Dossier zur Nutzenbewertung gemäß § 35a SGB V

Clascoteron (Winlevi®)

InfectoPharm Arzneimittel und Consilium GmbH

Separater Anhang 4-G: Ergänzende Unterlagen

Behandlung der Acne vulgaris bei Erwachsenen sowie der Acne vulgaris im Gesicht bei Jugendlichen ab 12 Jahren

Stand: 28.05.2026

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CB-03-01/25 - Clascoteron vs. Placebo
Disposition
Intention-to-treat

	Clascoteron (N=353)	Placebo (N=355)	Total (N=708)
	n (%)	n (%)	n (%)
Treated	353 (100.00)	355 (100.00)	708 (100.00)
Completed	287 (81.30)	290 (81.69)	577 (81.50)
Discontinued	66 (18.70)	65 (18.31)	131 (18.50)
Adverse event	3 (0.85)	6 (1.69)	9 (1.27)
Lack of efficacy	0 (0.00)	3 (0.85)	3 (0.42)
Lost to follow-up	39 (11.05)	32 (9.01)	71 (10.03)
Non-compliance with study drug	0 (0.00)	2 (0.56)	2 (0.28)
Other	0 (0.00)	2 (0.56)	2 (0.28)
Physician decision	0 (0.00)	1 (0.28)	1 (0.14)
Pregnancy	0 (0.00)	1 (0.28)	1 (0.14)
Progressive disease	1 (0.28)	0 (0.00)	1 (0.14)
Withdrawal by parent/guardian	2 (0.57)	3 (0.85)	5 (0.71)
Withdrawal by subject	21 (5.95)	15 (4.23)	36 (5.08)

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Demographic and Baseline Characteristics
Intention-to-treat

Endpoint		Clascoteron (N=353)	Placebo (N=355)	Total (N=708)
Sex, n (%)	Female	221 (62.61)	215 (60.56)	436 (61.58)
	Male	132 (37.39)	140 (39.44)	272 (38.42)
Race, n (%)	American Indian or Alaska Native	0 (0.00)	1 (0.28)	1 (0.14)
	Asian	9 (2.55)	10 (2.82)	19 (2.68)
	Native Hawaiian or Other Pacific Islander	2 (0.57)	0 (0.00)	2 (0.28)
	Black or African American	31 (8.78)	38 (10.70)	69 (9.75)
	White	298 (84.42)	297 (83.66)	595 (84.04)
	Multiple	9 (2.55)	7 (1.97)	16 (2.26)
	Other	4 (1.13)	2 (0.56)	6 (0.85)
Region, n (%)	USA	251 (71.10)	251 (70.70)	502 (70.90)
	Europe	102 (28.90)	104 (29.30)	206 (29.10)
Ethnicity, n (%)	Hispanic or Latino	94 (26.63)	80 (22.54)	174 (24.58)
	Not Hispanic or Latino	259 (73.37)	275 (77.46)	534 (75.42)
Age [years]	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	20.0 (6.65)	19.9 (6.77)	19.9 (6.71)
	Median	18.0	18.0	18.0
	Q1, Q3	16.0, 23.0	15.0, 22.0	15.5, 22.0
	Min, Max	10.0, 58.0	9.0, 50.0	9.0, 58.0
Age group, n (%)	9 - <12	11 (3.12)	5 (1.41)	16 (2.26)
	12 - <18	146 (41.36)	154 (43.38)	300 (42.37)
	18 - <65	196 (55.52)	196 (55.21)	392 (55.37)
Height [cm]	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	167.8 (10.08)	168.8 (9.49)	168.3 (9.79)
	Median	167.6	168.0	167.6
	Q1, Q3	161.0, 174.0	162.6, 175.0	162.0, 175.0
	Min, Max	121.9, 195.6	140.0, 197.1	121.9, 197.1
Weight [kg]	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	69.2 (20.55)	70.6 (20.13)	69.9 (20.34)
	Median	65.0	66.0	65.5
	Q1, Q3	56.1, 77.1	57.0, 80.0	56.5, 78.6
	Min, Max	31.9, 230.0	28.6, 188.1	28.6, 230.0
Investigator's Global Assessment, n (%)	3-Moderate	292 (82.72)	291 (81.97)	583 (82.34)
	4-Severe	61 (17.28)	64 (18.03)	125 (17.66)
Body Mass Index [kg/m^2]	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	24.5 (6.49)	24.7 (6.36)	24.6 (6.42)
	Median	23.1	23.0	23.0
	Q1, Q3	20.3, 26.6	20.0, 27.6	20.2, 27.1
	Min, Max	13.6, 77.1	11.9, 57.9	11.9, 77.1
Total Lesions (Whole Face)	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	101.5 (25.12)	103.6 (26.13)	102.6 (25.64)
	Median	98.0	101.0	99.0
	Q1, Q3	81.0, 122.0	81.0, 125.0	81.0, 123.0
	Min, Max	60.0, 170.0	61.0, 196.0	60.0, 196.0
Inflammatory Lesions (Whole Face)	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	42.4 (11.77)	42.9 (12.31)	42.7 (12.04)
	Median	38.0	39.0	39.0
	Q1, Q3	33.0, 48.0	33.0, 50.0	33.0, 49.0
	Min, Max	30.0, 83.0	30.0, 75.0	30.0, 83.0

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Min: Minimum, Max = Maximum.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Demographic and Baseline Characteristics
Intention-to-treat

Endpoint		Clascoteron (N=353)	Placebo (N=355)	Total (N=708)
Non-Inflammatory Lesions (Whole Face)	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	59.1 (22.19)	60.7 (22.09)	59.9 (22.14)
	Median	53.0	57.0	55.0
	Q1, Q3	39.0, 80.0	41.0, 78.0	40.0, 78.0
	Min, Max	30.0, 100.0	30.0, 144.0	30.0, 144.0
Total Lesions (Nose)	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	13.5 (14.07)	13.5 (13.98)	13.5 (14.01)
	Median	10.0	10.0	10.0
	Q1, Q3	4.0, 17.0	5.0, 17.0	4.5, 17.0
	Min, Max	0.0, 84.0	0.0, 89.0	0.0, 89.0
Inflammatory Lesions (Nose)	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	2.5 (3.39)	2.4 (2.86)	2.4 (3.13)
	Median	2.0	2.0	2.0
	Q1, Q3	0.0, 4.0	0.0, 4.0	0.0, 4.0
	Min, Max	0.0, 40.0	0.0, 25.0	0.0, 40.0
Non-Inflammatory Lesions (Nose)	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	11.0 (13.32)	11.1 (13.53)	11.1 (13.41)
	Median	7.0	7.0	7.0
	Q1, Q3	3.0, 13.0	3.0, 14.0	3.0, 14.0
	Min, Max	0.0, 79.0	0.0, 86.0	0.0, 86.0
Total Lesions (Rest of Face)	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	87.9 (22.81)	90.2 (25.32)	89.1 (24.11)
	Median	85.0	90.0	87.0
	Q1, Q3	71.0, 104.0	71.0, 107.0	71.0, 105.0
	Min, Max	19.0, 148.0	36.0, 184.0	19.0, 184.0
Inflammatory Lesions (Rest of Face)	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	39.9 (11.28)	40.5 (11.76)	40.2 (11.52)
	Median	37.0	37.0	37.0
	Q1, Q3	32.0, 45.0	31.0, 47.0	31.0, 46.5
	Min, Max	6.0, 77.0	22.0, 74.0	6.0, 77.0
Non-Inflammatory Lesions (Rest of Face)	n (missing)	353 (0)	355 (0)	708 (0)
	Mean (SD)	48.0 (19.72)	49.6 (20.90)	48.8 (20.32)
	Median	45.0	47.0	46.0
	Q1, Q3	33.0, 62.0	34.0, 65.0	33.0, 64.0
	Min, Max	6.0, 98.0	2.0, 134.0	2.0, 134.0
Fitzpatrick skin type assessment, n (%)	I - Pale white skin, blue/hazel eyes, blond/red hair; always burns, does not tan	7 (1.98)	7 (1.97)	14 (1.98)
	II - Fair skin, blue eyes; burns easily, tans poorly	111 (31.44)	111 (31.27)	222 (31.36)
	III - Darker white skin; tans after initial burn	122 (34.56)	121 (34.08)	243 (34.32)
	IV - Light brown skin; burns minimally, tans easily	63 (17.85)	64 (18.03)	127 (17.94)
	V - Brown skin; rarely burns, tans darkly easily	27 (7.65)	23 (6.48)	50 (7.06)
	VI - Dark brown or black skin; never burns, always tans darkly	23 (6.52)	29 (8.17)	52 (7.34)

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Min: Minimum, Max = Maximum.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Observation duration for Efficacy endpoints
Intention-to-treat

Endpoint		Clascoteron (N=353)	Placebo (N=355)
Study duration in days	Number of patients in analysis	353	355
	Mean (SD)	84.4 (19.50)	85.3 (18.67)
	Median	86.0	87.0
	Min, Max	1.0, 211.0	2.0, 149.0
Observation duration for Inflammatory Lesions (Nose) in days	Number of patients in analysis	353	355
	Mean (SD)	78.0 (25.28)	78.2 (26.26)
	Median	85.0	86.0
	Min, Max	1.0, 125.0	1.0, 147.0
Observation duration for Inflammatory Lesions (Rest of Face) in days	Number of patients in analysis	353	355
	Mean (SD)	78.0 (25.28)	78.2 (26.26)
	Median	85.0	86.0
	Min, Max	1.0, 125.0	1.0, 147.0
Observation duration for Inflammatory Lesions (Whole Face) in days	Number of patients in analysis	353	355
	Mean (SD)	78.0 (25.28)	78.2 (26.26)
	Median	85.0	86.0
	Min, Max	1.0, 125.0	1.0, 147.0
Observation duration for Investigator's Global Assessment in days	Number of patients in analysis	353	355
	Mean (SD)	78.0 (25.28)	78.2 (26.26)
	Median	85.0	86.0
	Min, Max	1.0, 125.0	1.0, 147.0
Observation duration for Non-Inflammatory Lesions (Nose) in days	Number of patients in analysis	353	355
	Mean (SD)	78.0 (25.28)	78.2 (26.26)
	Median	85.0	86.0
	Min, Max	1.0, 125.0	1.0, 147.0
Observation duration for Non-Inflammatory Lesions (Rest of Face) in days	Number of patients in analysis	353	355
	Mean (SD)	78.0 (25.28)	78.2 (26.26)
	Median	85.0	86.0
	Min, Max	1.0, 125.0	1.0, 147.0
Observation duration for Non-Inflammatory Lesions (Whole Face) in days	Number of patients in analysis	353	355
	Mean (SD)	78.0 (25.28)	78.2 (26.26)
	Median	85.0	86.0
	Min, Max	1.0, 125.0	1.0, 147.0
Observation duration for Total Lesions (Nose) in days	Number of patients in analysis	353	355
	Mean (SD)	78.0 (25.28)	78.2 (26.26)
	Median	85.0	86.0
	Min, Max	1.0, 125.0	1.0, 147.0
Observation duration for Total Lesions (Rest of Face) in days	Number of patients in analysis	353	355
	Mean (SD)	78.0 (25.28)	78.2 (26.26)
	Median	85.0	86.0
	Min, Max	1.0, 125.0	1.0, 147.0
Observation duration for Total Lesions (Whole Face) in days	Number of patients in analysis	353	355
	Mean (SD)	78.0 (25.28)	78.2 (26.26)
	Median	85.0	86.0
	Min, Max	1.0, 125.0	1.0, 147.0

Study duration is defined as time from randomization until date of study completion/discontinuation.
Observation period for endpoints is defined as time from treatment start until date of last non-missing assessment.
Min: Minimum, Max: Maximum, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Observation duration for Safety endpoints
Safety Analysis Set

Endpoint		Clascoteron (N=353)	Placebo (N=355)
Treatment duration in days	Number of patients in analysis	353	355
	Mean (SD)	76.6 (26.09)	77.9 (24.75)
	Median	85.0	85.0
	Min, Max	1.0, 124.0	1.0, 125.0
Observation duration for Safety in days	Number of patients in analysis	353	355
	Mean (SD)	84.4 (19.48)	85.3 (18.66)
	Median	86.0	87.0
	Min, Max	1.0, 211.0	2.0, 149.0

Treatment duration is defined as time from first dose of study treatment until last date of study treatment.
Safety period is defined as time from treatment start until date of study completion/discontinuation.
Min: Minimum, Max: Maximum, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients achieving Therapy success with at least a two-point reduction in IGA compared to Baseline AND an IGA score of 0 or 1 at Week 12
Intention-to-treat

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with reponse, n/N (%)	62.6/ 353 (17.73)	30.7/ 355 (8.65)
Number of imputed values	51	45
Adjusted Analysis Clascoteron vs. Placebo		
Odds Ratio (95% CI)	2.36 (1.43, 3.88)	
p-value	0.0008	
Risk Ratio (95% CI)	2.08 (1.36, 3.17)	
p-value	0.0007	
Risk Difference (95% CI)	0.09 (0.05, 0.13)	
p-value	0.0002	
Unadjusted Analysis Clascoteron vs. Placebo		
Odds Ratio (95% CI)	2.28 (1.40, 3.69)	
p-value	0.0009	
Risk Ratio (95% CI)	2.05 (1.34, 3.14)	
p-value	0.0010	
Risk Difference (95% CI)	0.09 (0.04, 0.14)	
p-value	0.0009	

Adjusted analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with treatment and pooled analysis centre as fixed effects.
Unadjusted RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients achieving Therapy success with at least a two-point reduction in IGA compared to Baseline AND an IGA score of 0 or 1 at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup Level	Clascoteron (N=353) n/ N (%)	Placebo (N=355) n/ N (%)	Risk Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)					0.1563
9 - <18	23.6/ 157 (15.03)	7.1/ 159 (4.47)	3.38 (1.43, 7.99)	0.0055	
18 - <65	39.0/ 196 (19.90)	23.6/ 196 (12.04)	1.65 (1.00, 2.72)	0.0487	
Gender					0.6446
Male	18.0/ 132 (13.64)	7.9/ 140 (5.64)	2.44 (0.96, 6.17)	0.0600	
Female	44.6/ 221 (20.18)	22.8/ 215 (10.60)	1.90 (1.15, 3.16)	0.0127	
Region					0.7192
USA	33.8/ 251 (13.47)	17.6/ 251 (7.01)	1.92 (1.08, 3.42)	0.0265	
Europe	28.8/ 102 (28.24)	13.1/ 104 (12.60)	2.25 (1.20, 4.22)	0.0120	
IGA					0.2287
3-Moderate	57.4/ 292 (19.66)	30.6/ 291 (10.52)	1.87 (1.22, 2.87)	0.0044	
4-Severe	5.2/ 61 (8.52)	0.1/ 64 (0.16)	11.02 (0.63, 192.20)	0.0999	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
Unadjusted RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients achieving Therapy success with at least a 15% in IGA compared to Baseline at Week 12
Intention-to-treat

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with reponse, n/N (%)	201.9/ 353 (57.20)	175.4/ 355 (49.41)
Number of imputed values	51	45
Adjusted Analysis Clascoteron vs. Placebo		
Odds Ratio (95% CI)	1.39 (1.01, 1.90)	
p-value	0.0423	
Risk Ratio (95% CI)	1.15 (1.00, 1.33)	
p-value	0.0516	
Risk Difference (95% CI)	0.08 (0.00, 0.15)	
p-value	0.0432	
Unadjusted Analysis Clascoteron vs. Placebo		
Odds Ratio (95% CI)	1.37 (1.01, 1.86)	
p-value	0.0460	
Risk Ratio (95% CI)	1.16 (1.00, 1.34)	
p-value	0.0460	
Risk Difference (95% CI)	0.08 (0.00, 0.15)	
p-value	0.0451	

Adjusted analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with treatment and pooled analysis centre as fixed effects.
Unadjusted RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients achieving Therapy success with at least a 15% in IGA compared to Baseline at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup Level	Clascoteron (N=353) n/ N (%)	Placebo (N=355) n/ N (%)	Risk Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)					0.9645
9 - <18	80.2/ 157 (51.08)	70.5/ 159 (44.34)	1.15 (0.90, 1.47)	0.2509	
18 - <65	121.7/ 196 (62.09)	104.9/ 196 (53.52)	1.16 (0.96, 1.40)	0.1148	
Gender					0.2173
Male	72.8/ 132 (55.15)	58.9/ 140 (42.07)	1.31 (1.01, 1.70)	0.0398	
Female	129.1/ 221 (58.42)	116.5/ 215 (54.19)	1.08 (0.91, 1.28)	0.4003	
Region					0.2859
USA	133.5/ 251 (53.19)	121.5/ 251 (48.41)	1.10 (0.92, 1.31)	0.3008	
Europe	68.4/ 102 (67.06)	53.9/ 104 (51.83)	1.29 (1.02, 1.65)	0.0375	
IGA					0.0752
3-Moderate	153.1/ 292 (52.43)	140.0/ 291 (48.11)	1.09 (0.92, 1.29)	0.3265	
4-Severe	48.8/ 61 (80.00)	35.4/ 64 (55.31)	1.45 (1.11, 1.88)	0.0055	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
Unadjusted RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in total lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	101.47 (25.12)	0	-	355	103.64 (26.13)	0	-
Day 29 ± 5	325	79.30 (35.15)	325	-22.83 (29.80)	318	80.62 (34.22)	318	-22.43 (26.15)
Day 57 ± 7	302	67.35 (36.60)	302	-34.22 (35.47)	300	73.83 (37.94)	300	-29.48 (32.59)
Day 85 ± 10	302	60.87 (38.32)	302	-40.06 (39.64)	310	74.37 (42.18)	310	-28.70 (37.89)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-39.18 (1.99)	51	355	-28.86 (1.96)	45	-10.32 (-15.68, -4.96)	0.0002	-0.28 (-0.42, -0.13)	0.0002

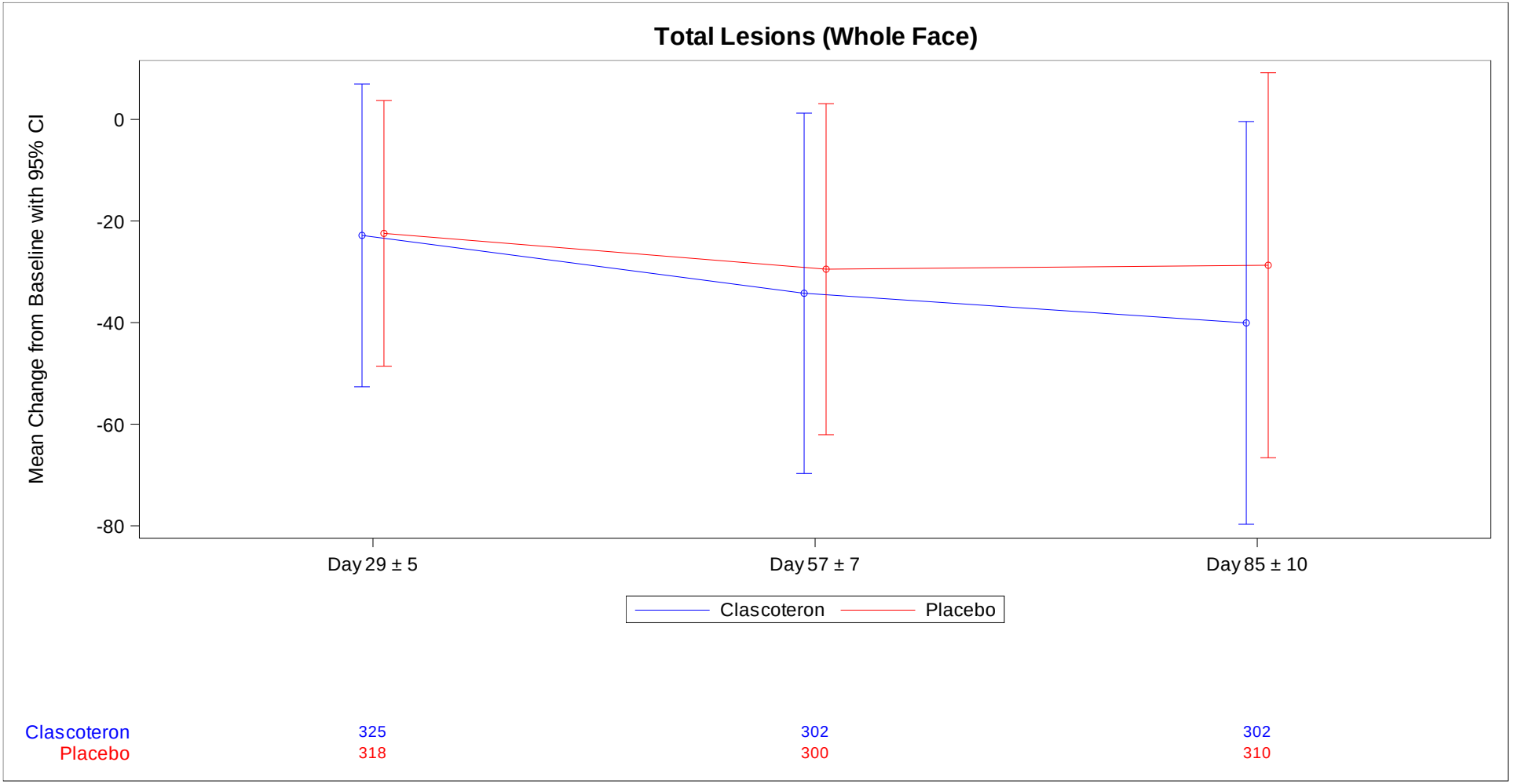
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)								Interaction
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of		Hedges'g (95% CI)		
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value		p-Value	p-Value
Age (years)													0.1890
9 - <18	157	104.31 (25.81)	157 (15)	-32.71 (3.26)	159	109.93 (25.01)	159 (8)	-26.32 (3.24)	-6.40 (-15.39, 2.59)	0.1625	-0.16 (-0.38, 0.06)	0.1659	
18 - <65	196	99.19 (24.38)	196 (36)	-45.12 (2.61)	196	98.53 (25.96)	196 (37)	-31.10 (2.52)	-14.02 (-21.08, -6.97)	0.0001	-0.39 (-0.59, -0.19)	0.0001	
Gender													0.9193
Male	132	101.14 (25.87)	132 (18)	-34.23 (3.52)	140	104.72 (24.67)	140 (15)	-23.33 (3.22)	-10.90 (-20.37, -1.42)	0.0245	-0.28 (-0.52, -0.04)	0.0230	
Female	221	101.67 (24.73)	221 (33)	-42.86 (2.55)	215	102.93 (27.07)	215 (30)	-32.57 (2.61)	-10.29 (-17.45, -3.13)	0.0050	-0.27 (-0.46, -0.08)	0.0051	
Region													<.0001
USA	251	97.96 (23.54)	251 (35)	-34.20 (2.47)	251	102.90 (26.25)	251 (30)	-32.03 (2.51)	-2.17 (-9.12, 4.78)	0.5390	-0.06 (-0.23, 0.12)	0.5377	
Europe	102	110.11 (26.87)	102 (16)	-53.08 (3.74)	104	105.42 (25.88)	104 (15)	-21.37 (3.81)	-31.71 (-42.37, -21.05)	<.0001	-0.82 (-1.11, -0.54)	<.0001	
IGA													0.8744
3-Moderate	292	101.84 (25.18)	292 (43)	-41.94 (2.16)	291	102.16 (26.13)	291 (41)	-31.52 (2.12)	-10.42 (-16.32, -4.52)	0.0006	-0.28 (-0.45, -0.12)	0.0006	
4-Severe	61	99.70 (24.97)	61 (8)	-28.75 (5.84)	64	110.36 (25.26)	64 (4)	-16.96 (5.62)	-11.79 (-27.95, 4.37)	0.1513	-0.26 (-0.61, 0.09)	0.1498	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of change from baseline of total lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in total lesions count (Nose) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	13.53 (14.07)	0	-	355	13.46 (13.98)	0	-
Day 29 ± 5	325	9.70 (11.19)	325	-4.08 (9.27)	318	10.35 (12.11)	318	-2.82 (8.06)
Day 57 ± 7	302	7.05 (8.17)	302	-6.26 (11.63)	300	8.30 (9.82)	300	-4.76 (10.69)
Day 85 ± 10	302	5.74 (6.96)	302	-7.60 (11.33)	310	7.71 (8.95)	310	-5.24 (11.26)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-7.49 (0.36)	51	355	-5.79 (0.37)	45	-1.70 (-2.68, -0.73)	0.0007	-0.25 (-0.40, -0.10)	0.0009

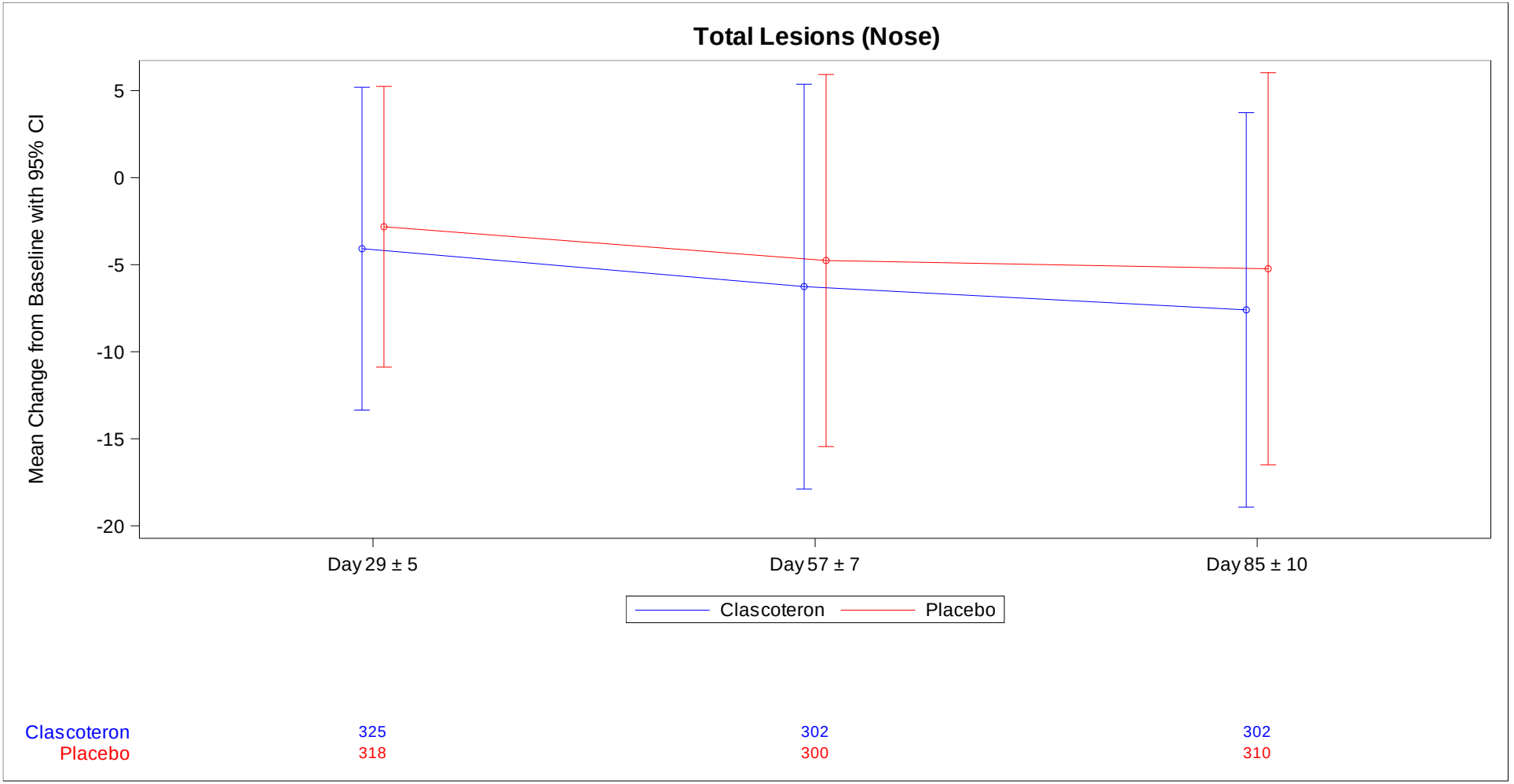
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)								Interaction
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of				
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.1830
9 - <18	157	13.01 (13.70)	157 (15)	-6.31 (0.58)	159	12.08 (9.24)	159 (8)	-3.80 (0.58)	-2.51 (-4.12, -0.91)	0.0022	-0.34 (-0.57, -0.12)	0.0024	
18 - <65	196	13.94 (14.38)	196 (36)	-7.68 (0.49)	196	14.58 (16.81)	196 (37)	-6.58 (0.48)	-1.10 (-2.44, 0.24)	0.1077	-0.16 (-0.36, 0.04)	0.1089	
Gender													0.0485
Male	132	14.20 (14.66)	132 (18)	-7.80 (0.60)	140	14.54 (13.55)	140 (15)	-4.76 (0.59)	-3.04 (-4.68, -1.41)	0.0003	-0.44 (-0.68, -0.20)	0.0004	
Female	221	13.12 (13.72)	221 (33)	-6.65 (0.47)	215	12.76 (14.24)	215 (30)	-5.70 (0.47)	-0.95 (-2.25, 0.36)	0.1538	-0.14 (-0.32, 0.05)	0.1573	
Region													0.0360
USA	251	9.77 (10.05)	251 (35)	-4.69 (0.39)	251	9.45 (8.08)	251 (30)	-3.74 (0.40)	-0.95 (-2.03, 0.13)	0.0850	-0.15 (-0.33, 0.02)	0.0861	
Europe	102	22.76 (17.85)	102 (16)	-12.87 (0.86)	104	23.13 (19.48)	104 (15)	-9.24 (0.81)	-3.63 (-5.91, -1.35)	0.0019	-0.43 (-0.70, -0.15)	0.0025	
IGA													0.0588
3-Moderate	292	14.03 (14.33)	292 (43)	-7.50 (0.39)	291	13.71 (14.73)	291 (41)	-6.25 (0.40)	-1.24 (-2.32, -0.16)	0.0241	-0.18 (-0.35, -0.02)	0.0261	
4-Severe	61	11.10 (12.59)	61 (8)	-5.17 (1.03)	64	12.33 (9.88)	64 (4)	-1.04 (0.99)	-4.13 (-6.96, -1.30)	0.0046	-0.51 (-0.87, -0.16)	0.0047	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of change from baseline of total lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in total lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	87.94 (22.81)	0	-	355	90.17 (25.32)	0	-
Day 29 ± 5	325	69.59 (32.21)	325	-18.75 (29.28)	318	70.27 (32.30)	318	-19.61 (24.61)
Day 57 ± 7	302	60.30 (33.38)	302	-27.96 (32.43)	300	65.53 (35.49)	300	-24.72 (30.47)
Day 85 ± 10	302	55.14 (35.61)	302	-32.46 (36.78)	310	66.66 (38.22)	310	-23.47 (34.75)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-31.42 (1.87)	51	355	-23.69 (1.79)	45	-7.72 (-12.75, -2.70)	0.0027	-0.22 (-0.37, -0.08)	0.0030

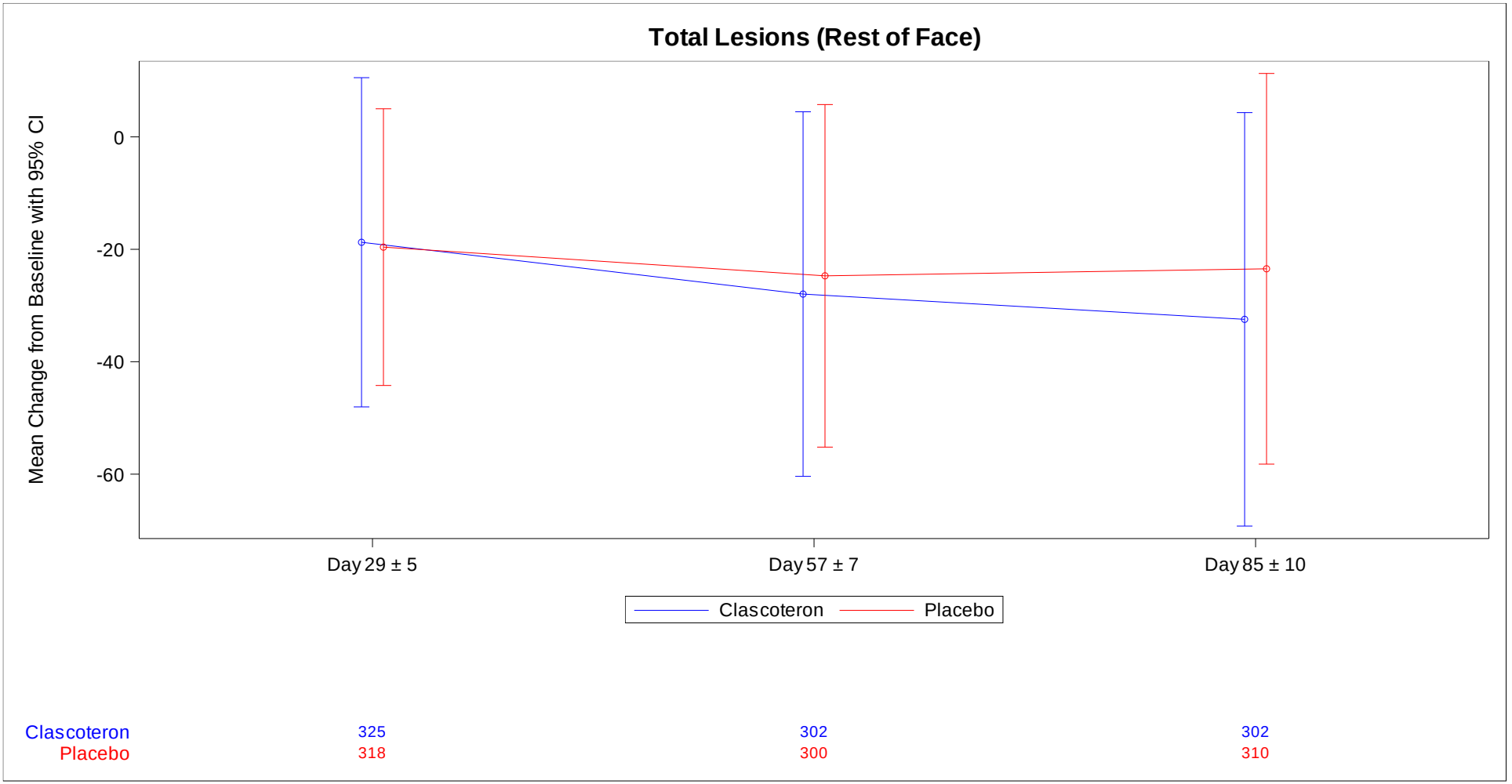
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)								Interaction
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of				
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.1127
9 - <18	157	91.30 (25.00)	157 (15)	-25.90 (3.07)	159	97.85 (25.89)	159 (8)	-22.75 (2.97)	-3.15 (-11.60, 5.30)	0.4634	-0.08 (-0.30, 0.14)	0.4624	
18 - <65	196	85.25 (20.57)	196 (36)	-36.30 (2.40)	196	83.95 (23.11)	196 (37)	-24.50 (2.27)	-11.80 (-18.46, -5.15)	0.0006	-0.36 (-0.56, -0.16)	0.0004	
Gender													0.7736
Male	132	86.93 (23.82)	132 (18)	-25.86 (3.08)	140	90.18 (26.39)	140 (15)	-18.88 (2.90)	-6.98 (-15.31, 1.35)	0.1000	-0.20 (-0.44, 0.04)	0.1005	
Female	221	88.54 (22.22)	221 (33)	-35.28 (2.45)	215	90.17 (24.67)	215 (30)	-26.73 (2.38)	-8.54 (-15.26, -1.82)	0.0129	-0.24 (-0.43, -0.05)	0.0130	
Region													<.0001
USA	251	88.18 (23.57)	251 (35)	-28.87 (2.39)	251	93.44 (25.51)	251 (30)	-28.30 (2.33)	-0.57 (-7.29, 6.16)	0.8679	-0.02 (-0.19, 0.16)	0.8650	
Europe	102	87.34 (20.94)	102 (16)	-39.30 (3.05)	104	82.29 (23.14)	104 (15)	-11.95 (3.17)	-27.35 (-36.12, -18.58)	<.0001	-0.86 (-1.15, -0.58)	<.0001	
IGA													0.8241
3-Moderate	292	87.80 (23.10)	292 (43)	-33.56 (2.04)	291	88.45 (25.20)	291 (41)	-25.39 (2.00)	-8.17 (-13.80, -2.54)	0.0046	-0.24 (-0.40, -0.07)	0.0044	
4-Severe	61	88.61 (21.55)	61 (8)	-22.60 (5.17)	64	98.03 (24.57)	64 (4)	-16.17 (4.99)	-6.43 (-20.82, 7.95)	0.3775	-0.16 (-0.51, 0.19)	0.3740	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of change from baseline of total lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in inflammatory lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	42.40 (11.77)	0	-	355	42.94 (12.31)	0	-
Day 29 ± 5	325	29.57 (16.27)	325	-12.89 (14.09)	318	29.53 (16.02)	318	-12.98 (13.30)
Day 57 ± 7	302	24.48 (16.97)	302	-17.76 (16.33)	300	26.25 (17.32)	300	-16.35 (15.41)
Day 85 ± 10	302	21.80 (16.57)	302	-20.06 (17.34)	310	27.10 (19.49)	310	-15.45 (18.31)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-19.39 (0.92)	51	355	-15.49 (0.91)	45	-3.90 (-6.46, -1.34)	0.0029	-0.23 (-0.37, -0.08)	0.0028

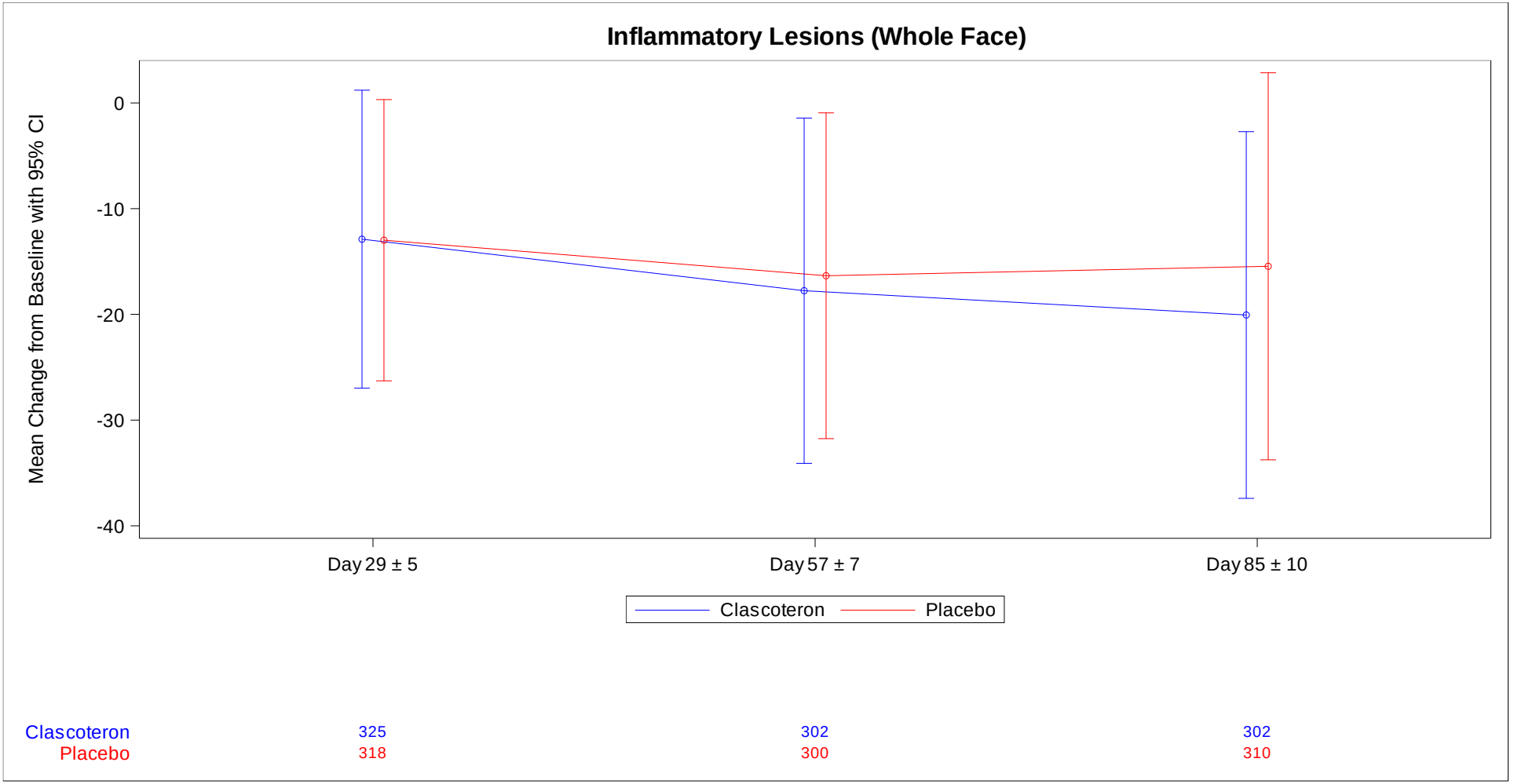
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.8460
9 - <18	157	42.13 (11.52)	157 (15)	-18.63 (1.51)	159	43.72 (11.68)	159 (8)	-14.94 (1.48)	-3.70 (-7.87, 0.48)	0.0825	-0.20 (-0.42, 0.02)	0.0821	
18 - <65	196	42.62 (12.00)	196 (36)	-20.66 (1.14)	196	42.31 (12.80)	196 (37)	-16.44 (1.13)	-4.22 (-7.47, -0.97)	0.0113	-0.26 (-0.46, -0.07)	0.0092	
Gender													0.6345
Male	132	44.04 (11.68)	132 (18)	-18.42 (1.64)	140	44.84 (12.37)	140 (15)	-13.61 (1.63)	-4.82 (-9.52, -0.11)	0.0450	-0.25 (-0.49, -0.01)	0.0389	
Female	221	41.42 (11.75)	221 (33)	-20.59 (1.12)	215	41.71 (12.15)	215 (30)	-17.13 (1.09)	-3.45 (-6.59, -0.31)	0.0312	-0.21 (-0.40, -0.02)	0.0277	
Region													0.0090
USA	251	42.12 (11.68)	251 (35)	-18.97 (1.11)	251	43.54 (12.26)	251 (30)	-17.00 (1.09)	-1.97 (-5.05, 1.12)	0.2108	-0.11 (-0.29, 0.06)	0.2058	
Europe	102	43.10 (12.04)	102 (16)	-21.97 (1.72)	104	41.49 (12.36)	104 (15)	-12.49 (1.62)	-9.48 (-14.24, -4.71)	0.0001	-0.56 (-0.84, -0.28)	<.0001	
IGA													0.3111
3-Moderate	292	41.76 (11.86)	292 (43)	-20.33 (0.91)	291	41.63 (11.52)	291 (41)	-17.16 (0.90)	-3.17 (-5.76, -0.58)	0.0167	-0.20 (-0.37, -0.04)	0.0138	
4-Severe	61	45.44 (10.94)	61 (8)	-17.05 (3.05)	64	48.91 (14.01)	64 (4)	-9.41 (2.91)	-7.64 (-16.00, 0.71)	0.0725	-0.32 (-0.68, 0.03)	0.0736	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of change from baseline of inflammatory lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	2.48 (3.39)	0	-	355	2.39 (2.86)	0	-
Day 29 ± 5	325	1.40 (2.13)	325	-1.11 (3.25)	318	1.48 (2.39)	318	-0.83 (2.47)
Day 57 ± 7	302	1.07 (1.80)	302	-1.45 (3.44)	300	1.30 (3.03)	300	-0.98 (3.22)
Day 85 ± 10	302	0.88 (1.61)	302	-1.71 (3.54)	310	1.31 (2.25)	310	-1.01 (2.83)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)						
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-1.45 (0.10)	51	355	-1.05 (0.10)	45	-0.40 (-0.67, -0.12)	0.0048	-0.21 (-0.35, -0.06)	0.0064

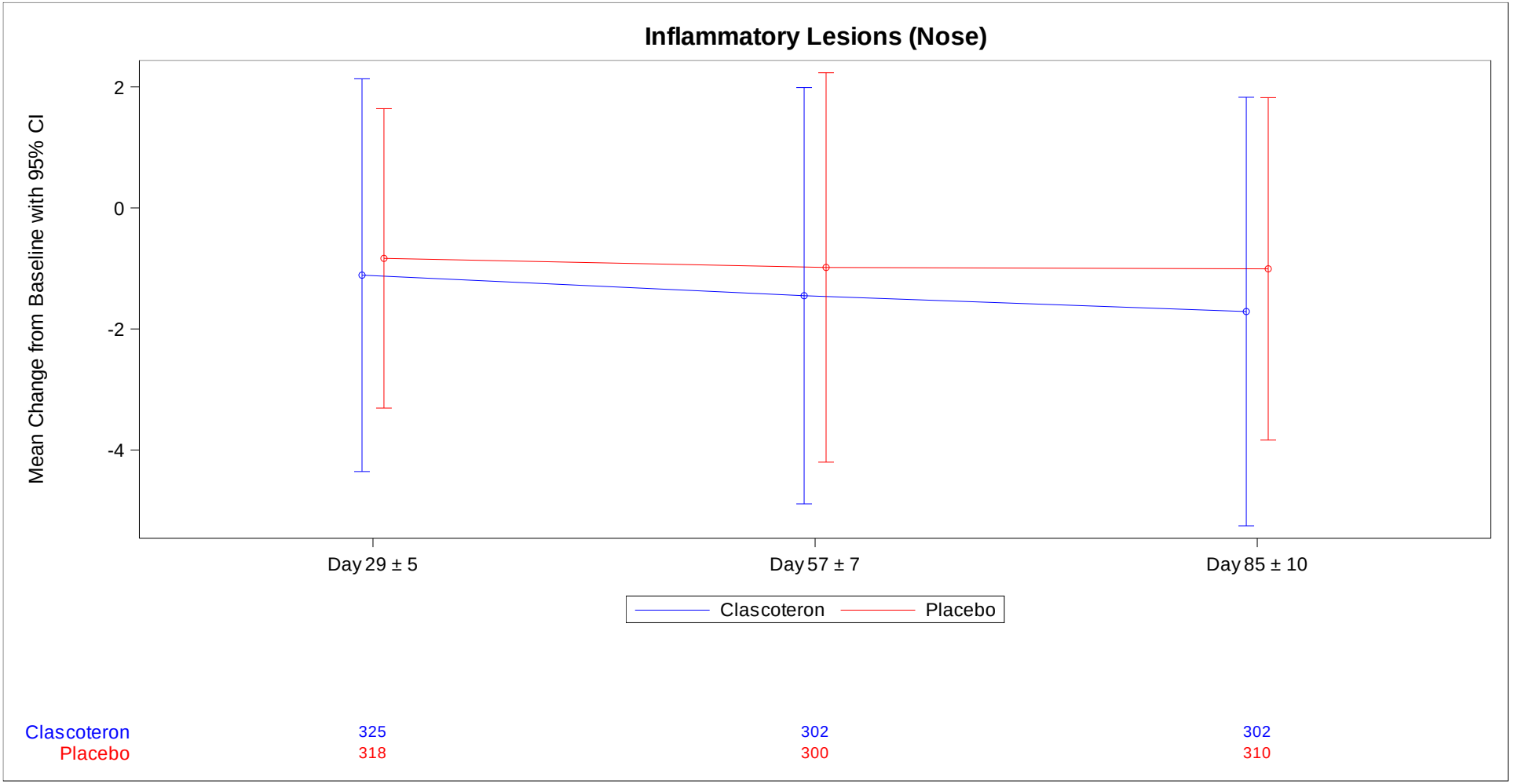
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup Level	Clascoteron (N=353) Baseline N	Clascoteron (N=353) Baseline Mean (SD)	Clascoteron (N=353) Change from Baseline N (IMP)	Clascoteron (N=353) Change from Baseline LSMean (SE)	Placebo (N=355) Baseline N	Placebo (N=355) Baseline Mean (SD)	Placebo (N=355) Change from Baseline N (IMP)	Placebo (N=355) Change from Baseline LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	Interaction p-Value
Age (years)													0.3772
9 - <18	157	3.00 (4.13)	157 (15)	-1.76 (0.16)	159	2.48 (2.64)	159 (8)	-1.24 (0.16)	-0.52 (-0.97, -0.07)	0.0246	-0.25 (-0.47, -0.03)	0.0250	
18 - <65	196	2.07 (2.58)	196 (36)	-1.13 (0.13)	196	2.33 (3.03)	196 (37)	-0.87 (0.13)	-0.26 (-0.62, 0.09)	0.1496	-0.14 (-0.34, 0.06)	0.1576	
Gender													0.2564
Male	132	2.92 (4.27)	132 (18)	-1.73 (0.20)	140	2.86 (3.44)	140 (15)	-1.12 (0.19)	-0.61 (-1.15, -0.07)	0.0283	-0.26 (-0.50, -0.03)	0.0299	
Female	221	2.23 (2.70)	221 (33)	-1.23 (0.11)	215	2.09 (2.37)	215 (30)	-0.98 (0.11)	-0.25 (-0.56, 0.06)	0.1132	-0.15 (-0.34, 0.04)	0.1217	
Region													0.1128
USA	251	2.65 (3.63)	251 (35)	-1.45 (0.13)	251	2.41 (2.74)	251 (30)	-1.21 (0.12)	-0.24 (-0.59, 0.10)	0.1679	-0.12 (-0.30, 0.05)	0.1719	
Europe	102	2.07 (2.65)	102 (16)	-1.34 (0.19)	104	2.37 (3.14)	104 (15)	-0.60 (0.18)	-0.74 (-1.25, -0.23)	0.0048	-0.40 (-0.67, -0.12)	0.0047	
IGA													0.7234
3-Moderate	292	2.66 (3.57)	292 (43)	-1.59 (0.10)	291	2.42 (2.76)	291 (41)	-1.29 (0.10)	-0.30 (-0.57, -0.04)	0.0249	-0.18 (-0.34, -0.02)	0.0283	
4-Severe	61	1.66 (2.14)	61 (8)	-0.47 (0.33)	64	2.30 (3.30)	64 (4)	0.00 (0.32)	-0.47 (-1.38, 0.43)	0.3023	-0.19 (-0.54, 0.17)	0.3022	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of change from baseline of inflammatory lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in inflammatory lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	39.92 (11.28)	0	-	355	40.55 (11.76)	0	-
Day 29 ± 5	325	28.17 (15.51)	325	-11.78 (13.42)	318	28.05 (15.25)	318	-12.15 (12.98)
Day 57 ± 7	302	23.41 (16.07)	302	-16.31 (15.44)	300	24.95 (16.40)	300	-15.36 (15.07)
Day 85 ± 10	302	20.92 (15.91)	302	-18.35 (16.59)	310	25.79 (18.33)	310	-14.45 (17.48)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-17.79 (0.87)	51	355	-14.46 (0.87)	45	-3.33 (-5.76, -0.90)	0.0073	-0.20 (-0.35, -0.06)	0.0071

