 Skin	x (x.x)	x (x.x)
	…		

Table 9.3.4.3 Descriptive results of ECG

		CD5024	Vehicle
Baseline	N (%)	xx	xx
	Normal	xx (xx.x)	xx (xx.x)
	Abnormal	xx (xx.x)	xx (xx.x)
Day 43/Early termination	N (%)	xx	xx
	Normal	xx (xx.x)	xx (xx.x)
	Abnormal	x (x.x)	x (x.x)

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