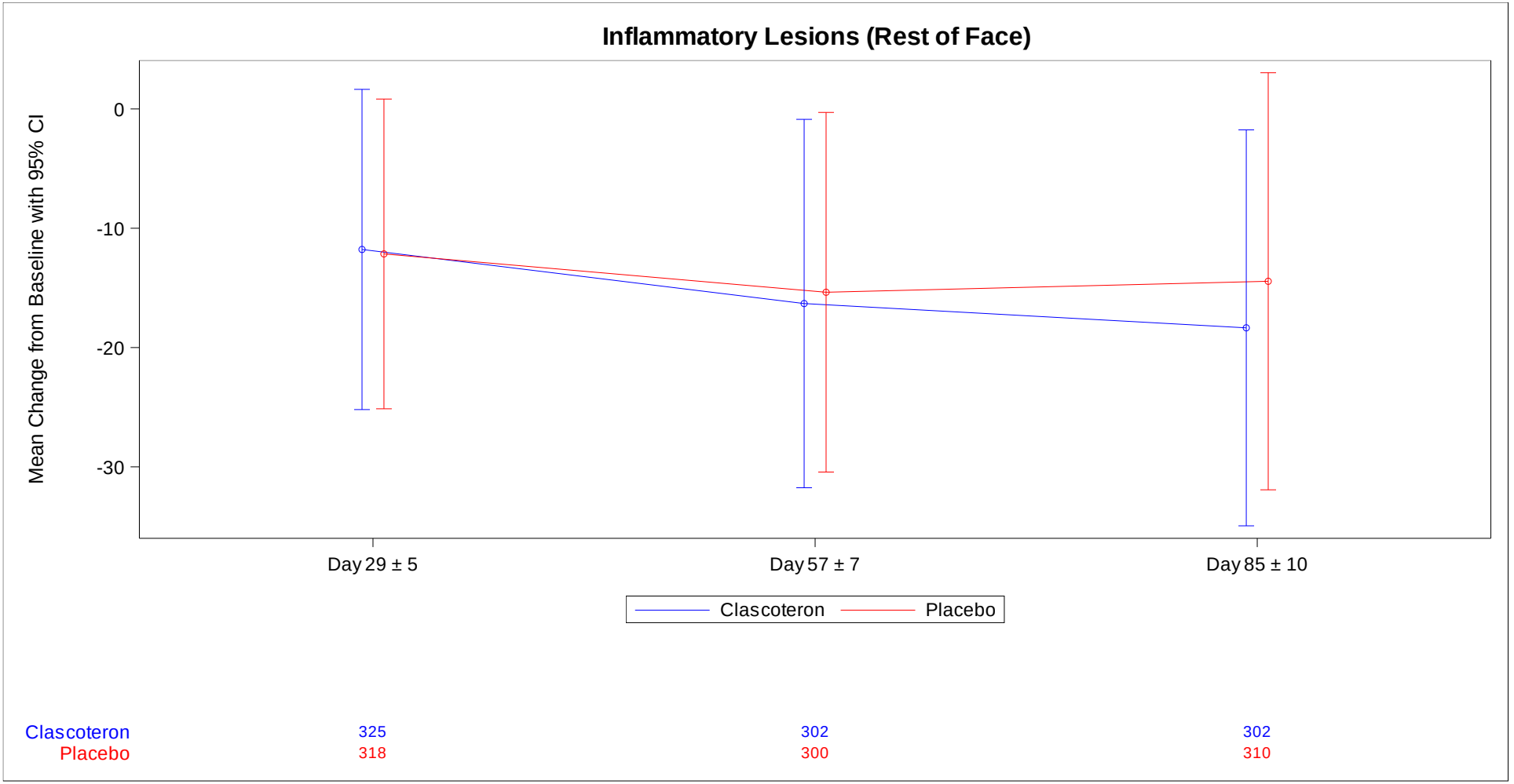
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.7571
9 - <18	157	39.13 (11.11)	157 (15)	-16.68 (1.42)	159	41.24 (11.41)	159 (8)	-13.75 (1.40)	-2.93 (-6.87, 1.01)	0.1447	-0.16 (-0.39, 0.06)	0.1433	
18 - <65	196	40.55 (11.40)	196 (36)	-19.29 (1.09)	196	39.98 (12.03)	196 (37)	-15.57 (1.09)	-3.72 (-6.83, -0.61)	0.0194	-0.24 (-0.44, -0.04)	0.0163	
Gender													0.7132
Male	132	41.12 (11.46)	132 (18)	-16.48 (1.58)	140	41.97 (11.71)	140 (15)	-12.46 (1.53)	-4.02 (-8.49, 0.45)	0.0774	-0.22 (-0.46, 0.02)	0.0697	
Female	221	39.19 (11.13)	221 (33)	-19.20 (1.04)	215	39.62 (11.72)	215 (30)	-16.17 (1.03)	-3.03 (-5.96, -0.10)	0.0427	-0.20 (-0.39, -0.01)	0.0399	
Region													0.0080
USA	251	39.46 (11.16)	251 (35)	-17.35 (1.04)	251	41.14 (11.60)	251 (30)	-15.83 (1.03)	-1.52 (-4.41, 1.38)	0.3042	-0.09 (-0.27, 0.08)	0.3019	
Europe	102	41.03 (11.54)	102 (16)	-20.50 (1.66)	104	39.13 (12.07)	104 (15)	-11.75 (1.54)	-8.74 (-13.28, -4.21)	0.0002	-0.54 (-0.81, -0.26)	0.0002	
IGA													0.2670
3-Moderate	292	39.11 (11.20)	292 (43)	-18.52 (0.87)	291	39.21 (10.98)	291 (41)	-15.88 (0.87)	-2.64 (-5.11, -0.17)	0.0366	-0.18 (-0.34, -0.01)	0.0325	
4-Severe	61	43.79 (10.91)	61 (8)	-16.58 (2.86)	64	46.61 (13.27)	64 (4)	-9.34 (2.73)	-7.24 (-15.08, 0.59)	0.0697	-0.33 (-0.68, 0.03)	0.0709	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of change from baseline of inflammatory lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in non-inflammatory lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	59.07 (22.19)	0	-	355	60.70 (22.09)	0	-
Day 29 ± 5	325	49.72 (28.52)	325	-9.94 (23.20)	318	51.08 (29.87)	318	-9.45 (20.78)
Day 57 ± 7	302	42.87 (28.66)	302	-16.46 (26.43)	300	47.58 (30.05)	300	-13.13 (24.08)
Day 85 ± 10	302	39.07 (30.53)	302	-20.00 (29.68)	310	47.27 (31.36)	310	-13.25 (25.67)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-19.44 (1.39)	51	355	-13.13 (1.39)	45	-6.30 (-10.20, -2.41)	0.0016	-0.24 (-0.39, -0.09)	0.0015

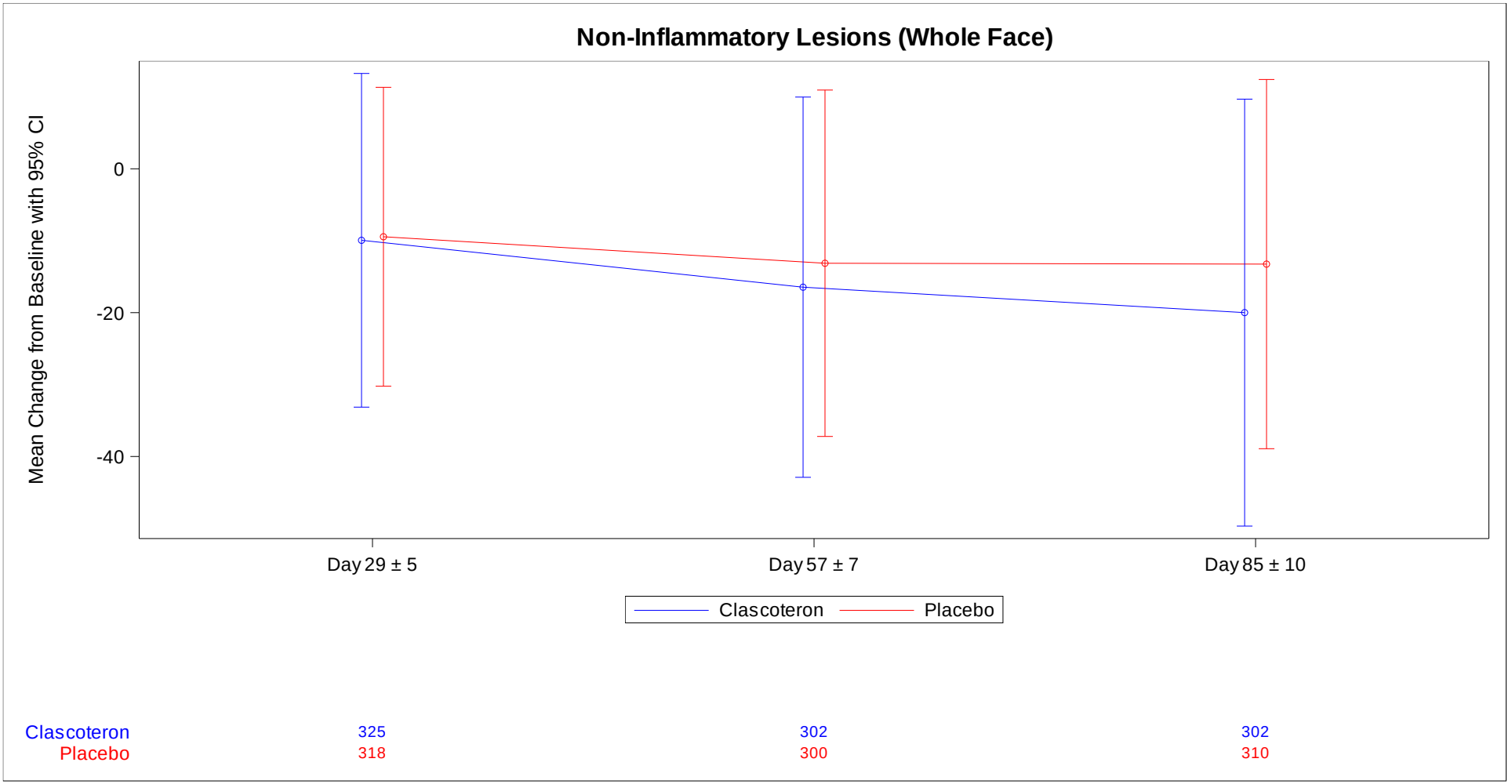
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.0576
9 - <18	157	62.18 (22.89)	157 (15)	-13.76 (2.39)	159	66.21 (21.94)	159 (8)	-11.78 (2.37)	-1.99 (-8.64, 4.67)	0.5574	-0.07 (-0.29, 0.15)	0.5559	
18 - <65	196	56.57 (21.33)	196 (36)	-24.21 (1.68)	196	56.22 (21.24)	196 (37)	-14.24 (1.79)	-9.97 (-14.90, -5.04)	<.0001	-0.41 (-0.61, -0.21)	<.0001	
Gender													0.9297
Male	132	57.10 (21.75)	132 (18)	-16.23 (2.24)	140	59.89 (21.57)	140 (15)	-10.03 (2.23)	-6.20 (-12.50, 0.11)	0.0539	-0.24 (-0.48, 0.00)	0.0515	
Female	221	60.24 (22.41)	221 (33)	-21.63 (1.87)	215	61.22 (22.46)	215 (30)	-15.07 (1.93)	-6.57 (-11.91, -1.22)	0.0161	-0.23 (-0.42, -0.05)	0.0149	
Region													<.0001
USA	251	55.84 (19.99)	251 (35)	-14.82 (1.76)	251	59.35 (20.99)	251 (30)	-14.87 (1.76)	0.05 (-4.95, 5.04)	0.9853	0.00 (-0.17, 0.18)	0.9850	
Europe	102	67.01 (25.22)	102 (16)	-31.22 (2.50)	104	63.93 (24.35)	104 (15)	-8.95 (2.44)	-22.27 (-29.20, -15.35)	<.0001	-0.88 (-1.17, -0.60)	<.0001	
IGA													0.5520
3-Moderate	292	60.07 (22.13)	292 (43)	-21.24 (1.54)	291	60.53 (22.45)	291 (41)	-14.16 (1.57)	-7.08 (-11.46, -2.70)	0.0016	-0.27 (-0.43, -0.10)	0.0014	
4-Severe	61	54.26 (21.99)	61 (8)	-11.84 (3.83)	64	61.45 (20.53)	64 (4)	-8.20 (3.64)	-3.64 (-14.21, 6.93)	0.4962	-0.12 (-0.47, 0.23)	0.4935	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of change from baseline of non-inflammatory lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in non-inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	11.04 (13.32)	0	-	355	11.07 (13.53)	0	-
Day 29 ± 5	325	8.30 (10.83)	325	-2.97 (8.04)	318	8.87 (11.75)	318	-1.99 (7.33)
Day 57 ± 7	302	5.98 (7.76)	302	-4.81 (10.50)	300	7.00 (8.79)	300	-3.78 (9.75)
Day 85 ± 10	302	4.85 (6.63)	302	-5.88 (10.17)	310	6.40 (8.05)	310	-4.23 (10.34)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-5.97 (0.31)	51	355	-4.66 (0.32)	45	-1.30 (-2.15, -0.45)	0.0027	-0.22 (-0.37, -0.07)	0.0036

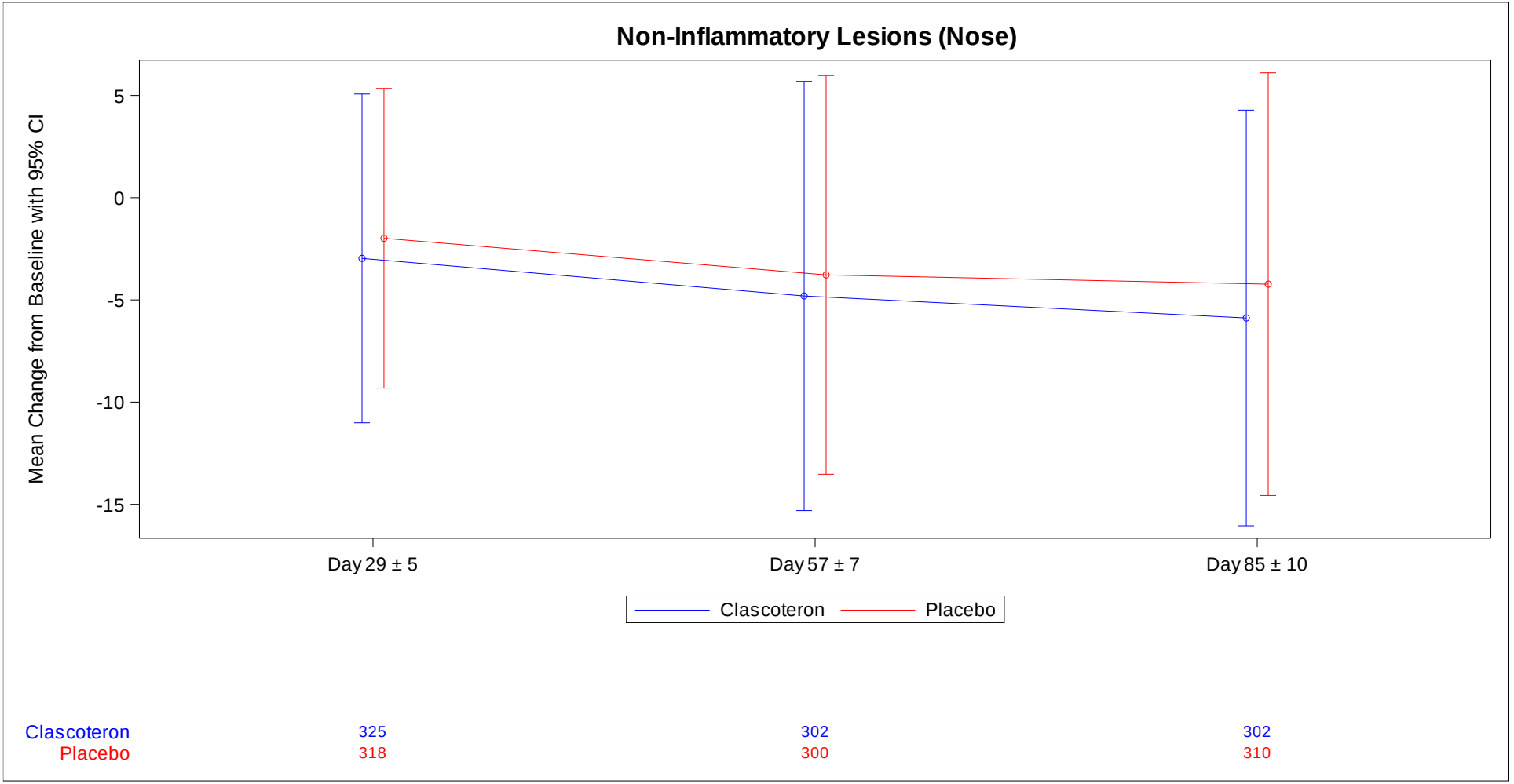
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)								Interaction
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of				
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.2995
9 - <18	157	10.01 (12.02)	157 (15)	-4.47 (0.52)	159	9.60 (8.38)	159 (8)	-2.58 (0.50)	-1.89 (-3.33, -0.45)	0.0103	-0.29 (-0.52, -0.07)	0.0094	
18 - <65	196	11.87 (14.25)	196 (36)	-6.45 (0.42)	196	12.26 (16.50)	196 (37)	-5.56 (0.45)	-0.90 (-2.12, 0.32)	0.1485	-0.15 (-0.35, 0.05)	0.1439	
Gender													0.0456
Male	132	11.29 (12.96)	132 (18)	-6.02 (0.52)	140	11.68 (12.96)	140 (15)	-3.52 (0.50)	-2.49 (-3.87, -1.12)	0.0004	-0.42 (-0.66, -0.18)	0.0007	
Female	221	10.90 (13.55)	221 (33)	-5.31 (0.43)	215	10.67 (13.90)	215 (30)	-4.68 (0.43)	-0.62 (-1.85, 0.60)	0.3190	-0.10 (-0.28, 0.09)	0.3109	
Region													0.0417
USA	251	7.12 (7.99)	251 (35)	-3.14 (0.32)	251	7.05 (6.73)	251 (30)	-2.50 (0.32)	-0.64 (-1.53, 0.25)	0.1566	-0.13 (-0.30, 0.05)	0.1578	
Europe	102	20.70 (18.10)	102 (16)	-11.50 (0.77)	104	20.77 (19.61)	104 (15)	-8.46 (0.81)	-3.04 (-5.18, -0.90)	0.0057	-0.38 (-0.65, -0.10)	0.0073	
IGA													0.0245
3-Moderate	292	11.38 (13.67)	292 (43)	-5.77 (0.35)	291	11.30 (14.31)	291 (41)	-4.92 (0.36)	-0.85 (-1.83, 0.13)	0.0890	-0.14 (-0.30, 0.02)	0.0927	
4-Severe	61	9.44 (11.44)	61 (8)	-4.70 (0.84)	64	10.03 (9.17)	64 (4)	-1.02 (0.81)	-3.68 (-5.96, -1.39)	0.0018	-0.56 (-0.92, -0.20)	0.0021	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of change from baseline of non-inflammatory lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in non-inflammatory lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	48.03 (19.72)	0	-	355	49.63 (20.90)	0	-
Day 29 ± 5	325	41.42 (26.08)	325	-6.97 (22.88)	318	42.21 (27.39)	318	-7.46 (19.60)
Day 57 ± 7	302	36.89 (26.45)	302	-11.65 (23.83)	300	40.58 (27.65)	300	-9.36 (22.36)
Day 85 ± 10	302	34.22 (28.61)	302	-14.11 (27.12)	310	40.87 (28.32)	310	-9.02 (23.82)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-13.56 (1.36)	51	355	-8.89 (1.29)	45	-4.68 (-8.35, -1.01)	0.0127	-0.19 (-0.33, -0.04)	0.0130

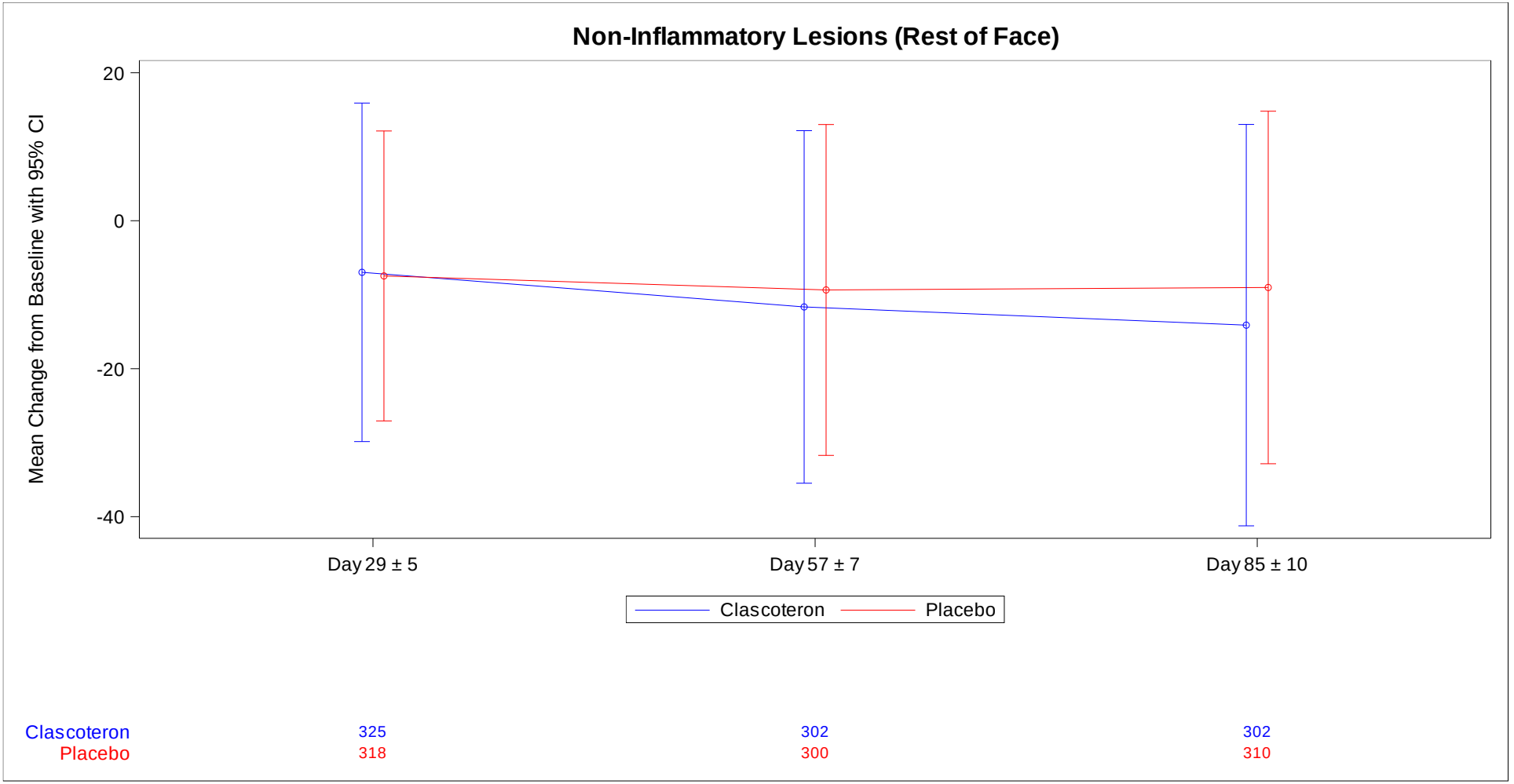
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)								Interaction
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of				
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.0269
9 - <18	157	52.17 (21.95)	157 (15)	-9.03 (2.22)	159	56.61 (22.22)	159 (8)	-9.03 (2.21)	-0.01 (-6.24, 6.23)	0.9985	-0.00 (-0.22, 0.22)	0.9985	
18 - <65	196	44.70 (17.08)	196 (36)	-17.07 (1.70)	196	43.96 (17.92)	196 (37)	-8.37 (1.62)	-8.70 (-13.29, -4.11)	0.0003	-0.37 (-0.57, -0.17)	0.0002	
Gender													0.6628
Male	132	45.81 (20.02)	132 (18)	-9.64 (2.19)	140	48.21 (22.41)	140 (15)	-5.87 (2.01)	-3.77 (-9.65, 2.11)	0.2074	-0.15 (-0.39, 0.08)	0.2061	
Female	221	49.35 (19.46)	221 (33)	-15.87 (1.78)	215	50.55 (19.86)	215 (30)	-10.40 (1.77)	-5.47 (-10.44, -0.51)	0.0308	-0.21 (-0.40, -0.02)	0.0302	
Region													<.0001
USA	251	48.72 (20.04)	251 (35)	-11.22 (1.69)	251	52.31 (20.80)	251 (30)	-12.12 (1.63)	0.90 (-3.74, 5.53)	0.7038	0.03 (-0.14, 0.21)	0.7036	
Europe	102	46.31 (18.90)	102 (16)	-19.38 (2.19)	104	43.16 (19.79)	104 (15)	-0.03 (2.13)	-19.35 (-25.46, -13.25)	<.0001	-0.88 (-1.17, -0.59)	<.0001	
IGA													0.1784
3-Moderate	292	48.70 (19.84)	292 (43)	-15.05 (1.47)	291	49.23 (20.80)	291 (41)	-9.01 (1.53)	-6.04 (-10.24, -1.84)	0.0050	-0.24 (-0.40, -0.07)	0.0046	
4-Severe	61	44.82 (18.96)	61 (8)	-6.01 (3.52)	64	51.42 (21.45)	64 (4)	-7.13 (3.31)	1.12 (-8.55, 10.80)	0.8185	0.04 (-0.31, 0.39)	0.8174	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of change from baseline of non-inflammatory lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in Investigator´s Global Assessment over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	3.17 (0.38)	0	-	355	3.18 (0.38)	0	-
Day 29 ± 5	325	2.83 (0.61)	325	-0.35 (0.54)	318	2.86 (0.62)	318	-0.31 (0.58)
Day 57 ± 7	302	2.59 (0.73)	302	-0.58 (0.71)	300	2.61 (0.68)	300	-0.56 (0.63)
Day 85 ± 10	302	2.38 (0.87)	302	-0.79 (0.85)	310	2.63 (0.80)	310	-0.56 (0.74)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in Investigator´s Global Assessment at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-0.74 (0.05)	51	355	-0.56 (0.05)	45	-0.18 (-0.31, -0.06)	0.0044	-0.21 (-0.36, -0.06)	0.0048

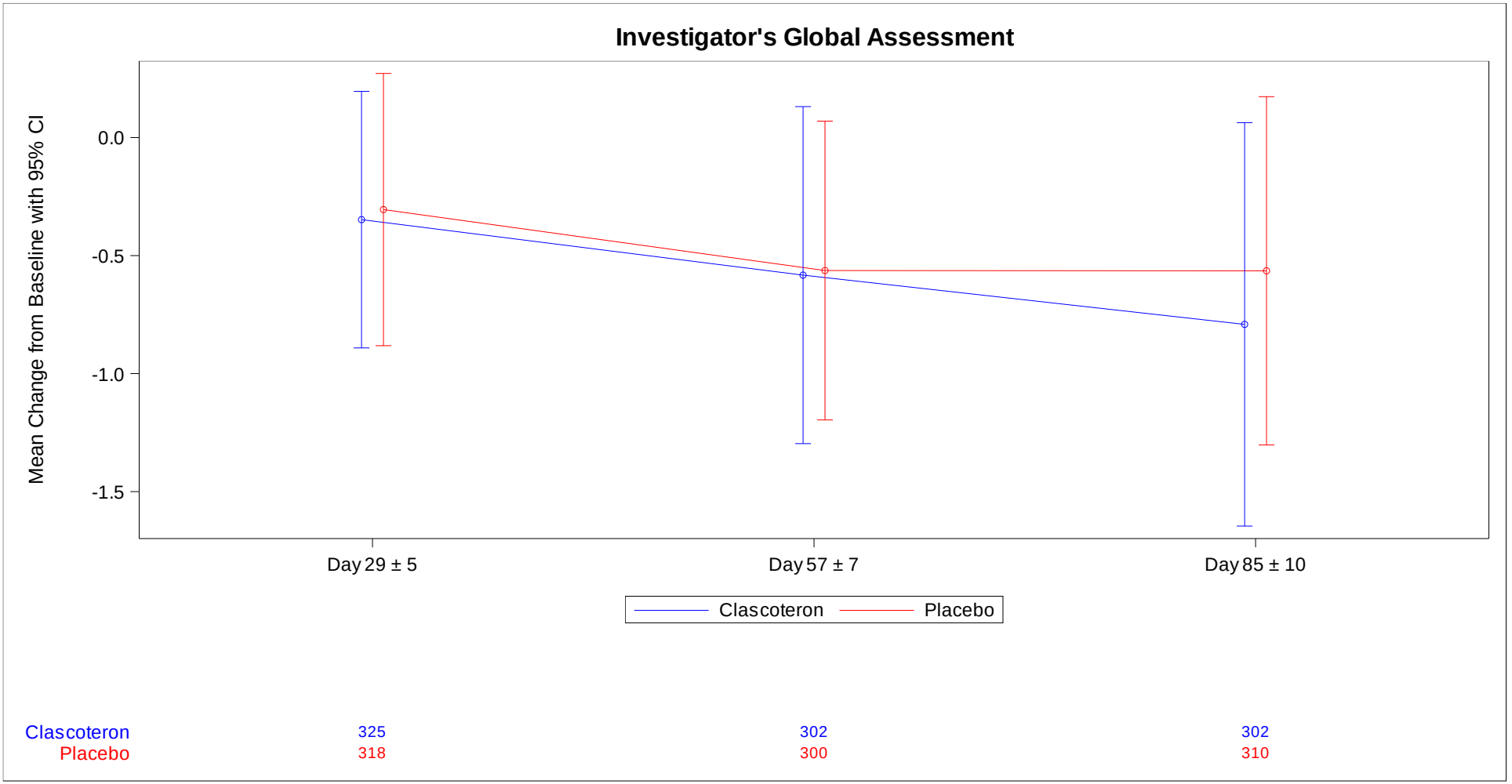
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in Investigator´s Global Assessment at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.7952
9 - <18	157	3.16 (0.37)	157 (15)	-0.65 (0.06)	159	3.22 (0.42)	159 (8)	-0.49 (0.06)	-0.16 (-0.34, 0.01)	0.0633	-0.21 (-0.43, 0.01)	0.0634	
18 - <65	196	3.18 (0.39)	196 (36)	-0.86 (0.07)	196	3.15 (0.36)	196 (37)	-0.66 (0.06)	-0.20 (-0.38, -0.01)	0.0355	-0.22 (-0.41, -0.02)	0.0331	
Gender													0.4801
Male	132	3.27 (0.44)	132 (18)	-0.72 (0.07)	140	3.21 (0.41)	140 (15)	-0.47 (0.07)	-0.24 (-0.43, -0.05)	0.0121	-0.30 (-0.54, -0.06)	0.0142	
Female	221	3.12 (0.32)	221 (33)	-0.80 (0.06)	215	3.16 (0.37)	215 (30)	-0.65 (0.06)	-0.15 (-0.33, 0.03)	0.1070	-0.16 (-0.35, 0.03)	0.0902	
Region													0.1674
USA	251	3.19 (0.39)	251 (35)	-0.68 (0.06)	251	3.19 (0.39)	251 (30)	-0.56 (0.05)	-0.12 (-0.27, 0.02)	0.0973	-0.15 (-0.32, 0.03)	0.0974	
Europe	102	3.13 (0.34)	102 (16)	-0.98 (0.09)	104	3.16 (0.37)	104 (15)	-0.65 (0.09)	-0.34 (-0.60, -0.07)	0.0131	-0.36 (-0.63, -0.08)	0.0105	
IGA													0.1618
3-Moderate	292	3.00 (0.00)	292 (43)	-0.70 (0.05)	291	3.00 (0.00)	291 (41)	-0.55 (0.05)	-0.15 (-0.29, -0.00)	0.0440	-0.17 (-0.33, -0.01)	0.0425	
4-Severe	61	4.00 (0.00)	61 (8)	-1.11 (0.11)	64	4.00 (0.00)	64 (4)	-0.74 (0.10)	-0.38 (-0.68, -0.08)	0.0137	-0.44 (-0.79, -0.08)	0.0157	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of change from baseline of Investigator´s Global Assessment over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in total lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	101.47 (25.12)	0	-	355	103.64 (26.13)	0	-
Day 29 ± 5	325	79.30 (35.15)	325	-22.29 (28.65)	318	80.62 (34.22)	318	-22.48 (25.73)
Day 57 ± 7	302	67.35 (36.60)	302	-33.02 (33.37)	300	73.83 (37.94)	300	-29.17 (31.50)
Day 85 ± 10	302	60.87 (38.32)	302	-38.48 (37.01)	310	74.37 (42.18)	310	-28.42 (37.10)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-37.13 (1.96)	51	355	-28.46 (1.97)	45	-8.66 (-14.03, -3.30)	0.0017	-0.23 (-0.38, -0.09)	0.0019

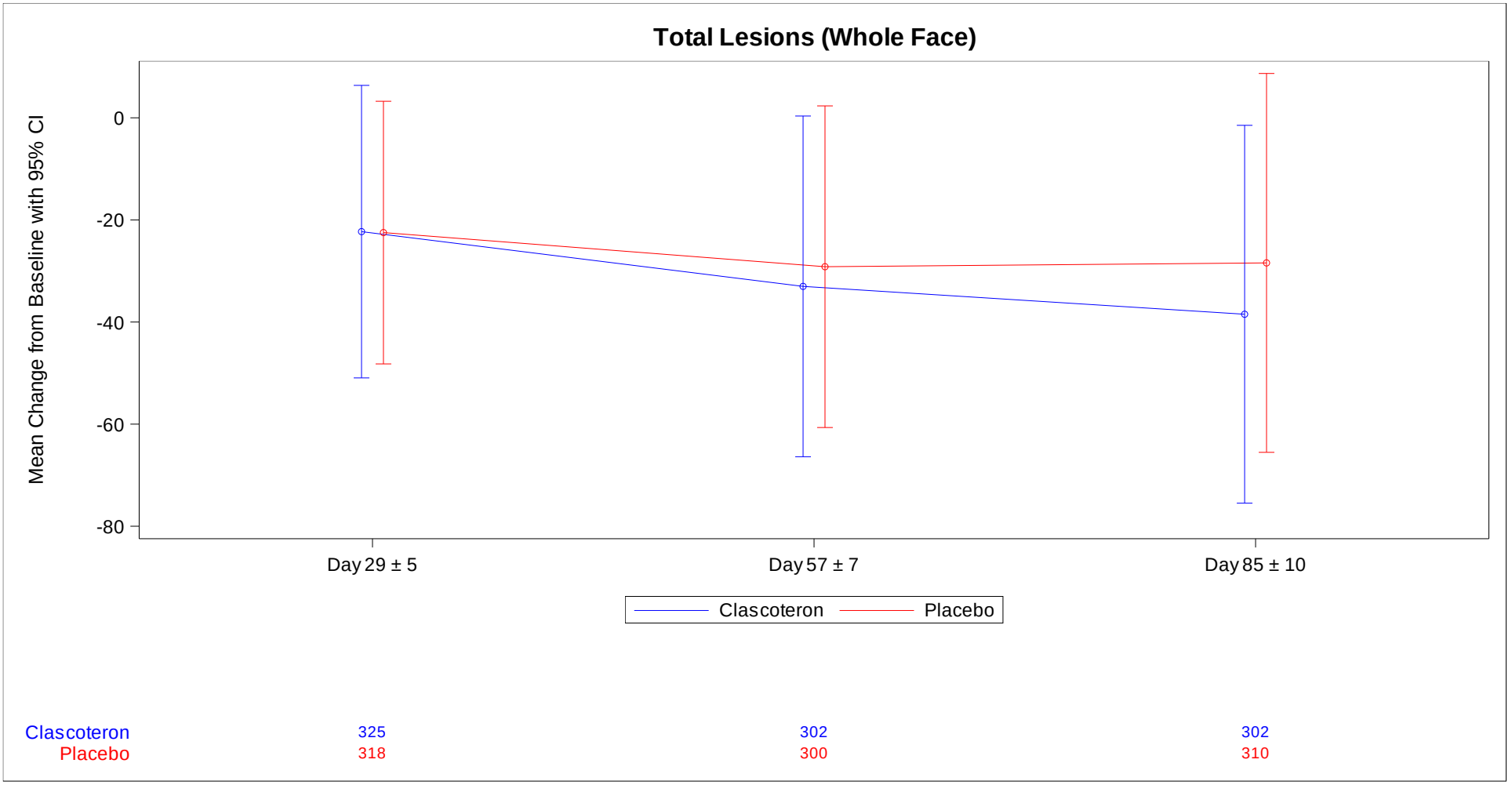
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.0923
9 - <18	157	104.31 (25.81)	157 (15)	-28.87 (3.24)	159	109.93 (25.01)	159 (8)	-25.15 (3.21)	-3.72 (-12.67, 5.22)	0.4131	-0.09 (-0.31, 0.13)	0.4162	
18 - <65	196	99.19 (24.38)	196 (36)	-44.68 (2.58)	196	98.53 (25.96)	196 (37)	-31.16 (2.57)	-13.52 (-20.72, -6.32)	0.0003	-0.37 (-0.57, -0.17)	0.0002	
Gender													0.8741
Male	132	101.14 (25.87)	132 (18)	-32.14 (3.52)	140	104.72 (24.67)	140 (15)	-22.59 (3.21)	-9.55 (-19.11, 0.00)	0.0501	-0.24 (-0.48, -0.00)	0.0458	
Female	221	101.67 (24.73)	221 (33)	-40.91 (2.52)	215	102.93 (27.07)	215 (30)	-32.32 (2.62)	-8.60 (-15.76, -1.43)	0.0190	-0.23 (-0.41, -0.04)	0.0186	
Region													<.0001
USA	251	97.96 (23.54)	251 (35)	-33.23 (2.51)	251	102.90 (26.25)	251 (30)	-32.11 (2.62)	-1.12 (-8.36, 6.12)	0.7600	-0.03 (-0.20, 0.15)	0.7577	
Europe	102	110.11 (26.87)	102 (16)	-48.40 (3.33)	104	105.42 (25.88)	104 (15)	-19.77 (3.42)	-28.62 (-38.21, -19.04)	<.0001	-0.83 (-1.12, -0.55)	<.0001	
IGA													0.9458
3-Moderate	292	101.84 (25.18)	292 (43)	-40.21 (2.13)	291	102.16 (26.13)	291 (41)	-31.12 (2.13)	-9.10 (-15.03, -3.17)	0.0028	-0.25 (-0.41, -0.09)	0.0027	
4-Severe	61	99.70 (24.97)	61 (8)	-25.74 (5.85)	64	110.36 (25.26)	64 (4)	-16.05 (5.62)	-9.69 (-25.96, 6.58)	0.2390	-0.21 (-0.56, 0.14)	0.2362	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of total lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in total lesions count (Nose) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	13.53 (14.07)	0	-	355	13.46 (13.98)	0	-
Day 29 ± 5	325	9.70 (11.19)	301	-18.39 (72.80)	318	10.35 (12.11)	293	-9.10 (96.66)
Day 57 ± 7	302	7.05 (8.17)	279	-26.12 (100.76)	300	8.30 (9.82)	278	-23.89 (81.96)
Day 85 ± 10	302	5.74 (6.96)	281	-41.46 (84.34)	310	7.71 (8.95)	286	-21.07 (111.50)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	327	-35.69 (6.77)	46	328	-19.66 (7.15)	42	-16.02 (-34.03, 1.98)	0.0808	-0.13 (-0.28, 0.03)	0.1044

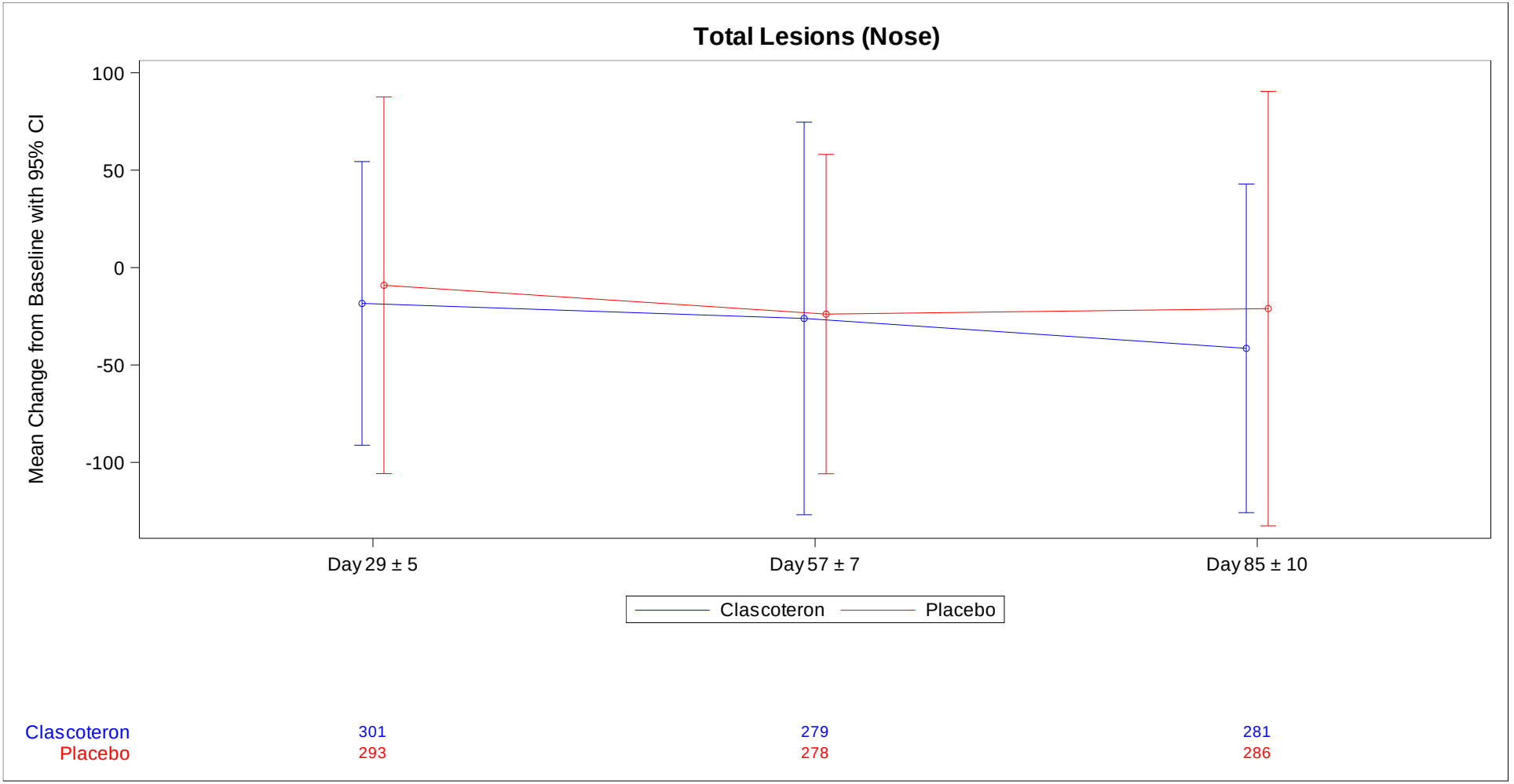
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.8284
9 - <18	157	13.01 (13.70)	147 (14)	-26.33 (9.02)	159	12.08 (9.24)	153 (8)	-13.73 (9.05)	-12.59 (-37.32, 12.14)	0.3166	-0.11 (-0.34, 0.11)	0.3263	
18 - <65	196	13.94 (14.38)	180 (32)	-33.84 (10.06)	196	14.58 (16.81)	175 (34)	-17.27 (9.73)	-16.56 (-42.98, 9.85)	0.2171	-0.13 (-0.33, 0.08)	0.2384	
Gender													0.9829
Male	132	14.20 (14.66)	124 (17)	-27.63 (10.12)	140	14.54 (13.55)	135 (15)	-12.57 (10.44)	-15.06 (-44.48, 14.36)	0.3125	-0.13 (-0.37, 0.12)	0.3035	
Female	221	13.12 (13.72)	203 (29)	-32.30 (8.91)	215	12.76 (14.24)	193 (27)	-17.65 (8.61)	-14.65 (-38.23, 8.93)	0.2219	-0.12 (-0.32, 0.08)	0.2389	
Region													0.3626
USA	251	9.77 (10.05)	227 (30)	-24.82 (8.60)	251	9.45 (8.08)	227 (29)	-14.96 (9.13)	-9.86 (-34.32, 14.60)	0.4276	-0.07 (-0.26, 0.11)	0.4325	
Europe	102	22.76 (17.85)	100 (16)	-42.71 (8.51)	104	23.13 (19.48)	101 (13)	-17.66 (7.31)	-25.05 (-47.24, -2.86)	0.0274	-0.31 (-0.59, -0.04)	0.0270	
IGA													0.2775
3-Moderate	292	14.03 (14.33)	272 (39)	-34.64 (6.23)	291	13.71 (14.73)	267 (38)	-26.21 (6.89)	-8.43 (-26.34, 9.48)	0.3540	-0.08 (-0.25, 0.09)	0.3647	
4-Severe	61	11.10 (12.59)	55 (7)	-11.39 (23.63)	64	12.33 (9.88)	61 (4)	32.20 (20.36)	-43.58 (-105.75, 18.59)	0.1660	-0.26 (-0.63, 0.11)	0.1648	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of total lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in total lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	87.94 (22.81)	0	-	355	90.17 (25.32)	0	-
Day 29 ± 5	325	69.59 (32.21)	325	-19.79 (39.72)	318	70.27 (32.30)	318	-22.43 (27.67)
Day 57 ± 7	302	60.30 (33.38)	302	-29.96 (38.21)	300	65.53 (35.49)	300	-27.66 (33.64)
Day 85 ± 10	302	55.14 (35.61)	302	-34.77 (43.21)	310	66.66 (38.22)	310	-25.93 (38.73)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-33.28 (2.20)	51	355	-26.25 (2.10)	45	-7.03 (-12.86, -1.20)	0.0182	-0.17 (-0.32, -0.03)	0.0210

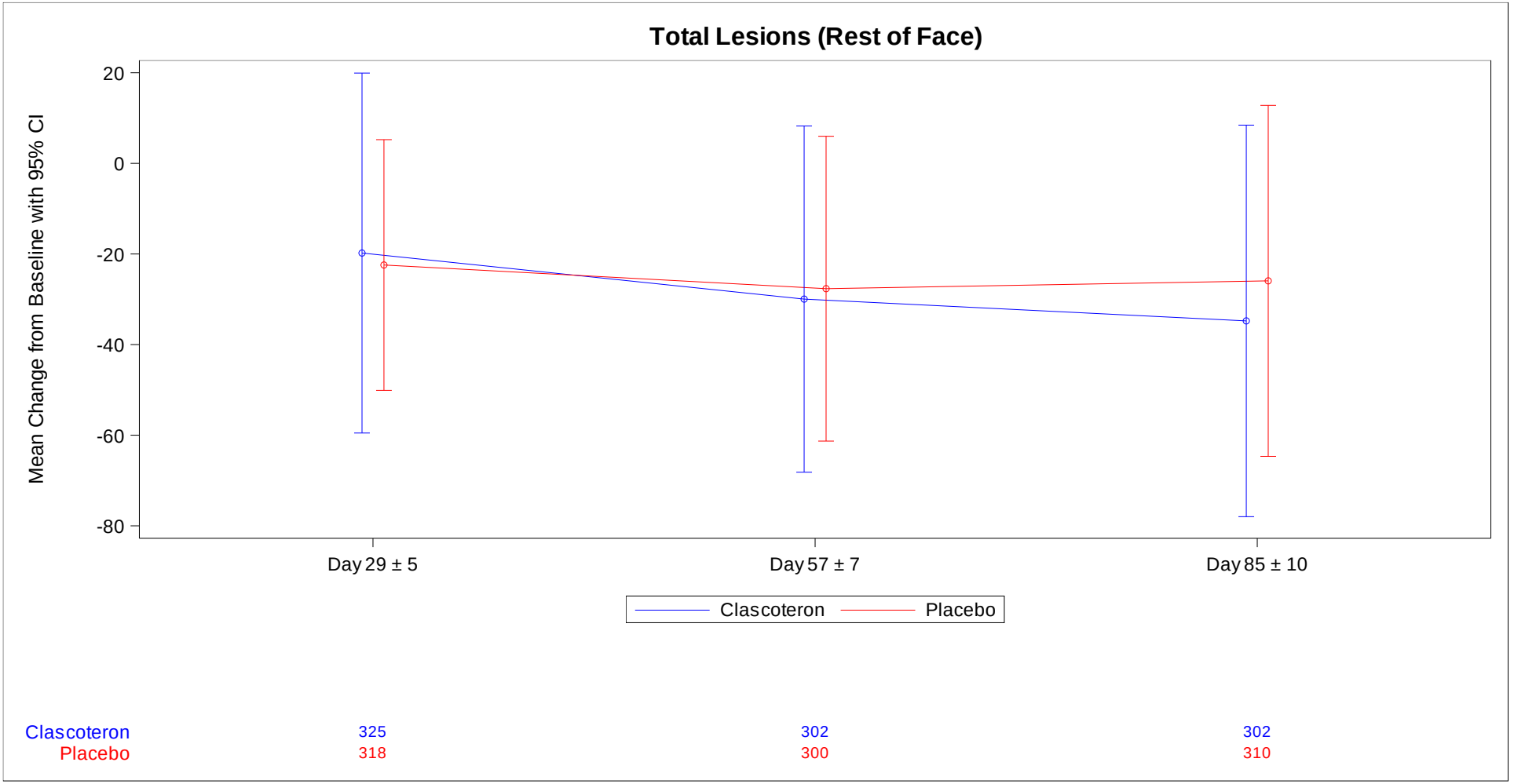
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)			Placebo (N=355)						Interaction
	Baseline		Percent change from Baseline	Baseline		Percent change from Baseline		Difference of		
Level	N	Mean (SD)	N (imp) LSMean (SE)	N	Mean (SD)	N (imp) LSMean (SE)		LSMeans (95% CI)	p-Value	Hedges'g (95% CI) p-Value	p-Value
Age (years)											0.0598
9 - <18	157	91.30 (25.00)	157 (15) -24.45 (3.72)	159	97.85 (25.89)	159 (8) -23.57 (3.61)		-0.88 (-11.15, 9.38)	0.8652	-0.02 (-0.24, 0.20) 0.8648	
18 - <65	196	85.25 (20.57)	196 (36) -41.21 (2.78)	196	83.95 (23.11)	196 (37) -28.19 (2.59)		-13.01 (-20.51, -5.52)	0.0008	-0.35 (-0.55, -0.15) 0.0007	
Gender											0.8574
Male	132	86.93 (23.82)	132 (18) -26.58 (3.79)	140	90.18 (26.39)	140 (15) -19.99 (3.61)		-6.58 (-16.87, 3.71)	0.2086	-0.15 (-0.39, 0.09) 0.2105	
Female	221	88.54 (22.22)	221 (33) -37.95 (2.82)	215	90.17 (24.67)	215 (30) -30.20 (2.74)		-7.75 (-15.44, -0.07)	0.0481	-0.19 (-0.38, -0.00) 0.0498	
Region											<.0001
USA	251	88.18 (23.57)	251 (35) -29.60 (2.83)	251	93.44 (25.51)	251 (30) -30.78 (2.78)		1.18 (-6.74, 9.11)	0.7687	0.03 (-0.15, 0.20) 0.7660	
Europe	102	87.34 (20.94)	102 (16) -44.06 (3.49)	104	82.29 (23.14)	104 (15) -14.79 (3.58)		-29.27 (-39.25, -19.28)	<.0001	-0.81 (-1.10, -0.53) <.0001	
IGA											0.8689
3-Moderate	292	87.80 (23.10)	292 (43) -35.83 (2.45)	291	88.45 (25.20)	291 (41) -28.26 (2.38)		-7.57 (-14.24, -0.90)	0.0263	-0.18 (-0.35, -0.02) 0.0273	
4-Severe	61	88.61 (21.55)	61 (8) -23.15 (5.88)	64	98.03 (24.57)	64 (4) -17.05 (5.65)		-6.10 (-22.53, 10.33)	0.4613	-0.13 (-0.48, 0.22) 0.4573	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of total lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in inflammatory lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	42.40 (11.77)	0	-	355	42.94 (12.31)	0	-
Day 29 ± 5	325	29.57 (16.27)	325	-30.91 (32.30)	318	29.53 (16.02)	318	-31.11 (31.21)
Day 57 ± 7	302	24.48 (16.97)	302	-42.24 (35.78)	300	26.25 (17.32)	300	-39.19 (34.74)
Day 85 ± 10	302	21.80 (16.57)	302	-47.41 (36.07)	310	27.10 (19.49)	310	-36.81 (41.69)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-44.84 (2.14)	51	355	-36.56 (2.14)	45	-8.29 (-14.29, -2.28)	0.0071	-0.21 (-0.35, -0.06)	0.0063

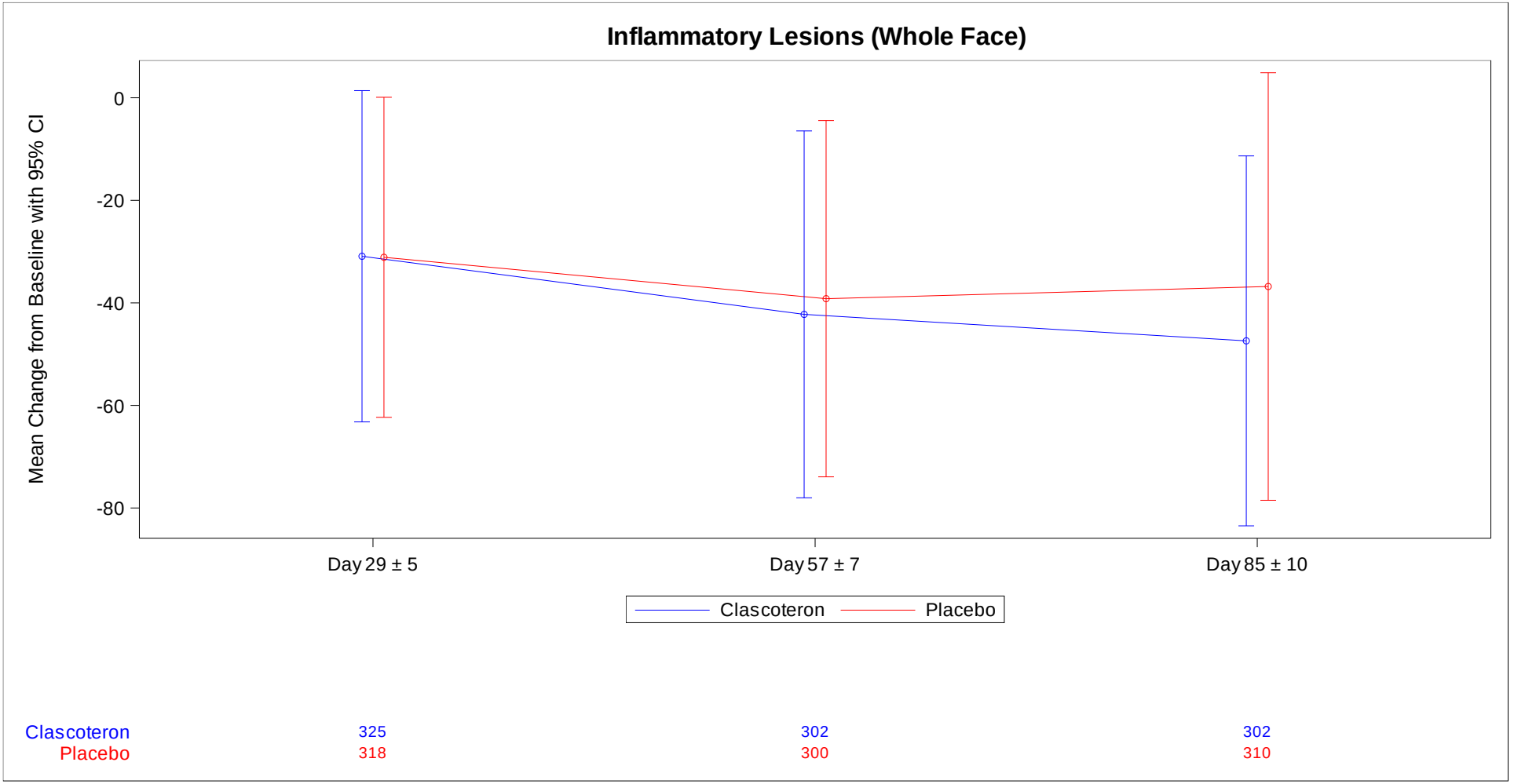
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup Level	Clascoteron (N=353) Baseline N	Clascoteron (N=353) Baseline Mean (SD)	Clascoteron (N=353) Percent change from Baseline N (imp)	Clascoteron (N=353) Percent change from Baseline LSMean (SE)	Placebo (N=355) Baseline N	Placebo (N=355) Baseline Mean (SD)	Placebo (N=355) Percent change from Baseline N (imp)	Placebo (N=355) Percent change from Baseline LSMean (SE)	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	Interaction p-Value
Age (years)													0.7598
9 - <18	157	42.13 (11.52)	157 (15)	-43.13 (3.46)	159	43.72 (11.68)	159 (8)	-35.63 (3.41)	-7.50 (-17.11, 2.11)	0.1254	-0.17 (-0.39, 0.05)	0.1240	
18 - <65	196	42.62 (12.00)	196 (36)	-47.66 (2.67)	196	42.31 (12.80)	196 (37)	-38.25 (2.67)	-9.41 (-17.09, -1.73)	0.0168	-0.25 (-0.45, -0.05)	0.0134	
Gender													0.8021
Male	132	44.04 (11.68)	132 (18)	-40.52 (3.48)	140	44.84 (12.37)	140 (15)	-31.01 (3.51)	-9.51 (-19.72, 0.69)	0.0674	-0.23 (-0.47, 0.01)	0.0561	
Female	221	41.42 (11.75)	221 (33)	-48.81 (2.73)	215	41.71 (12.15)	215 (30)	-40.92 (2.67)	-7.90 (-15.55, -0.25)	0.0431	-0.20 (-0.39, -0.01)	0.0396	
Region													0.0026
USA	251	42.12 (11.68)	251 (35)	-43.09 (2.53)	251	43.54 (12.26)	251 (30)	-40.20 (2.52)	-2.89 (-9.99, 4.21)	0.4233	-0.07 (-0.25, 0.10)	0.4192	
Europe	102	43.10 (12.04)	102 (16)	-52.31 (4.05)	104	41.49 (12.36)	104 (15)	-29.16 (3.73)	-23.15 (-34.45, -11.85)	0.0001	-0.58 (-0.86, -0.31)	<.0001	
IGA													0.3050
3-Moderate	292	41.76 (11.86)	292 (43)	-47.81 (2.18)	291	41.63 (11.52)	291 (41)	-40.92 (2.19)	-6.89 (-13.16, -0.62)	0.0316	-0.18 (-0.35, -0.02)	0.0261	
4-Severe	61	45.44 (10.94)	61 (8)	-35.92 (6.73)	64	48.91 (14.01)	64 (4)	-18.98 (6.39)	-16.95 (-35.46, 1.57)	0.0722	-0.32 (-0.68, 0.03)	0.0713	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of inflammatory lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in inflammatory lesions count (Nose) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	2.48 (3.39)	0	-	355	2.39 (2.86)	0	-
Day 29 ± 5	325	1.40 (2.13)	216	-36.49 (92.70)	318	1.48 (2.39)	216	-31.57 (100.85)
Day 57 ± 7	302	1.07 (1.80)	206	-46.78 (97.61)	300	1.30 (3.03)	204	-41.66 (157.39)
Day 85 ± 10	302	0.88 (1.61)	213	-61.22 (71.70)	310	1.31 (2.25)	213	-38.96 (113.72)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	236	-59.06 (6.64)	23	245	-38.58 (6.35)	32	-20.48 (-37.68, -3.28)	0.0197	-0.20 (-0.38, -0.02)	0.0264

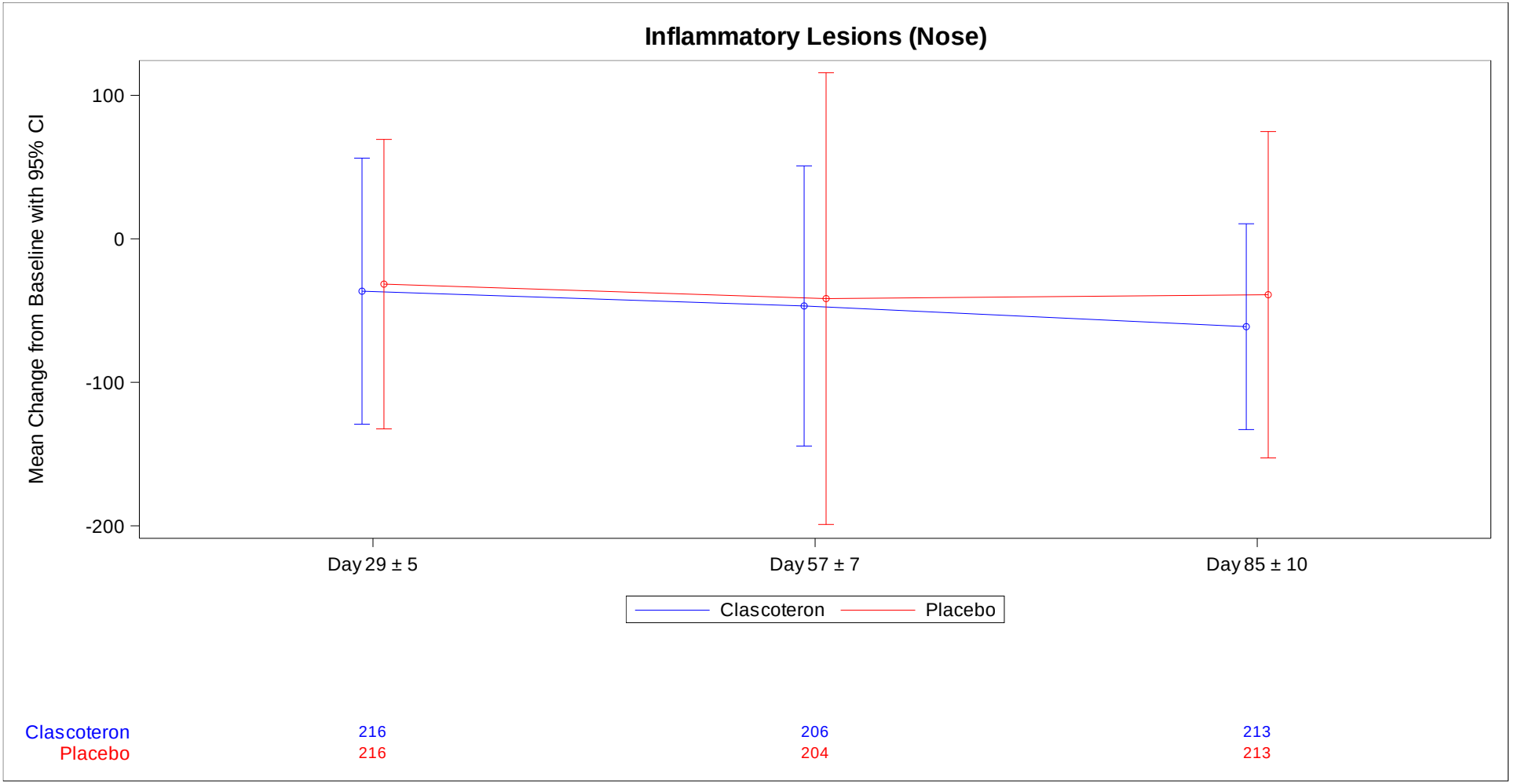
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.4339
9 - <18	157	3.00 (4.13)	116 (10)	-56.52 (10.44)	159	2.48 (2.64)	118 (6)	-30.13 (10.35)	-26.39 (-55.47, 2.69)	0.0750	-0.23 (-0.49, 0.02)	0.0745	
18 - <65	196	2.07 (2.58)	120 (13)	-56.23 (7.18)	196	2.33 (3.03)	127 (26)	-43.65 (6.61)	-12.58 (-31.68, 6.52)	0.1954	-0.16 (-0.41, 0.09)	0.1990	
Gender													0.6506
Male	132	2.92 (4.27)	99 (10)	-53.87 (10.55)	140	2.86 (3.44)	105 (13)	-40.06 (10.11)	-13.81 (-42.68, 15.05)	0.3461	-0.13 (-0.41, 0.14)	0.3466	
Female	221	2.23 (2.70)	137 (13)	-57.58 (7.70)	215	2.09 (2.37)	140 (19)	-35.53 (7.55)	-22.05 (-43.35, -0.75)	0.0425	-0.25 (-0.48, -0.01)	0.0422	
Region													0.2985
USA	251	2.65 (3.63)	177 (18)	-55.76 (6.87)	251	2.41 (2.74)	174 (23)	-42.76 (6.75)	-13.00 (-31.99, 5.99)	0.1790	-0.14 (-0.35, 0.07)	0.1786	
Europe	102	2.07 (2.65)	59 (5)	-58.63 (14.45)	104	2.37 (3.14)	71 (9)	-23.03 (13.24)	-35.60 (-74.18, 2.98)	0.0702	-0.32 (-0.67, 0.03)	0.0729	
IGA													0.1073
3-Moderate	292	2.66 (3.57)	201 (20)	-57.23 (5.35)	291	2.42 (2.76)	204 (30)	-48.10 (5.10)	-9.13 (-23.57, 5.30)	0.2142	-0.12 (-0.32, 0.07)	0.2179	
4-Severe	61	1.66 (2.14)	35 (3)	-53.21 (28.18)	64	2.30 (3.30)	41 (2)	18.94 (25.96)	-72.15 (-148.80, 4.50)	0.0646	-0.43 (-0.89, 0.03)	0.0654	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of inflammatory lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in inflammatory lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	39.92 (11.28)	0	-	355	40.55 (11.76)	0	-
Day 29 ± 5	325	28.17 (15.51)	325	-29.66 (33.60)	318	28.05 (15.25)	318	-30.53 (31.64)
Day 57 ± 7	302	23.41 (16.07)	302	-40.70 (36.95)	300	24.95 (16.40)	300	-38.47 (35.55)
Day 85 ± 10	302	20.92 (15.91)	302	-45.27 (40.22)	310	25.79 (18.33)	310	-36.14 (41.80)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-42.90 (2.21)	51	355	-35.86 (2.24)	45	-7.03 (-13.23, -0.84)	0.0262	-0.17 (-0.32, -0.02)	0.0258

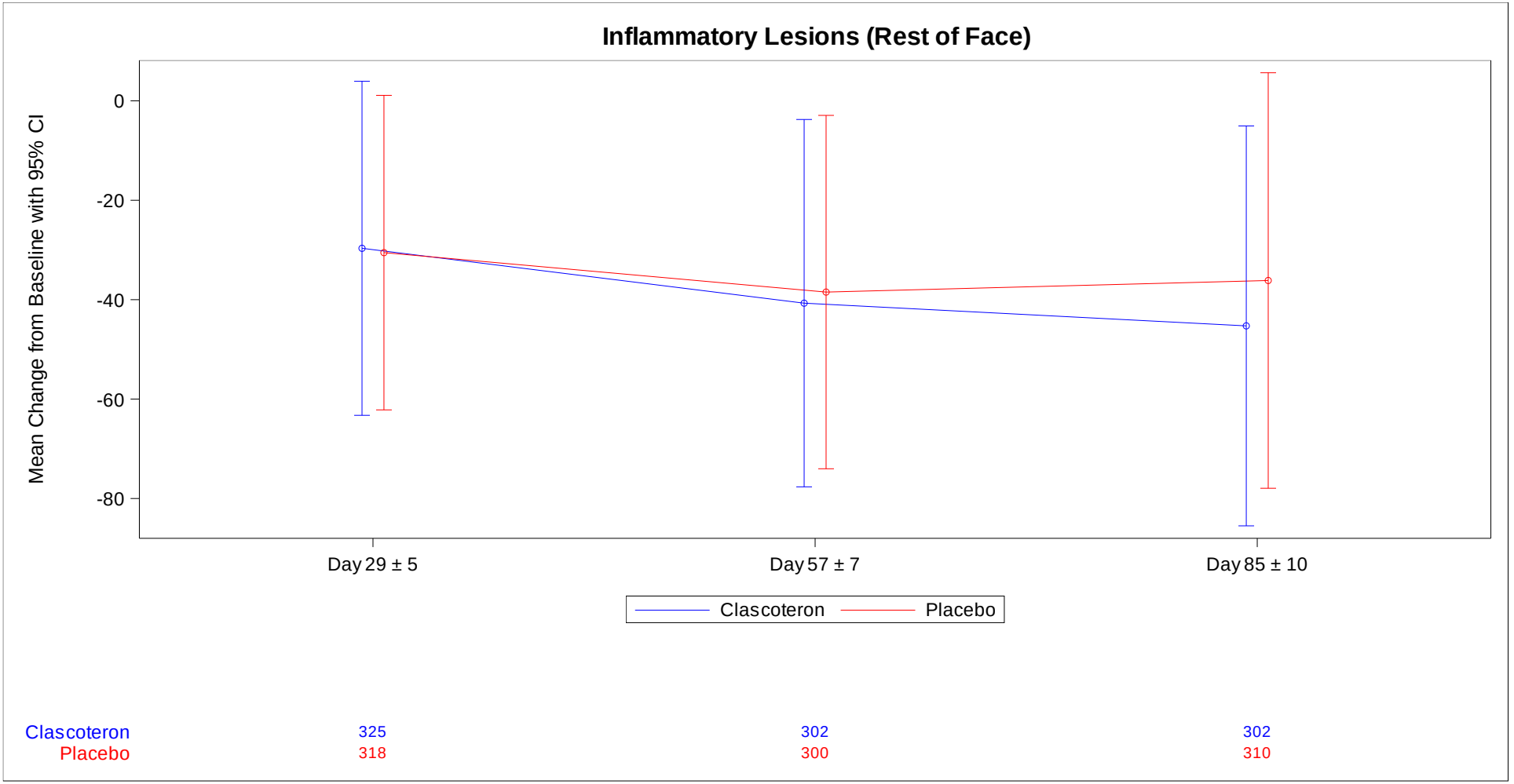
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)							Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of			
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Age (years)												0.5091
9 - <18	157	39.13 (11.11)	157 (15)	-39.94 (3.67)	159	41.24 (11.41)	159 (8)	-34.99 (3.61)	-4.95 (-15.15, 5.25)	0.3395	-0.11 (-0.33, 0.11)	0.3371
18 - <65	196	40.55 (11.40)	196 (36)	-46.89 (2.73)	196	39.98 (12.03)	196 (37)	-37.62 (2.78)	-9.27 (-17.20, -1.34)	0.0223	-0.24 (-0.44, -0.04)	0.0179
Gender												0.9450
Male	132	41.12 (11.46)	132 (18)	-36.96 (3.83)	140	41.97 (11.71)	140 (15)	-29.96 (3.76)	-7.00 (-17.89, 3.89)	0.2059	-0.16 (-0.40, 0.08)	0.1947
Female	221	39.19 (11.13)	221 (33)	-48.00 (2.70)	215	39.62 (11.72)	215 (30)	-40.54 (2.68)	-7.46 (-15.07, 0.15)	0.0546	-0.19 (-0.38, 0.00)	0.0508
Region												0.0011
USA	251	39.46 (11.16)	251 (35)	-40.78 (2.66)	251	41.14 (11.60)	251 (30)	-39.51 (2.66)	-1.27 (-8.70, 6.16)	0.7368	-0.03 (-0.21, 0.14)	0.7358
Europe	102	41.03 (11.54)	102 (16)	-51.86 (4.03)	104	39.13 (12.07)	104 (15)	-28.42 (3.80)	-23.45 (-34.67, -12.23)	<.0001	-0.59 (-0.87, -0.31)	<.0001
IGA												0.2590
3-Moderate	292	39.11 (11.20)	292 (43)	-45.54 (2.30)	291	39.21 (10.98)	291 (41)	-40.05 (2.34)	-5.48 (-12.07, 1.10)	0.1023	-0.14 (-0.30, 0.02)	0.0957
4-Severe	61	43.79 (10.91)	61 (8)	-35.97 (6.58)	64	46.61 (13.27)	64 (4)	-19.57 (6.25)	-16.40 (-34.53, 1.72)	0.0753	-0.32 (-0.67, 0.03)	0.0742

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of inflammatory lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in non-inflammatory lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	59.07 (22.19)	0	-	355	60.70 (22.09)	0	-
Day 29 ± 5	325	49.72 (28.52)	325	-15.73 (40.20)	318	51.08 (29.87)	318	-17.19 (35.28)
Day 57 ± 7	302	42.87 (28.66)	302	-25.99 (43.38)	300	47.58 (30.05)	300	-22.07 (40.85)
Day 85 ± 10	302	39.07 (30.53)	302	-32.02 (49.57)	310	47.27 (31.36)	310	-22.51 (43.44)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-30.72 (2.49)	51	355	-21.88 (2.48)	45	-8.83 (-15.88, -1.79)	0.0142	-0.19 (-0.34, -0.04)	0.0122

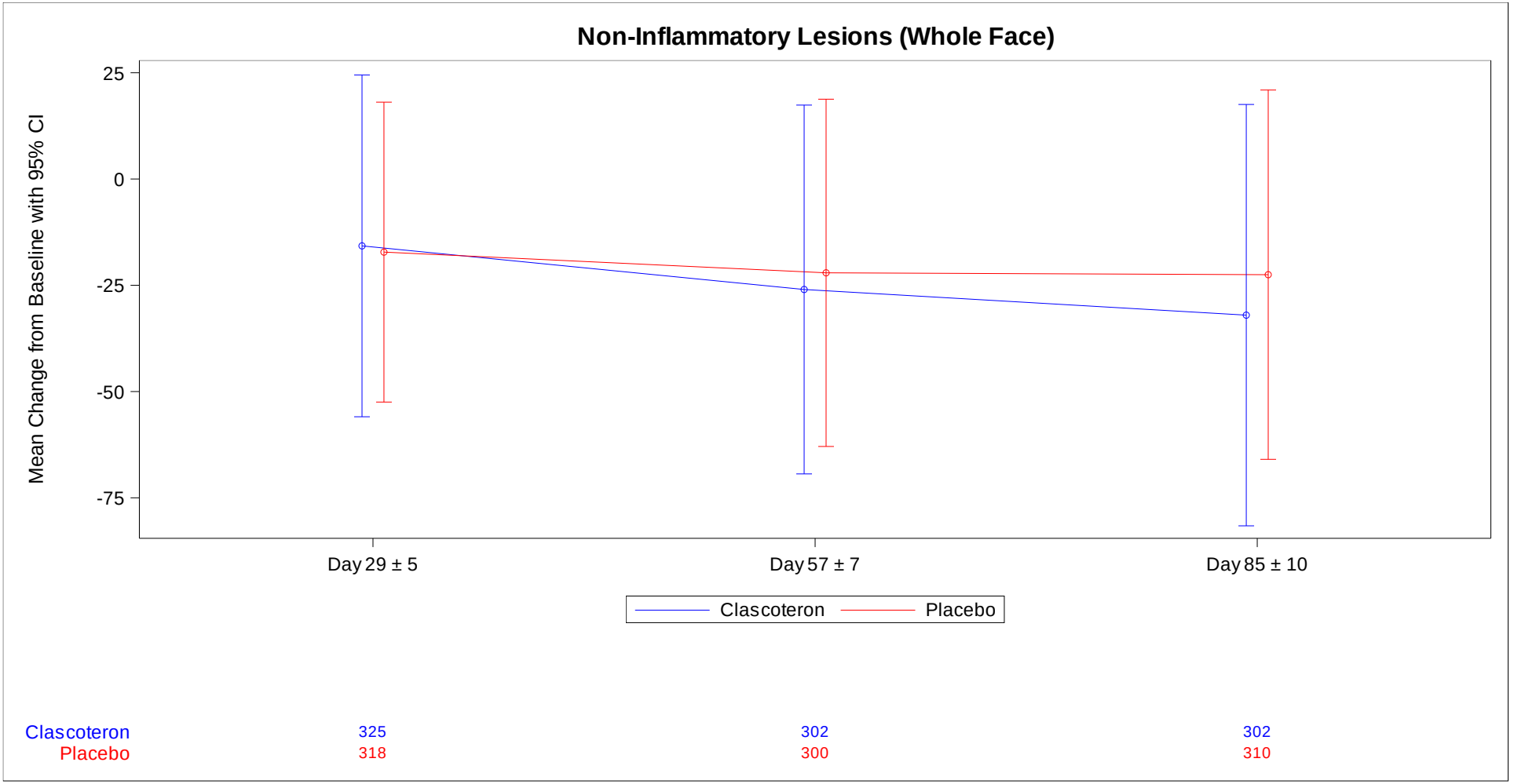
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.0169
9 - <18	157	62.18 (22.89)	157 (15)	-18.37 (4.22)	159	66.21 (21.94)	159 (8)	-19.08 (4.12)	0.71 (-11.01, 12.43)	0.9047	0.01 (-0.21, 0.23)	0.9040	
18 - <65	196	56.57 (21.33)	196 (36)	-41.06 (3.06)	196	56.22 (21.24)	196 (37)	-23.82 (3.30)	-17.24 (-26.37, -8.12)	0.0003	-0.39 (-0.59, -0.19)	0.0002	
Gender													0.7889
Male	132	57.10 (21.75)	132 (18)	-26.54 (4.16)	140	59.89 (21.57)	140 (15)	-16.18 (4.14)	-10.37 (-22.22, 1.48)	0.0857	-0.21 (-0.45, 0.02)	0.0793	
Female	221	60.24 (22.41)	221 (33)	-33.61 (3.25)	215	61.22 (22.46)	215 (30)	-25.29 (3.38)	-8.32 (-17.73, 1.09)	0.0827	-0.17 (-0.36, 0.02)	0.0772	
Region													<.0001
USA	251	55.84 (19.99)	251 (35)	-24.81 (3.30)	251	59.35 (20.99)	251 (30)	-25.31 (3.30)	0.50 (-8.95, 9.95)	0.9166	0.01 (-0.17, 0.18)	0.9145	
Europe	102	67.01 (25.22)	102 (16)	-46.05 (3.73)	104	63.93 (24.35)	104 (15)	-13.06 (3.59)	-32.99 (-43.46, -22.51)	<.0001	-0.88 (-1.17, -0.60)	<.0001	
IGA													0.6982
3-Moderate	292	60.07 (22.13)	292 (43)	-33.52 (2.75)	291	60.53 (22.45)	291 (41)	-23.58 (2.81)	-9.94 (-17.84, -2.05)	0.0138	-0.21 (-0.37, -0.05)	0.0118	
4-Severe	61	54.26 (21.99)	61 (8)	-18.93 (6.83)	64	61.45 (20.53)	64 (4)	-12.93 (6.26)	-6.00 (-24.68, 12.69)	0.5237	-0.12 (-0.47, 0.24)	0.5196	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of non-inflammatory lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in non-inflammatory lesions count (Nose) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	11.04 (13.32)	0	-	355	11.07 (13.53)	0	-
Day 29 ± 5	325	8.30 (10.83)	282	-18.70 (67.49)	318	8.87 (11.75)	267	-3.67 (111.12)
Day 57 ± 7	302	5.98 (7.76)	260	-25.79 (122.79)	300	7.00 (8.79)	254	-24.70 (72.91)
Day 85 ± 10	302	4.85 (6.63)	262	-46.15 (67.41)	310	6.40 (8.05)	261	-28.38 (81.19)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	306	-40.34 (6.45)	44	300	-27.57 (6.53)	39	-12.76 (-29.32, 3.80)	0.1298	-0.11 (-0.27, 0.05)	0.1653

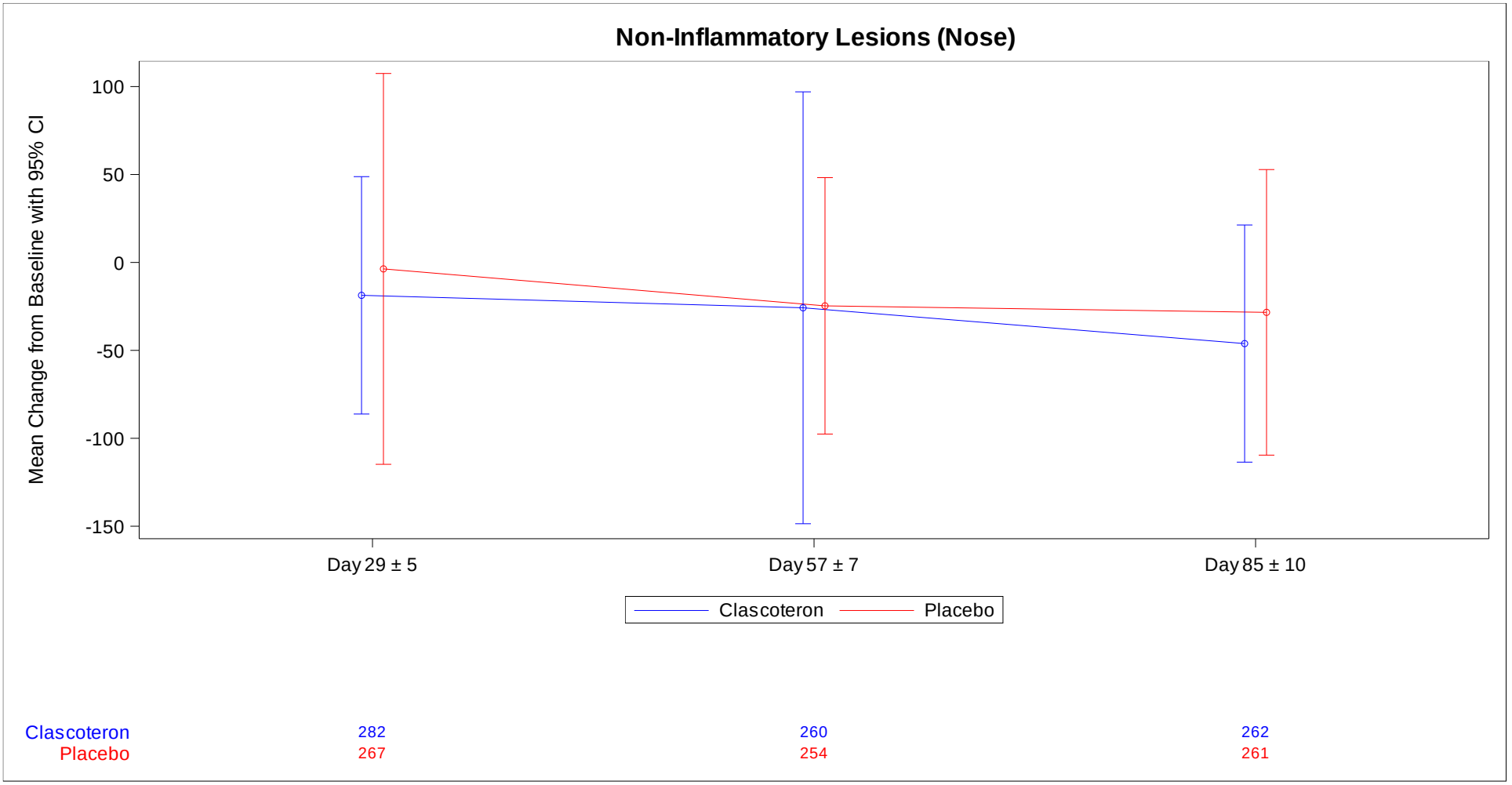
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)							Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of			
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Age (years)												0.6341
9 - <18	157	10.01 (12.02)	135 (14)	-26.45 (9.40)	159	9.60 (8.38)	142 (7)	-18.29 (9.18)	-8.16 (-35.87, 19.55)	0.5590	-0.07 (-0.31, 0.16)	0.5359
18 - <65	196	11.87 (14.25)	171 (30)	-41.17 (7.89)	196	12.26 (16.50)	158 (32)	-24.52 (8.19)	-16.65 (-38.79, 5.49)	0.1389	-0.16 (-0.38, 0.06)	0.1448
Gender												0.2927
Male	132	11.29 (12.96)	115 (16)	-39.49 (9.98)	140	11.68 (12.96)	126 (13)	-15.27 (8.37)	-24.21 (-49.76, 1.34)	0.0630	-0.24 (-0.49, 0.01)	0.0633
Female	221	10.90 (13.55)	191 (28)	-31.93 (8.00)	215	10.67 (13.90)	174 (26)	-25.98 (8.49)	-5.95 (-29.05, 17.16)	0.6105	-0.05 (-0.26, 0.15)	0.6106
Region												0.2705
USA	251	7.12 (7.99)	207 (28)	-29.72 (7.76)	251	7.05 (6.73)	203 (26)	-22.00 (8.25)	-7.72 (-30.05, 14.60)	0.4952	-0.07 (-0.26, 0.13)	0.4959
Europe	102	20.70 (18.10)	99 (16)	-45.34 (8.28)	104	20.77 (19.61)	97 (13)	-20.40 (7.30)	-24.94 (-46.42, -3.47)	0.0233	-0.32 (-0.60, -0.04)	0.0256
IGA												0.4742
3-Moderate	292	11.38 (13.67)	256 (37)	-36.49 (6.65)	291	11.30 (14.31)	243 (35)	-26.46 (7.05)	-10.03 (-29.33, 9.28)	0.3052	-0.09 (-0.27, 0.08)	0.3013
4-Severe	61	9.44 (11.44)	50 (7)	-25.83 (14.71)	64	10.03 (9.17)	57 (4)	-0.38 (12.74)	-25.45 (-63.90, 13.00)	0.1906	-0.25 (-0.63, 0.13)	0.1937

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of non-inflammatory lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in non-inflammatory lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	48.03 (19.72)	0	-	355	49.63 (20.90)	0	-
Day 29 ± 5	325	41.42 (26.08)	325	-8.48 (84.36)	318	42.21 (27.39)	318	-16.17 (40.24)
Day 57 ± 7	302	36.89 (26.45)	302	-18.64 (67.99)	300	40.58 (27.65)	300	-17.41 (49.28)
Day 85 ± 10	302	34.22 (28.61)	302	-24.64 (65.64)	310	40.87 (28.32)	310	-13.68 (66.40)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-23.56 (3.55)	51	355	-13.03 (3.45)	45	-10.53 (-20.06, -0.99)	0.0306	-0.16 (-0.31, -0.01)	0.0338

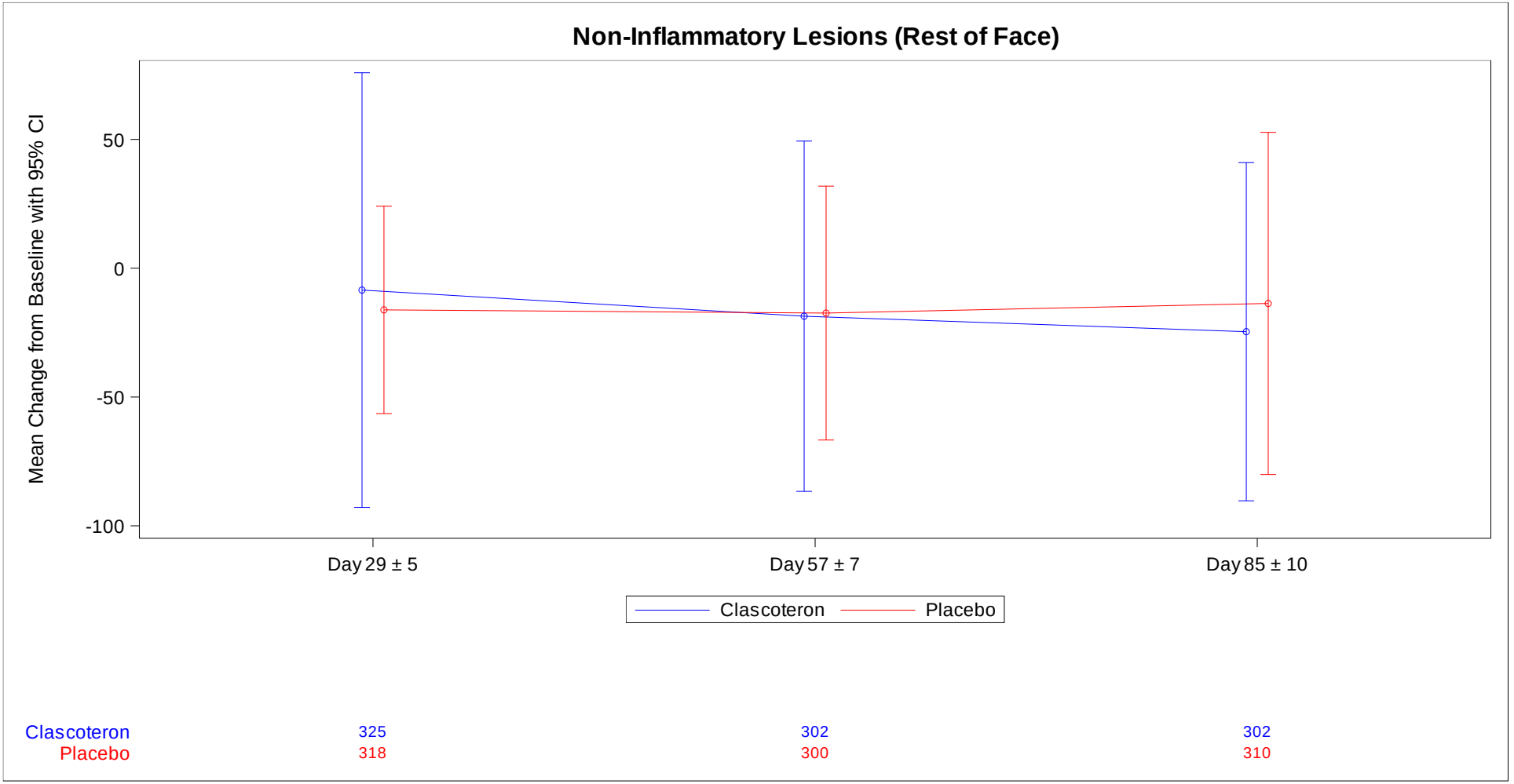
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.0106
9 - <18	157	52.17 (21.95)	157 (15)	-9.78 (5.50)	159	56.61 (22.22)	159 (8)	-13.34 (5.44)	3.56 (-11.80, 18.92)	0.6480	0.05 (-0.17, 0.27)	0.6457	
18 - <65	196	44.70 (17.08)	196 (36)	-34.60 (4.80)	196	43.96 (17.92)	196 (37)	-12.05 (4.70)	-22.55 (-35.65, -9.45)	0.0009	-0.34 (-0.54, -0.14)	0.0009	
Gender													0.4489
Male	132	45.81 (20.02)	132 (18)	-16.03 (7.06)	140	48.21 (22.41)	140 (15)	-0.02 (6.72)	-16.01 (-35.04, 3.03)	0.0987	-0.20 (-0.44, 0.04)	0.1021	
Female	221	49.35 (19.46)	221 (33)	-28.26 (3.83)	215	50.55 (19.86)	215 (30)	-20.63 (3.81)	-7.63 (-18.35, 3.10)	0.1624	-0.13 (-0.32, 0.05)	0.1595	
Region													<.0001
USA	251	48.72 (20.04)	251 (35)	-17.79 (4.02)	251	52.31 (20.80)	251 (30)	-20.77 (4.02)	2.99 (-8.19, 14.16)	0.5991	0.05 (-0.13, 0.22)	0.5996	
Europe	102	46.31 (18.90)	102 (16)	-37.36 (7.41)	104	43.16 (19.79)	104 (15)	6.64 (6.83)	-44.00 (-64.04, -23.96)	<.0001	-0.61 (-0.89, -0.33)	<.0001	
IGA													0.5847
3-Moderate	292	48.70 (19.84)	292 (43)	-25.90 (3.91)	291	49.23 (20.80)	291 (41)	-13.78 (4.17)	-12.12 (-23.32, -0.93)	0.0340	-0.18 (-0.34, -0.01)	0.0344	
4-Severe	61	44.82 (18.96)	61 (8)	-12.40 (8.55)	64	51.42 (21.45)	64 (4)	-7.36 (7.82)	-5.04 (-28.38, 18.29)	0.6668	-0.08 (-0.43, 0.27)	0.6650	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of non-inflammatory lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in Investigator´s Global Assessment over time
Intention-to-treat

	Clascoteron (N=353)				Placebo (N=355)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	353	3.17 (0.38)	0	-	355	3.18 (0.38)	0	-
Day 29 ± 5	325	2.83 (0.61)	325	-10.79 (17.22)	318	2.86 (0.62)	318	-9.36 (17.87)
Day 57 ± 7	302	2.59 (0.73)	302	-18.10 (22.36)	300	2.61 (0.68)	300	-17.61 (19.75)
Day 85 ± 10	302	2.38 (0.87)	302	-24.72 (26.93)	310	2.63 (0.80)	310	-17.66 (23.34)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in Investigator´s Global Assessment at Week 12
Intention-to-treat

	Clascoteron (N=353)			Placebo (N=355)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	353	-23.17 (1.51)	51	355	-17.56 (1.44)	45	-5.62 (-9.67, -1.56)	0.0069	-0.20 (-0.35, -0.05)	0.0073

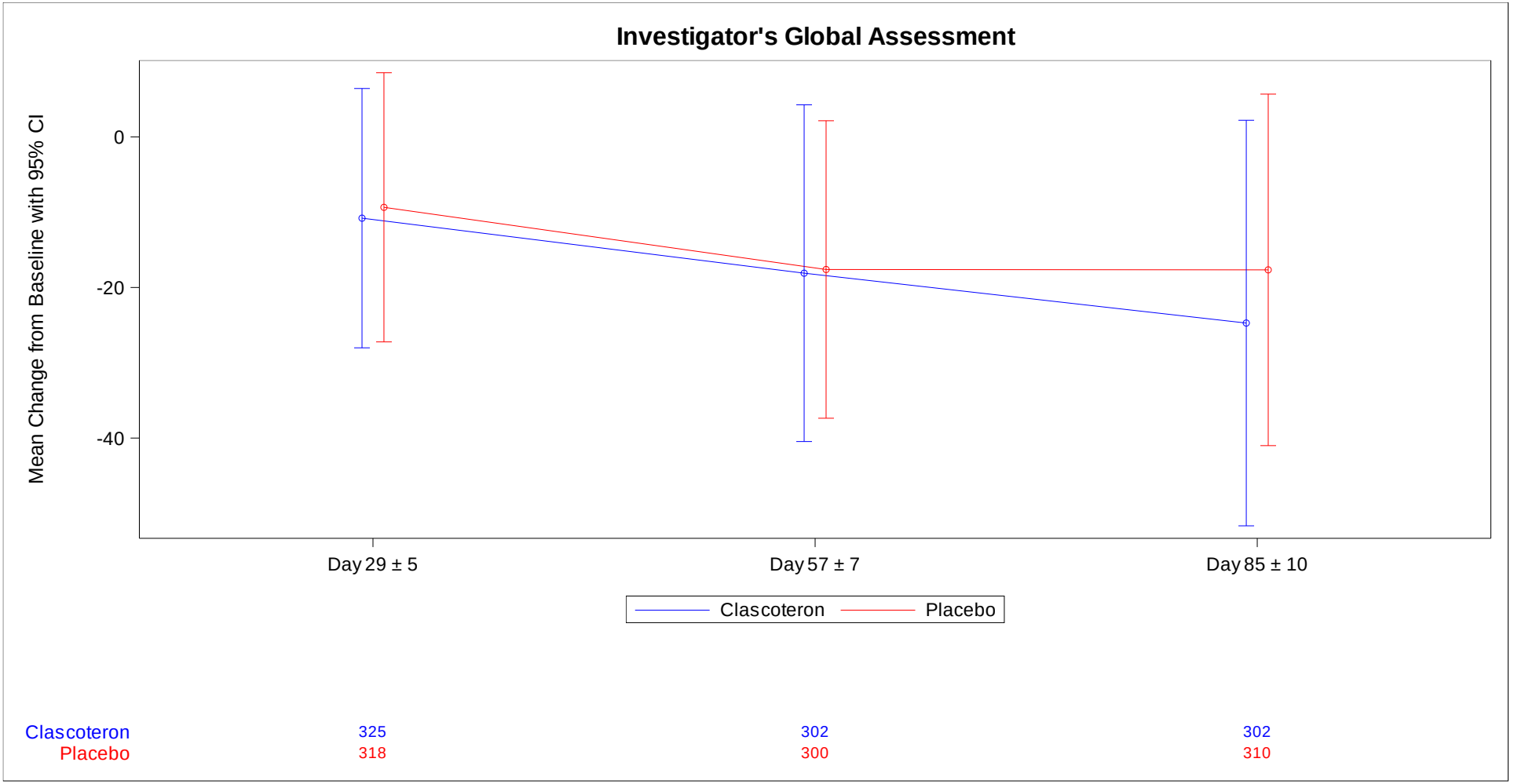
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in Investigator´s Global Assessment at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=353)				Placebo (N=355)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.7897
9 - <18	157	3.16 (0.37)	157 (15)	-20.35 (2.03)	159	3.22 (0.42)	159 (8)	-15.39 (1.90)	-4.96 (-10.45, 0.53)	0.0762	-0.20 (-0.42, 0.02)	0.0758	
18 - <65	196	3.18 (0.39)	196 (36)	-26.85 (2.10)	196	3.15 (0.36)	196 (37)	-20.80 (2.07)	-6.05 (-11.95, -0.14)	0.0448	-0.21 (-0.41, -0.01)	0.0414	
Gender													0.5770
Male	132	3.27 (0.44)	132 (18)	-21.69 (2.20)	140	3.21 (0.41)	140 (15)	-14.64 (2.17)	-7.05 (-12.99, -1.11)	0.0204	-0.28 (-0.51, -0.04)	0.0237	
Female	221	3.12 (0.32)	221 (33)	-25.40 (1.99)	215	3.16 (0.37)	215 (30)	-20.72 (2.05)	-4.68 (-10.63, 1.27)	0.1209	-0.16 (-0.34, 0.03)	0.1020	
Region													0.1347
USA	251	3.19 (0.39)	251 (35)	-20.94 (1.73)	251	3.19 (0.39)	251 (30)	-17.43 (1.63)	-3.52 (-8.19, 1.15)	0.1389	-0.13 (-0.31, 0.04)	0.1396	
Europe	102	3.13 (0.34)	102 (16)	-31.43 (3.01)	104	3.16 (0.37)	104 (15)	-20.61 (2.91)	-10.82 (-19.31, -2.33)	0.0132	-0.36 (-0.63, -0.08)	0.0107	
IGA													0.2992
3-Moderate	292	3.00 (0.00)	292 (43)	-23.17 (1.69)	291	3.00 (0.00)	291 (41)	-18.34 (1.67)	-4.83 (-9.54, -0.13)	0.0442	-0.17 (-0.33, -0.01)	0.0425	
4-Severe	61	4.00 (0.00)	61 (8)	-27.87 (2.82)	64	4.00 (0.00)	64 (4)	-18.40 (2.62)	-9.47 (-17.02, -1.92)	0.0147	-0.44 (-0.79, -0.08)	0.0157	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of Investigator´s Global Assessment over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events
Safety Analysis Set

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with event, n/N (%)	40/ 353 (11.33)	41/ 355 (11.55)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	1.00 (0.64, 1.54)	
p-value	0.9847	
Odds Ratio (95% CI)	0.98 (0.62, 1.55)	
p-value	0.9275	
Risk Ratio (95% CI)	0.98 (0.65, 1.48)	
p-value	0.9275	
Risk Difference (95% CI)	-0.00 (-0.05, 0.04)	
p-value	0.9274	

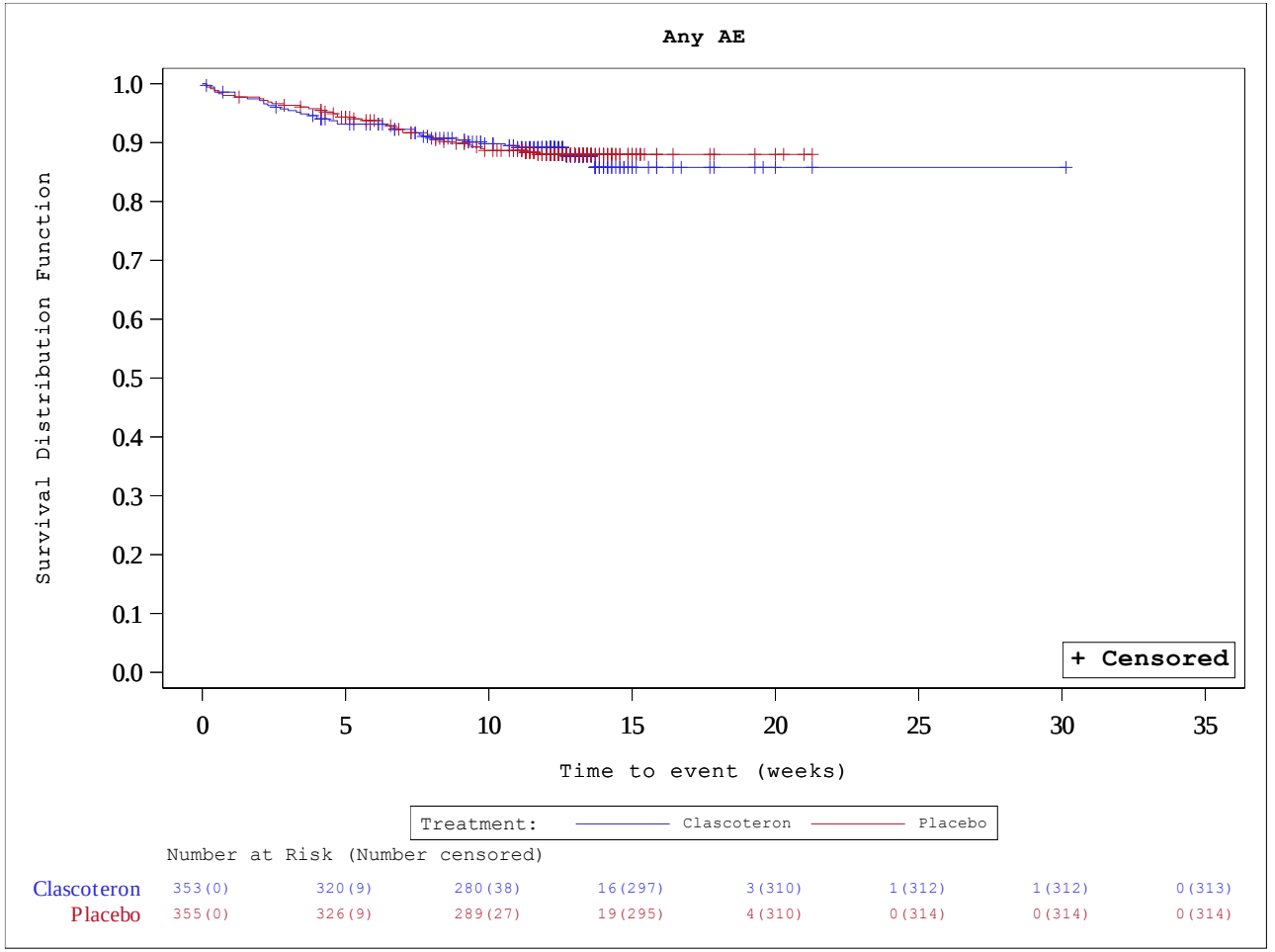
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=353) n/ N (%)	Clascoteron (N=353) Median (95% CI)	Placebo (N=355) n/ N (%)	Placebo (N=355) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							0.3785
9 - <18	20/ 157 (12.74)	NE (NE, NE)	17/ 159 (10.69)	NE (NE, NE)	1.22 (0.64, 2.33)	0.5445	
18 - <65	20/ 196 (10.20)	NE (NE, NE)	24/ 196 (12.24)	NE (NE, NE)	0.83 (0.46, 1.51)	0.5421	
Gender							0.1414
Male	14/ 132 (10.61)	NE (NE, NE)	9/ 140 (6.43)	NE (NE, NE)	1.69 (0.73, 3.91)	0.2190	
Female	26/ 221 (11.76)	NE (NE, NE)	32/ 215 (14.88)	NE (NE, NE)	0.80 (0.48, 1.34)	0.3988	
Region							0.4371
USA	35/ 251 (13.94)	NE (NE, NE)	38/ 251 (15.14)	NE (NE, NE)	0.93 (0.59, 1.48)	0.7690	
Europe	5/ 102 (4.90)	NE (NE, NE)	3/ 104 (2.88)	NE (NE, NE)	1.65 (0.39, 6.93)	0.4920	
IGA							0.4716
3-Moderate	33/ 292 (11.30)	NE (NE, NE)	31/ 291 (10.65)	NE (NE, NE)	1.08 (0.66, 1.77)	0.7462	
4-Severe	7/ 61 (11.48)	NE (NE, NE)	10/ 64 (15.63)	NE (NE, NE)	0.72 (0.27, 1.90)	0.5080	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events excluding disease-related events
Safety Analysis Set

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with event, n/N (%)	40/ 353 (11.33)	40/ 355 (11.27)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	1.02 (0.66, 1.58)	
p-value	0.9249	
Odds Ratio (95% CI)	1.01 (0.63, 1.60)	
p-value	0.9786	
Risk Ratio (95% CI)	1.01 (0.67, 1.52)	
p-value	0.9786	
Risk Difference (95% CI)	0.00 (-0.05, 0.05)	
p-value	0.9786	

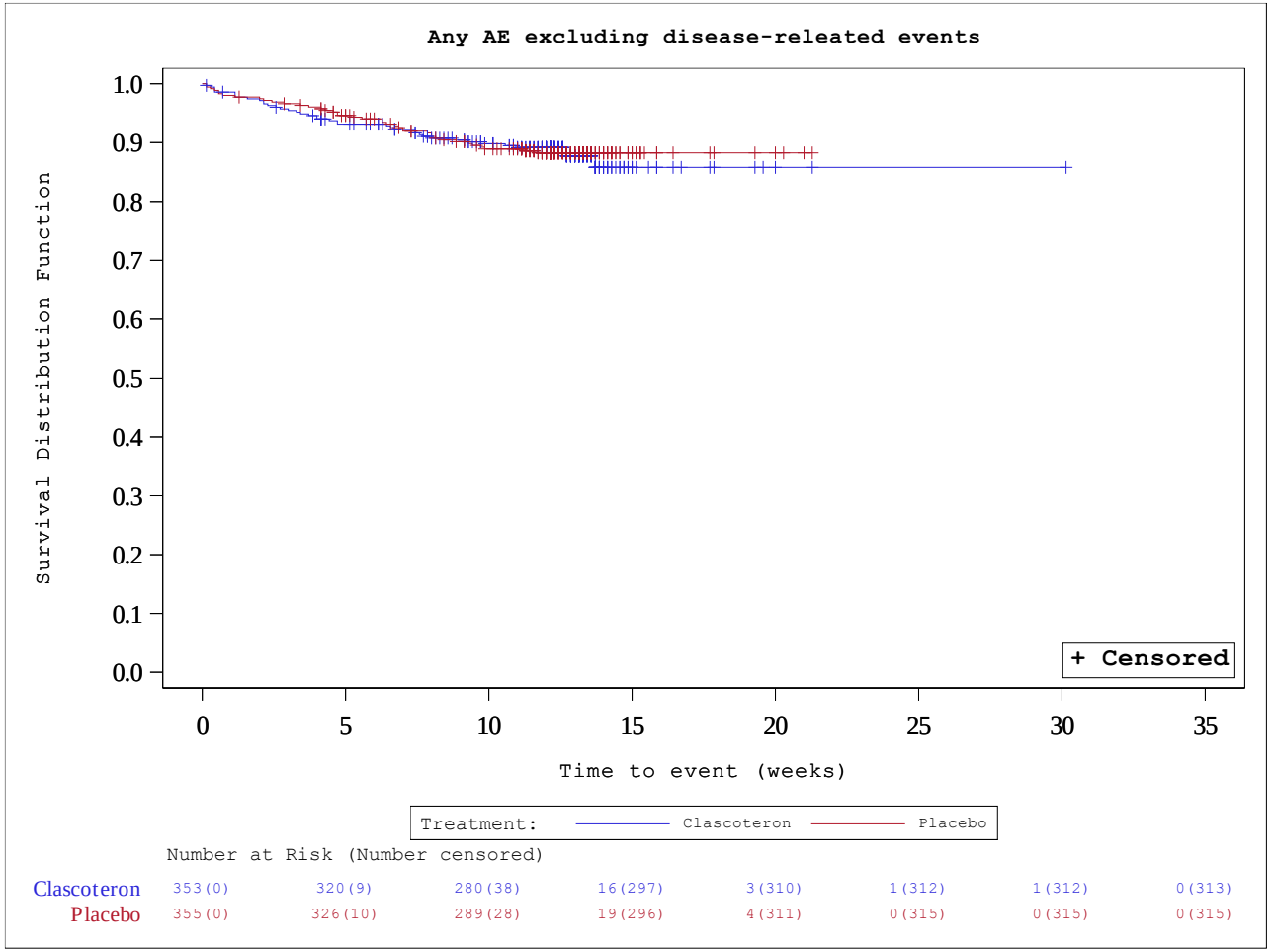
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events excluding disease-related events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=353) n/ N (%)	Clascoteron (N=353) Median (95% CI)	Placebo (N=355) n/ N (%)	Placebo (N=355) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							0.3127
9 - <18	20/ 157 (12.74)	NE (NE, NE)	16/ 159 (10.06)	NE (NE, NE)	1.30 (0.67, 2.51)	0.4340	
18 - <65	20/ 196 (10.20)	NE (NE, NE)	24/ 196 (12.24)	NE (NE, NE)	0.83 (0.46, 1.51)	0.5421	
Gender							0.1608
Male	14/ 132 (10.61)	NE (NE, NE)	9/ 140 (6.43)	NE (NE, NE)	1.69 (0.73, 3.91)	0.2190	
Female	26/ 221 (11.76)	NE (NE, NE)	31/ 215 (14.42)	NE (NE, NE)	0.83 (0.49, 1.39)	0.4764	
Region							0.4588
USA	35/ 251 (13.94)	NE (NE, NE)	37/ 251 (14.74)	NE (NE, NE)	0.96 (0.60, 1.52)	0.8609	
Europe	5/ 102 (4.90)	NE (NE, NE)	3/ 104 (2.88)	NE (NE, NE)	1.65 (0.39, 6.93)	0.4920	
IGA							0.6061
3-Moderate	33/ 292 (11.30)	NE (NE, NE)	31/ 291 (10.65)	NE (NE, NE)	1.08 (0.66, 1.77)	0.7462	
4-Severe	7/ 61 (11.48)	NE (NE, NE)	9/ 64 (14.06)	NE (NE, NE)	0.80 (0.30, 2.15)	0.6624	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events excluding disease-related events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Seroius Adverse Events
Safety Analysis Set

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with event, n/N (%)	0/ 353 (0.00)	1/ 355 (0.28)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	
Odds Ratio (95% CI)	0.33 (0.01, 8.23)	
p-value	0.5027	
Risk Ratio (95% CI)	0.34 (0.01, 8.20)	
p-value	0.5028	
Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
p-value	0.3166	

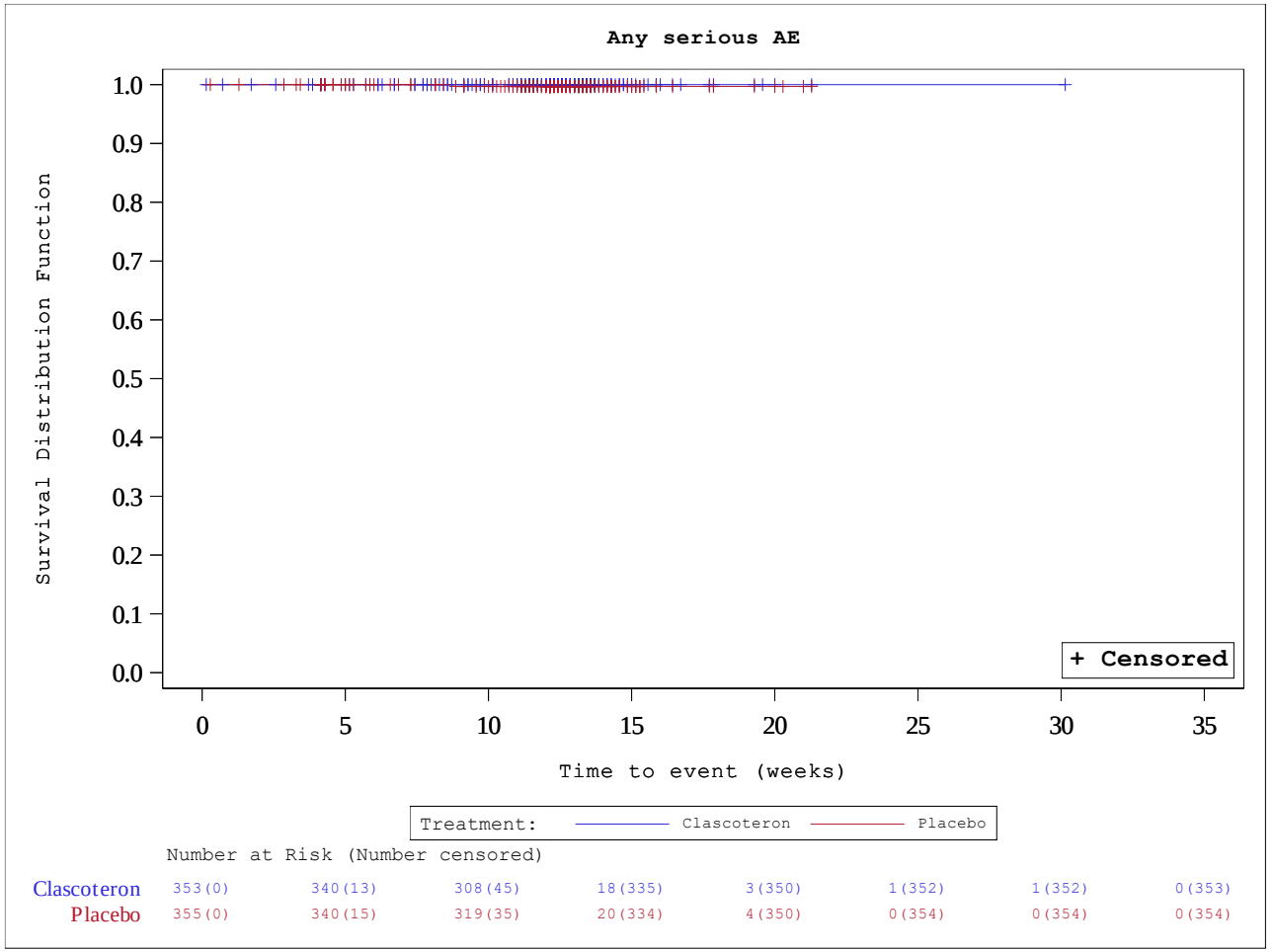
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Seroius Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=353) n/ N (%)	Clascoteron (N=353) Median (95% CI)	Placebo (N=355) n/ N (%)	Placebo (N=355) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	0/ 157 (0.00)	NE (NE, NE)	0/ 159 (0.00)	NE (NE, NE)			
18 - <65	0/ 196 (0.00)	NE (NE, NE)	1/ 196 (0.51)	NE (NE, NE)			
Gender							
Male	0/ 132 (0.00)	NE (NE, NE)	0/ 140 (0.00)	NE (NE, NE)			
Female	0/ 221 (0.00)	NE (NE, NE)	1/ 215 (0.47)	NE (NE, NE)			
Region							
USA	0/ 251 (0.00)	NE (NE, NE)	1/ 251 (0.40)	NE (NE, NE)			
Europe	0/ 102 (0.00)	NE (NE, NE)	0/ 104 (0.00)	NE (NE, NE)			
IGA							
3-Moderate	0/ 292 (0.00)	NE (NE, NE)	1/ 291 (0.34)	NE (NE, NE)			
4-Severe	0/ 61 (0.00)	NE (NE, NE)	0/ 64 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Seroius Adverse Events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Seroius Adverse Events excluding disease-related events
Safety Analysis Set

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with event, n/N (%)	0/ 353 (0.00)	1/ 355 (0.28)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	
Odds Ratio (95% CI)	0.33 (0.01, 8.23)	
p-value	0.5027	
Risk Ratio (95% CI)	0.34 (0.01, 8.20)	
p-value	0.5028	
Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
p-value	0.3166	

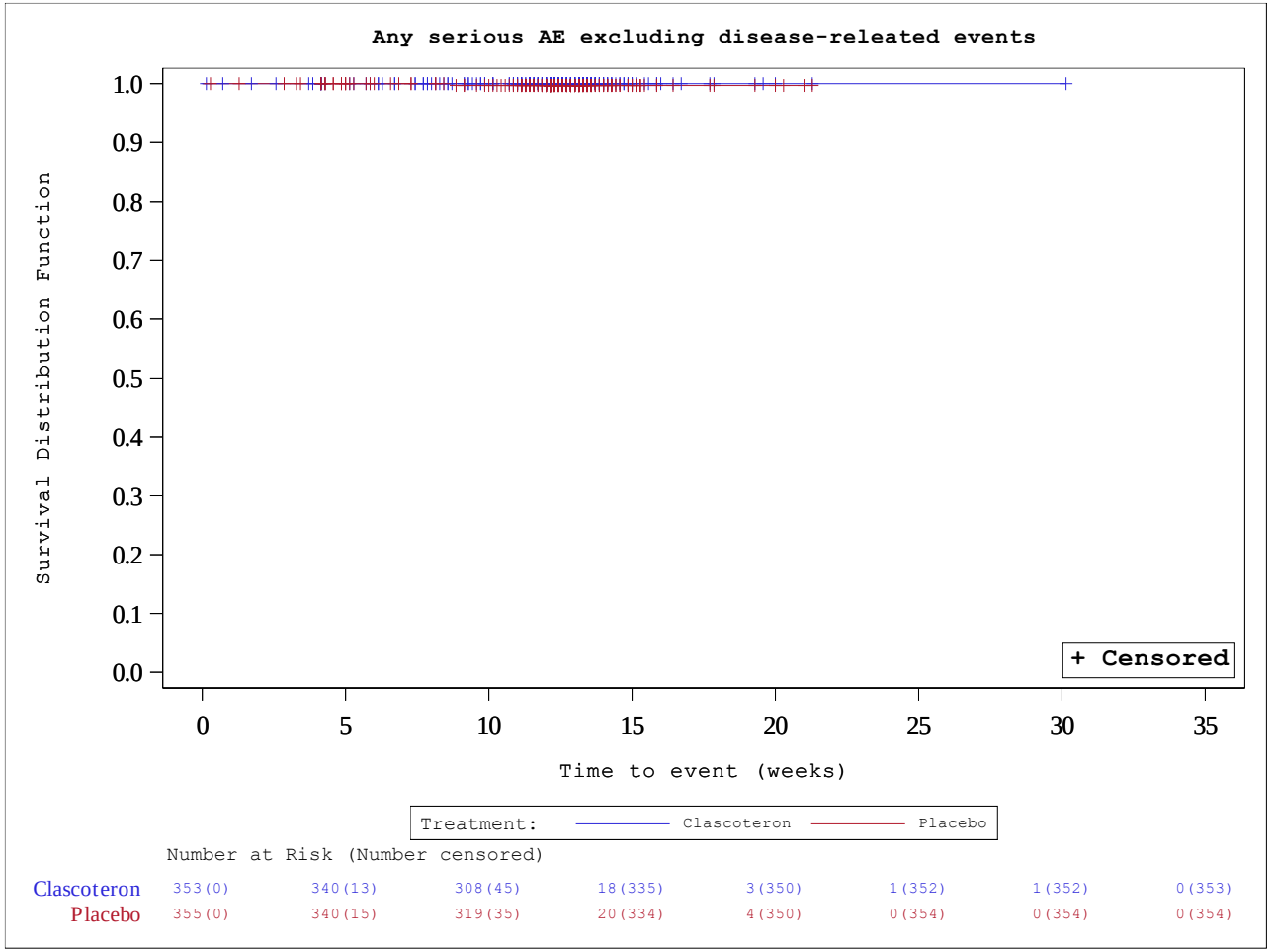
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Seroius Adverse Events excluding disease-related events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=353) n/ N (%)	Clascoteron (N=353) Median (95% CI)	Placebo (N=355) n/ N (%)	Placebo (N=355) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	0/ 157 (0.00)	NE (NE, NE)	0/ 159 (0.00)	NE (NE, NE)			
18 - <65	0/ 196 (0.00)	NE (NE, NE)	1/ 196 (0.51)	NE (NE, NE)			
Gender							
Male	0/ 132 (0.00)	NE (NE, NE)	0/ 140 (0.00)	NE (NE, NE)			
Female	0/ 221 (0.00)	NE (NE, NE)	1/ 215 (0.47)	NE (NE, NE)			
Region							
USA	0/ 251 (0.00)	NE (NE, NE)	1/ 251 (0.40)	NE (NE, NE)			
Europe	0/ 102 (0.00)	NE (NE, NE)	0/ 104 (0.00)	NE (NE, NE)			
IGA							
3-Moderate	0/ 292 (0.00)	NE (NE, NE)	1/ 291 (0.34)	NE (NE, NE)			
4-Severe	0/ 61 (0.00)	NE (NE, NE)	0/ 64 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Seroius Adverse Events excluding disease-related events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events
Safety Analysis Set

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with event, n/N (%)	0/ 353 (0.00)	2/ 355 (0.56)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	
Odds Ratio (95% CI)	0.20 (0.01, 4.18)	
p-value	0.2994	
Risk Ratio (95% CI)	0.20 (0.01, 4.17)	
p-value	0.3000	
Risk Difference (95% CI)	-0.01 (-0.01, 0.00)	
p-value	0.1561	

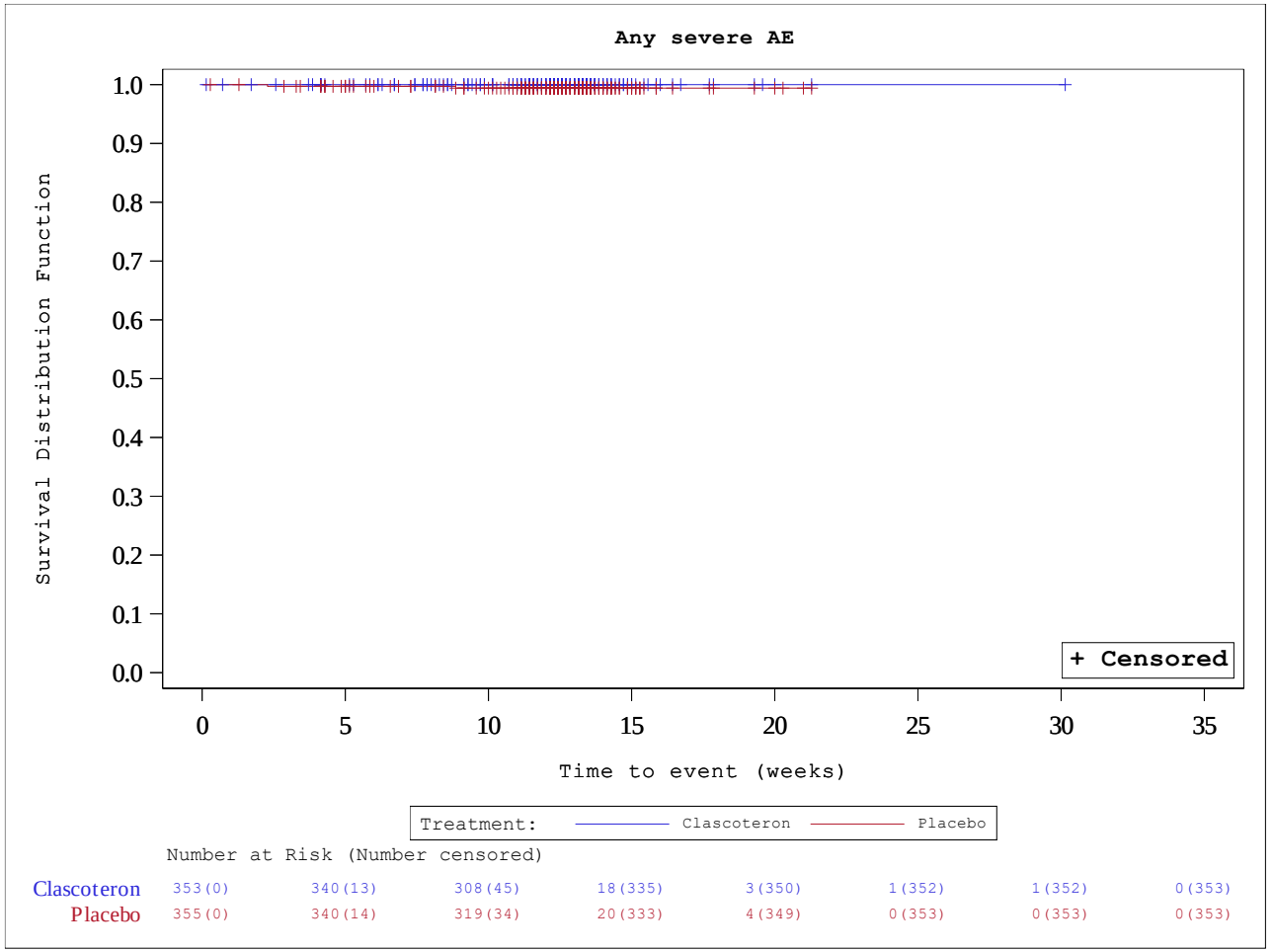
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=353) n/ N (%)	Clascoteron (N=353) Median (95% CI)	Placebo (N=355) n/ N (%)	Placebo (N=355) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	0/ 157 (0.00)	NE (NE, NE)	1/ 159 (0.63)	NE (NE, NE)			
18 - <65	0/ 196 (0.00)	NE (NE, NE)	1/ 196 (0.51)	NE (NE, NE)			
Gender							
Male	0/ 132 (0.00)	NE (NE, NE)	0/ 140 (0.00)	NE (NE, NE)			
Female	0/ 221 (0.00)	NE (NE, NE)	2/ 215 (0.93)	NE (NE, NE)			
Region							
USA	0/ 251 (0.00)	NE (NE, NE)	2/ 251 (0.80)	NE (NE, NE)			
Europe	0/ 102 (0.00)	NE (NE, NE)	0/ 104 (0.00)	NE (NE, NE)			
IGA							
3-Moderate	0/ 292 (0.00)	NE (NE, NE)	1/ 291 (0.34)	NE (NE, NE)			
4-Severe	0/ 61 (0.00)	NE (NE, NE)	1/ 64 (1.56)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Severe Adverse Events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events excluding disease-related events
Safety Analysis Set

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with event, n/N (%)	0/ 353 (0.00)	1/ 355 (0.28)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	
Odds Ratio (95% CI)	0.33 (0.01, 8.23)	
p-value	0.5027	
Risk Ratio (95% CI)	0.34 (0.01, 8.20)	
p-value	0.5028	
Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
p-value	0.3166	

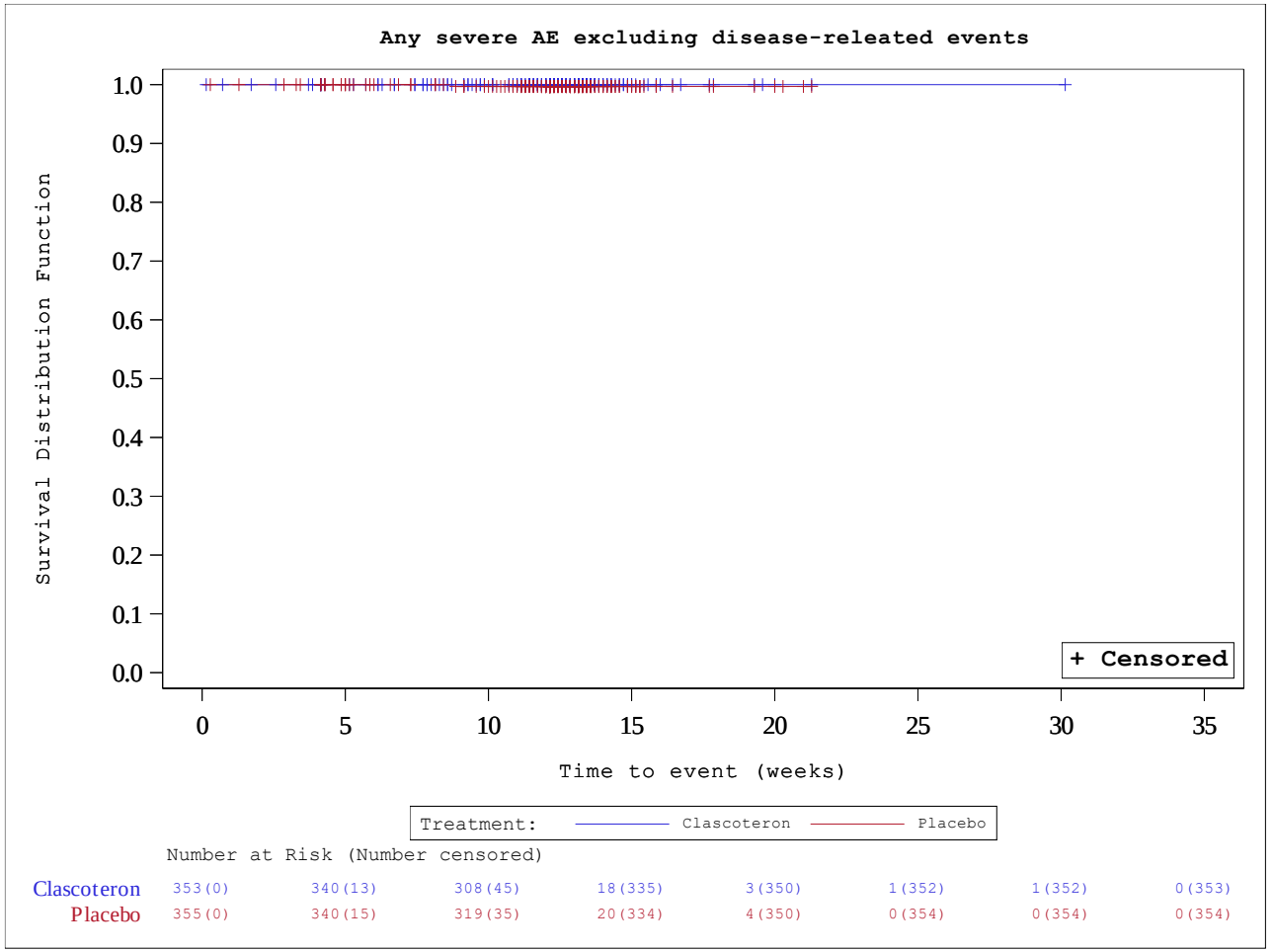
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events excluding disease-related events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=353) n/ N (%)	Clascoteron (N=353) Median (95% CI)	Placebo (N=355) n/ N (%)	Placebo (N=355) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	0/ 157 (0.00)	NE (NE, NE)	0/ 159 (0.00)	NE (NE, NE)			
18 - <65	0/ 196 (0.00)	NE (NE, NE)	1/ 196 (0.51)	NE (NE, NE)			
Gender							
Male	0/ 132 (0.00)	NE (NE, NE)	0/ 140 (0.00)	NE (NE, NE)			
Female	0/ 221 (0.00)	NE (NE, NE)	1/ 215 (0.47)	NE (NE, NE)			
Region							
USA	0/ 251 (0.00)	NE (NE, NE)	1/ 251 (0.40)	NE (NE, NE)			
Europe	0/ 102 (0.00)	NE (NE, NE)	0/ 104 (0.00)	NE (NE, NE)			
IGA							
3-Moderate	0/ 292 (0.00)	NE (NE, NE)	1/ 291 (0.34)	NE (NE, NE)			
4-Severe	0/ 61 (0.00)	NE (NE, NE)	0/ 64 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Severe Adverse Events excluding disease-related events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment
Safety Analysis Set

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with event, n/N (%)	3/ 353 (0.85)	4/ 355 (1.13)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	0.75 (0.17, 3.36)	
p-value	0.7092	
Odds Ratio (95% CI)	0.75 (0.17, 3.39)	
p-value	0.7105	
Risk Ratio (95% CI)	0.75 (0.17, 3.35)	
p-value	0.7106	
Risk Difference (95% CI)	-0.00 (-0.02, 0.01)	
p-value	0.7095	

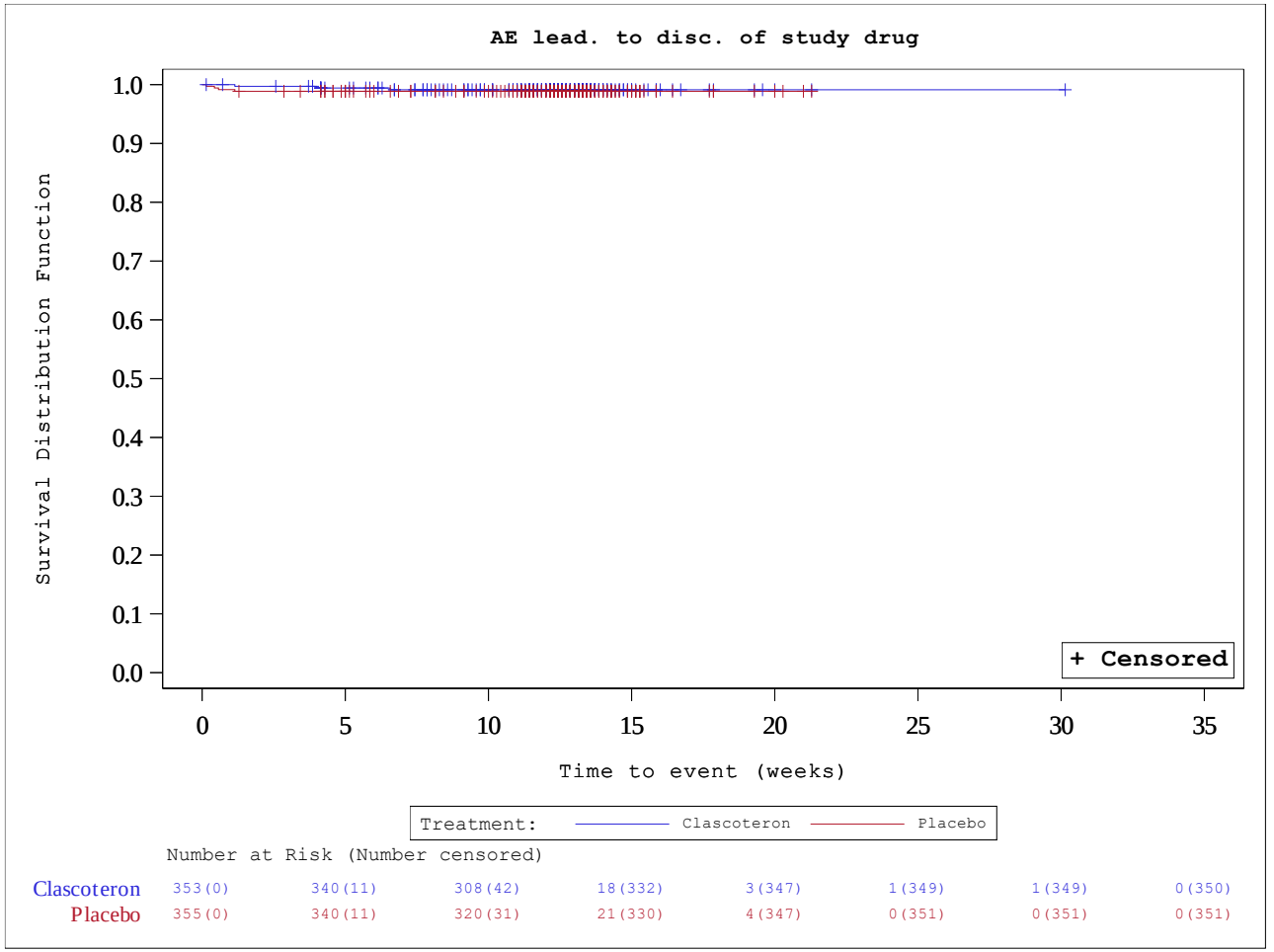
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=353) n/ N (%)	Clascoteron (N=353) Median (95% CI)	Placebo (N=355) n/ N (%)	Placebo (N=355) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	1/ 157 (0.64)	NE (NE, NE)	1/ 159 (0.63)	NE (NE, NE)			
18 - <65	2/ 196 (1.02)	NE (NE, NE)	3/ 196 (1.53)	NE (NE, NE)			
Gender							
Male	1/ 132 (0.76)	NE (NE, NE)	2/ 140 (1.43)	NE (NE, NE)			
Female	2/ 221 (0.90)	NE (NE, NE)	2/ 215 (0.93)	NE (NE, NE)			
Region							
USA	3/ 251 (1.20)	NE (NE, NE)	3/ 251 (1.20)	NE (NE, NE)			
Europe	0/ 102 (0.00)	NE (NE, NE)	1/ 104 (0.96)	NE (NE, NE)			
IGA							
3-Moderate	3/ 292 (1.03)	NE (NE, NE)	2/ 291 (0.69)	NE (NE, NE)			
4-Severe	0/ 61 (0.00)	NE (NE, NE)	2/ 64 (3.13)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events leading to discontinuation of study treatment
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment excluding disease-related events
Safety Analysis Set

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with event, n/N (%)	3/ 353 (0.85)	4/ 355 (1.13)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	0.75 (0.17, 3.36)	
p-value	0.7092	
Odds Ratio (95% CI)	0.75 (0.17, 3.39)	
p-value	0.7105	
Risk Ratio (95% CI)	0.75 (0.17, 3.35)	
p-value	0.7106	
Risk Difference (95% CI)	-0.00 (-0.02, 0.01)	
p-value	0.7095	

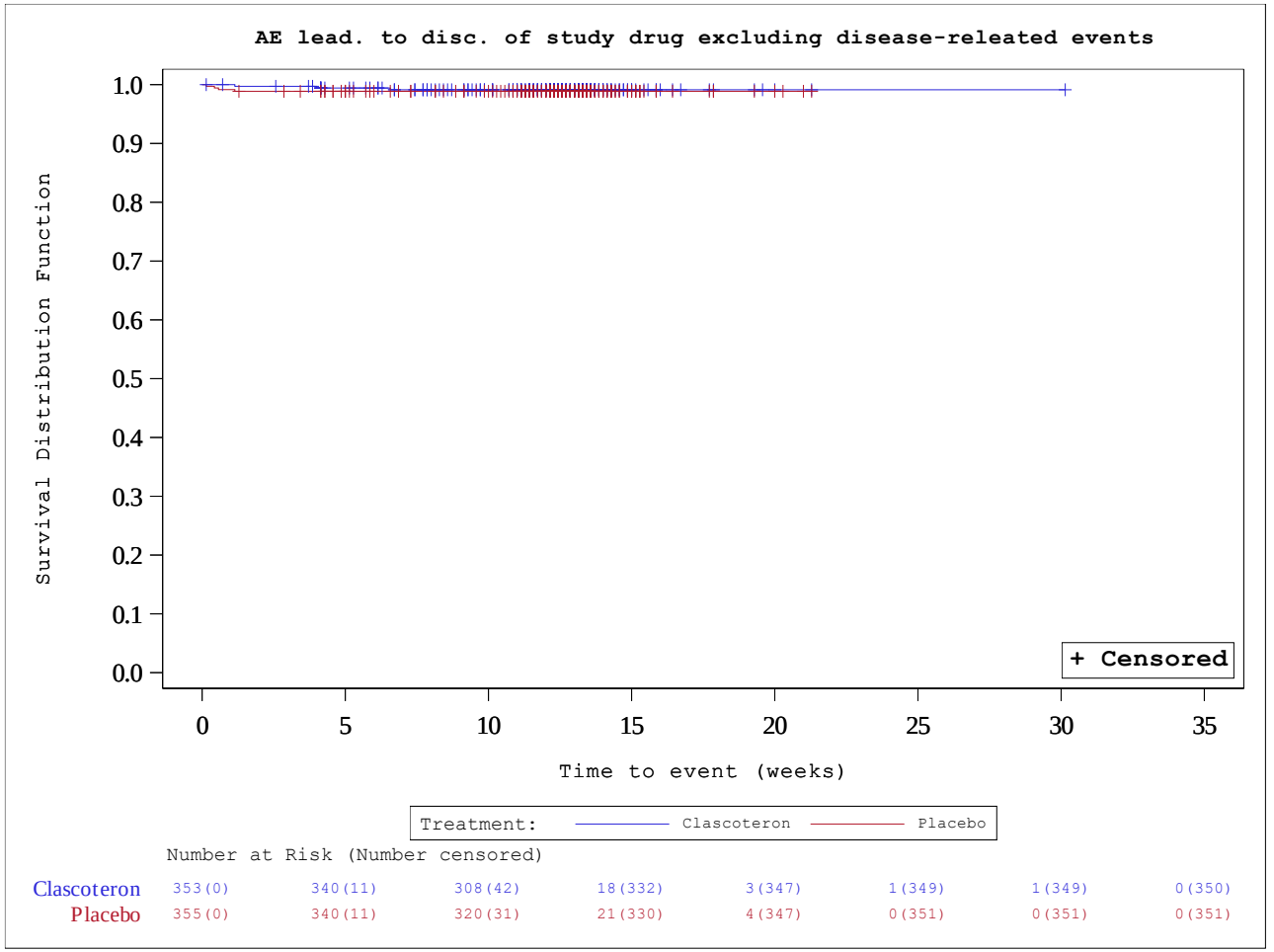
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment excluding disease-related events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=353) n/ N (%)	Clascoteron (N=353) Median (95% CI)	Placebo (N=355) n/ N (%)	Placebo (N=355) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	1/ 157 (0.64)	NE (NE, NE)	1/ 159 (0.63)	NE (NE, NE)			
18 - <65	2/ 196 (1.02)	NE (NE, NE)	3/ 196 (1.53)	NE (NE, NE)			
Gender							
Male	1/ 132 (0.76)	NE (NE, NE)	2/ 140 (1.43)	NE (NE, NE)			
Female	2/ 221 (0.90)	NE (NE, NE)	2/ 215 (0.93)	NE (NE, NE)			
Region							
USA	3/ 251 (1.20)	NE (NE, NE)	3/ 251 (1.20)	NE (NE, NE)			
Europe	0/ 102 (0.00)	NE (NE, NE)	1/ 104 (0.96)	NE (NE, NE)			
IGA							
3-Moderate	3/ 292 (1.03)	NE (NE, NE)	2/ 291 (0.69)	NE (NE, NE)			
4-Severe	0/ 61 (0.00)	NE (NE, NE)	2/ 64 (3.13)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events leading to discontinuation of study treatment excluding disease-related events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study
Safety Analysis Set

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with event, n/N (%)	3/ 353 (0.85)	6/ 355 (1.69)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	0.50 (0.13, 2.00)	
p-value	0.3281	
Odds Ratio (95% CI)	0.50 (0.12, 2.01)	
p-value	0.3277	
Risk Ratio (95% CI)	0.50 (0.13, 1.99)	
p-value	0.3282	
Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
p-value	0.3175	

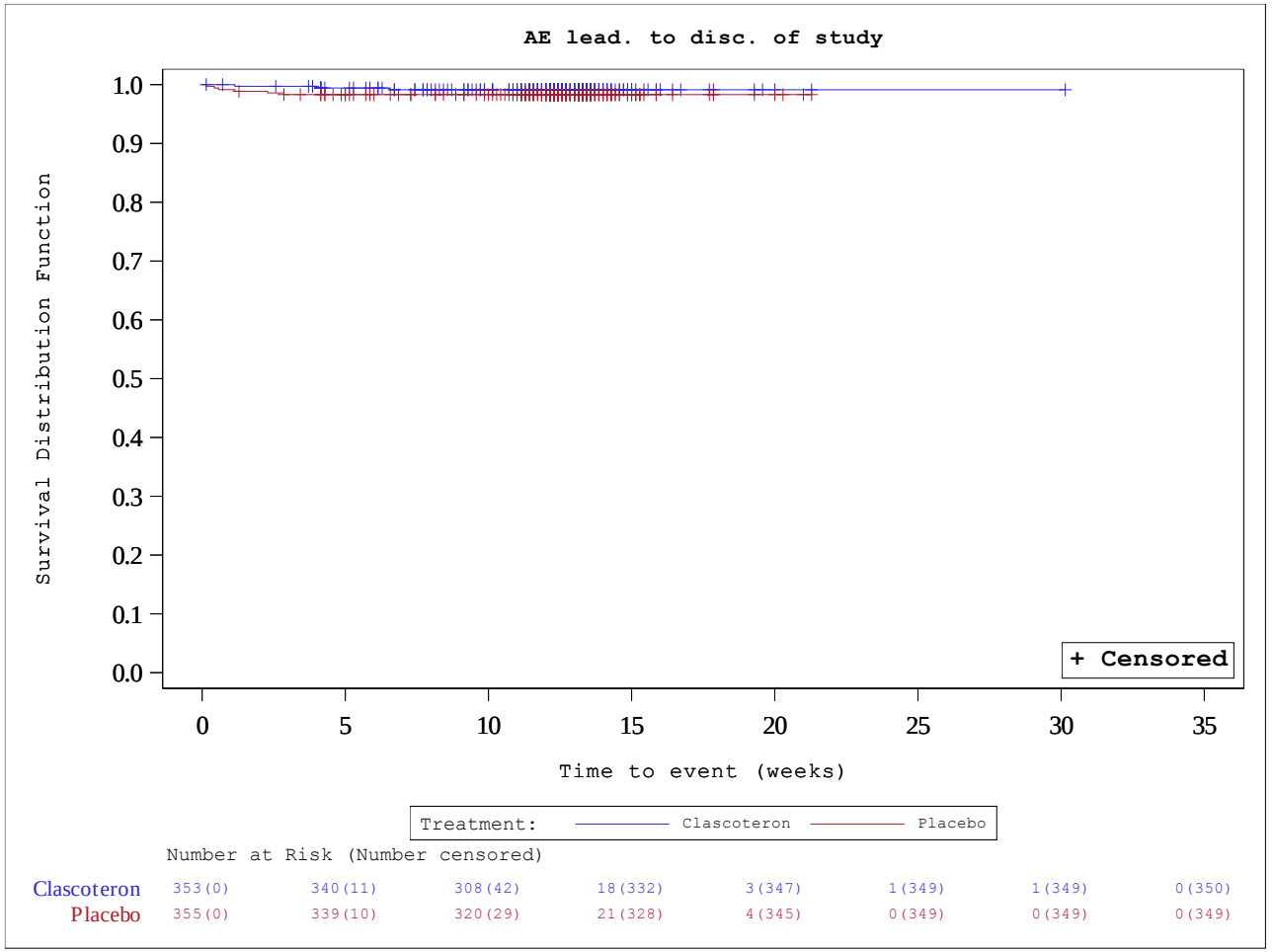
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=353) n/ N (%)	Clascoteron (N=353) Median (95% CI)	Placebo (N=355) n/ N (%)	Placebo (N=355) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	1/ 157 (0.64)	NE (NE, NE)	2/ 159 (1.26)	NE (NE, NE)			
18 - <65	2/ 196 (1.02)	NE (NE, NE)	4/ 196 (2.04)	NE (NE, NE)			
Gender							
Male	1/ 132 (0.76)	NE (NE, NE)	2/ 140 (1.43)	NE (NE, NE)			
Female	2/ 221 (0.90)	NE (NE, NE)	4/ 215 (1.86)	NE (NE, NE)			
Region							
USA	3/ 251 (1.20)	NE (NE, NE)	5/ 251 (1.99)	NE (NE, NE)			
Europe	0/ 102 (0.00)	NE (NE, NE)	1/ 104 (0.96)	NE (NE, NE)			
IGA							
3-Moderate	3/ 292 (1.03)	NE (NE, NE)	2/ 291 (0.69)	NE (NE, NE)			
4-Severe	0/ 61 (0.00)	NE (NE, NE)	4/ 64 (6.25)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events leading to discontinuation of study
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study excluding disease-related events
Safety Analysis Set

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with event, n/N (%)	3/ 353 (0.85)	5/ 355 (1.41)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	0.60 (0.14, 2.52)	
p-value	0.4864	
Odds Ratio (95% CI)	0.60 (0.14, 2.53)	
p-value	0.4866	
Risk Ratio (95% CI)	0.60 (0.15, 2.51)	
p-value	0.4868	
Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
p-value	0.4815	

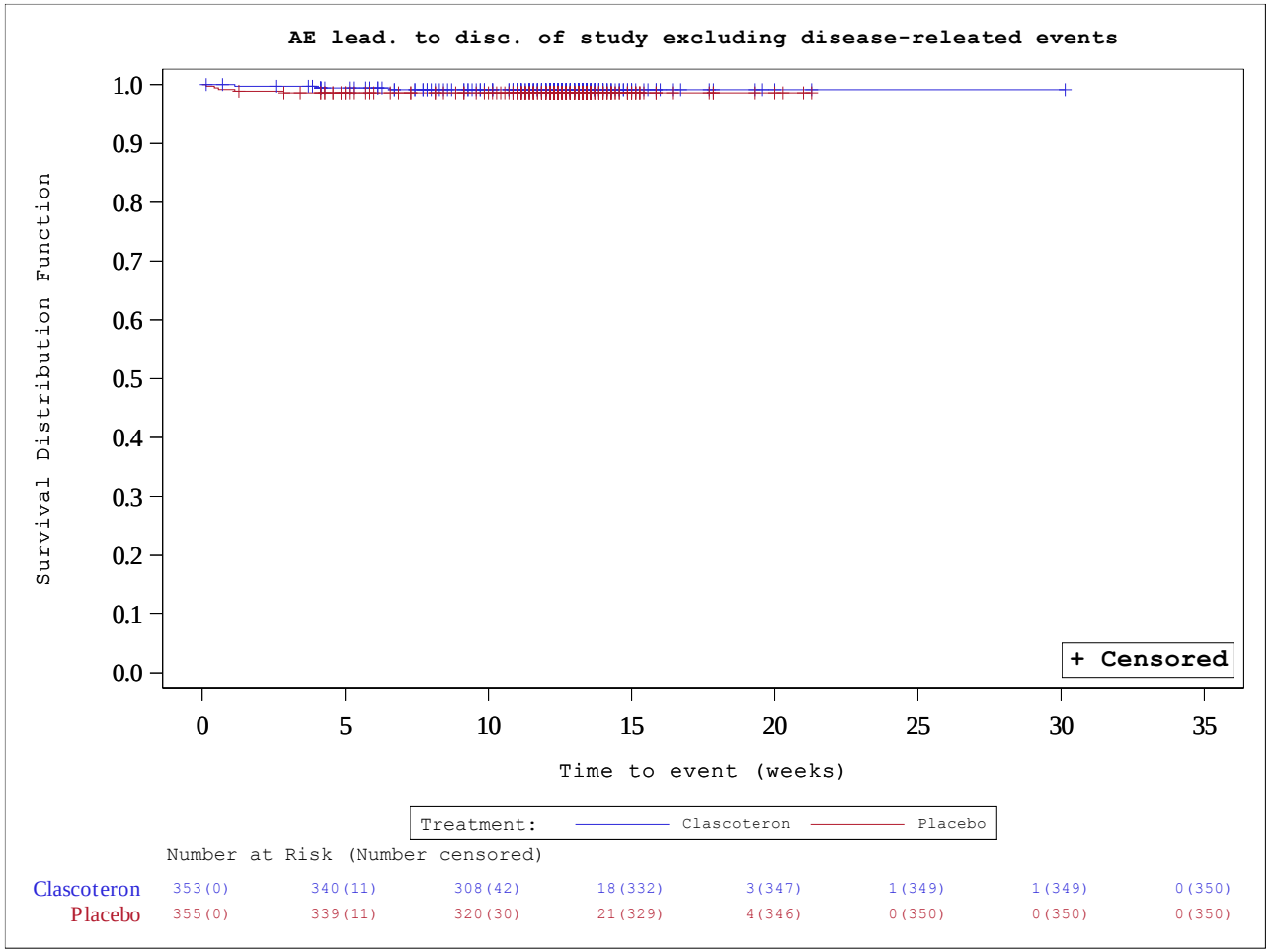
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study excluding disease-related events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=353) n/ N (%)	Clascoteron (N=353) Median (95% CI)	Placebo (N=355) n/ N (%)	Placebo (N=355) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	1/ 157 (0.64)	NE (NE, NE)	1/ 159 (0.63)	NE (NE, NE)			
18 - <65	2/ 196 (1.02)	NE (NE, NE)	4/ 196 (2.04)	NE (NE, NE)			
Gender							
Male	1/ 132 (0.76)	NE (NE, NE)	2/ 140 (1.43)	NE (NE, NE)			
Female	2/ 221 (0.90)	NE (NE, NE)	3/ 215 (1.40)	NE (NE, NE)			
Region							
USA	3/ 251 (1.20)	NE (NE, NE)	4/ 251 (1.59)	NE (NE, NE)			
Europe	0/ 102 (0.00)	NE (NE, NE)	1/ 104 (0.96)	NE (NE, NE)			
IGA							
3-Moderate	3/ 292 (1.03)	NE (NE, NE)	2/ 291 (0.69)	NE (NE, NE)			
4-Severe	0/ 61 (0.00)	NE (NE, NE)	3/ 64 (4.69)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events leading to discontinuation of study excluding disease-related events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to death
Safety Analysis Set

	Clascoteron (N=353)	Placebo (N=355)
Number of subjects with event, n/N (%)	0/ 353 (0.00)	0/ 355 (0.00)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	
Odds Ratio (95% CI)	NE	
p-value	NE	
Risk Ratio (95% CI)	NE	
p-value	NE	
Risk Difference (95% CI)	NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to death - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=353) n/ N (%)	Clascoteron (N=353) Median (95% CI)	Placebo (N=355) n/ N (%)	Placebo (N=355) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	0/ 157 (0.00)	NE (NE, NE)	0/ 159 (0.00)	NE (NE, NE)			
18 - <65	0/ 196 (0.00)	NE (NE, NE)	0/ 196 (0.00)	NE (NE, NE)			
Gender							
Male	0/ 132 (0.00)	NE (NE, NE)	0/ 140 (0.00)	NE (NE, NE)			
Female	0/ 221 (0.00)	NE (NE, NE)	0/ 215 (0.00)	NE (NE, NE)			
Region							
USA	0/ 251 (0.00)	NE (NE, NE)	0/ 251 (0.00)	NE (NE, NE)			
Europe	0/ 102 (0.00)	NE (NE, NE)	0/ 104 (0.00)	NE (NE, NE)			
IGA							
3-Moderate	0/ 292 (0.00)	NE (NE, NE)	0/ 291 (0.00)	NE (NE, NE)			
4-Severe	0/ 61 (0.00)	NE (NE, NE)	0/ 64 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	16/ 353 (4.53)	19/ 355 (5.35)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	0.85 (0.44, 1.65)	
	p-value	0.6288	
	Odds Ratio (95% CI)	0.84 (0.42, 1.66)	
	p-value	0.6154	
	Risk Ratio (95% CI)	0.85 (0.44, 1.62)	
	p-value	0.6155	
	Risk Difference (95% CI)	-0.01 (-0.04, 0.02)	
	p-value	0.6148	

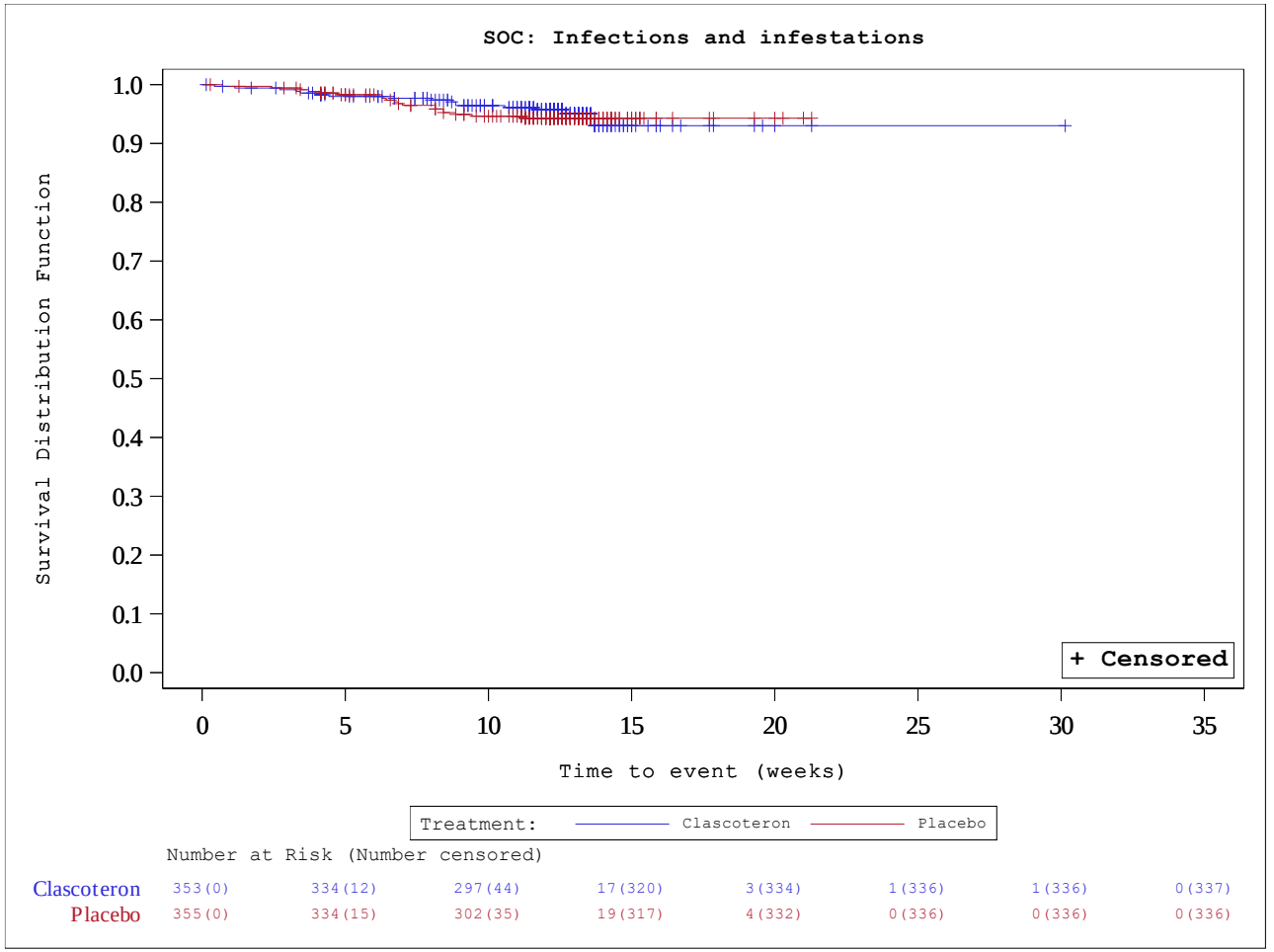
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with event, n/N (%)	6/ 353 (1.70)	12/ 355 (3.38)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	0.50 (0.19, 1.34)	
	p-value	0.1672	
	Odds Ratio (95% CI)	0.49 (0.18, 1.33)	
	p-value	0.1635	
	Risk Ratio (95% CI)	0.50 (0.19, 1.32)	
	p-value	0.1643	
	Risk Difference (95% CI)	-0.02 (-0.04, 0.01)	
	p-value	0.1545	

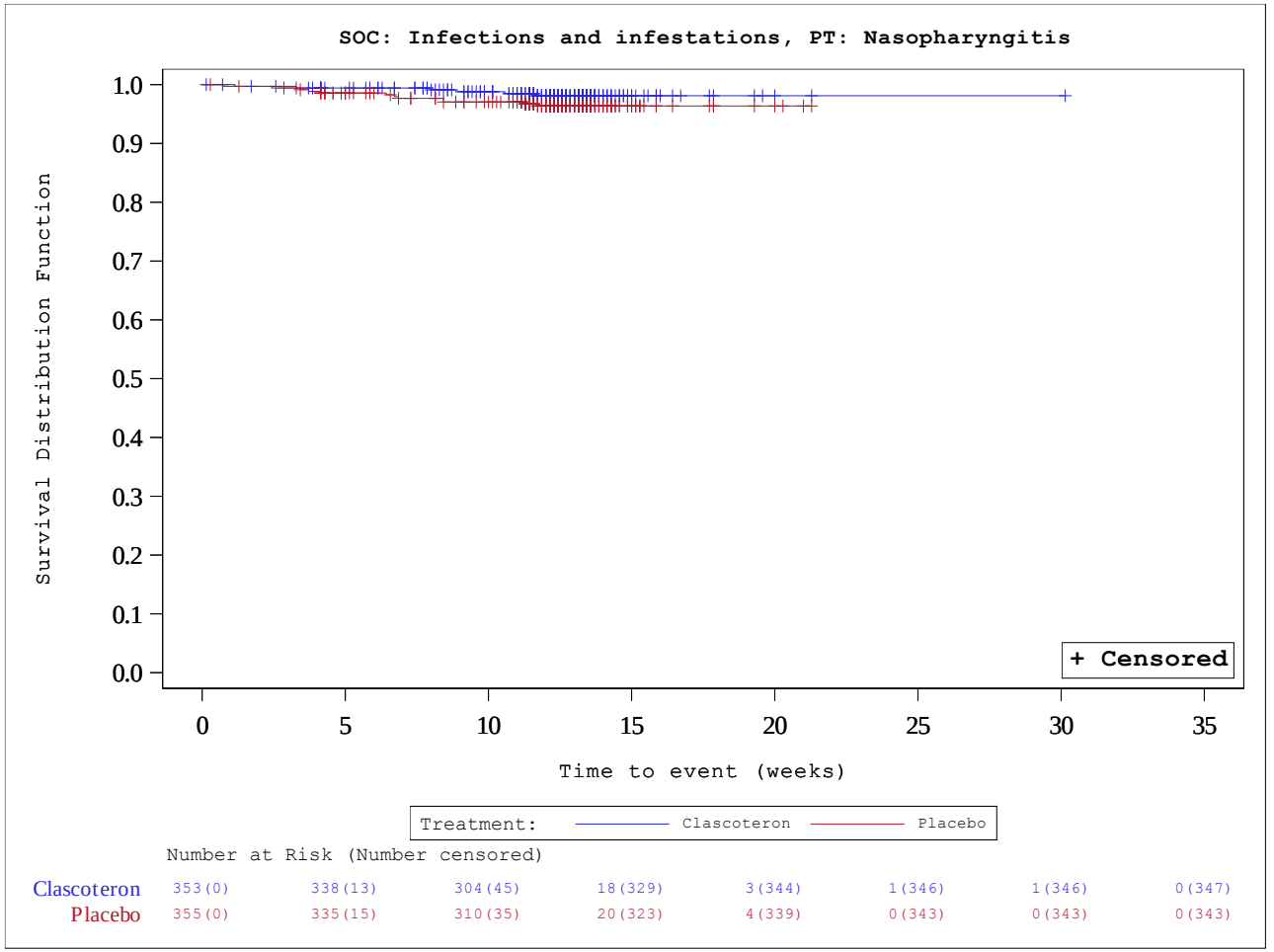
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
&set.



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
&set.



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

---- NO OBSERVATION FOR THE REPORT ----

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Hazard Ratio (alpha=0.05).
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate..
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

---- NO OBSERVATION FOR THE REPORT ----

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event (CTCAE Grade >=3) by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

---- NO OBSERVATION FOR THE REPORT ----

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	1/ 353 (0.28)	3/ 355 (0.85)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	0.34 (0.03, 3.22)	
	p-value	0.3439	
	Odds Ratio (95% CI)	0.33 (0.03, 3.22)	
	p-value	0.3424	
	Risk Ratio (95% CI)	0.34 (0.04, 3.21)	
	p-value	0.3429	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
	p-value	0.3177	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: General disorders and administration site conditions, PT: Application site hypersensitivity	Number of subjects with event, n/N (%)	1/ 353 (0.28)	0/ 355 (0.00)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	3.03 (0.12, 74.52)	
	p-value	0.4983	
	Risk Ratio (95% CI)	3.02 (0.12, 73.81)	
	p-value	0.4985	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: General disorders and administration site conditions, PT: Application site pain	Number of subjects with event, n/N (%)	0/ 353 (0.00)	2/ 355 (0.56)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.20 (0.01, 4.18)	
	p-value	0.2994	
	Risk Ratio (95% CI)	0.20 (0.01, 4.17)	
	p-value	0.3000	
	Risk Difference (95% CI)	-0.01 (-0.01, 0.00)	
	p-value	0.1561	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: General disorders and administration site conditions, PT: Application site urticaria	Number of subjects with event, n/N (%)	0/ 353 (0.00)	1/ 355 (0.28)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.33 (0.01, 8.23)	
	p-value	0.5027	
	Risk Ratio (95% CI)	0.34 (0.01, 8.20)	
	p-value	0.5028	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: Injury, poisoning and procedural complications	Number of subjects with event, n/N (%)	0/ 353 (0.00)	2/ 355 (0.56)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.20 (0.01, 4.18)	
	p-value	0.2994	
	Risk Ratio (95% CI)	0.20 (0.01, 4.17)	
	p-value	0.3000	
	Risk Difference (95% CI)	-0.01 (-0.01, 0.00)	
	p-value	0.1561	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: Injury, poisoning and procedural complications, PT: Application site dermatitis	Number of subjects with event, n/N (%)	0/ 353 (0.00)	1/ 355 (0.28)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.33 (0.01, 8.23)	
	p-value	0.5027	
	Risk Ratio (95% CI)	0.34 (0.01, 8.20)	
	p-value	0.5028	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: Injury, poisoning and procedural complications, PT: Application site pruritus	Number of subjects with event, n/N (%)	0/ 353 (0.00)	1/ 355 (0.28)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.33 (0.01, 8.23)	
	p-value	0.5027	
	Risk Ratio (95% CI)	0.34 (0.01, 8.20)	
	p-value	0.5028	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with event, n/N (%)	1/ 353 (0.28)	0/ 355 (0.00)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	3.03 (0.12, 74.52)	
	p-value	0.4983	
	Risk Ratio (95% CI)	3.02 (0.12, 73.81)	
	p-value	0.4985	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain	Number of subjects with event, n/N (%)	1/ 353 (0.28)	0/ 355 (0.00)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	3.03 (0.12, 74.52)	
	p-value	0.4983	
	Risk Ratio (95% CI)	3.02 (0.12, 73.81)	
	p-value	0.4985	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with event, n/N (%)	1/ 353 (0.28)	0/ 355 (0.00)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	3.03 (0.12, 74.52)	
	p-value	0.4983	
	Risk Ratio (95% CI)	3.02 (0.12, 73.81)	
	p-value	0.4985	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3166	

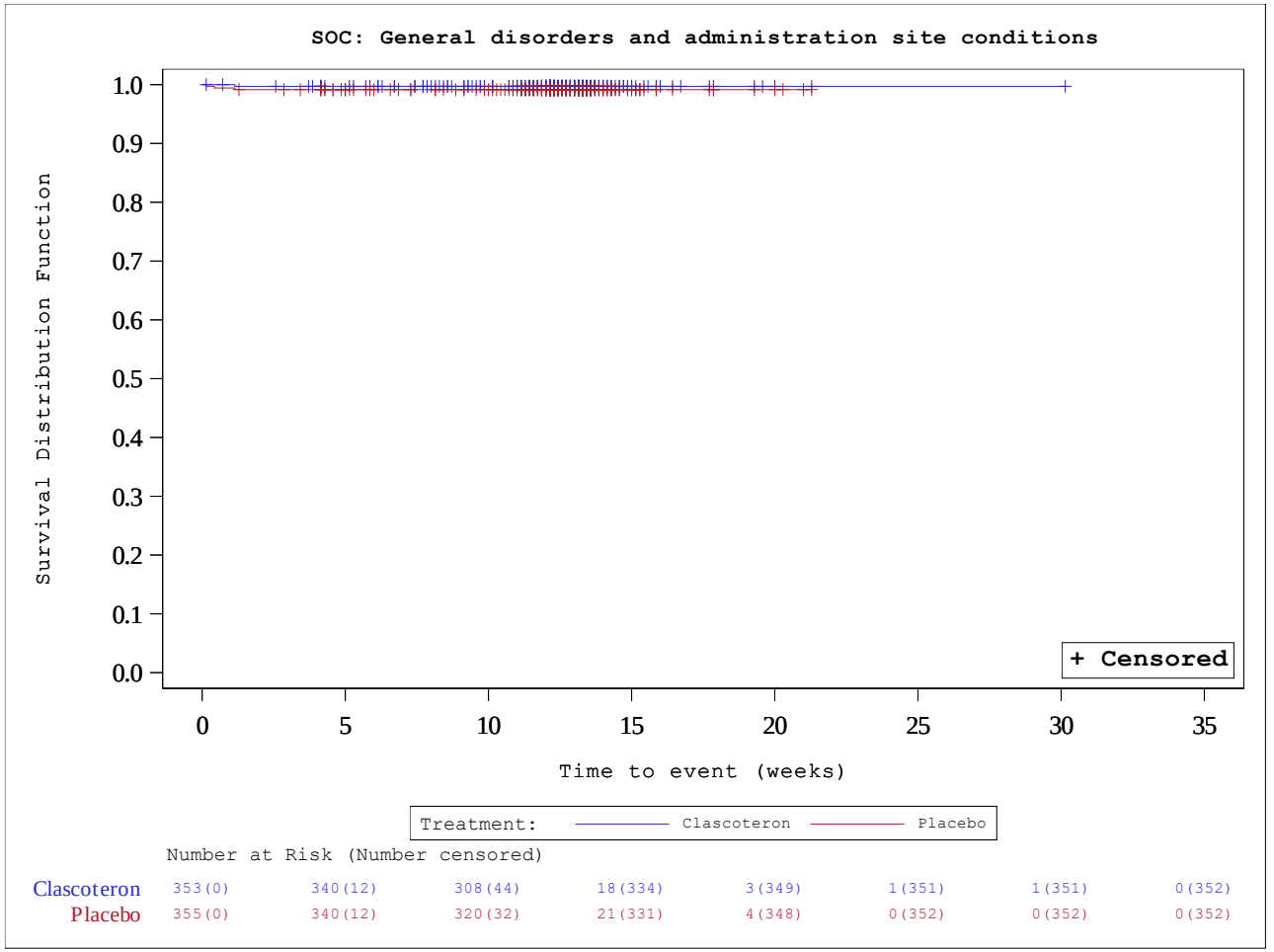
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=353)	Placebo (N=355)
SOC: Skin and subcutaneous tissue disorders, PT: Sebaceous hyperplasia	Number of subjects with event, n/N (%)	1/ 353 (0.28)	0/ 355 (0.00)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	3.03 (0.12, 74.52)	
	p-value	0.4983	
	Risk Ratio (95% CI)	3.02 (0.12, 73.81)	
	p-value	0.4985	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3166	

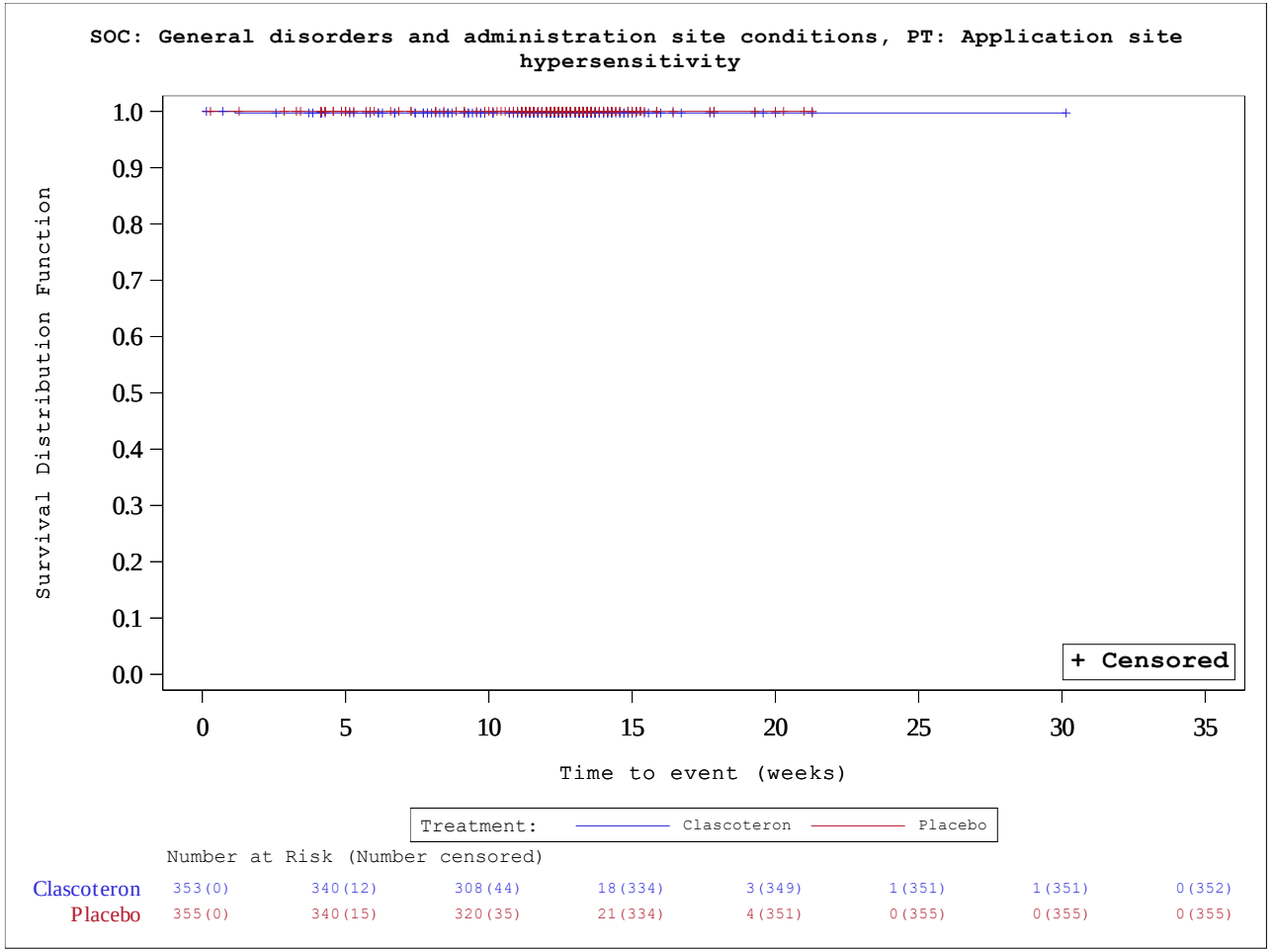
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
&set.



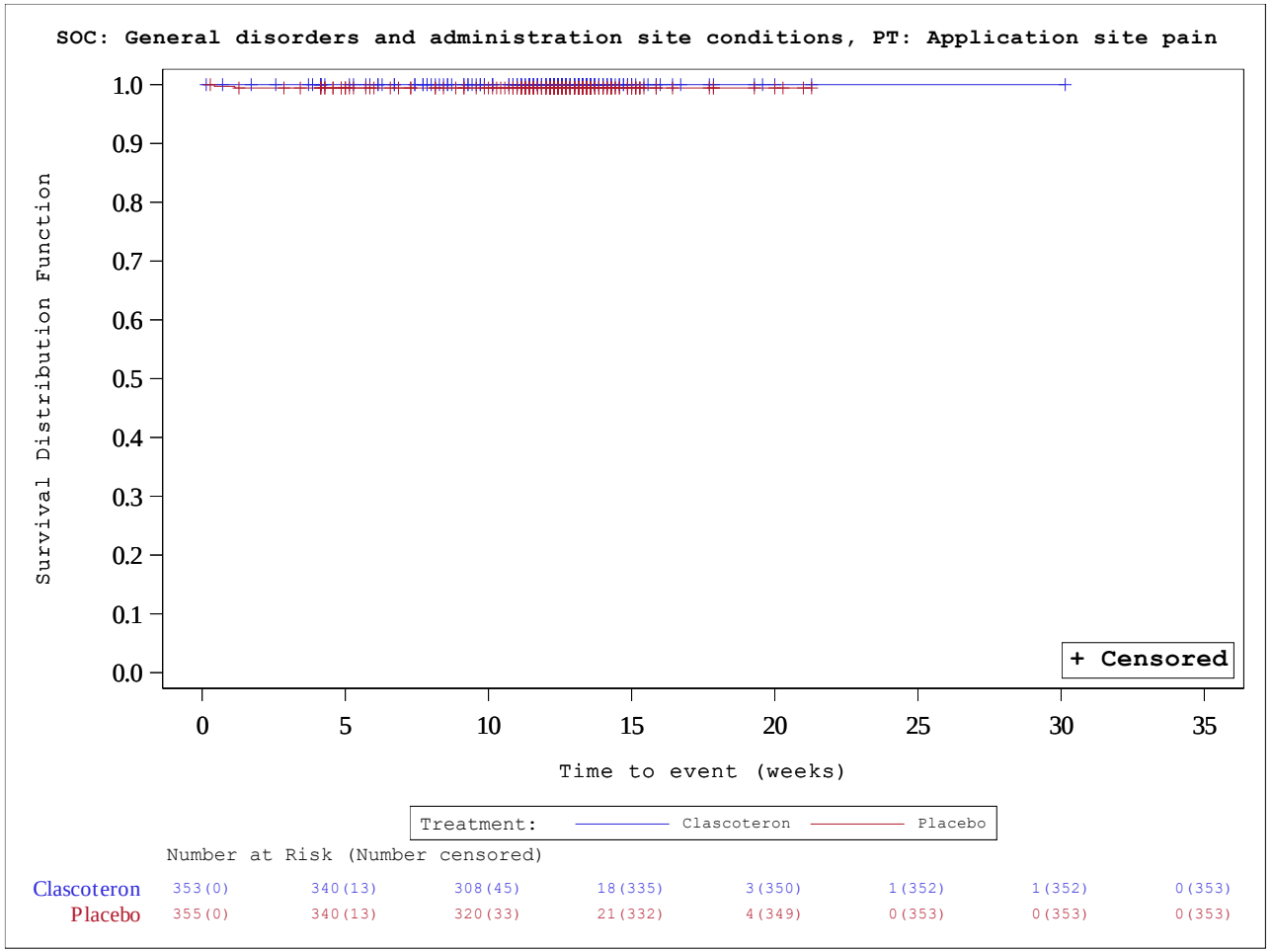
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
&set.



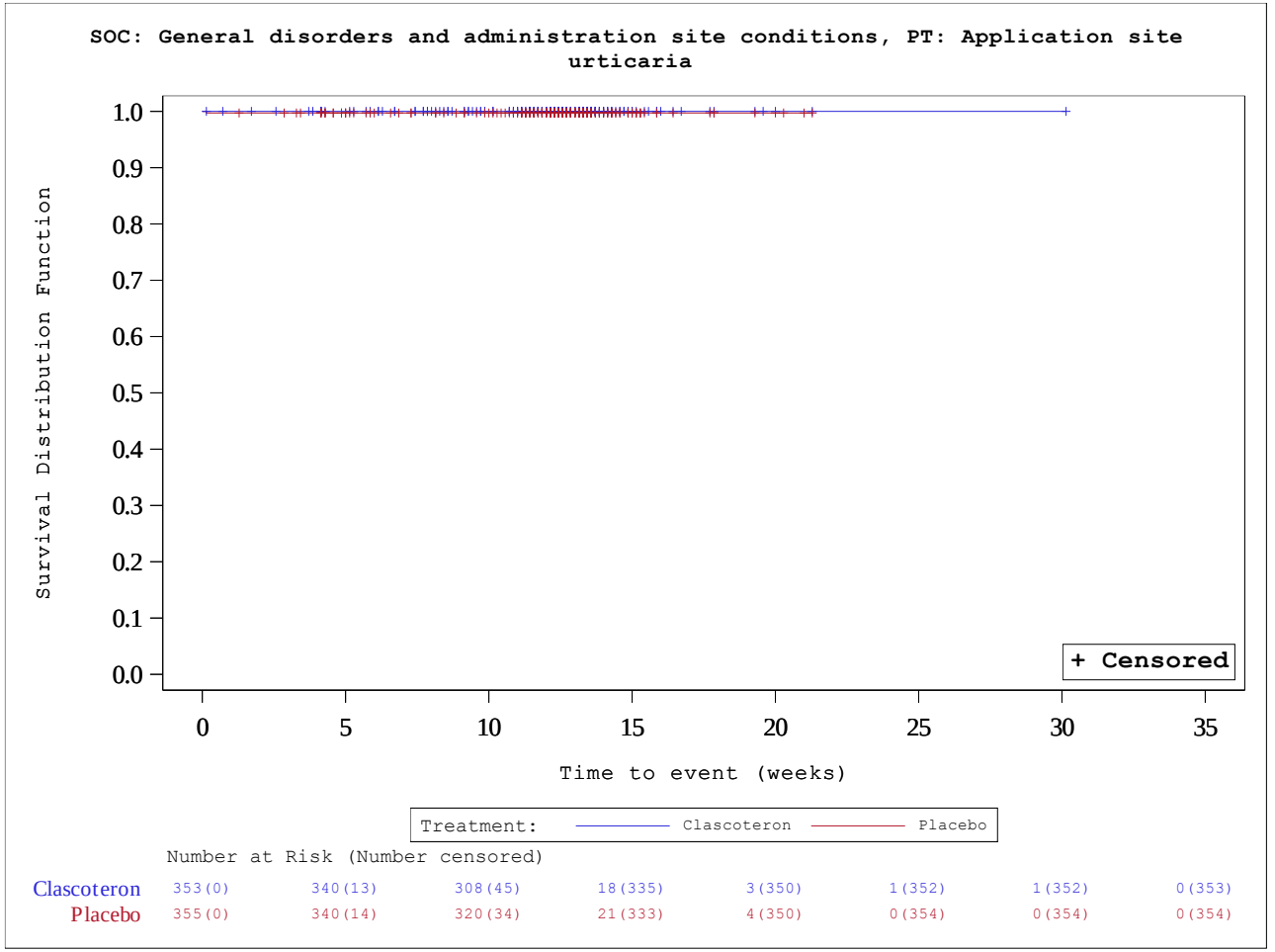
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
&set.



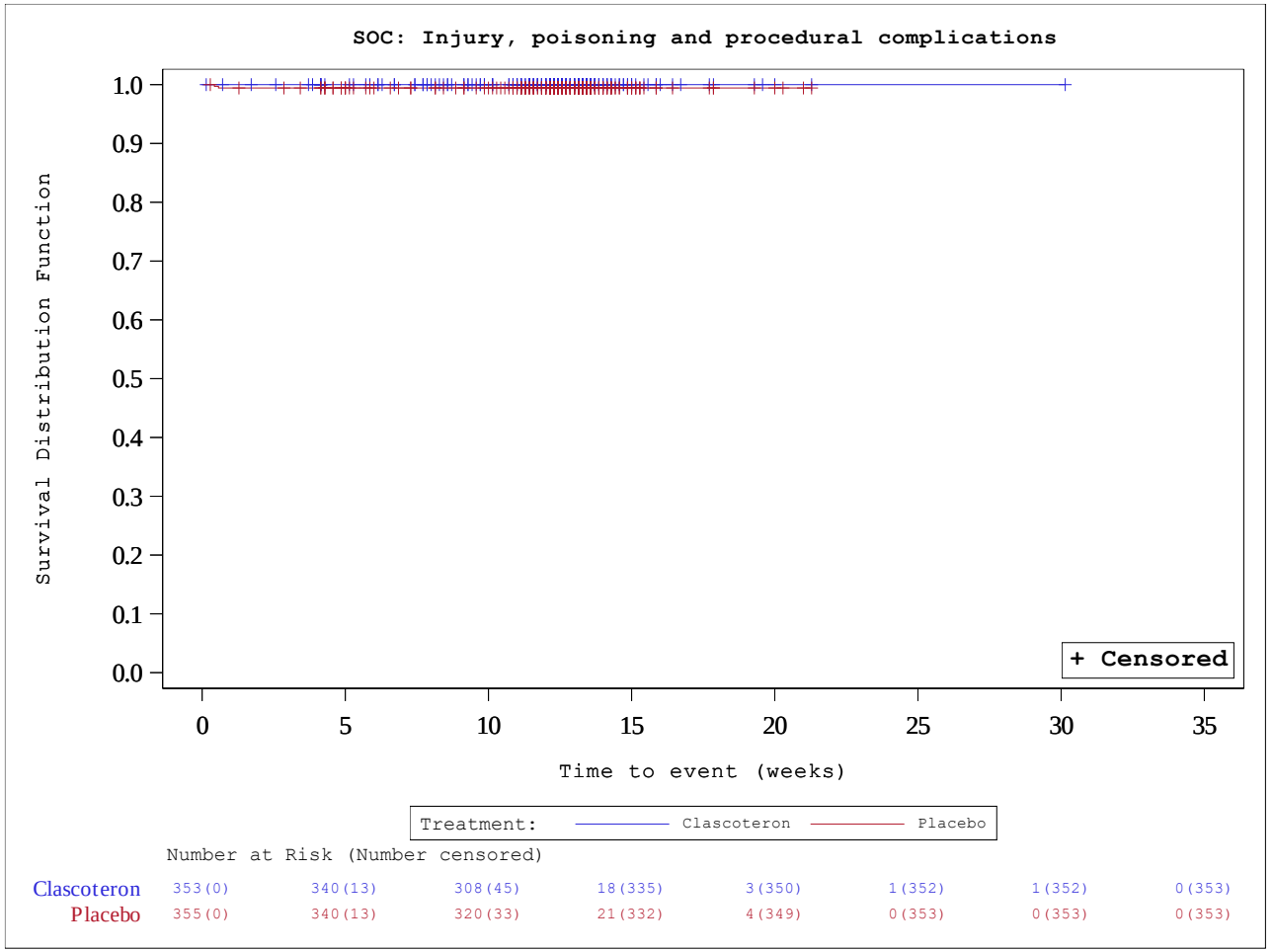
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
&set.



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
&set.



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
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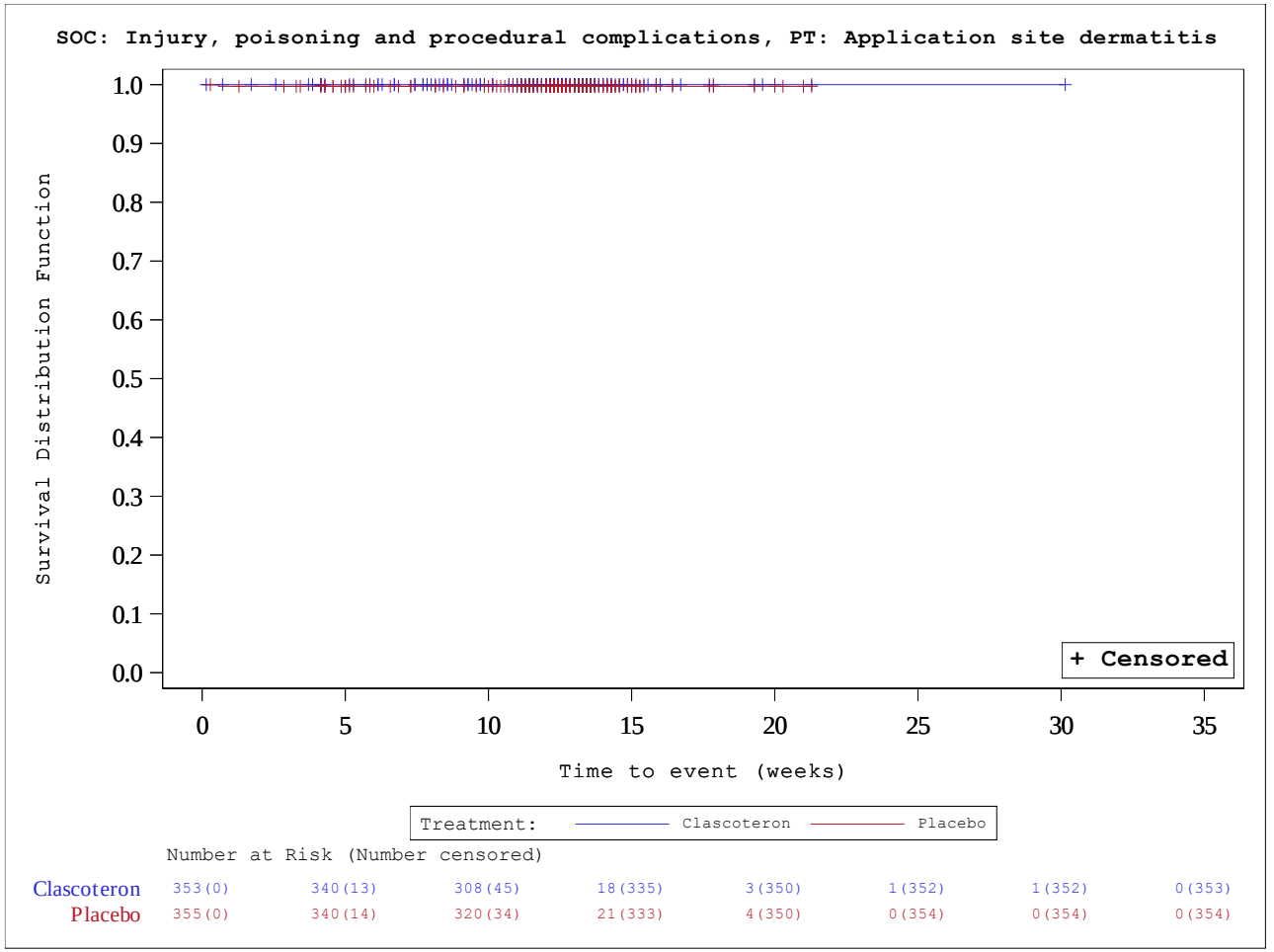
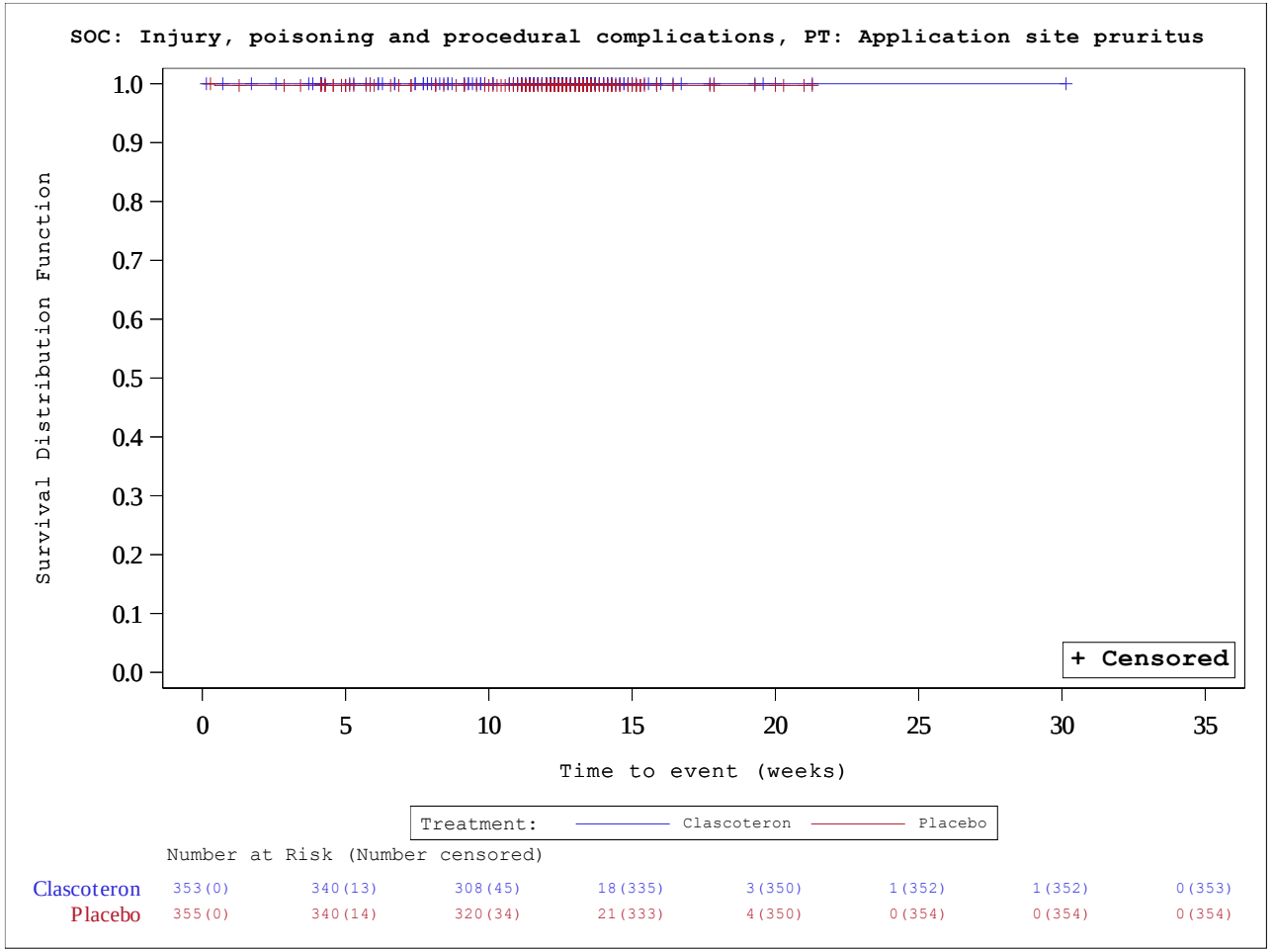


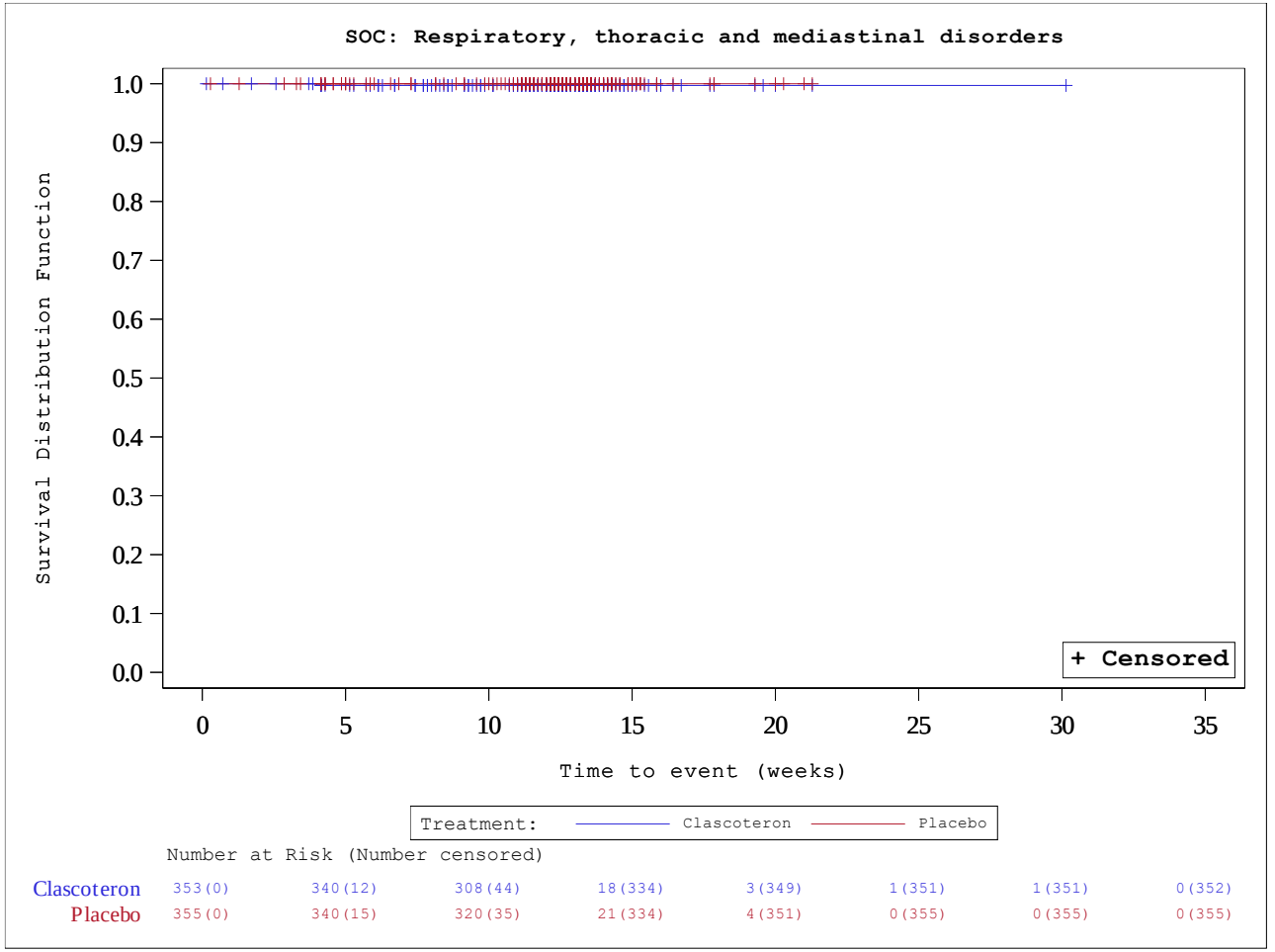
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
&set.



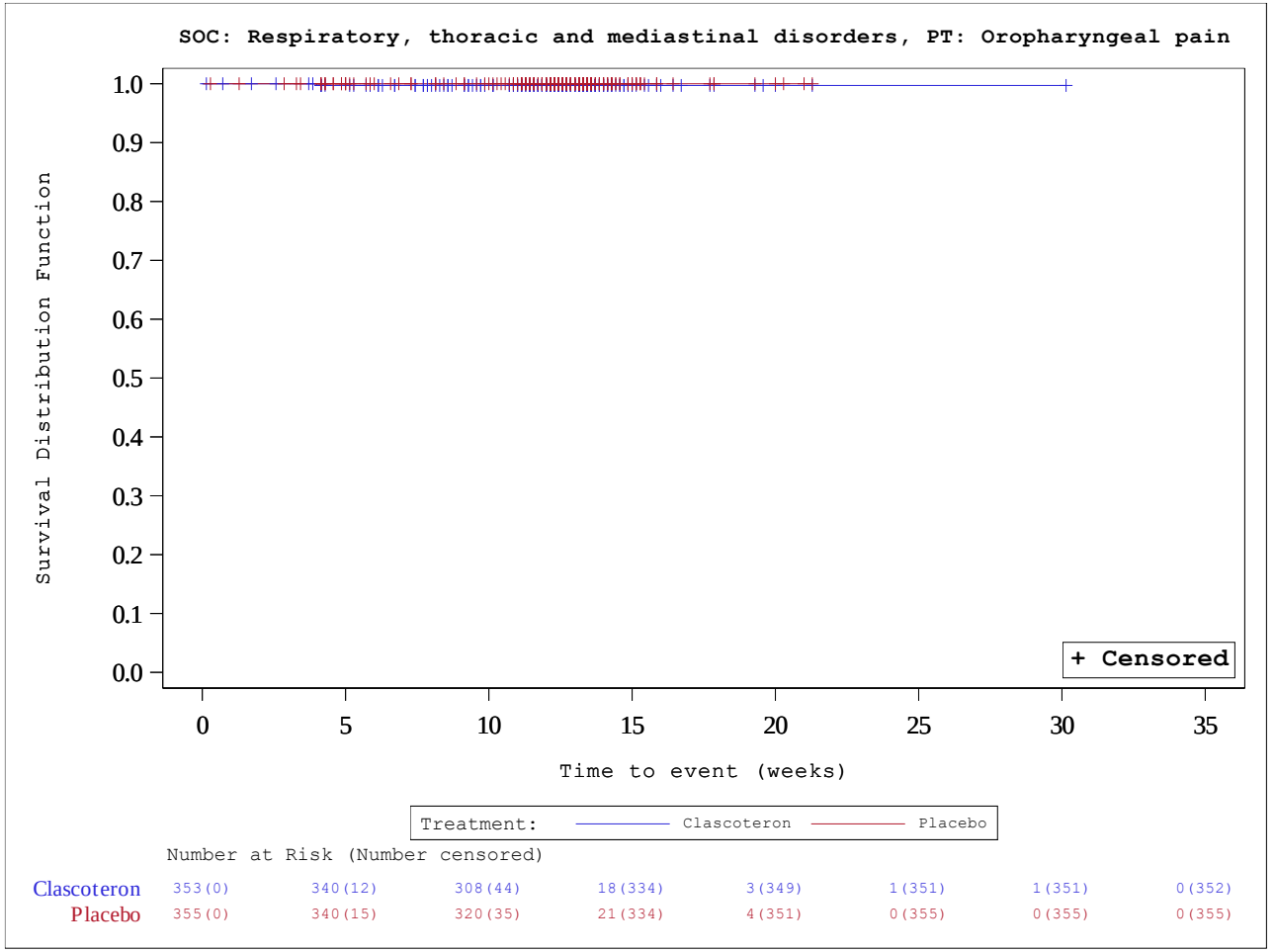
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
&set.



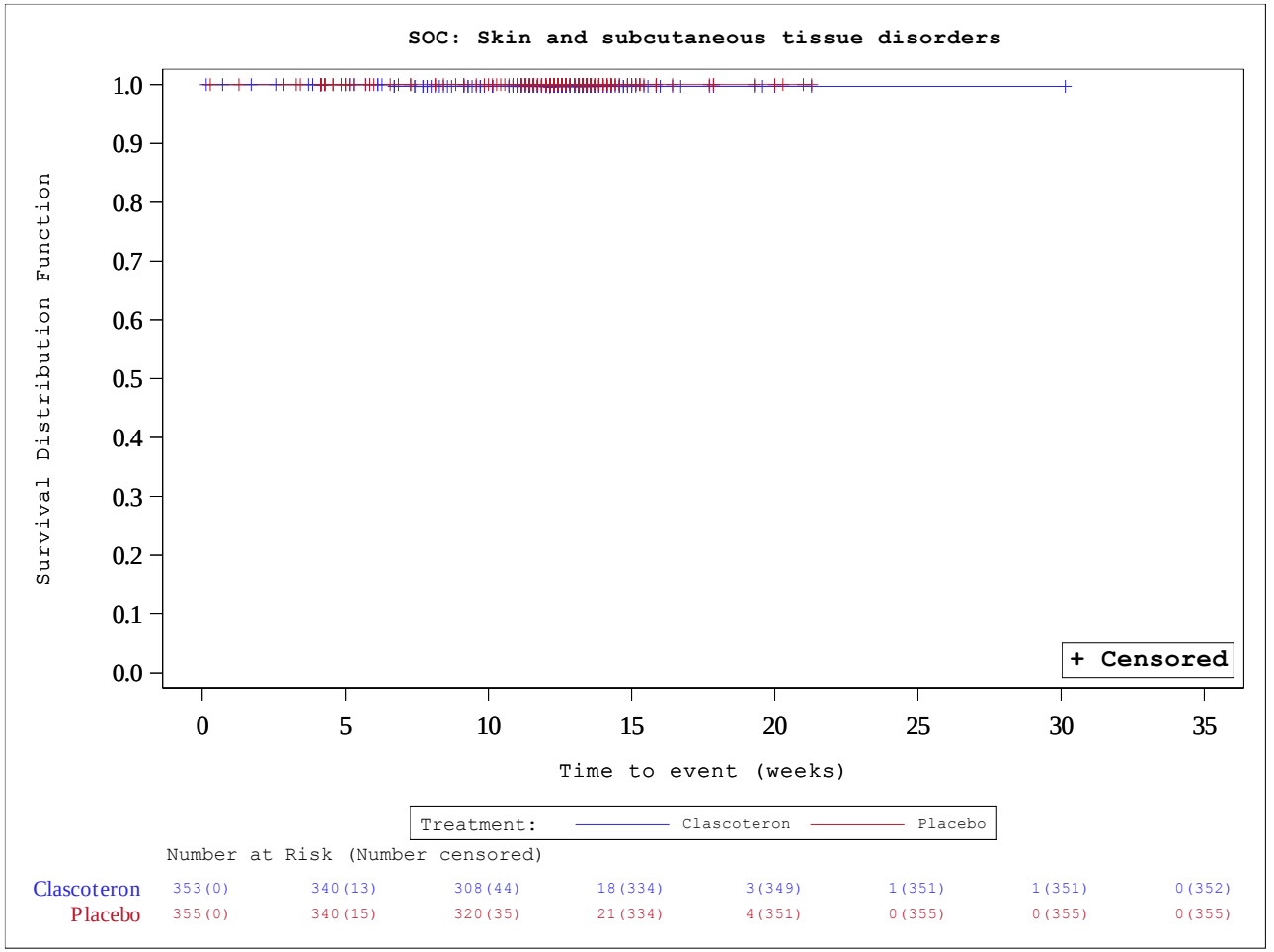
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
&set.



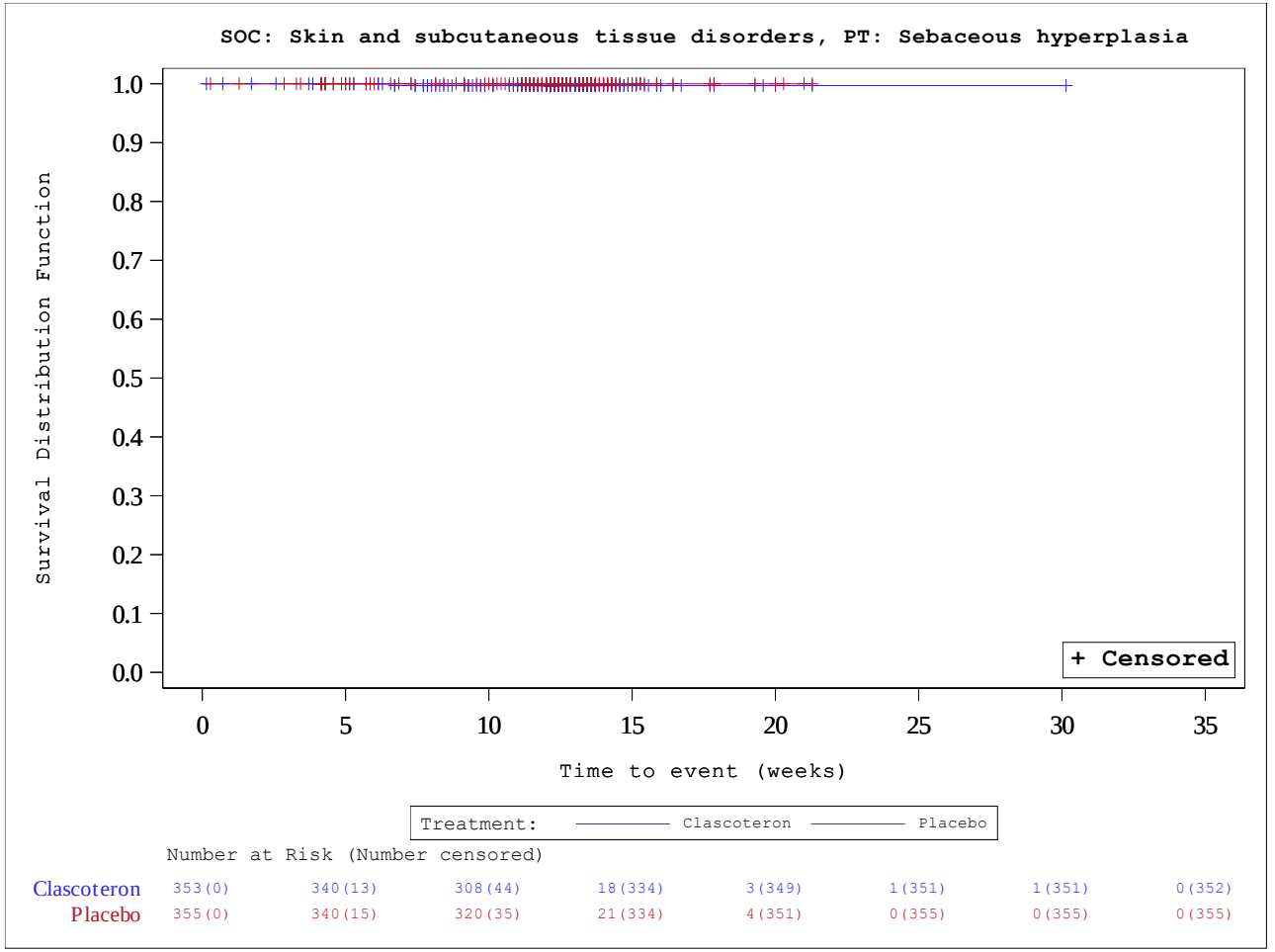
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
&set.



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
&set.



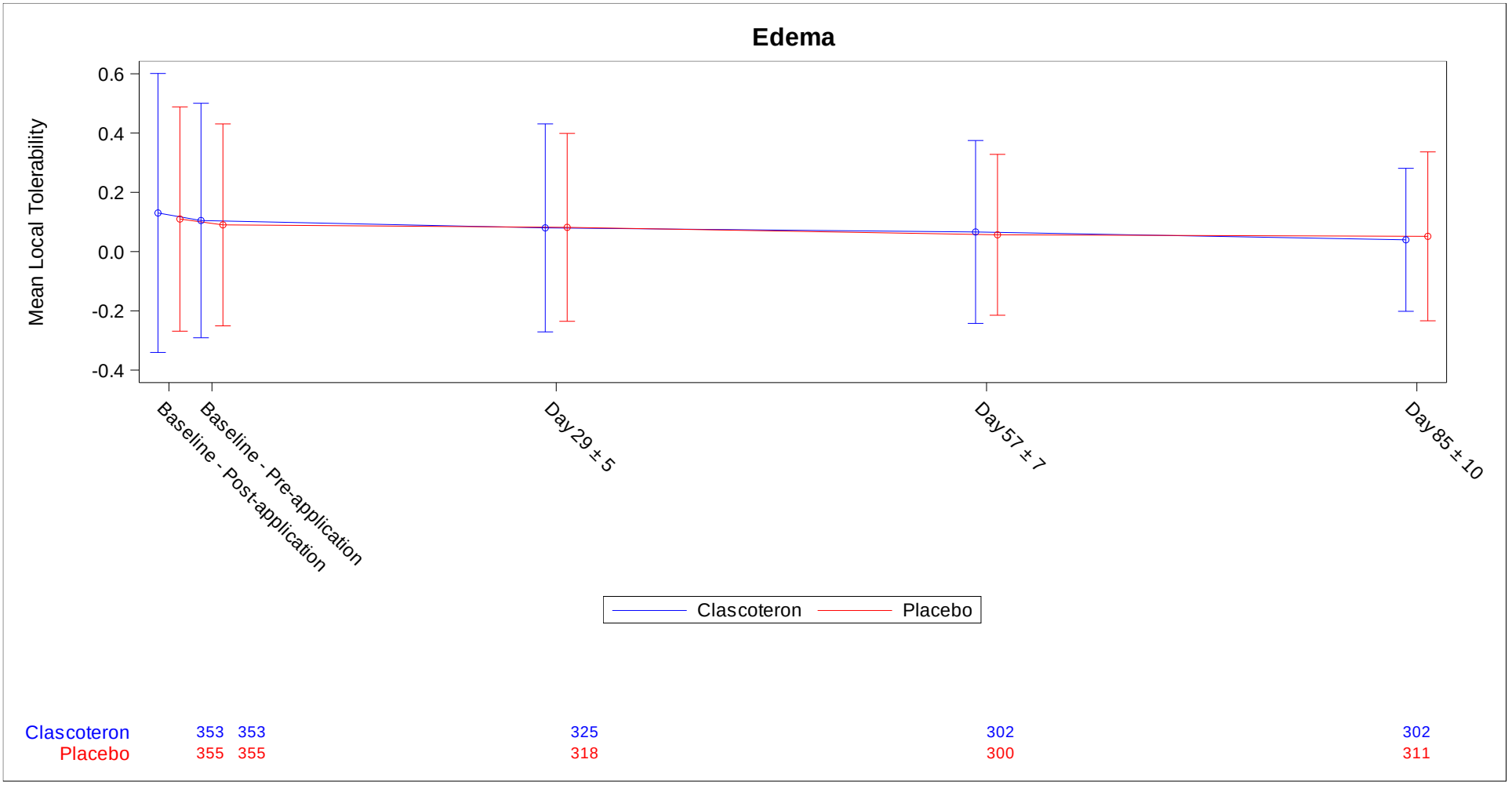
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Edema
Safety Analysis Set

		Clascoteron (N=353) n (%)	Placebo (N=355) n (%)
Baseline - Pre-application	0-None	322 (91.2)	323 (91.0)
	1-Minimal	20 (5.7)	26 (7.3)
	2-Mild	7 (2.0)	5 (1.4)
	3-Moderate	4 (1.1)	1 (0.3)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	326 (92.4)	328 (92.4)
	1-Minimal	18 (5.1)	23 (6.5)
	2-Mild	8 (2.3)	3 (0.8)
	3-Moderate	1 (0.3)	1 (0.3)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	306 (86.7)	296 (83.4)
	1-Minimal	13 (3.7)	18 (5.1)
	2-Mild	5 (1.4)	4 (1.1)
	3-Moderate	1 (0.3)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	28 (7.9)	37 (10.4)
Day 57 ± 7	0-None	287 (81.3)	286 (80.6)
	1-Minimal	10 (2.8)	11 (3.1)
	2-Mild	5 (1.4)	3 (0.8)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	55 (15.5)
Day 85 ± 10	0-None	293 (83.0)	299 (84.2)
	1-Minimal	6 (1.7)	9 (2.5)
	2-Mild	3 (0.8)	2 (0.6)
	3-Moderate	0 (0.0)	1 (0.3)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	44 (12.4)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Edema
Safety Analysis Set

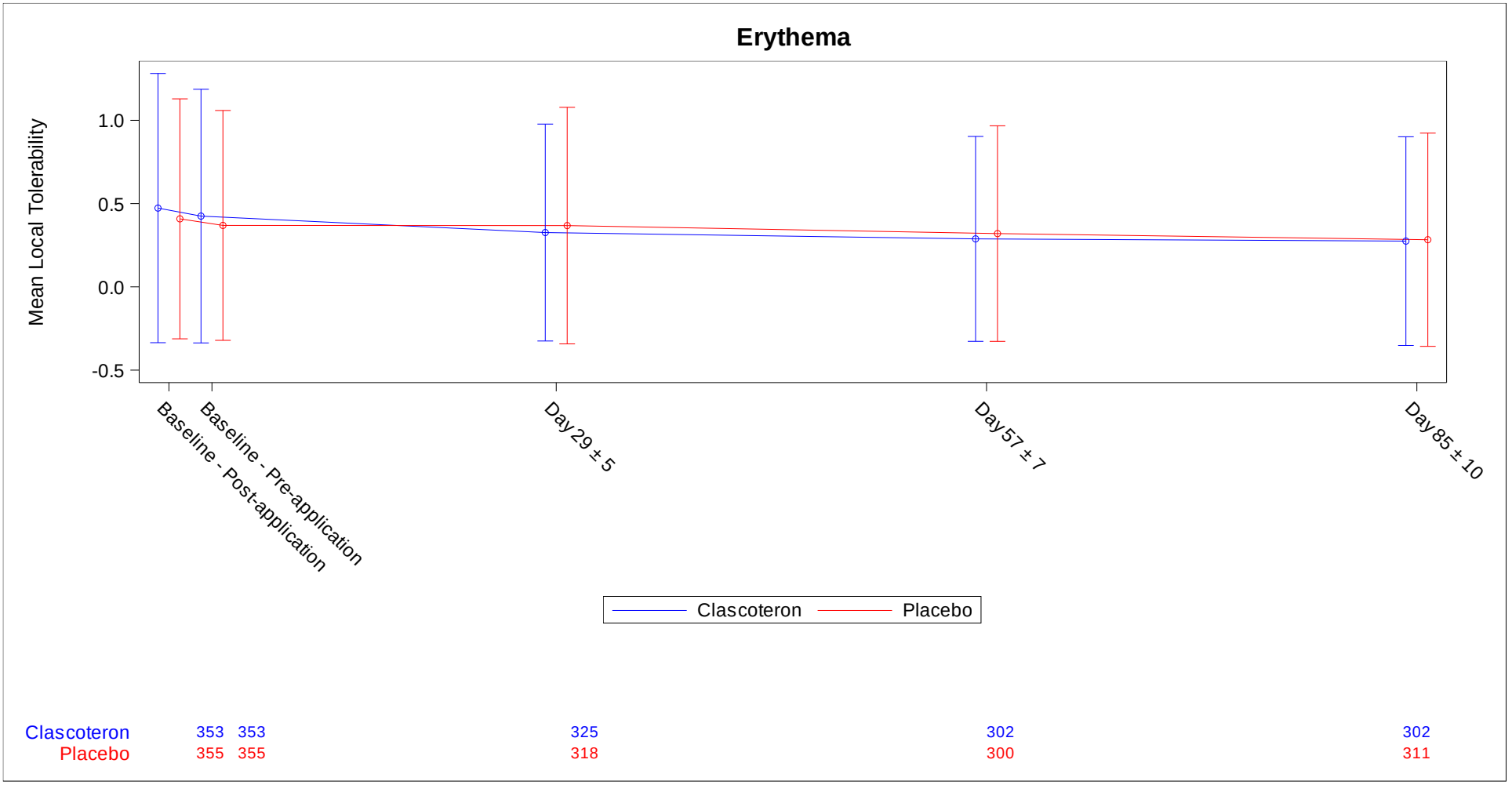


InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Erythema
Safety Analysis Set

		Clascoteron (N=353) n (%)	Placebo (N=355) n (%)
Baseline - Pre-application	0-None	242 (68.6)	251 (70.7)
	1-Minimal	69 (19.5)	71 (20.0)
	2-Mild	29 (8.2)	25 (7.0)
	3-Moderate	12 (3.4)	8 (2.3)
	4-Severe	1 (0.3)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	251 (71.1)	262 (73.8)
	1-Minimal	64 (18.1)	60 (16.9)
	2-Mild	29 (8.2)	28 (7.9)
	3-Moderate	8 (2.3)	5 (1.4)
	4-Severe	1 (0.3)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	247 (70.0)	237 (66.8)
	1-Minimal	55 (15.6)	51 (14.4)
	2-Mild	18 (5.1)	25 (7.0)
	3-Moderate	5 (1.4)	4 (1.1)
	4-Severe	0 (0.0)	1 (0.3)
	Not Done	28 (7.9)	37 (10.4)
Day 57 ± 7	0-None	238 (67.4)	231 (65.1)
	1-Minimal	44 (12.5)	45 (12.7)
	2-Mild	17 (4.8)	21 (5.9)
	3-Moderate	3 (0.8)	3 (0.8)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	55 (15.5)
Day 85 ± 10	0-None	245 (69.4)	249 (70.1)
	1-Minimal	34 (9.6)	42 (11.8)
	2-Mild	20 (5.7)	14 (3.9)
	3-Moderate	3 (0.8)	6 (1.7)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	44 (12.4)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Erythema
Safety Analysis Set



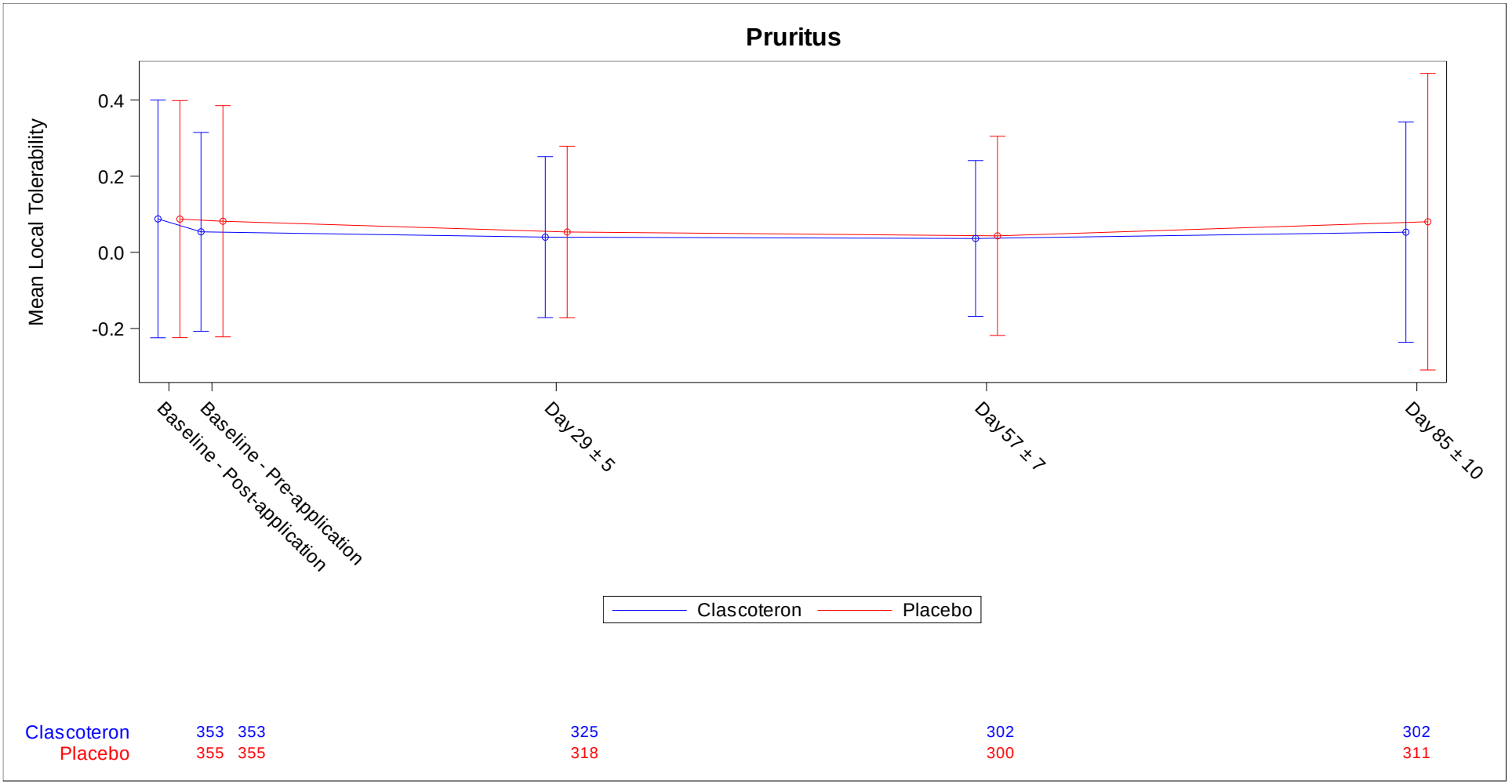
Clascoteron	353	353	325	302	302
Placebo	355	355	318	300	311

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Pruritus
Safety Analysis Set

		Clascoteron (N=353) n (%)	Placebo (N=355) n (%)
Baseline - Pre-application	0-None	325 (92.1)	327 (92.1)
	1-Mild	25 (7.1)	25 (7.0)
	2-Moderate	3 (0.8)	3 (0.8)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	337 (95.5)	329 (92.7)
	1-Mild	13 (3.7)	23 (6.5)
	2-Moderate	3 (0.8)	3 (0.8)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	313 (88.7)	301 (84.8)
	1-Mild	11 (3.1)	17 (4.8)
	2-Moderate	1 (0.3)	0 (0.0)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	28 (7.9)	37 (10.4)
Day 57 ± 7	0-None	292 (82.7)	290 (81.7)
	1-Mild	9 (2.5)	8 (2.3)
	2-Moderate	1 (0.3)	1 (0.3)
	3-Severe	0 (0.0)	1 (0.3)
	Not Done	51 (14.4)	55 (15.5)
Day 85 ± 10	0-None	290 (82.2)	296 (83.4)
	1-Mild	9 (2.5)	7 (2.0)
	2-Moderate	2 (0.6)	6 (1.7)
	3-Severe	1 (0.3)	2 (0.6)
	Not Done	51 (14.4)	44 (12.4)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Pruritus
Safety Analysis Set

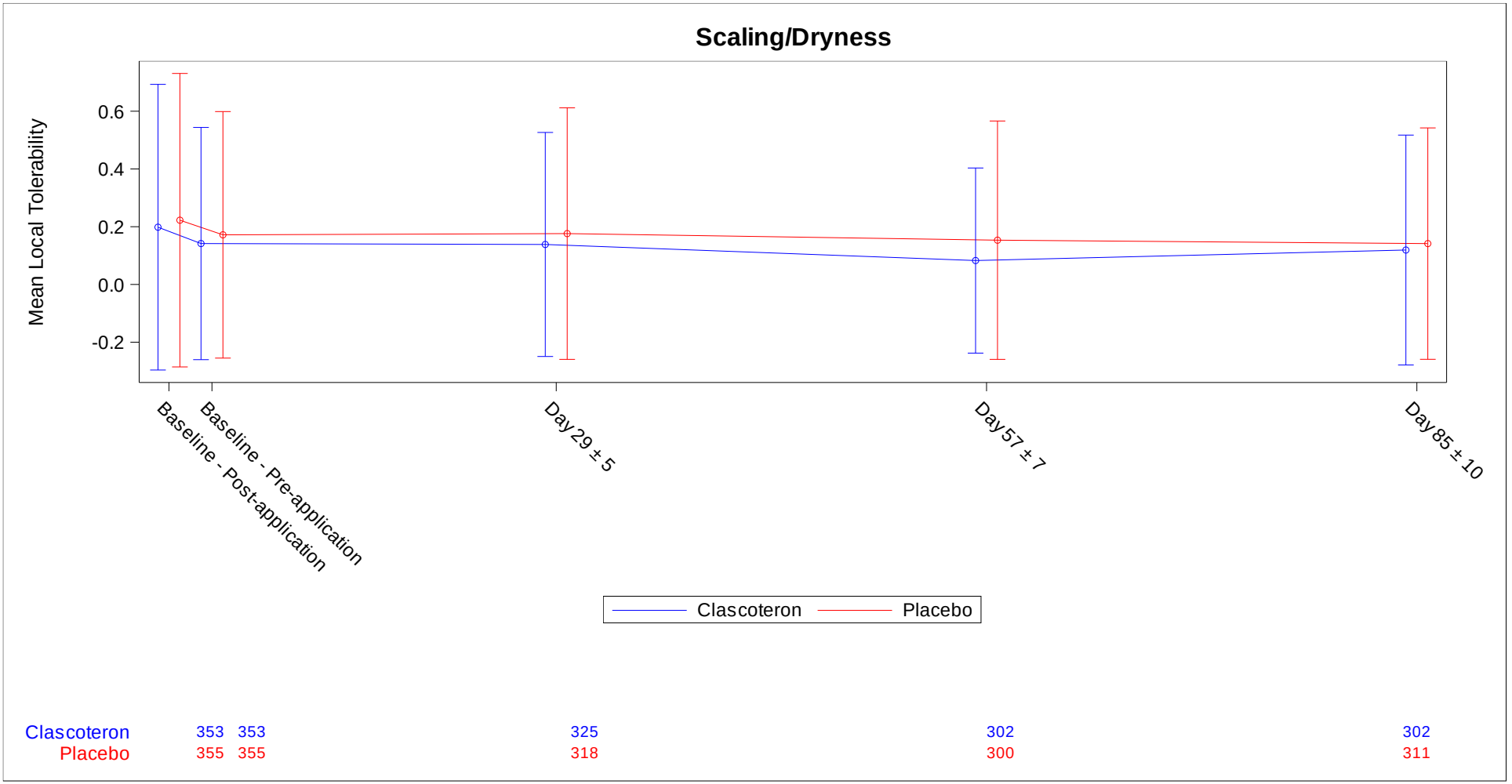


InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Scaling/Dryness
Safety Analysis Set

		Clascoteron (N=353) n (%)	Placebo (N=355) n (%)
Baseline - Pre-application	0-None	296 (83.9)	290 (81.7)
	1-Minimal	46 (13.0)	52 (14.6)
	2-Mild	9 (2.5)	12 (3.4)
	3-Moderate	2 (0.6)	1 (0.3)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	310 (87.8)	301 (84.8)
	1-Minimal	36 (10.2)	47 (13.2)
	2-Mild	7 (2.0)	7 (2.0)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	284 (80.5)	269 (75.8)
	1-Minimal	38 (10.8)	42 (11.8)
	2-Mild	2 (0.6)	7 (2.0)
	3-Moderate	1 (0.3)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	28 (7.9)	37 (10.4)
Day 57 ± 7	0-None	280 (79.3)	260 (73.2)
	1-Minimal	20 (5.7)	34 (9.6)
	2-Mild	1 (0.3)	6 (1.7)
	3-Moderate	1 (0.3)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	55 (15.5)
Day 85 ± 10	0-None	274 (77.6)	273 (76.9)
	1-Minimal	20 (5.7)	32 (9.0)
	2-Mild	8 (2.3)	6 (1.7)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	44 (12.4)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Scaling/Dryness
Safety Analysis Set



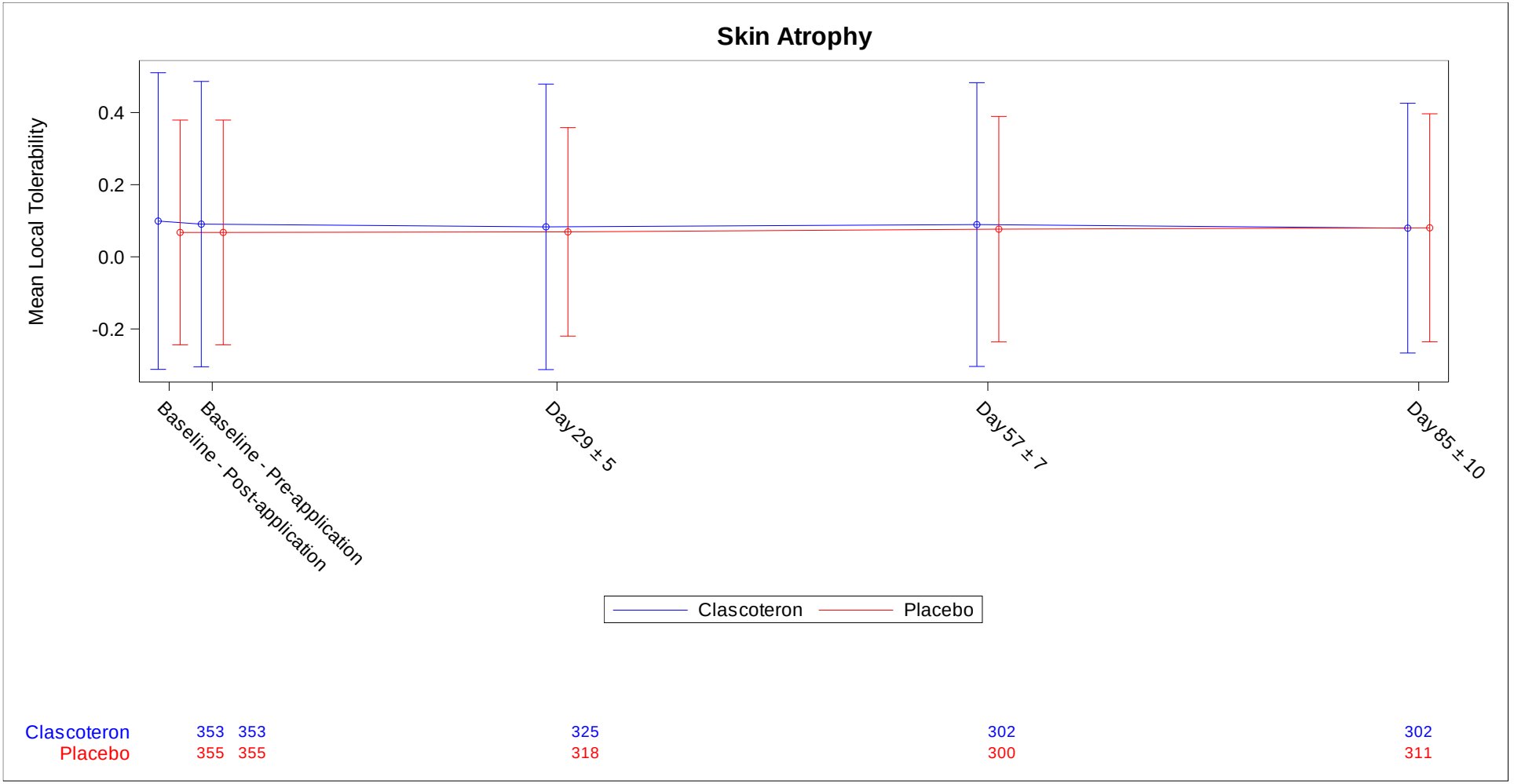
Clascoteron	353 353	325	302	302
Placebo	355 355	318	300	311

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Skin Atrophy
Safety Analysis Set

		Clascoteron (N=353) n (%)	Placebo (N=355) n (%)
Baseline - Pre-application	0-None	330 (93.5)	336 (94.6)
	1-Trace	13 (3.7)	15 (4.2)
	2-Mild	8 (2.3)	3 (0.8)
	3-Moderate	2 (0.6)	1 (0.3)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	332 (94.1)	336 (94.6)
	1-Trace	12 (3.4)	15 (4.2)
	2-Mild	7 (2.0)	3 (0.8)
	3-Moderate	2 (0.6)	1 (0.3)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	309 (87.5)	299 (84.2)
	1-Trace	7 (2.0)	16 (4.5)
	2-Mild	7 (2.0)	3 (0.8)
	3-Moderate	2 (0.6)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	28 (7.9)	37 (10.4)
Day 57 ± 7	0-None	285 (80.7)	281 (79.2)
	1-Trace	8 (2.3)	15 (4.2)
	2-Mild	8 (2.3)	4 (1.1)
	3-Moderate	1 (0.3)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	55 (15.5)
Day 85 ± 10	0-None	285 (80.7)	290 (81.7)
	1-Trace	10 (2.8)	17 (4.8)
	2-Mild	7 (2.0)	4 (1.1)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	44 (12.4)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Skin Atrophy
Safety Analysis Set

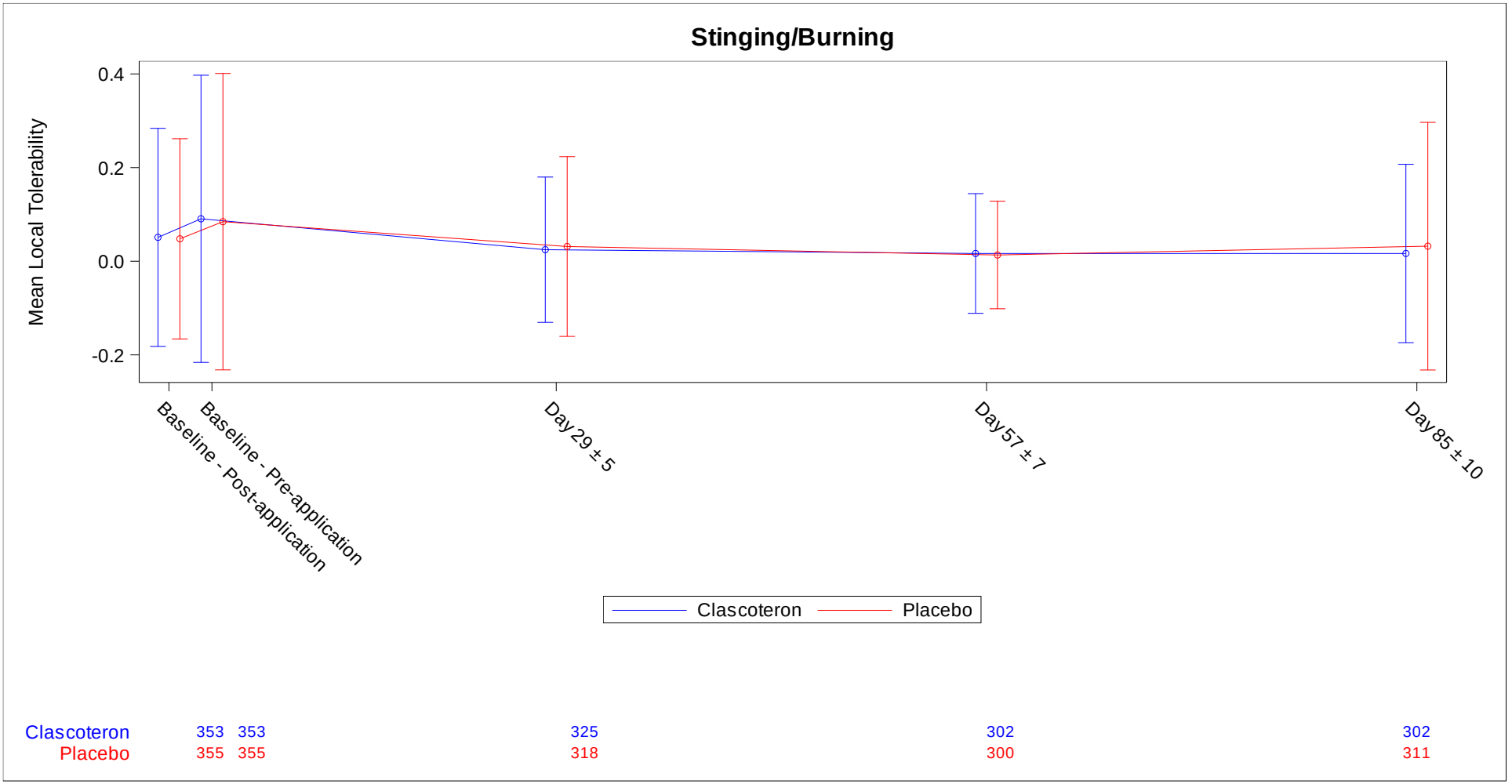


InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Stinging/Burning
Safety Analysis Set

		Clascoteron (N=353) n (%)	Placebo (N=355) n (%)
Baseline - Pre-application	0-None	336 (95.2)	338 (95.2)
	1-Minimal	16 (4.5)	17 (4.8)
	2-Moderate	1 (0.3)	0 (0.0)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	323 (91.5)	329 (92.7)
	1-Minimal	28 (7.9)	22 (6.2)
	2-Moderate	2 (0.6)	4 (1.1)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	317 (89.8)	309 (87.0)
	1-Minimal	8 (2.3)	8 (2.3)
	2-Moderate	0 (0.0)	1 (0.3)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	28 (7.9)	37 (10.4)
Day 57 ± 7	0-None	297 (84.1)	296 (83.4)
	1-Minimal	5 (1.4)	4 (1.1)
	2-Moderate	0 (0.0)	0 (0.0)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	55 (15.5)
Day 85 ± 10	0-None	299 (84.7)	305 (85.9)
	1-Minimal	2 (0.6)	4 (1.1)
	2-Moderate	0 (0.0)	0 (0.0)
	3-Severe	1 (0.3)	2 (0.6)
	Not Done	51 (14.4)	44 (12.4)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Stinging/Burning
Safety Analysis Set



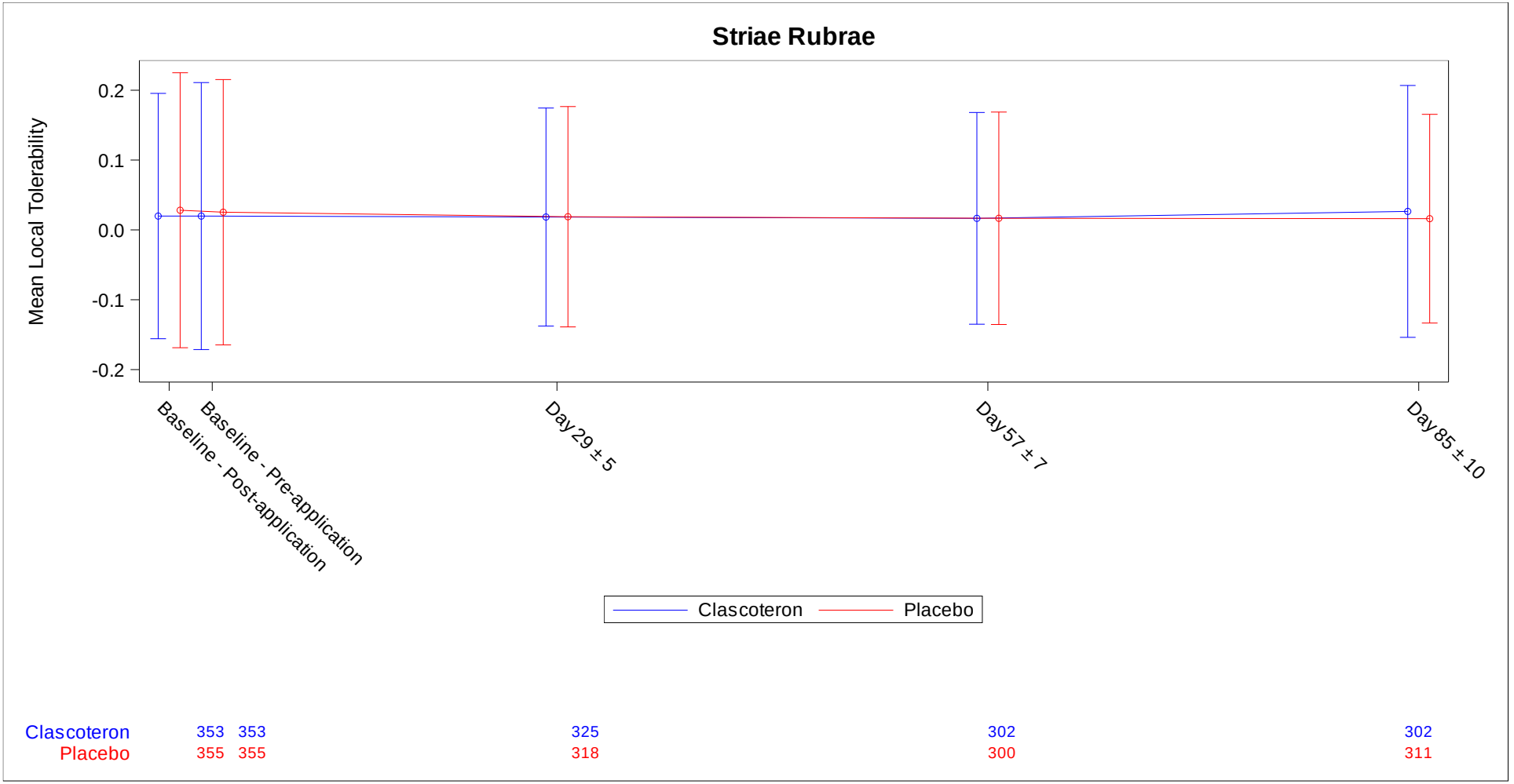
Clascoteron	353	353	325	302	302
Placebo	355	355	318	300	311

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Striae Rubrae
Safety Analysis Set

		Clascoteron (N=353) n (%)	Placebo (N=355) n (%)
Baseline - Pre-application	0-None	348 (98.6)	347 (97.7)
	1-Trace	3 (0.8)	6 (1.7)
	2-Mild	2 (0.6)	2 (0.6)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	349 (98.9)	348 (98.0)
	1-Trace	1 (0.3)	5 (1.4)
	2-Mild	3 (0.8)	2 (0.6)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	320 (90.7)	313 (88.2)
	1-Trace	4 (1.1)	4 (1.1)
	2-Mild	1 (0.3)	1 (0.3)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	28 (7.9)	37 (10.4)
Day 57 ± 7	0-None	298 (84.4)	296 (83.4)
	1-Trace	3 (0.8)	3 (0.8)
	2-Mild	1 (0.3)	1 (0.3)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	55 (15.5)
Day 85 ± 10	0-None	295 (83.6)	307 (86.5)
	1-Trace	6 (1.7)	3 (0.8)
	2-Mild	1 (0.3)	1 (0.3)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	44 (12.4)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Striae Rubrae
Safety Analysis Set

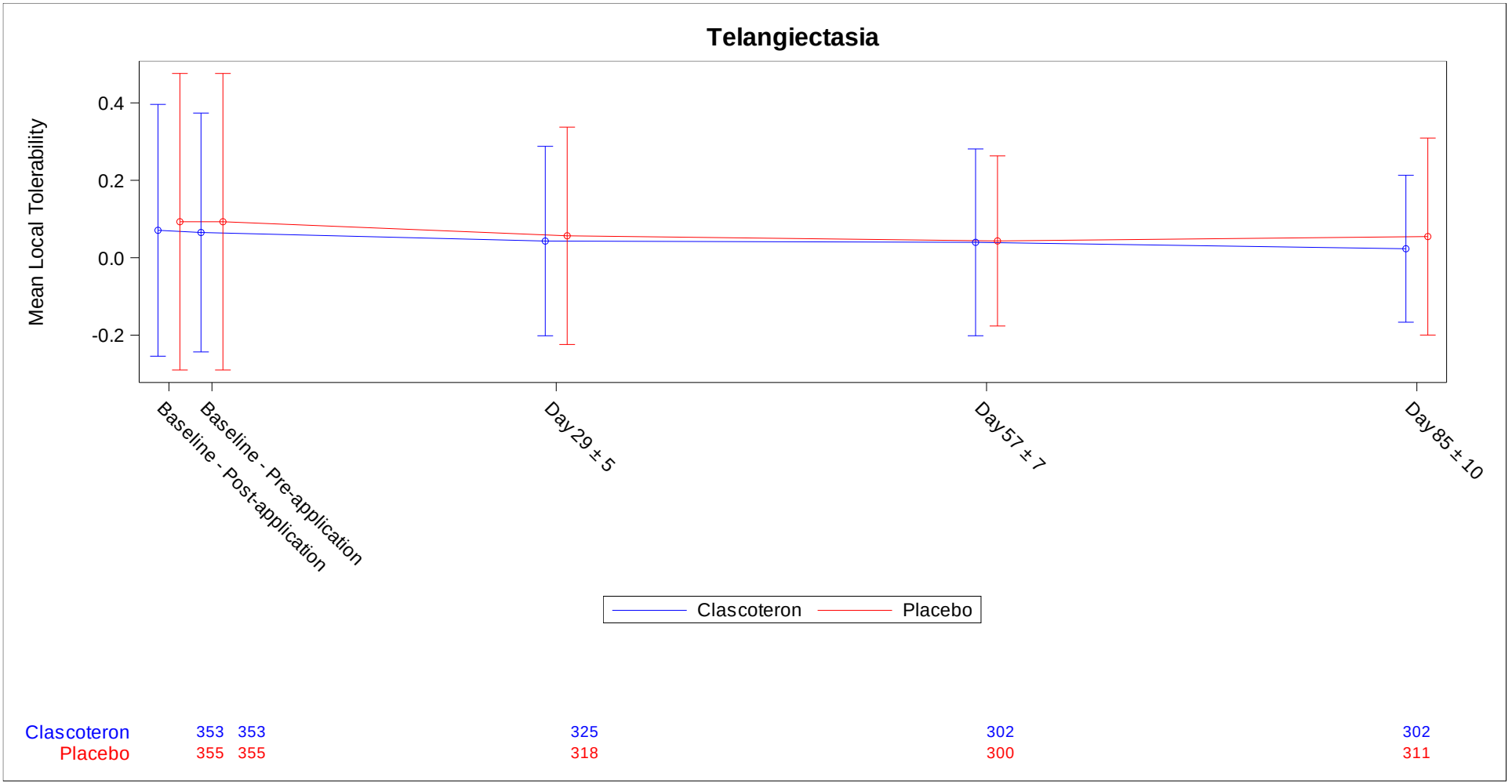


InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Telangiectasia
Safety Analysis Set

		Clascoteron (N=353) n (%)	Placebo (N=355) n (%)
Baseline - Pre-application	0-None	335 (94.9)	331 (93.2)
	1-Trace	11 (3.1)	17 (4.8)
	2-Mild	7 (2.0)	5 (1.4)
	3-Moderate	0 (0.0)	2 (0.6)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	336 (95.2)	331 (93.2)
	1-Trace	11 (3.1)	17 (4.8)
	2-Mild	6 (1.7)	5 (1.4)
	3-Moderate	0 (0.0)	2 (0.6)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	314 (89.0)	303 (85.4)
	1-Trace	8 (2.3)	13 (3.7)
	2-Mild	3 (0.8)	1 (0.3)
	3-Moderate	0 (0.0)	1 (0.3)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	28 (7.9)	37 (10.4)
Day 57 ± 7	0-None	293 (83.0)	288 (81.1)
	1-Trace	6 (1.7)	11 (3.1)
	2-Mild	3 (0.8)	1 (0.3)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	55 (15.5)
Day 85 ± 10	0-None	297 (84.1)	296 (83.4)
	1-Trace	3 (0.8)	13 (3.7)
	2-Mild	2 (0.6)	2 (0.6)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	51 (14.4)	44 (12.4)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Telangiectasia
Safety Analysis Set



InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Summary of on treatment/follow-up medications
Safety Analysis Set

Medication Class Standardised Medication Name	Clascoteron (N=353)	Placebo (N=355)
ANILIDES	5 (1.42 %)	7 (1.97 %)
DAYQUIL	3 (0.85 %)	3 (0.85 %)
NYQUIL	2 (0.57 %)	2 (0.56 %)
TYLENOL	1 (0.28 %)	2 (0.56 %)
ACETAMINOPHEN W/PHENYLEPHRINE HYDROCHLORIDE	0 (0.00 %)	1 (0.28 %)
EXCEDRIN	1 (0.28 %)	0 (0.00 %)
MIDOL COMPLETE	1 (0.28 %)	0 (0.00 %)
TYLENOL COLD	1 (0.28 %)	0 (0.00 %)
PROPIONIC ACID DERIVATIVES	4 (1.13 %)	8 (2.25 %)
IBUPROFEN	2 (0.57 %)	5 (1.41 %)
ADVIL	2 (0.57 %)	2 (0.56 %)
MOTRIN	1 (0.28 %)	1 (0.28 %)
PENICILLINS WITH EXTENDED SPECTRUM	5 (1.42 %)	2 (0.56 %)
AMOXICILLIN	5 (1.42 %)	2 (0.56 %)
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	2 (0.57 %)	2 (0.56 %)
DESOGESTREL AND ETHINYL ESTRADIOL	0 (0.00 %)	1 (0.28 %)
LO LOESTRIN FE	1 (0.28 %)	0 (0.00 %)
LOESTRIN FE	1 (0.28 %)	0 (0.00 %)
MINASTRIN 24 FE	0 (0.00 %)	1 (0.28 %)
AMINOALKYL ETHERS	1 (0.28 %)	2 (0.56 %)
BENADRYL	1 (0.28 %)	0 (0.00 %)
DIPHENHYDRAMINE	0 (0.00 %)	1 (0.28 %)
TAVEGIL	0 (0.00 %)	1 (0.28 %)
BENZODIAZEPINE DERIVATIVES	2 (0.57 %)	1 (0.28 %)
KLONOPIN	1 (0.28 %)	0 (0.00 %)
LORAZEPAM	1 (0.28 %)	0 (0.00 %)
VERSED	0 (0.00 %)	1 (0.28 %)
NATURAL OPIUM ALKALOIDS	0 (0.00 %)	3 (0.85 %)
NORCO	0 (0.00 %)	2 (0.56 %)
HYDROCODONE/ACETAMINOPHEN	0 (0.00 %)	1 (0.28 %)
MORPHINE	0 (0.00 %)	1 (0.28 %)
GLUCOCORTICOIDS	1 (0.28 %)	1 (0.28 %)
DEXAMETHASONE	0 (0.00 %)	1 (0.28 %)
MEDROL	1 (0.28 %)	0 (0.00 %)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	0 (0.00 %)	2 (0.56 %)
LORATADINE	0 (0.00 %)	1 (0.28 %)
QUIFENADINE	0 (0.00 %)	1 (0.28 %)
OTHER COLD PREPARATIONS	2 (0.57 %)	0 (0.00 %)
HALLS	2 (0.57 %)	0 (0.00 %)
PIPERAZINE DERIVATIVES	2 (0.57 %)	0 (0.00 %)
ZYRTEC	2 (0.57 %)	0 (0.00 %)
PROGESTOGENS	2 (0.57 %)	0 (0.00 %)
DEPO PROVERA	1 (0.28 %)	0 (0.00 %)
DEPOPROVERA	1 (0.28 %)	0 (0.00 %)
SALT SOLUTIONS	1 (0.28 %)	1 (0.28 %)
SODIUM CHLORIDE	1 (0.28 %)	1 (0.28 %)

The number and the proportion of subjects with any on treatment/follow-up medication for each classification level are reported.
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall.
WHO Drug Dictionary 2015 SEP B2.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Summary of on treatment/follow-up medications
Safety Analysis Set

Medication Class Standardised Medication Name	Clascoteron (N=353)	Placebo (N=355)
SEROTONIN (5HT3) ANTAGONISTS	1 (0.28 %)	1 (0.28 %)
ZOFRAN	1 (0.28 %)	1 (0.28 %)
ONDANSETRON	0 (0.00 %)	1 (0.28 %)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	0 (0.00 %)	1 (0.28 %)
KETOROLAC	0 (0.00 %)	1 (0.28 %)
AMIDES	0 (0.00 %)	1 (0.28 %)
LIDOCAINE W/EPINEPHRINE	0 (0.00 %)	1 (0.28 %)
ANTIBACTERIALS FOR SYSTEMIC USE	0 (0.00 %)	1 (0.28 %)
ANTIBIOTICS	0 (0.00 %)	1 (0.28 %)
ANTIBIOTICS	0 (0.00 %)	1 (0.28 %)
TOBRAMYCIN	0 (0.00 %)	1 (0.28 %)
ANTIVIRALS	1 (0.28 %)	0 (0.00 %)
ACICLOVIRUM	1 (0.28 %)	0 (0.00 %)
BETA-LACTAMASE SENSITIVE PENICILLINS	1 (0.28 %)	0 (0.00 %)
PENICILLIN	1 (0.28 %)	0 (0.00 %)
BULK-FORMING LAXATIVES	0 (0.00 %)	1 (0.28 %)
PSYLLIUM HYDROPHILIC MUCILLOID	0 (0.00 %)	1 (0.28 %)
CENTRALLY ACTING ANTIOBESITY PRODUCTS	0 (0.00 %)	1 (0.28 %)
PHENTERMINE	0 (0.00 %)	1 (0.28 %)
CENTRALLY ACTING SYMPATHOMIMETICS	1 (0.28 %)	0 (0.00 %)
VYVANSE	1 (0.28 %)	0 (0.00 %)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	1 (0.28 %)	0 (0.00 %)
TRIAMCINOLONE	1 (0.28 %)	0 (0.00 %)
CORTICOSTEROIDS, PLAIN	0 (0.00 %)	1 (0.28 %)
FLUOROMETHOLONE	0 (0.00 %)	1 (0.28 %)
EXPECTORANTS	1 (0.28 %)	0 (0.00 %)
ROBITUSSIN	1 (0.28 %)	0 (0.00 %)
IMIDAZOLE AND TRIAZOLE DERIVATIVES	0 (0.00 %)	1 (0.28 %)
KETOCONAZOLE	0 (0.00 %)	1 (0.28 %)
IMIDAZOLE DERIVATIVES	0 (0.00 %)	1 (0.28 %)
METRONIDAZOLE	0 (0.00 %)	1 (0.28 %)
INFLUENZA VACCINES	1 (0.28 %)	0 (0.00 %)
INFLUENZA VACCINE	1 (0.28 %)	0 (0.00 %)
INTRAVAGINAL CONTRACEPTIVES	1 (0.28 %)	0 (0.00 %)
NUVARING	1 (0.28 %)	0 (0.00 %)
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	0 (0.00 %)	1 (0.28 %)
ESTRADIOL	0 (0.00 %)	1 (0.28 %)
NEURAMINIDASE INHIBITORS	0 (0.00 %)	1 (0.28 %)
TAMIFLU	0 (0.00 %)	1 (0.28 %)

The number and the proportion of subjects with any on treatment/follow-up medication for each classification level are reported.
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall.
WHO Drug Dictionary 2015 SEP B2.

InfectoPharm
Study CB-03-01/25 - Datacut: 11APR2018
CB-03-01/25 - Clascoteron vs. Placebo
Summary of on treatment/follow-up medications
Safety Analysis Set

Medication Class Standardised Medication Name	Clascoteron (N=353)	Placebo (N=355)
NITROFURAN DERIVATIVES	0 (0.00 %)	1 (0.28 %)
MACROBID	0 (0.00 %)	1 (0.28 %)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	1 (0.28 %)	0 (0.00 %)
ACICLOVIRUM	1 (0.28 %)	0 (0.00 %)
OPIUM ALKALOIDS AND DERIVATIVES	0 (0.00 %)	1 (0.28 %)
CHILDREN'S DIMETAPP COLD & COUGH	0 (0.00 %)	1 (0.28 %)
OPIUM DERIVATIVES AND EXPECTORANTS	0 (0.00 %)	1 (0.28 %)
Q-TUSSIN DM	0 (0.00 %)	1 (0.28 %)
OTHER ANTIDEPRESSANTS	1 (0.28 %)	0 (0.00 %)
WELLBUTRIN	1 (0.28 %)	0 (0.00 %)
OTHER ANTIFUNGALS FOR TOPICAL USE	1 (0.28 %)	0 (0.00 %)
FUCHSINE	1 (0.28 %)	0 (0.00 %)
OTHER ANTISEPTICS AND DISINFECTANTS	1 (0.28 %)	0 (0.00 %)
BRILLIANT GREEN	1 (0.28 %)	0 (0.00 %)
OTHER GENERAL ANESTHETICS	0 (0.00 %)	1 (0.28 %)
KETAMINE	0 (0.00 %)	1 (0.28 %)
OTHER HYPNOTICS AND SEDATIVES	0 (0.00 %)	1 (0.28 %)
BELSOMRA	0 (0.00 %)	1 (0.28 %)
OTHER NASAL PREPARATIONS	1 (0.28 %)	0 (0.00 %)
ATROVENT	1 (0.28 %)	0 (0.00 %)
PROTON PUMP INHIBITORS	0 (0.00 %)	1 (0.28 %)
OMEPRAZOLE	0 (0.00 %)	1 (0.28 %)
PYRETHRINES, INCL. SYNTHETIC COMPOUNDS	0 (0.00 %)	1 (0.28 %)
ELIMITE	0 (0.00 %)	1 (0.28 %)
SALICYLIC ACID AND DERIVATIVES	1 (0.28 %)	0 (0.00 %)
ASPIRIN	1 (0.28 %)	0 (0.00 %)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	1 (0.28 %)	0 (0.00 %)
PROZAC	1 (0.28 %)	0 (0.00 %)
SYMPATHOMIMETICS	0 (0.00 %)	1 (0.28 %)
PSEUDOEPHEDRINE HYDROCHLORIDE	0 (0.00 %)	1 (0.28 %)
SYMPATHOMIMETICS, PLAIN	0 (0.00 %)	1 (0.28 %)
TRAMAZOLINE	0 (0.00 %)	1 (0.28 %)
THIRD-GENERATION CEPHALOSPORINS	1 (0.28 %)	0 (0.00 %)
CEFDINIR	1 (0.28 %)	0 (0.00 %)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	1 (0.28 %)	0 (0.00 %)
TEA TREE OIL	1 (0.28 %)	0 (0.00 %)

The number and the proportion of subjects with any on treatment/follow-up medication for each classification level are reported.
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WHO Drug Dictionary 2015 SEP B2.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Disposition
Intention-to-treat

	Clascoteron (N=369)	Placebo (N=363)	Total (N=732)
	n (%)	n (%)	n (%)
Treated	369 (100.00)	363 (100.00)	732 (100.00)
Completed	302 (81.84)	282 (77.69)	584 (79.78)
Discontinued	67 (18.16)	81 (22.31)	148 (20.22)
Adverse event	2 (0.54)	8 (2.20)	10 (1.37)
Lack of efficacy	3 (0.81)	1 (0.28)	4 (0.55)
Lost to follow-up	24 (6.50)	24 (6.61)	48 (6.56)
Non-compliance with study drug	1 (0.27)	5 (1.38)	6 (0.82)
Other	0 (0.00)	1 (0.28)	1 (0.14)
Physician decision	1 (0.27)	0 (0.00)	1 (0.14)
Pregnancy	0 (0.00)	1 (0.28)	1 (0.14)
Progressive disease	1 (0.27)	0 (0.00)	1 (0.14)
Withdrawal by parent/guardian	5 (1.36)	4 (1.10)	9 (1.23)
Withdrawal by subject	30 (8.13)	37 (10.19)	67 (9.15)

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Demographic and Baseline Characteristics
Intention-to-treat

Endpoint		Clascoteron (N=369)	Placebo (N=363)	Total (N=732)
Sex, n (%)	Female	243 (65.85)	221 (60.88)	464 (63.39)
	Male	126 (34.15)	142 (39.12)	268 (36.61)
Race, n (%)	American Indian or Alaska Native	1 (0.27)	1 (0.28)	2 (0.27)
	Asian	0 (0.00)	4 (1.10)	4 (0.55)
	Native Hawaiian or Other Pacific Islander	0 (0.00)	1 (0.28)	1 (0.14)
	Black or African American	7 (1.90)	6 (1.65)	13 (1.78)
	White	357 (96.75)	348 (95.87)	705 (96.31)
	Multiple	0 (0.00)	1 (0.28)	1 (0.14)
	Other	4 (1.08)	2 (0.55)	6 (0.82)
Region, n (%)	USA	47 (12.74)	46 (12.67)	93 (12.70)
	Europe	322 (87.26)	317 (87.33)	639 (87.30)
Ethnicity, n (%)	Hispanic or Latino	20 (5.42)	9 (2.48)	29 (3.96)
	Not Hispanic or Latino	349 (94.58)	354 (97.52)	703 (96.04)
Age [years]	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	19.3 (5.63)	19.0 (5.39)	19.2 (5.51)
	Median	18.0	18.0	18.0
	Q1, Q3	16.0, 22.0	15.0, 21.0	15.5, 21.0
	Min, Max	10.0, 50.0	11.0, 42.0	10.0, 50.0
Age group, n (%)	9 - <12	2 (0.54)	1 (0.28)	3 (0.41)
	12 - <18	170 (46.07)	171 (47.11)	341 (46.58)
	18 - <65	197 (53.39)	191 (52.62)	388 (53.01)
Height [cm]	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	168.6 (9.56)	169.4 (8.93)	169.0 (9.26)
	Median	167.0	169.0	168.0
	Q1, Q3	161.5, 174.5	163.0, 175.0	162.6, 175.0
	Min, Max	137.2, 198.1	135.0, 203.2	135.0, 203.2
Weight [kg]	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	63.1 (13.60)	63.5 (13.78)	63.3 (13.68)
	Median	60.0	60.0	60.0
	Q1, Q3	54.0, 70.0	54.2, 69.8	54.0, 70.0
	Min, Max	30.0, 127.0	36.6, 133.8	30.0, 133.8
Investigator's Global Assessment, n (%)	3-Moderate	305 (82.66)	313 (86.23)	618 (84.43)
	4-Severe	64 (17.34)	50 (13.77)	114 (15.57)
Body Mass Index [kg/m^2]	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	22.1 (4.05)	22.0 (3.94)	22.1 (3.99)
	Median	21.2	21.2	21.2
	Q1, Q3	19.4, 24.1	19.5, 23.7	19.4, 23.8
	Min, Max	13.2, 39.8	15.5, 40.6	13.2, 40.6
Total Lesions (Whole Face)	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	105.7 (25.76)	104.6 (24.18)	105.2 (24.98)
	Median	103.0	103.0	103.0
	Q1, Q3	87.0, 122.0	85.0, 121.0	86.0, 122.0
	Min, Max	60.0, 241.0	60.0, 170.0	60.0, 241.0
Inflammatory Lesions (Whole Face)	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	42.9 (12.20)	41.3 (10.96)	42.1 (11.62)
	Median	39.0	37.0	38.0
	Q1, Q3	33.0, 49.0	32.0, 47.0	33.0, 48.0
	Min, Max	30.0, 75.0	30.0, 74.0	30.0, 75.0

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Min: Minimum, Max = Maximum.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Demographic and Baseline Characteristics
Intention-to-treat

Endpoint		Clascoteron (N=369)	Placebo (N=363)	Total (N=732)
Non-Inflammatory Lesions (Whole Face)	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	62.8 (21.37)	63.3 (20.52)	63.1 (20.94)
	Median	61.0	63.0	61.0
	Q1, Q3	45.0, 77.0	45.0, 81.0	45.0, 80.0
	Min, Max	30.0, 177.0	30.0, 100.0	30.0, 177.0
Total Lesions (Nose)	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	11.2 (10.90)	11.4 (10.40)	11.3 (10.65)
	Median	9.0	9.0	9.0
	Q1, Q3	3.0, 16.0	4.0, 17.0	3.0, 16.0
	Min, Max	0.0, 76.0	0.0, 58.0	0.0, 76.0
Inflammatory Lesions (Nose)	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	2.4 (3.03)	2.5 (3.00)	2.5 (3.01)
	Median	1.0	2.0	2.0
	Q1, Q3	0.0, 4.0	0.0, 4.0	0.0, 4.0
	Min, Max	0.0, 24.0	0.0, 19.0	0.0, 24.0
Non-Inflammatory Lesions (Nose)	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	8.8 (9.33)	8.9 (8.69)	8.8 (9.01)
	Median	7.0	7.0	7.0
	Q1, Q3	1.0, 13.0	2.0, 14.0	2.0, 13.5
	Min, Max	0.0, 62.0	0.0, 45.0	0.0, 62.0
Total Lesions (Rest of Face)	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	94.5 (24.07)	93.2 (21.41)	93.9 (22.78)
	Median	91.0	93.0	92.0
	Q1, Q3	78.0, 109.0	77.0, 108.0	77.0, 109.0
	Min, Max	24.0, 214.0	46.0, 152.0	24.0, 214.0
Inflammatory Lesions (Rest of Face)	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	40.5 (11.94)	38.8 (10.15)	39.7 (11.11)
	Median	37.0	36.0	36.0
	Q1, Q3	32.0, 47.0	31.0, 44.0	31.0, 45.0
	Min, Max	7.0, 74.0	20.0, 72.0	7.0, 74.0
Non-Inflammatory Lesions (Rest of Face)	n (missing)	369 (0)	363 (0)	732 (0)
	Mean (SD)	54.0 (19.88)	54.4 (18.61)	54.2 (19.25)
	Median	53.0	53.0	53.0
	Q1, Q3	39.0, 67.0	39.0, 69.0	39.0, 68.5
	Min, Max	14.0, 159.0	17.0, 99.0	14.0, 159.0
Fitzpatrick skin type assessment, n (%)	I - Pale white skin, blue/hazel eyes, blond/red hair; always burns, does not tan	7 (1.90)	12 (3.31)	19 (2.60)
	II - Fair skin, blue eyes; burns easily, tans poorly	122 (33.06)	107 (29.48)	229 (31.28)
	III - Darker white skin; tans after initial burn	170 (46.07)	166 (45.73)	336 (45.90)
	IV - Light brown skin; burns minimally, tans easily	57 (15.45)	54 (14.88)	111 (15.16)
	V - Brown skin; rarely burns, tans darkly easily	7 (1.90)	21 (5.79)	28 (3.83)
	VI - Dark brown or black skin; never burns, always tans darkly	6 (1.63)	3 (0.83)	9 (1.23)

n: Number of non-missing values, SD: Standard deviation, Q1: 25% Quantil, Q3: 75% Quantile, Min: Minimum, Max = Maximum.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Observation duration for Efficacy endpoints
Intention-to-treat

Endpoint		Clascoteron (N=369)	Placebo (N=363)
Study duration in days	Number of patients in analysis	369	363
	Mean (SD)	84.7 (23.46)	81.7 (24.23)
	Median	87.0	86.0
	Min, Max	1.0, 273.0	1.0, 207.0
Observation duration for Inflammatory Lesions (Nose) in days	Number of patients in analysis	369	363
	Mean (SD)	79.2 (25.06)	74.5 (30.35)
	Median	86.0	85.0
	Min, Max	1.0, 153.0	1.0, 127.0
Observation duration for Inflammatory Lesions (Rest of Face) in days	Number of patients in analysis	369	363
	Mean (SD)	79.2 (25.06)	74.5 (30.35)
	Median	86.0	85.0
	Min, Max	1.0, 153.0	1.0, 127.0
Observation duration for Inflammatory Lesions (Whole Face) in days	Number of patients in analysis	369	363
	Mean (SD)	79.2 (25.06)	74.5 (30.35)
	Median	86.0	85.0
	Min, Max	1.0, 153.0	1.0, 127.0
Observation duration for Investigator's Global Assessment in days	Number of patients in analysis	369	363
	Mean (SD)	79.2 (24.97)	74.5 (30.24)
	Median	86.0	85.0
	Min, Max	1.0, 153.0	1.0, 127.0
Observation duration for Non-Inflammatory Lesions (Nose) in days	Number of patients in analysis	369	363
	Mean (SD)	79.2 (25.06)	74.5 (30.35)
	Median	86.0	85.0
	Min, Max	1.0, 153.0	1.0, 127.0
Observation duration for Non-Inflammatory Lesions (Rest of Face) in days	Number of patients in analysis	369	363
	Mean (SD)	79.2 (25.06)	74.5 (30.35)
	Median	86.0	85.0
	Min, Max	1.0, 153.0	1.0, 127.0
Observation duration for Non-Inflammatory Lesions (Whole Face) in days	Number of patients in analysis	369	363
	Mean (SD)	79.2 (25.06)	74.5 (30.35)
	Median	86.0	85.0
	Min, Max	1.0, 153.0	1.0, 127.0
Observation duration for Total Lesions (Nose) in days	Number of patients in analysis	369	363
	Mean (SD)	79.2 (25.06)	74.5 (30.35)
	Median	86.0	85.0
	Min, Max	1.0, 153.0	1.0, 127.0
Observation duration for Total Lesions (Rest of Face) in days	Number of patients in analysis	369	363
	Mean (SD)	79.2 (25.06)	74.5 (30.35)
	Median	86.0	85.0
	Min, Max	1.0, 153.0	1.0, 127.0
Observation duration for Total Lesions (Whole Face) in days	Number of patients in analysis	369	363
	Mean (SD)	79.2 (25.06)	74.5 (30.35)
	Median	86.0	85.0
	Min, Max	1.0, 153.0	1.0, 127.0

Study duration is defined as time from randomization until date of study completion/discontinuation.
Observation period for endpoints is defined as time from treatment start until date of last non-missing assessment.
Min: Minimum, Max: Maximum, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Observation duration for Safety endpoints
Safety Analysis Set

Endpoint		Clascoteron (N=369)	Placebo (N=363)
Treatment duration in days	Number of patients in analysis	369	363
	Mean (SD)	77.9 (24.87)	74.9 (33.16)
	Median	85.0	85.0
	Min, Max	1.0, 120.0	1.0, 366.0
Observation duration for Safety in days	Number of patients in analysis	369	363
	Mean (SD)	84.7 (23.46)	81.6 (24.22)
	Median	87.0	86.0
	Min, Max	1.0, 273.0	1.0, 207.0

Treatment duration is defined as time from first dose of study treatment until last date of study treatment.
Safety period is defined as time from treatment start until date of study completion/discontinuation.
Min: Minimum, Max: Maximum, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients achieving Therapy success with at least a two-point reduction in IGA compared to Baseline AND an IGA score of 0 or 1 at Week 12
Intention-to-treat

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with reponse, n/N (%)	75.3/ 369 (20.41)	23.5/ 363 (6.47)
Number of imputed values	41	53
Adjusted Analysis Clascoteron vs. Placebo		
Odds Ratio (95% CI)	3.76 (2.19, 6.43)	
p-value	<.0001	
Risk Ratio (95% CI)	3.17 (1.96, 5.12)	
p-value	<.0001	
Risk Difference (95% CI)	0.14 (0.09, 0.19)	
p-value	<.0001	
Unadjusted Analysis Clascoteron vs. Placebo		
Odds Ratio (95% CI)	3.72 (2.19, 6.32)	
p-value	<.0001	
Risk Ratio (95% CI)	3.16 (1.95, 5.12)	
p-value	<.0001	
Risk Difference (95% CI)	0.14 (0.09, 0.19)	
p-value	<.0001	

Adjusted analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with treatment and pooled analysis centre as fixed effects.
Unadjusted RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients achieving Therapy success with at least a two-point reduction in IGA compared to Baseline AND an IGA score of 0 or 1 at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup Level	Clascoteron (N=369) n/ N (%)	Placebo (N=363) n/ N (%)	Risk Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)					0.6679
9 - <18	28.9/ 172 (16.80)	8.0/ 172 (4.65)	3.62 (1.68, 7.79)	0.0010	
18 - <65	46.4/ 197 (23.55)	15.5/ 191 (8.12)	2.92 (1.59, 5.39)	0.0007	
Gender					0.5901
Male	18.6/ 126 (14.76)	8.2/ 142 (5.77)	2.56 (1.13, 5.83)	0.0246	
Female	56.7/ 243 (23.33)	15.3/ 221 (6.92)	3.40 (1.83, 6.32)	0.0001	
Region					0.0240
USA	3.6/ 47 (7.66)	5.6/ 46 (12.17)	0.61 (0.13, 2.86)	0.5255	
Europe	71.7/ 322 (22.27)	17.9/ 317 (5.65)	3.96 (2.30, 6.82)	<.0001	
IGA					0.7749
3-Moderate	67.2/ 305 (22.03)	21.0/ 313 (6.71)	3.30 (2.00, 5.44)	<.0001	
4-Severe	8.1/ 64 (12.66)	2.5/ 50 (5.00)	2.61 (0.57, 11.88)	0.2136	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
Unadjusted RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients achieving Therapy success with at least a 15% in IGA compared to Baseline at Week 12
Intention-to-treat

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with reponse, n/N (%)	235.1/ 369 (63.71)	201.6/ 363 (55.54)
Number of imputed values	41	53
Adjusted Analysis Clascoteron vs. Placebo		
Odds Ratio (95% CI)	1.43 (1.05, 1.95)	
p-value	0.0244	
Risk Ratio (95% CI)	1.16 (1.02, 1.31)	
p-value	0.0243	
Risk Difference (95% CI)	0.08 (0.01, 0.16)	
p-value	0.0236	
Unadjusted Analysis Clascoteron vs. Placebo		
Odds Ratio (95% CI)	1.41 (1.03, 1.91)	
p-value	0.0302	
Risk Ratio (95% CI)	1.15 (1.01, 1.30)	
p-value	0.0313	
Risk Difference (95% CI)	0.08 (0.01, 0.16)	
p-value	0.0296	

Adjusted analyses done using logistic regression model (RR: log-link, OR: logit-link, RD: identity-link) with treatment and pooled analysis centre as fixed effects.
Unadjusted RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients achieving Therapy success with at least a 15% in IGA compared to Baseline at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup Level	Clascoteron (N=369) n/ N (%)	Placebo (N=363) n/ N (%)	Risk Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)					0.2145
9 - <18	105.7/ 172 (61.45)	84.1/ 172 (48.90)	1.26 (1.03, 1.53)	0.0248	
18 - <65	129.4/ 197 (65.69)	117.5/ 191 (61.52)	1.07 (0.91, 1.26)	0.4258	
Gender					0.0517
Male	83.1/ 126 (65.95)	69.0/ 142 (48.59)	1.36 (1.09, 1.69)	0.0068	
Female	152.0/ 243 (62.55)	132.6/ 221 (60.00)	1.04 (0.90, 1.21)	0.5810	
Region					0.0589
USA	26.7/ 47 (56.81)	31.3/ 46 (68.04)	0.83 (0.58, 1.19)	0.3178	
Europe	208.4/ 322 (64.72)	170.3/ 317 (53.72)	1.20 (1.05, 1.39)	0.0094	
IGA					0.6539
3-Moderate	182.5/ 305 (59.84)	167.1/ 313 (53.39)	1.12 (0.97, 1.29)	0.1187	
4-Severe	52.6/ 64 (82.19)	34.5/ 50 (69.00)	1.19 (0.95, 1.49)	0.1279	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
Unadjusted RR, OR and RD estimated using Mantel-Haenszel method. 95% confidence intervals and p-values constructed using normal approximation (Wald test).
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in total lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	105.69 (25.76)	0	-	363	104.63 (24.18)	0	-
Day 29 ± 5	335	77.49 (33.69)	335	-28.92 (26.57)	310	79.63 (33.40)	310	-24.95 (29.89)
Day 57 ± 7	315	70.21 (37.63)	315	-36.17 (32.24)	289	71.49 (36.28)	289	-33.04 (33.54)
Day 85 ± 10	327	64.32 (38.80)	327	-41.97 (37.16)	309	81.98 (41.40)	309	-22.53 (38.28)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-40.27 (1.93)	42	363	-23.70 (1.98)	54	-16.57 (-22.04, -11.09)	<.0001	-0.44 (-0.59, -0.30)	<.0001

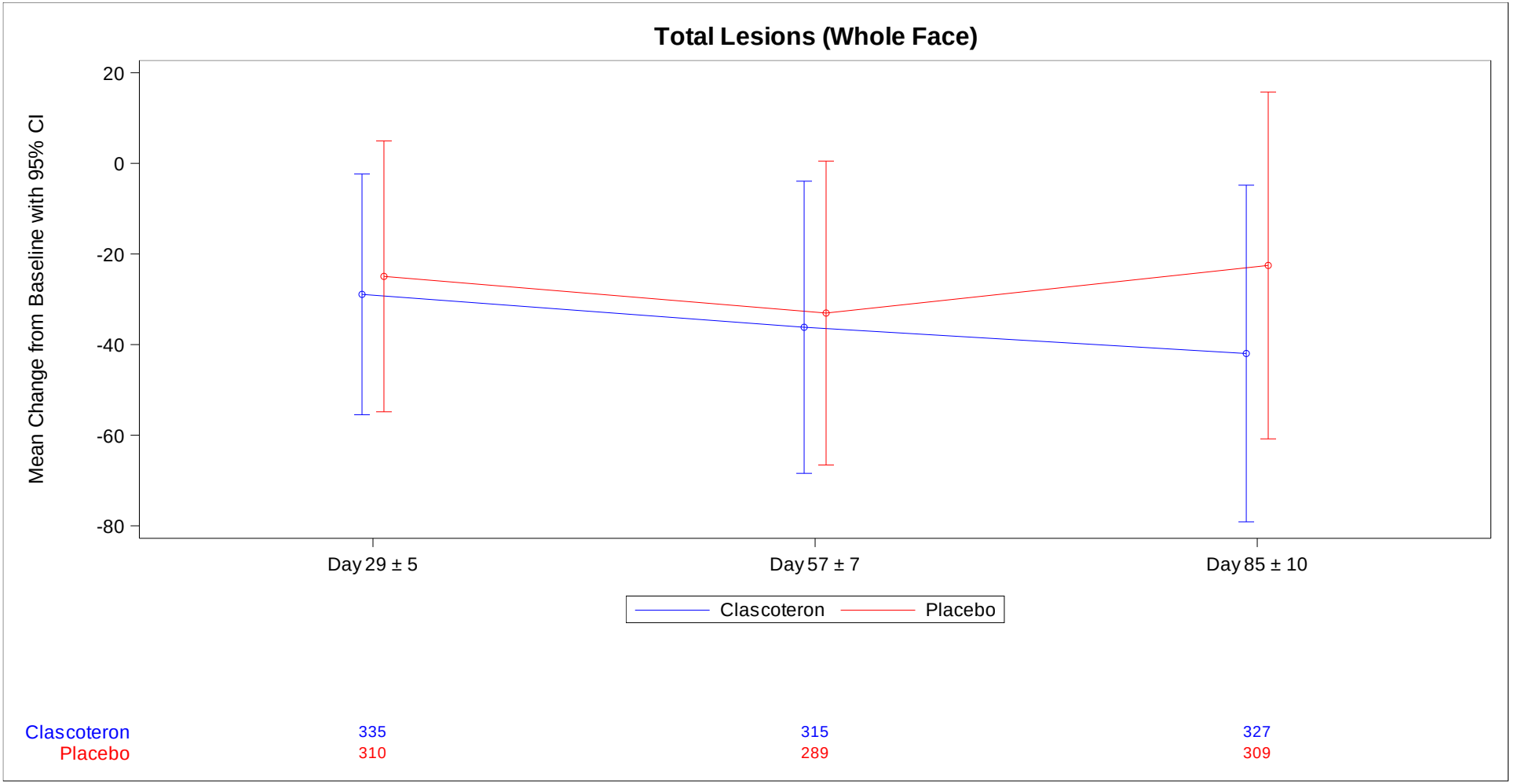
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							Interaction
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.5425
9 - <18	172	111.62 (26.42)	172 (14)	-37.02 (3.05)	172	108.29 (24.65)	172 (13)	-18.46 (3.01)	-18.56 (-27.16, -9.96)	<.0001	-0.47 (-0.68, -0.25)	<.0001	
18 - <65	197	100.52 (24.06)	197 (28)	-43.68 (2.64)	191	101.33 (23.33)	191 (41)	-28.66 (2.81)	-15.02 (-22.62, -7.41)	0.0001	-0.40 (-0.60, -0.19)	0.0001	
Gender													0.4989
Male	126	109.59 (26.97)	126 (13)	-38.63 (3.40)	142	106.58 (23.91)	142 (16)	-19.58 (3.19)	-19.05 (-28.18, -9.93)	<.0001	-0.50 (-0.74, -0.26)	<.0001	
Female	243	103.67 (24.92)	243 (29)	-41.61 (2.41)	221	103.37 (24.33)	221 (38)	-26.54 (2.60)	-15.07 (-22.25, -7.90)	<.0001	-0.40 (-0.58, -0.21)	<.0001	
Region													0.0051
USA	47	107.45 (30.94)	47 (9)	-34.85 (5.65)	46	102.52 (21.47)	46 (9)	-39.09 (5.56)	4.24 (-11.88, 20.36)	0.6006	0.11 (-0.30, 0.52)	0.5965	
Europe	322	105.44 (24.96)	322 (33)	-41.50 (2.14)	317	104.93 (24.57)	317 (45)	-21.52 (2.17)	-19.98 (-26.16, -13.80)	<.0001	-0.52 (-0.67, -0.36)	<.0001	
IGA													0.1726
3-Moderate	305	104.26 (25.24)	305 (39)	-39.55 (2.19)	313	103.05 (24.16)	313 (48)	-24.36 (2.18)	-15.19 (-21.41, -8.97)	<.0001	-0.39 (-0.55, -0.24)	<.0001	
4-Severe	64	112.55 (27.27)	64 (3)	-45.55 (4.35)	50	114.48 (22.12)	50 (6)	-20.36 (5.06)	-25.19 (-38.31, -12.07)	0.0002	-0.71 (-1.09, -0.33)	0.0003	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of change from baseline of total lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in total lesions count (Nose) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	11.16 (10.90)	0	-	363	11.43 (10.40)	0	-
Day 29 ± 5	335	7.97 (9.04)	335	-3.36 (7.73)	310	8.83 (9.54)	310	-2.42 (6.95)
Day 57 ± 7	315	6.83 (8.17)	315	-4.51 (7.89)	289	7.40 (8.04)	289	-3.86 (8.06)
Day 85 ± 10	327	5.59 (7.18)	327	-5.47 (9.59)	309	8.80 (11.91)	309	-2.30 (11.98)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-5.07 (0.47)	42	363	-2.31 (0.52)	54	-2.77 (-4.15, -1.38)	0.0001	-0.29 (-0.44, -0.15)	<.0001

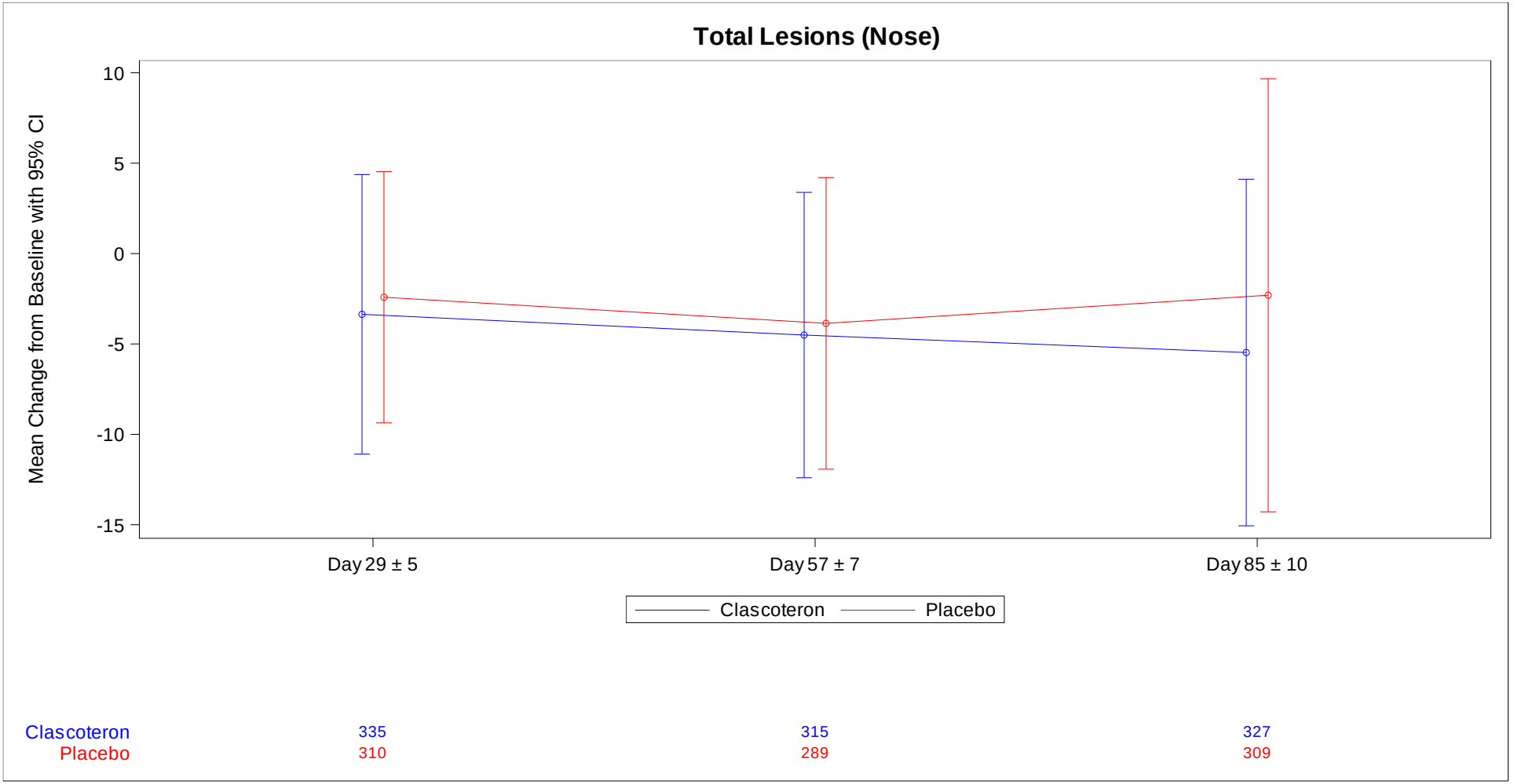
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.5017
9 - <18	172	11.91 (11.68)	172 (14)	-4.84 (0.80)	172	12.01 (10.97)	172 (13)	-1.42 (0.80)	-3.42 (-5.66, -1.18)	0.0028	-0.32 (-0.54, -0.11)	0.0028	
18 - <65	197	10.50 (10.17)	197 (28)	-5.11 (0.55)	191	10.91 (9.86)	191 (41)	-2.65 (0.62)	-2.47 (-4.15, -0.78)	0.0045	-0.30 (-0.50, -0.10)	0.0030	
Gender													0.6737
Male	126	11.91 (11.26)	126 (13)	-4.42 (0.71)	142	12.81 (10.57)	142 (16)	-1.96 (0.69)	-2.45 (-4.44, -0.47)	0.0157	-0.30 (-0.54, -0.06)	0.0142	
Female	243	10.77 (10.72)	243 (29)	-5.23 (0.62)	221	10.55 (10.22)	221 (38)	-2.19 (0.69)	-3.03 (-4.89, -1.18)	0.0014	-0.30 (-0.49, -0.12)	0.0012	
Region													0.0260
USA	47	10.17 (11.07)	47 (9)	-2.58 (1.16)	46	11.50 (8.57)	46 (9)	-3.27 (1.22)	0.69 (-2.71, 4.09)	0.6862	0.08 (-0.32, 0.49)	0.6846	
Europe	322	11.30 (10.89)	322 (33)	-5.35 (0.51)	317	11.42 (10.65)	317 (45)	-1.88 (0.56)	-3.47 (-4.99, -1.94)	<.0001	-0.36 (-0.52, -0.21)	<.0001	
IGA													0.3219
3-Moderate	305	11.07 (10.64)	305 (39)	-4.91 (0.55)	313	10.93 (10.06)	313 (48)	-2.20 (0.57)	-2.71 (-4.31, -1.12)	0.0010	-0.28 (-0.43, -0.12)	0.0006	
4-Severe	64	11.61 (12.18)	64 (3)	-5.42 (0.94)	50	14.60 (11.94)	50 (6)	-1.10 (1.05)	-4.33 (-7.14, -1.51)	0.0029	-0.58 (-0.95, -0.20)	0.0028	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of change from baseline of total lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in total lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	94.53 (24.07)	0	-	363	93.20 (21.41)	0	-
Day 29 ± 5	335	69.52 (30.71)	335	-25.56 (24.24)	310	70.79 (30.22)	310	-22.53 (27.43)
Day 57 ± 7	315	63.38 (34.49)	315	-31.67 (29.92)	289	64.09 (32.94)	289	-29.18 (30.01)
Day 85 ± 10	327	58.73 (35.75)	327	-36.49 (33.54)	309	73.17 (36.17)	309	-20.22 (33.64)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)						
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-34.61 (1.75)	42	363	-21.24 (1.78)	54	-13.37 (-18.37, -8.38)	<.0001	-0.40 (-0.54, -0.25)	<.0001

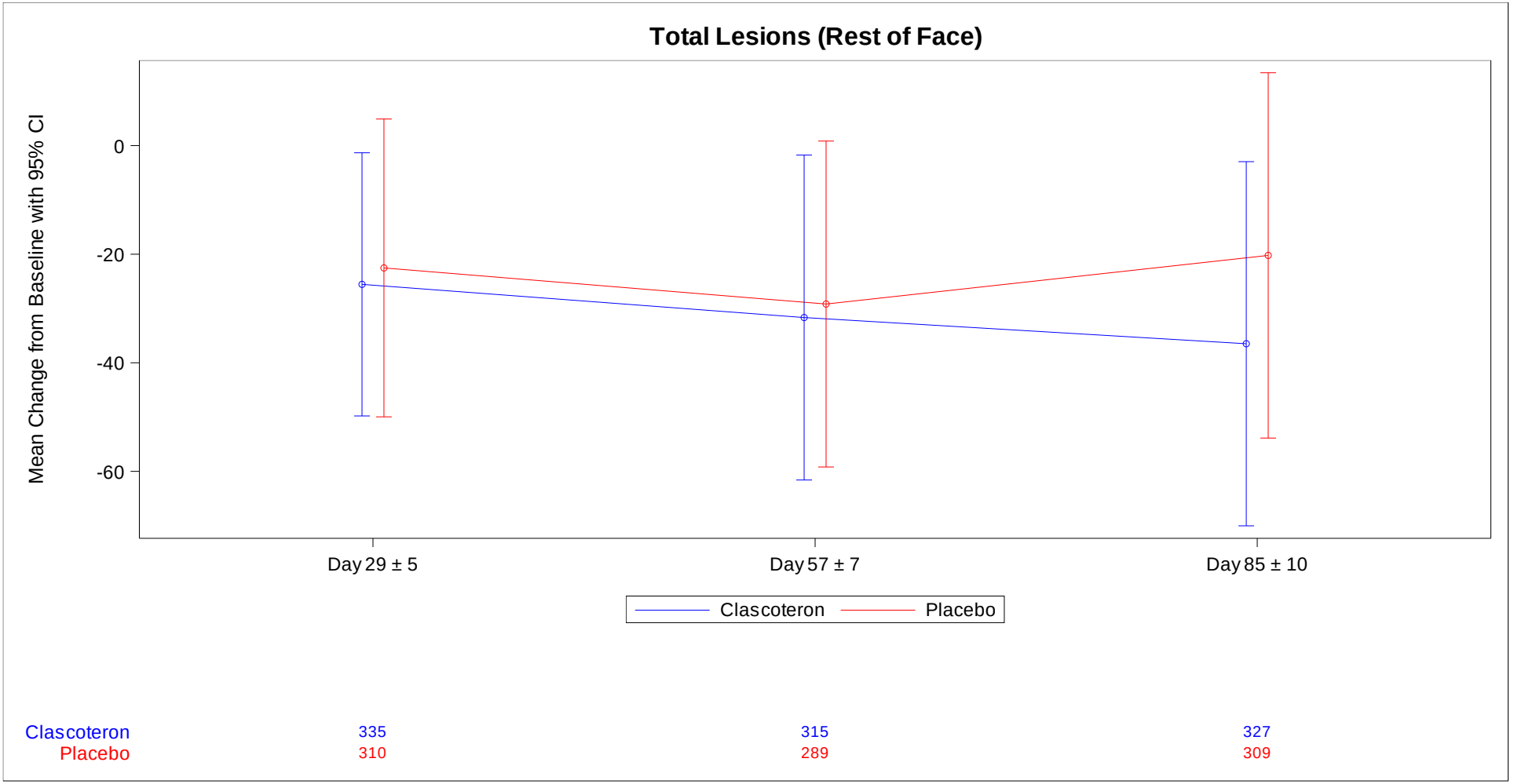
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in total lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.6620
9 - <18	172	99.70 (25.71)	172 (14)	-31.49 (2.67)	172	96.28 (21.56)	172 (13)	-16.86 (2.65)	-14.63 (-22.22, -7.05)	0.0002	-0.42 (-0.63, -0.20)	0.0001	
18 - <65	197	90.02 (21.62)	197 (28)	-37.99 (2.25)	191	90.42 (20.94)	191 (41)	-25.59 (2.39)	-12.40 (-19.03, -5.77)	0.0003	-0.38 (-0.58, -0.18)	0.0002	
Gender													0.4877
Male	126	97.67 (24.95)	126 (13)	-33.08 (3.02)	142	93.77 (22.07)	142 (16)	-17.34 (2.94)	-15.74 (-24.22, -7.25)	0.0003	-0.45 (-0.70, -0.21)	0.0002	
Female	243	92.91 (23.49)	243 (29)	-36.03 (2.20)	221	92.82 (21.02)	221 (38)	-23.99 (2.22)	-12.04 (-18.25, -5.82)	0.0002	-0.36 (-0.54, -0.17)	0.0001	
Region													0.0099
USA	47	97.28 (31.42)	47 (9)	-31.12 (5.11)	46	91.02 (20.07)	46 (9)	-35.60 (5.16)	4.48 (-10.73, 19.68)	0.5571	0.13 (-0.28, 0.53)	0.5413	
Europe	322	94.13 (22.84)	322 (33)	-35.60 (1.86)	317	93.51 (21.61)	317 (45)	-19.32 (1.90)	-16.28 (-21.58, -10.98)	<.0001	-0.48 (-0.64, -0.33)	<.0001	
IGA													0.1458
3-Moderate	305	93.19 (23.74)	305 (39)	-33.91 (1.99)	313	92.13 (21.22)	313 (48)	-21.82 (1.95)	-12.09 (-17.75, -6.44)	<.0001	-0.35 (-0.51, -0.19)	<.0001	
4-Severe	64	100.94 (24.77)	64 (3)	-40.33 (3.92)	50	99.88 (21.61)	50 (6)	-18.70 (4.48)	-21.63 (-33.32, -9.94)	0.0004	-0.68 (-1.06, -0.30)	0.0004	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of change from baseline of total lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in inflammatory lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	42.88 (12.20)	0	-	363	41.31 (10.96)	0	-
Day 29 ± 5	335	28.00 (15.35)	335	-15.18 (14.10)	310	28.23 (15.30)	310	-12.99 (13.94)
Day 57 ± 7	315	23.10 (15.65)	315	-19.91 (15.60)	289	24.91 (14.36)	289	-16.53 (14.05)
Day 85 ± 10	327	22.07 (15.79)	327	-21.06 (16.01)	309	29.50 (17.79)	309	-11.81 (16.42)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-20.02 (0.86)	42	363	-12.61 (0.87)	54	-7.41 (-9.78, -5.04)	<.0001	-0.45 (-0.59, -0.30)	<.0001

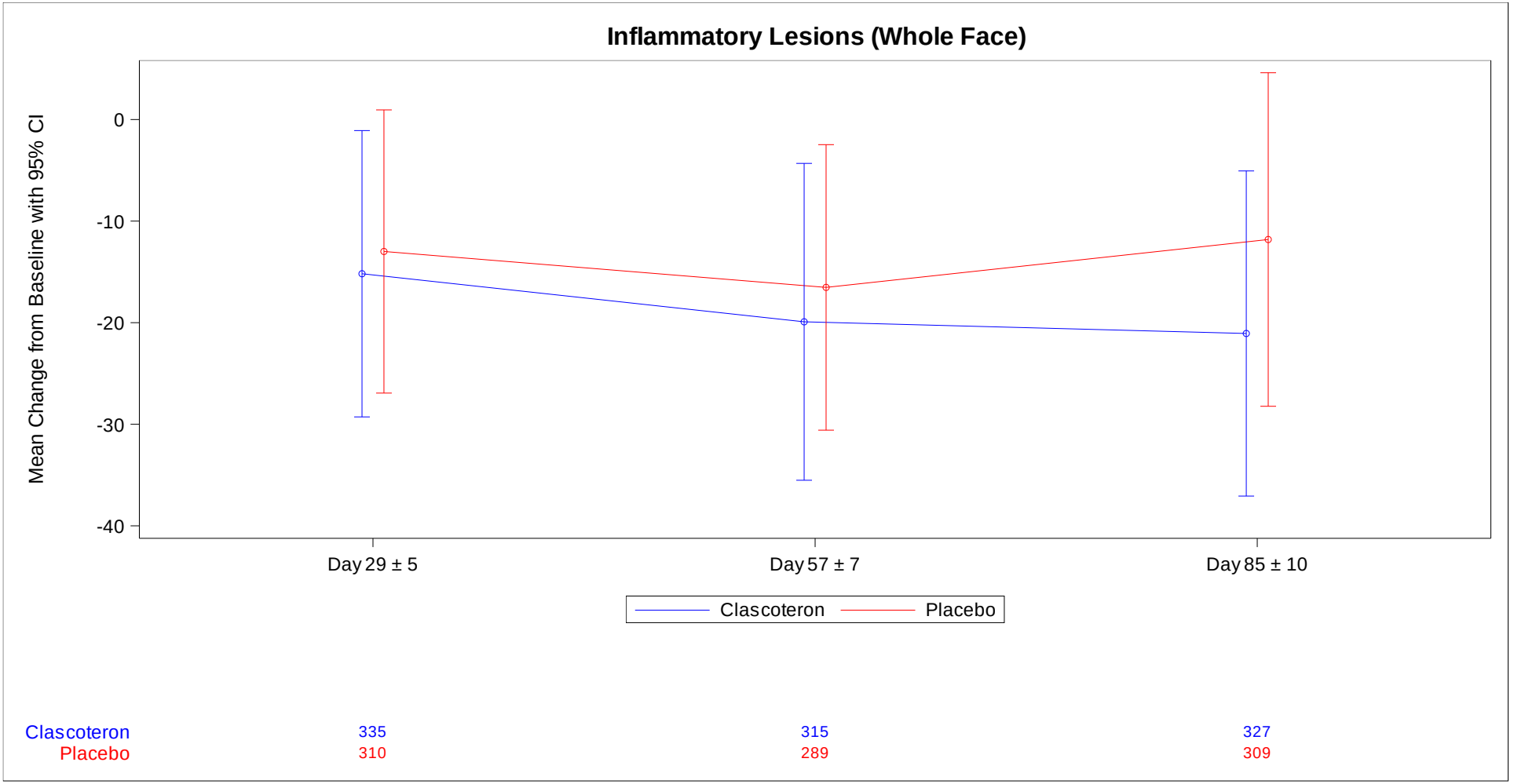
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.8514
9 - <18	172	43.51 (12.71)	172 (14)	-18.24 (1.23)	172	41.49 (11.41)	172 (13)	-10.50 (1.20)	-7.74 (-11.14, -4.33)	<.0001	-0.48 (-0.70, -0.27)	<.0001	
18 - <65	197	42.34 (11.74)	197 (28)	-21.37 (1.12)	191	41.16 (10.57)	191 (41)	-14.09 (1.24)	-7.28 (-10.63, -3.93)	<.0001	-0.44 (-0.64, -0.24)	<.0001	
Gender													0.4705
Male	126	44.16 (12.55)	126 (13)	-19.86 (1.41)	142	42.79 (10.94)	142 (16)	-11.33 (1.33)	-8.53 (-12.40, -4.65)	<.0001	-0.54 (-0.78, -0.29)	<.0001	
Female	243	42.22 (11.99)	243 (29)	-19.87 (1.05)	221	40.37 (10.89)	221 (38)	-13.14 (1.15)	-6.72 (-9.77, -3.68)	<.0001	-0.40 (-0.58, -0.22)	<.0001	
Region													0.0078
USA	47	45.38 (13.54)	47 (9)	-17.26 (2.54)	46	43.17 (10.42)	46 (9)	-18.70 (2.59)	1.44 (-5.83, 8.71)	0.6940	0.08 (-0.33, 0.49)	0.6939	
Europe	322	42.52 (11.97)	322 (33)	-20.29 (0.87)	317	41.04 (11.02)	317 (45)	-11.48 (0.91)	-8.81 (-11.28, -6.33)	<.0001	-0.55 (-0.71, -0.40)	<.0001	
IGA													0.6306
3-Moderate	305	41.79 (11.65)	305 (39)	-19.37 (0.93)	313	39.98 (9.99)	313 (48)	-12.20 (0.94)	-7.17 (-9.81, -4.52)	<.0001	-0.44 (-0.60, -0.28)	<.0001	
4-Severe	64	48.09 (13.46)	64 (3)	-22.45 (2.10)	50	49.68 (13.01)	50 (6)	-13.61 (2.42)	-8.84 (-15.20, -2.48)	0.0069	-0.52 (-0.90, -0.14)	0.0068	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of change from baseline of inflammatory lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	2.36 (3.03)	0	-	363	2.54 (3.00)	0	-
Day 29 ± 5	335	1.50 (2.06)	335	-0.92 (2.73)	310	1.39 (2.08)	310	-1.07 (2.24)
Day 57 ± 7	315	1.13 (1.71)	315	-1.24 (2.49)	289	1.14 (1.75)	289	-1.30 (2.39)
Day 85 ± 10	327	0.94 (1.44)	327	-1.39 (2.85)	309	1.36 (1.88)	309	-1.08 (2.83)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)						
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-1.44 (0.09)	42	363	-1.06 (0.09)	54	-0.38 (-0.62, -0.14)	0.0017	-0.23 (-0.38, -0.09)	0.0019

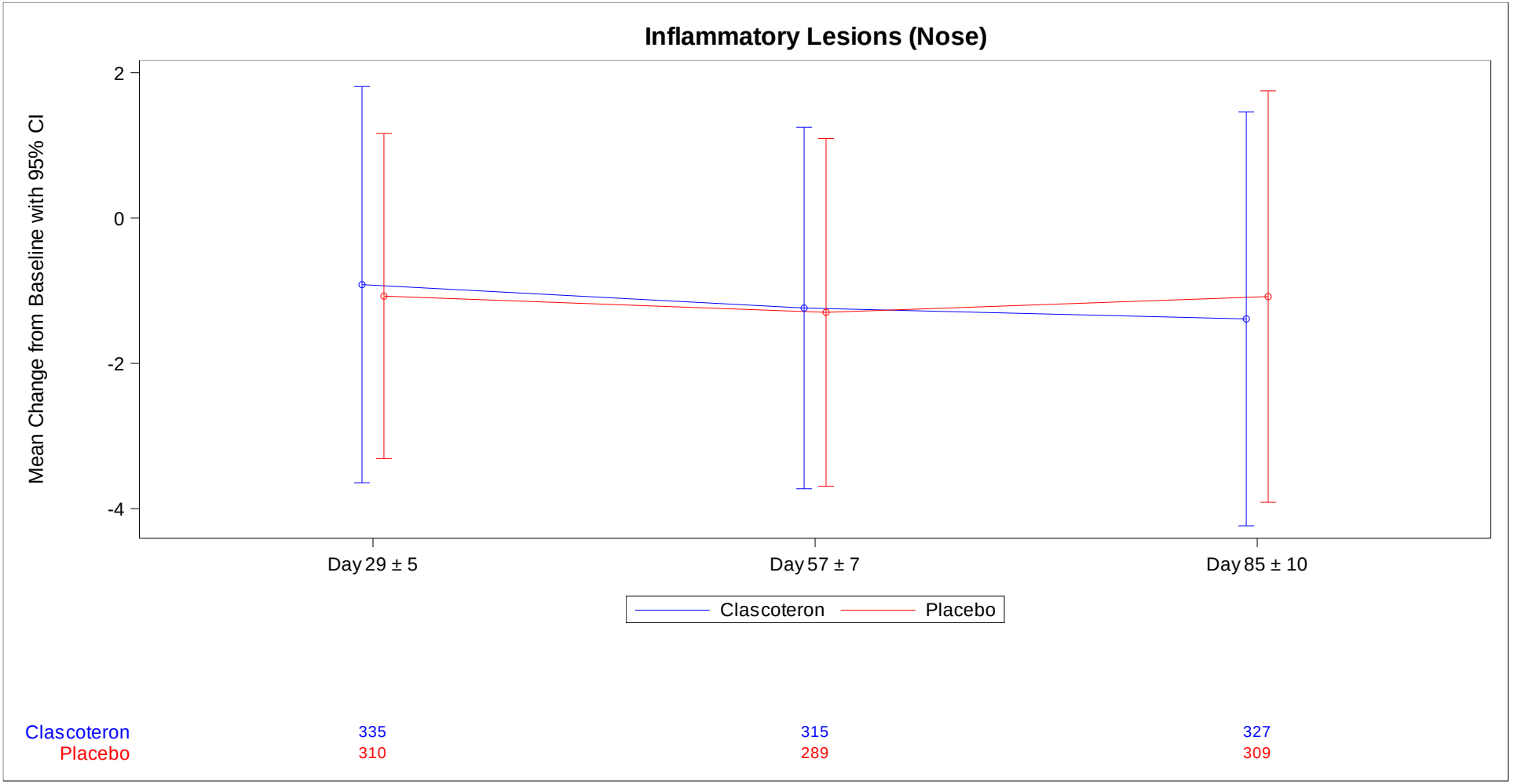
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.8824
9 - <18	172	2.74 (3.44)	172 (14)	-1.65 (0.13)	172	2.92 (3.14)	172 (13)	-1.24 (0.13)	-0.41 (-0.78, -0.04)	0.0295	-0.24 (-0.45, -0.02)	0.0288	
18 - <65	197	2.04 (2.58)	197 (28)	-1.22 (0.11)	191	2.19 (2.82)	191 (41)	-0.85 (0.11)	-0.37 (-0.69, -0.06)	0.0202	-0.24 (-0.44, -0.04)	0.0176	
Gender													0.3239
Male	126	2.48 (2.67)	126 (13)	-1.46 (0.17)	142	3.06 (3.15)	142 (16)	-0.93 (0.17)	-0.53 (-1.00, -0.06)	0.0280	-0.27 (-0.51, -0.03)	0.0276	
Female	243	2.30 (3.20)	243 (29)	-1.38 (0.09)	221	2.20 (2.85)	221 (38)	-1.12 (0.10)	-0.26 (-0.53, 0.01)	0.0604	-0.18 (-0.36, 0.00)	0.0544	
Region													0.1282
USA	47	2.62 (3.95)	47 (9)	-1.20 (0.25)	46	3.00 (3.04)	46 (9)	-1.33 (0.26)	0.13 (-0.61, 0.87)	0.7287	0.07 (-0.33, 0.48)	0.7237	
Europe	322	2.33 (2.87)	322 (33)	-1.46 (0.09)	317	2.47 (2.99)	317 (45)	-0.99 (0.09)	-0.47 (-0.73, -0.21)	0.0004	-0.29 (-0.44, -0.13)	0.0003	
IGA													<.0001
3-Moderate	305	2.23 (2.97)	305 (39)	-1.31 (0.09)	313	2.43 (2.95)	313 (48)	-1.09 (0.09)	-0.22 (-0.47, 0.03)	0.0822	-0.14 (-0.30, 0.02)	0.0772	
4-Severe	64	3.02 (3.24)	64 (3)	-2.05 (0.23)	50	3.24 (3.22)	50 (6)	-0.60 (0.27)	-1.45 (-2.14, -0.75)	<.0001	-0.78 (-1.16, -0.39)	<.0001	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of change from baseline of inflammatory lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in inflammatory lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	40.52 (11.94)	0	-	363	38.77 (10.15)	0	-
Day 29 ± 5	335	26.50 (14.72)	335	-14.27 (13.65)	310	26.83 (14.44)	310	-11.92 (13.40)
Day 57 ± 7	315	21.97 (15.24)	315	-18.68 (15.33)	289	23.77 (13.73)	289	-15.23 (13.74)
Day 85 ± 10	327	21.13 (15.33)	327	-19.68 (15.37)	309	28.15 (16.95)	309	-10.73 (15.96)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-18.65 (0.78)	42	363	-11.43 (0.83)	54	-7.21 (-9.40, -5.02)	<.0001	-0.47 (-0.62, -0.32)	<.0001

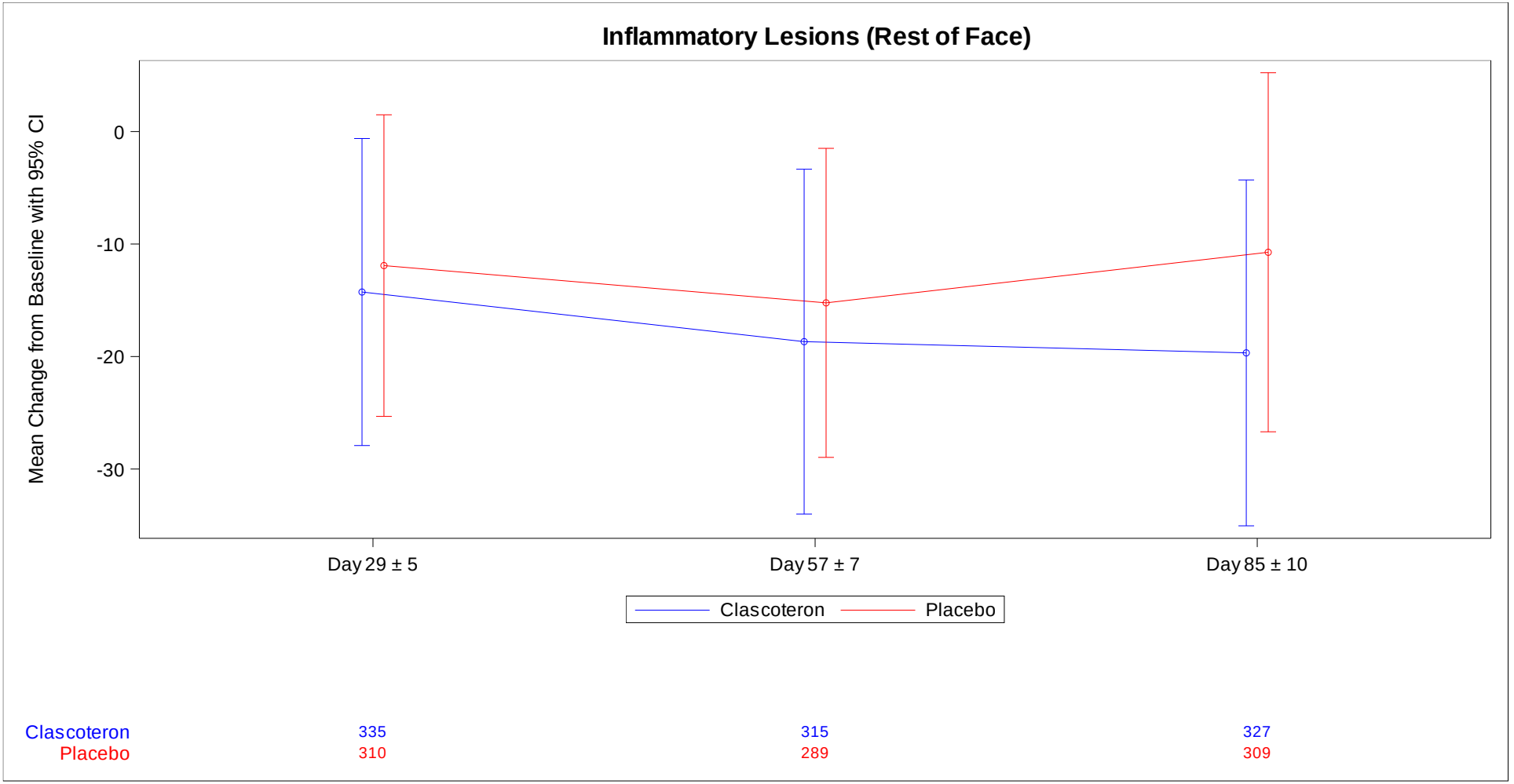
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in inflammatory lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.7995
9 - <18	172	40.77 (12.87)	172 (14)	-16.68 (1.16)	172	38.56 (10.21)	172 (13)	-9.00 (1.19)	-7.68 (-10.96, -4.39)	<.0001	-0.50 (-0.71, -0.28)	<.0001	
18 - <65	197	40.30 (11.09)	197 (28)	-20.18 (1.03)	191	38.96 (10.12)	191 (41)	-13.08 (1.09)	-7.10 (-10.11, -4.09)	<.0001	-0.48 (-0.68, -0.28)	<.0001	
Gender													0.4044
Male	126	41.67 (12.15)	126 (13)	-18.50 (1.35)	142	39.73 (9.87)	142 (16)	-9.99 (1.27)	-8.51 (-12.17, -4.85)	<.0001	-0.56 (-0.80, -0.32)	<.0001	
Female	243	39.92 (11.80)	243 (29)	-18.52 (0.96)	221	38.16 (10.30)	221 (38)	-11.96 (1.04)	-6.56 (-9.34, -3.79)	<.0001	-0.43 (-0.62, -0.25)	<.0001	
Region													0.0067
USA	47	42.77 (13.86)	47 (9)	-16.08 (2.45)	46	40.17 (9.14)	46 (9)	-17.47 (2.54)	1.39 (-5.60, 8.38)	0.6931	0.08 (-0.33, 0.49)	0.6965	
Europe	322	40.19 (11.62)	322 (33)	-18.89 (0.81)	317	38.57 (10.29)	317 (45)	-10.25 (0.85)	-8.65 (-10.99, -6.31)	<.0001	-0.58 (-0.74, -0.42)	<.0001	
IGA													0.8319
3-Moderate	305	39.56 (11.34)	305 (39)	-18.12 (0.84)	313	37.55 (9.07)	313 (48)	-10.94 (0.86)	-7.18 (-9.56, -4.81)	<.0001	-0.48 (-0.64, -0.32)	<.0001	
4-Severe	64	45.08 (13.64)	64 (3)	-20.48 (1.98)	50	46.44 (12.96)	50 (6)	-12.60 (2.31)	-7.88 (-13.93, -1.83)	0.0112	-0.49 (-0.86, -0.11)	0.0109	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of change from baseline of inflammatory lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in non-inflammatory lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	62.81 (21.37)	0	-	363	63.31 (20.52)	0	-
Day 29 ± 5	335	49.49 (27.37)	335	-13.73 (20.86)	310	51.40 (28.12)	310	-11.95 (23.74)
Day 57 ± 7	315	47.11 (29.74)	315	-16.26 (24.08)	289	46.58 (28.09)	289	-16.51 (24.67)
Day 85 ± 10	327	42.25 (29.94)	327	-20.90 (27.25)	309	52.48 (30.44)	309	-10.72 (27.33)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-19.37 (1.36)	42	363	-10.92 (1.43)	54	-8.44 (-12.37, -4.51)	<.0001	-0.32 (-0.46, -0.17)	<.0001

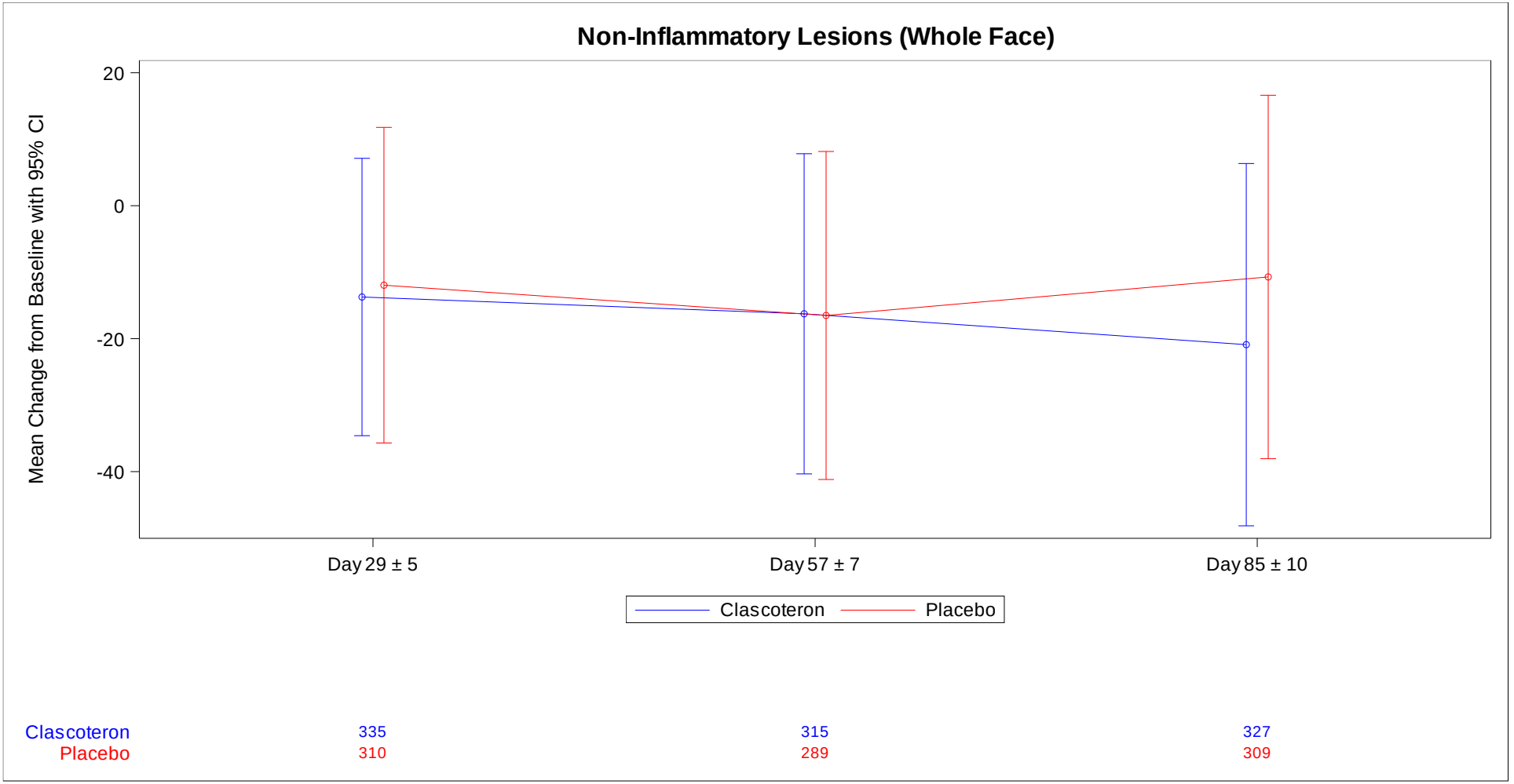
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.3394
9 - <18	172	68.11 (21.98)	172 (14)	-18.32 (2.20)	172	66.80 (19.91)	172 (13)	-7.54 (2.25)	-10.78 (-16.96, -4.60)	0.0007	-0.37 (-0.58, -0.16)	0.0007	
18 - <65	197	58.19 (19.75)	197 (28)	-21.25 (1.75)	191	60.17 (20.59)	191 (41)	-14.43 (1.85)	-6.83 (-12.17, -1.49)	0.0127	-0.27 (-0.47, -0.07)	0.0077	
Gender													0.6395
Male	126	65.43 (23.14)	126 (13)	-17.65 (2.39)	142	63.80 (20.30)	142 (16)	-7.85 (2.26)	-9.80 (-16.30, -3.30)	0.0033	-0.36 (-0.61, -0.12)	0.0032	
Female	243	61.46 (20.32)	243 (29)	-21.09 (1.76)	221	63.00 (20.69)	221 (38)	-13.25 (1.83)	-7.83 (-12.92, -2.75)	0.0027	-0.29 (-0.47, -0.10)	0.0022	
Region													0.0235
USA	47	62.06 (24.82)	47 (9)	-16.00 (3.94)	46	59.35 (16.46)	46 (9)	-19.75 (4.28)	3.75 (-8.23, 15.72)	0.5335	0.13 (-0.27, 0.54)	0.5228	
Europe	322	62.92 (20.87)	322 (33)	-20.51 (1.49)	317	63.89 (21.00)	317 (45)	-9.86 (1.50)	-10.65 (-14.88, -6.42)	<.0001	-0.40 (-0.56, -0.24)	<.0001	
IGA													0.1093
3-Moderate	305	62.47 (21.48)	305 (39)	-19.23 (1.58)	313	63.08 (20.90)	313 (48)	-11.79 (1.58)	-7.44 (-11.96, -2.92)	0.0013	-0.27 (-0.43, -0.11)	0.0010	
4-Severe	64	64.45 (20.93)	64 (3)	-22.89 (2.87)	50	64.80 (18.04)	50 (6)	-7.45 (3.40)	-15.44 (-24.26, -6.63)	0.0008	-0.65 (-1.03, -0.27)	0.0007	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of change from baseline of non-inflammatory lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in non-inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	8.80 (9.33)	0	-	363	8.89 (8.69)	0	-
Day 29 ± 5	335	6.47 (8.25)	335	-2.44 (6.63)	310	7.44 (8.63)	310	-1.34 (6.25)
Day 57 ± 7	315	5.69 (7.38)	315	-3.27 (7.07)	289	6.27 (7.38)	289	-2.56 (7.29)
Day 85 ± 10	327	4.65 (6.61)	327	-4.09 (8.41)	309	7.45 (11.39)	309	-1.22 (11.53)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-3.69 (0.45)	42	363	-1.23 (0.46)	54	-2.46 (-3.69, -1.23)	<.0001	-0.28 (-0.43, -0.14)	0.0001

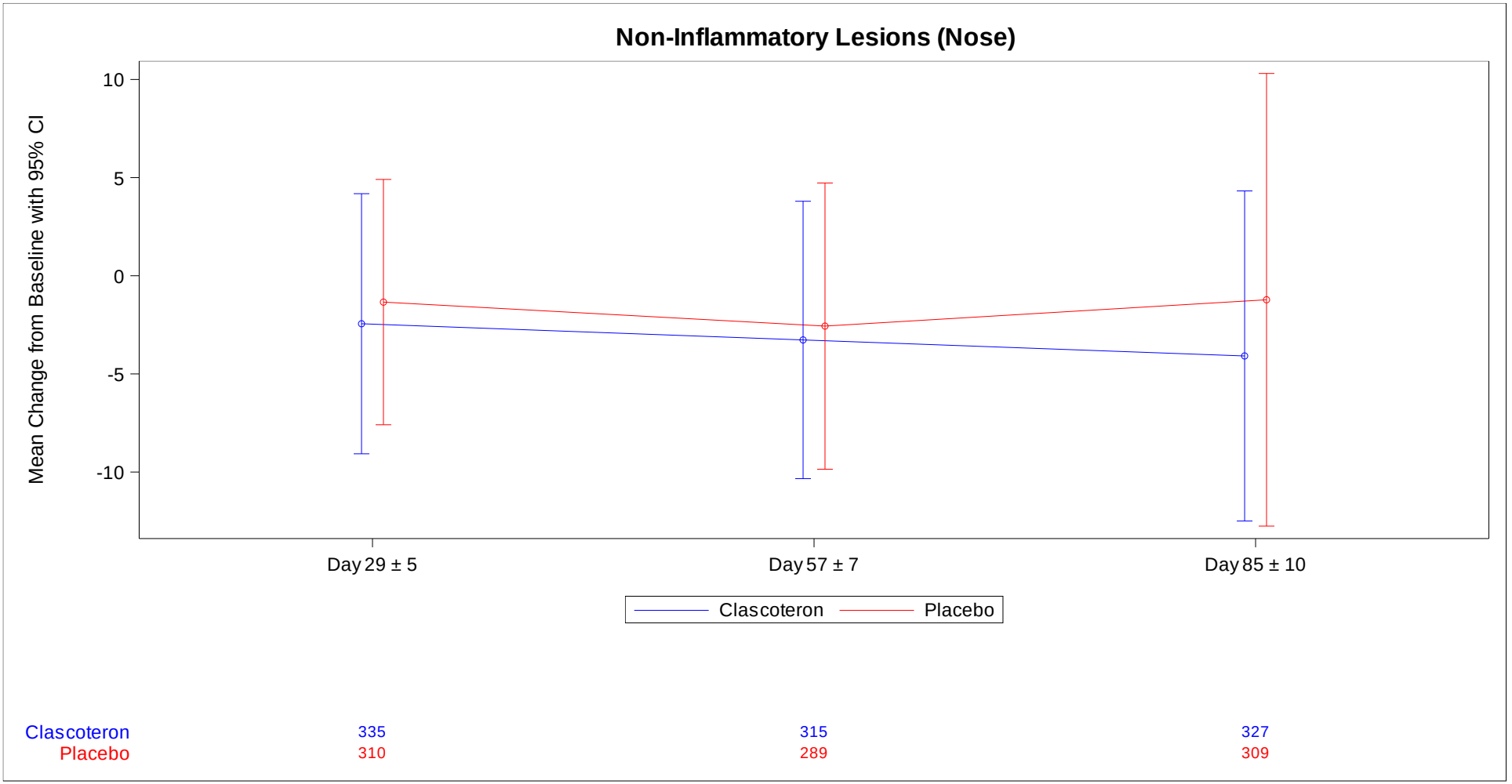
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.4868
9 - <18	172	9.17 (9.88)	172 (14)	-3.26 (0.78)	172	9.09 (9.12)	172 (13)	-0.17 (0.77)	-3.09 (-5.24, -0.94)	0.0049	-0.31 (-0.52, -0.09)	0.0049	
18 - <65	197	8.47 (8.85)	197 (28)	-3.92 (0.49)	191	8.72 (8.29)	191 (41)	-1.73 (0.54)	-2.18 (-3.59, -0.78)	0.0024	-0.30 (-0.50, -0.10)	0.0030	
Gender													0.6342
Male	126	9.43 (9.75)	126 (13)	-3.08 (0.67)	142	9.75 (8.83)	142 (16)	-0.91 (0.60)	-2.16 (-3.96, -0.37)	0.0184	-0.30 (-0.54, -0.05)	0.0165	
Female	243	8.47 (9.11)	243 (29)	-3.85 (0.59)	221	8.34 (8.57)	221 (38)	-1.08 (0.65)	-2.77 (-4.50, -1.03)	0.0018	-0.29 (-0.48, -0.11)	0.0018	
Region													0.0536
USA	47	7.55 (7.91)	47 (9)	-1.45 (1.12)	46	8.50 (6.81)	46 (9)	-1.61 (1.05)	0.15 (-2.83, 3.13)	0.9191	0.02 (-0.39, 0.43)	0.9216	
Europe	322	8.98 (9.52)	322 (33)	-3.93 (0.49)	317	8.95 (8.93)	317 (45)	-0.90 (0.50)	-3.03 (-4.41, -1.66)	<.0001	-0.34 (-0.50, -0.19)	<.0001	
IGA													0.7926
3-Moderate	305	8.84 (9.09)	305 (39)	-3.64 (0.53)	313	8.50 (8.38)	313 (48)	-1.06 (0.52)	-2.58 (-3.99, -1.16)	0.0004	-0.28 (-0.44, -0.12)	0.0005	
4-Severe	64	8.59 (10.51)	64 (3)	-3.48 (0.80)	50	11.36 (10.18)	50 (6)	-0.53 (0.93)	-2.95 (-5.37, -0.53)	0.0175	-0.45 (-0.83, -0.08)	0.0180	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of change from baseline of non-inflammatory lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in non-inflammatory lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	54.02 (19.88)	0	-	363	54.42 (18.61)	0	-
Day 29 ± 5	335	43.02 (24.81)	335	-11.29 (18.24)	310	43.96 (25.59)	310	-10.61 (21.70)
Day 57 ± 7	315	41.42 (27.05)	315	-12.99 (21.83)	289	40.32 (25.40)	289	-13.95 (21.45)
Day 85 ± 10	327	37.60 (27.27)	327	-16.82 (24.21)	309	45.03 (25.53)	309	-9.49 (22.34)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-15.34 (1.20)	42	363	-9.39 (1.20)	54	-5.94 (-9.22, -2.67)	0.0004	-0.26 (-0.41, -0.11)	0.0005

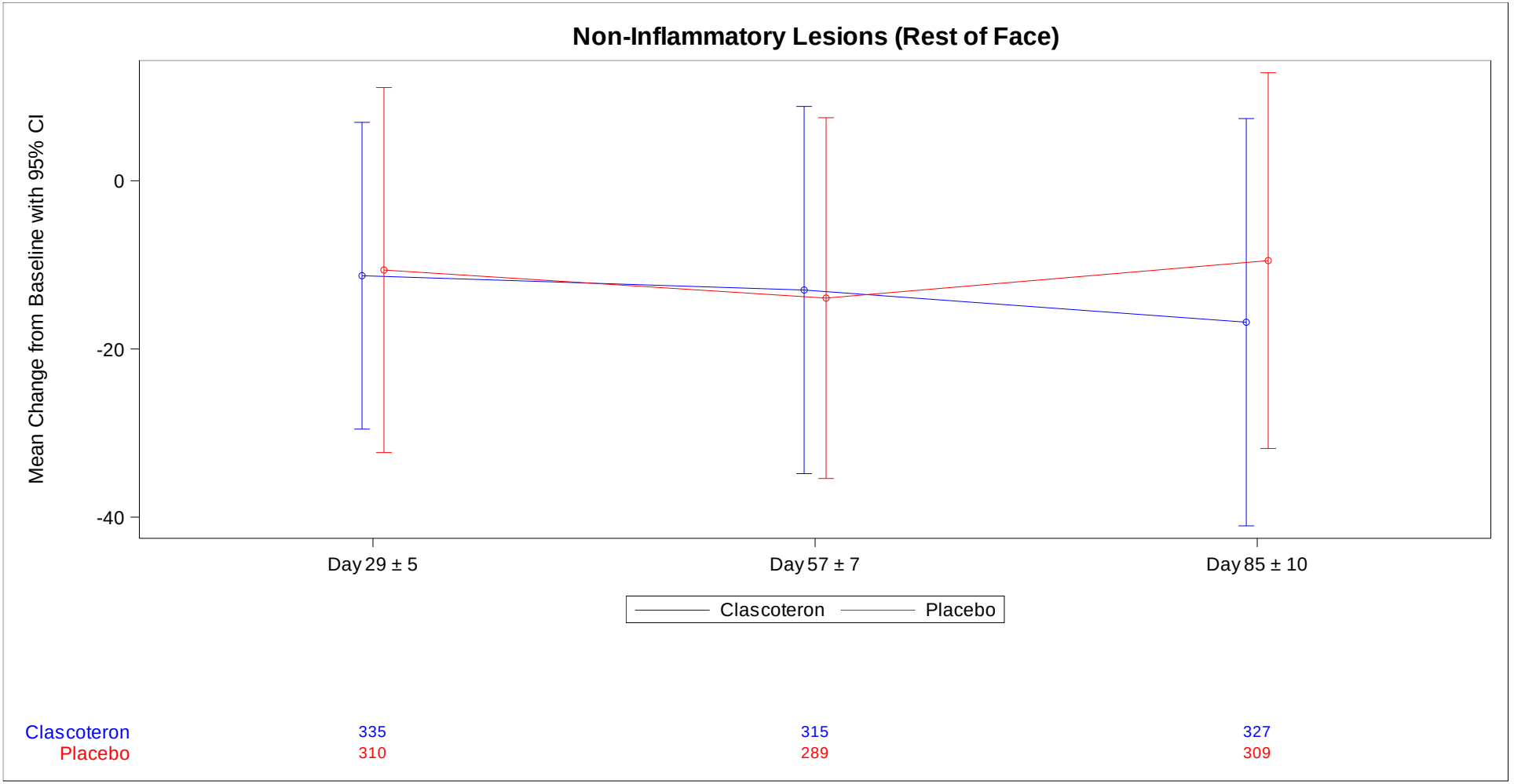
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in non-inflammatory lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of			Interaction
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.4046
9 - <18	172	58.94 (20.89)	172 (14)	-14.88 (1.86)	172	57.72 (18.49)	172 (13)	-7.31 (1.87)	-7.58 (-12.80, -2.35)	0.0046	-0.31 (-0.52, -0.10)	0.0045	
18 - <65	197	49.72 (17.93)	197 (28)	-16.74 (1.56)	191	51.46 (18.26)	191 (41)	-12.03 (1.52)	-4.71 (-9.02, -0.40)	0.0324	-0.22 (-0.42, -0.02)	0.0317	
Gender													0.3891
Male	126	56.00 (21.72)	126 (13)	-14.39 (2.10)	142	54.05 (19.43)	142 (16)	-6.49 (2.03)	-7.90 (-13.60, -2.20)	0.0068	-0.33 (-0.57, -0.09)	0.0076	
Female	243	52.99 (18.81)	243 (29)	-16.68 (1.49)	221	54.66 (18.10)	221 (38)	-11.87 (1.51)	-4.81 (-8.96, -0.66)	0.0232	-0.21 (-0.39, -0.03)	0.0239	
Region													0.0490
USA	47	54.51 (24.16)	47 (9)	-14.36 (3.58)	46	50.85 (17.44)	46 (9)	-17.35 (3.67)	3.00 (-6.99, 12.98)	0.5520	0.12 (-0.29, 0.53)	0.5625	
Europe	322	53.94 (19.21)	322 (33)	-16.15 (1.29)	317	54.94 (18.74)	317 (45)	-8.63 (1.29)	-7.52 (-11.11, -3.93)	<.0001	-0.33 (-0.48, -0.17)	<.0001	
IGA													0.0298
3-Moderate	305	53.63 (20.23)	305 (39)	-15.07 (1.37)	313	54.58 (18.94)	313 (48)	-10.47 (1.32)	-4.61 (-8.36, -0.85)	0.0164	-0.19 (-0.35, -0.04)	0.0157	
4-Severe	64	55.86 (18.13)	64 (3)	-19.66 (2.54)	50	53.44 (16.56)	50 (6)	-5.62 (2.94)	-14.04 (-21.77, -6.30)	0.0005	-0.68 (-1.06, -0.30)	0.0005	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of change from baseline of non-inflammatory lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and absolute change from Baseline in Investigator´s Global Assessment over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Change from Baseline		Value at timepoint		Change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	3.17 (0.38)	0	-	363	3.14 (0.35)	0	-
Day 29 ± 5	335	2.66 (0.63)	335	-0.52 (0.60)	310	2.70 (0.63)	310	-0.44 (0.59)
Day 57 ± 7	315	2.45 (0.67)	315	-0.74 (0.69)	289	2.51 (0.67)	289	-0.64 (0.65)
Day 85 ± 10	328	2.27 (0.87)	328	-0.91 (0.89)	310	2.55 (0.74)	310	-0.59 (0.74)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in Investigator´s Global Assessment at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-0.88 (0.04)	41	363	-0.61 (0.05)	53	-0.27 (-0.39, -0.15)	<.0001	-0.31 (-0.46, -0.17)	<.0001

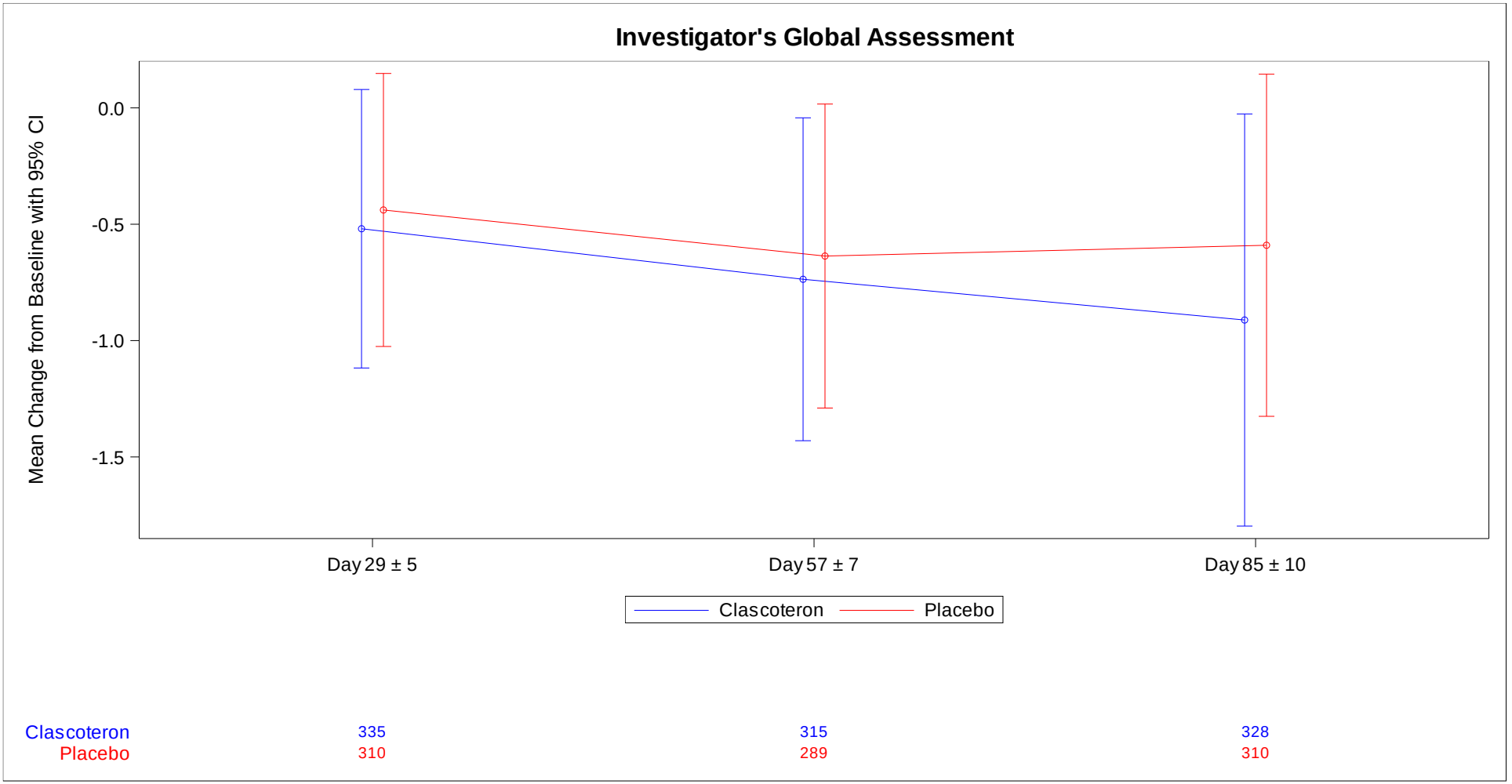
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of absolute change from Baseline in Investigator´s Global Assessment at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)								Interaction
	Baseline		Change from Baseline		Baseline		Change from Baseline		Difference of				
Level	N	Mean (SD)	N (IMP)	LSMean (SE)	N	Mean (SD)	N (IMP)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.5397
9 - <18	172	3.22 (0.42)	172 (14)	-0.83 (0.06)	172	3.14 (0.35)	172 (12)	-0.51 (0.06)	-0.32 (-0.49, -0.14)	0.0004	-0.39 (-0.60, -0.17)	0.0004	
18 - <65	197	3.13 (0.34)	197 (27)	-0.94 (0.06)	191	3.14 (0.34)	191 (41)	-0.70 (0.06)	-0.24 (-0.42, -0.06)	0.0076	-0.28 (-0.48, -0.08)	0.0063	
Gender													0.3504
Male	126	3.19 (0.39)	126 (12)	-0.88 (0.07)	142	3.20 (0.40)	142 (15)	-0.53 (0.07)	-0.35 (-0.54, -0.16)	0.0004	-0.44 (-0.68, -0.19)	0.0004	
Female	243	3.16 (0.37)	243 (29)	-0.89 (0.06)	221	3.10 (0.29)	221 (38)	-0.66 (0.06)	-0.23 (-0.39, -0.07)	0.0053	-0.26 (-0.45, -0.08)	0.0048	
Region													0.0055
USA	47	3.19 (0.40)	47 (9)	-0.65 (0.12)	46	3.17 (0.38)	46 (9)	-0.81 (0.12)	0.16 (-0.17, 0.49)	0.3314	0.19 (-0.22, 0.60)	0.3547	
Europe	322	3.17 (0.38)	322 (32)	-0.92 (0.05)	317	3.13 (0.34)	317 (44)	-0.58 (0.05)	-0.34 (-0.47, -0.20)	<.0001	-0.39 (-0.55, -0.24)	<.0001	
IGA													0.4081
3-Moderate	305	3.00 (0.00)	305 (38)	-0.79 (0.05)	313	3.00 (0.00)	313 (47)	-0.54 (0.05)	-0.25 (-0.38, -0.12)	0.0002	-0.30 (-0.46, -0.14)	0.0002	
4-Severe	64	4.00 (0.00)	64 (3)	-1.40 (0.12)	50	4.00 (0.00)	50 (6)	-0.99 (0.13)	-0.41 (-0.76, -0.05)	0.0242	-0.43 (-0.81, -0.06)	0.0237	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of change from baseline of Investigator´s Global Assessment over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in total lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	105.69 (25.76)	0	-	363	104.63 (24.18)	0	-
Day 29 ± 5	335	77.49 (33.69)	335	-27.50 (24.64)	310	79.63 (33.40)	310	-23.44 (27.83)
Day 57 ± 7	315	70.21 (37.63)	315	-34.49 (29.37)	289	71.49 (36.28)	289	-31.45 (31.78)
Day 85 ± 10	327	64.32 (38.80)	327	-39.05 (33.06)	309	81.98 (41.40)	309	-21.14 (36.56)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)						
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-37.74 (1.84)	42	363	-22.15 (1.91)	54	-15.59 (-20.89, -10.30)	<.0001	-0.43 (-0.58, -0.29)	<.0001

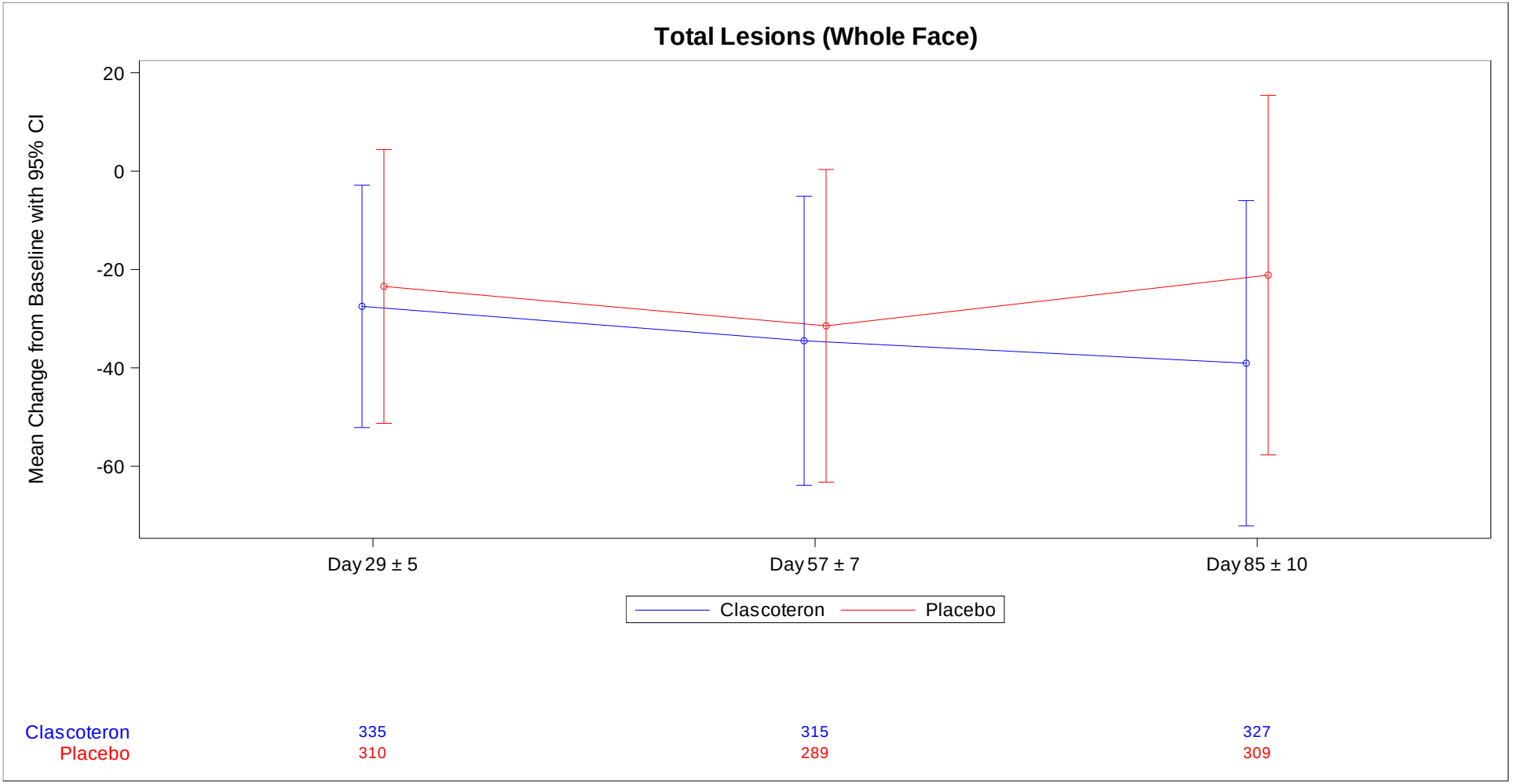
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of			
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.8162
9 - <18	172	111.62 (26.42)	172 (14)	-32.55 (2.85)	172	108.29 (24.65)	172 (13)	-16.06 (2.80)	-16.49 (-24.54, -8.43)	<.0001	-0.44 (-0.66, -0.23)	<.0001	
18 - <65	197	100.52 (24.06)	197 (28)	-42.89 (2.61)	191	101.33 (23.33)	191 (41)	-27.70 (2.77)	-15.19 (-22.76, -7.62)	0.0001	-0.41 (-0.61, -0.20)	<.0001	
Gender													0.9067
Male	126	109.59 (26.97)	126 (13)	-34.82 (3.12)	142	106.58 (23.91)	142 (16)	-18.66 (2.95)	-16.16 (-24.56, -7.75)	0.0002	-0.46 (-0.70, -0.22)	0.0002	
Female	243	103.67 (24.92)	243 (29)	-39.85 (2.37)	221	103.37 (24.33)	221 (38)	-24.34 (2.54)	-15.51 (-22.59, -8.42)	<.0001	-0.41 (-0.60, -0.23)	<.0001	
Region													0.0044
USA	47	107.45 (30.94)	47 (9)	-34.20 (5.43)	46	102.52 (21.47)	46 (9)	-38.67 (5.17)	4.46 (-11.17, 20.10)	0.5656	0.12 (-0.28, 0.53)	0.5558	
Europe	322	105.44 (24.96)	322 (33)	-38.76 (2.07)	317	104.93 (24.57)	317 (45)	-19.67 (2.12)	-19.09 (-25.12, -13.07)	<.0001	-0.51 (-0.67, -0.35)	<.0001	
IGA													0.3160
3-Moderate	305	104.26 (25.24)	305 (39)	-37.59 (2.12)	313	103.05 (24.16)	313 (48)	-22.69 (2.12)	-14.90 (-20.96, -8.84)	<.0001	-0.40 (-0.56, -0.24)	<.0001	
4-Severe	64	112.55 (27.27)	64 (3)	-40.43 (3.78)	50	114.48 (22.12)	50 (6)	-18.95 (4.46)	-21.48 (-33.04, -9.93)	0.0004	-0.69 (-1.07, -0.31)	0.0004	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of total lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in total lesions count (Nose) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	11.16 (10.90)	0	-	363	11.43 (10.40)	0	-
Day 29 ± 5	335	7.97 (9.04)	295	-19.80 (84.70)	310	8.83 (9.54)	278	-15.28 (91.21)
Day 57 ± 7	315	6.83 (8.17)	277	-27.69 (104.12)	289	7.40 (8.04)	261	-24.02 (92.21)
Day 85 ± 10	327	5.59 (7.18)	285	-26.97 (121.94)	309	8.80 (11.91)	277	5.92 (179.14)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	321	-20.46 (8.81)	36	321	0.43 (8.83)	44	-20.88 (-44.65, 2.88)	0.0848	-0.13 (-0.29, 0.02)	0.0948

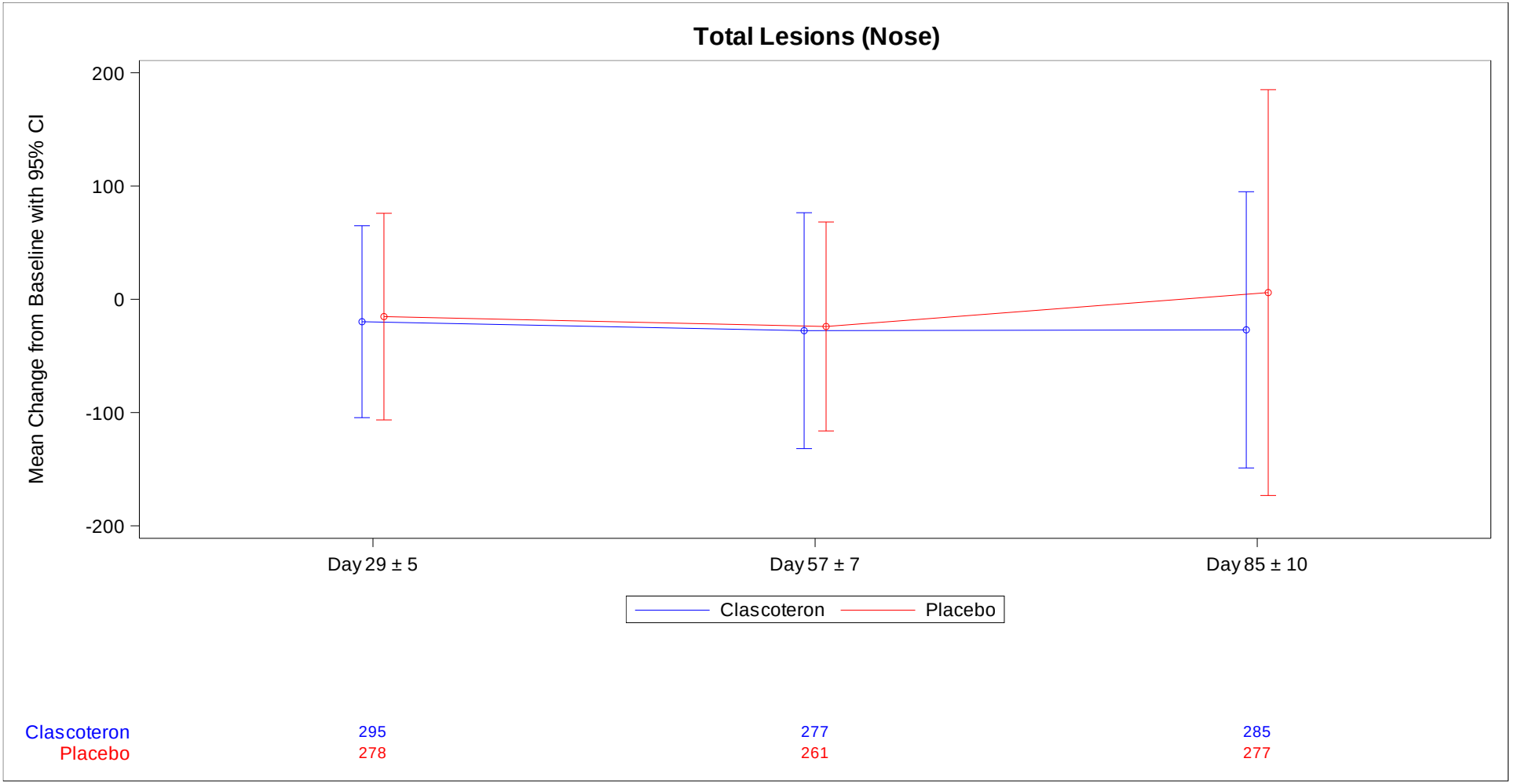
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.6854
9 - <18	172	11.91 (11.68)	154 (14)	-8.19 (13.47)	172	12.01 (10.97)	153 (9)	22.14 (13.57)	-30.33 (-68.12, 7.47)	0.1152	-0.18 (-0.40, 0.04)	0.1143	
18 - <65	197	10.50 (10.17)	167 (22)	-27.16 (11.20)	191	10.91 (9.86)	168 (35)	-6.79 (10.79)	-20.36 (-50.73, 10.01)	0.1875	-0.14 (-0.36, 0.07)	0.1919	
Gender													0.3413
Male	126	11.91 (11.26)	111 (13)	7.35 (15.74)	142	12.81 (10.57)	134 (13)	15.07 (13.76)	-7.72 (-49.17, 33.74)	0.7138	-0.05 (-0.30, 0.20)	0.7120	
Female	243	10.77 (10.72)	210 (23)	-31.26 (10.59)	221	10.55 (10.22)	187 (31)	0.96 (11.12)	-32.23 (-61.60, -2.85)	0.0317	-0.21 (-0.41, -0.01)	0.0368	
Region													0.0770
USA	47	10.17 (11.07)	41 (8)	-4.45 (18.76)	46	11.50 (8.57)	43 (6)	-22.49 (17.97)	18.04 (-31.40, 67.48)	0.4647	0.15 (-0.28, 0.58)	0.4919	
Europe	322	11.30 (10.89)	280 (28)	-19.98 (9.70)	317	11.42 (10.65)	278 (38)	11.49 (9.53)	-31.48 (-58.43, -4.52)	0.0222	-0.20 (-0.36, -0.03)	0.0211	
IGA													0.8376
3-Moderate	305	11.07 (10.64)	262 (34)	-19.63 (10.06)	313	10.93 (10.06)	274 (39)	6.40 (9.68)	-26.03 (-53.46, 1.40)	0.0628	-0.16 (-0.33, 0.01)	0.0630	
4-Severe	64	11.61 (12.18)	59 (2)	-10.40 (17.45)	50	14.60 (11.94)	47 (5)	9.61 (18.91)	-20.01 (-71.51, 31.50)	0.4413	-0.15 (-0.53, 0.23)	0.4426	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of total lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in total lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	94.53 (24.07)	0	-	363	93.20 (21.41)	0	-
Day 29 ± 5	335	69.52 (30.71)	335	-27.03 (25.32)	310	70.79 (30.22)	310	-23.59 (28.90)
Day 57 ± 7	315	63.38 (34.49)	315	-33.64 (30.31)	289	64.09 (32.94)	289	-31.21 (32.02)
Day 85 ± 10	327	58.73 (35.75)	327	-38.02 (33.53)	309	73.17 (36.17)	309	-20.95 (35.99)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-36.32 (1.93)	42	363	-22.06 (1.94)	54	-14.25 (-19.80, -8.71)	<.0001	-0.38 (-0.53, -0.24)	<.0001

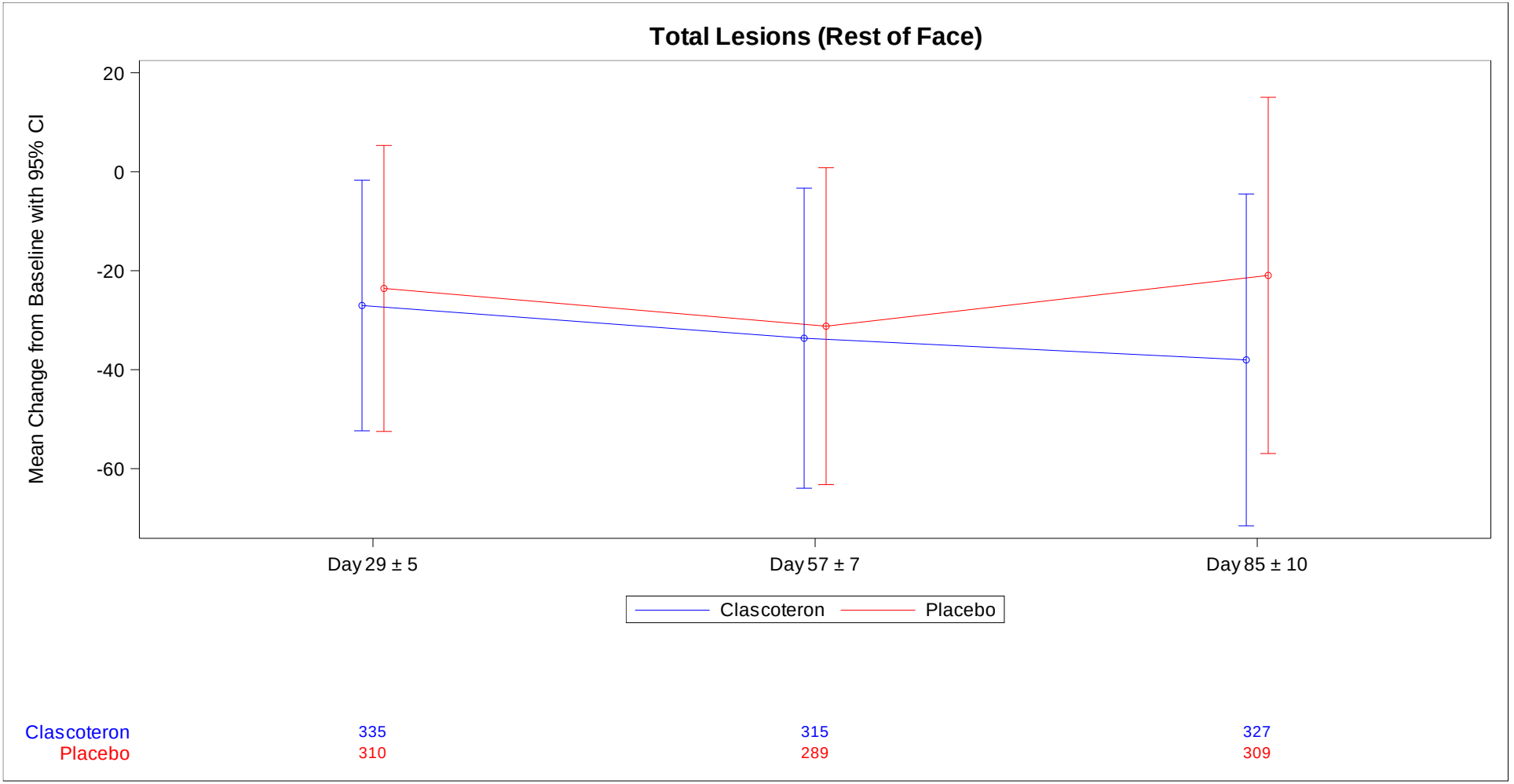
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in total lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.9755
9 - <18	172	99.70 (25.71)	172 (14)	-30.76 (2.91)	172	96.28 (21.56)	172 (13)	-16.40 (2.77)	-14.36 (-22.55, -6.17)	0.0007	-0.38 (-0.60, -0.17)	0.0004	
18 - <65	197	90.02 (21.62)	197 (28)	-41.94 (2.53)	191	90.42 (20.94)	191 (41)	-27.41 (2.67)	-14.53 (-21.96, -7.10)	0.0002	-0.40 (-0.60, -0.20)	<.0001	
Gender													0.8441
Male	126	97.67 (24.95)	126 (13)	-33.56 (3.17)	142	93.77 (22.07)	142 (16)	-18.40 (3.12)	-15.17 (-24.10, -6.23)	0.0010	-0.41 (-0.66, -0.17)	0.0008	
Female	243	92.91 (23.49)	243 (29)	-38.52 (2.51)	221	92.82 (21.02)	221 (38)	-24.48 (2.45)	-14.03 (-21.09, -6.98)	0.0001	-0.37 (-0.55, -0.19)	<.0001	
Region													0.0088
USA	47	97.28 (31.42)	47 (9)	-31.87 (6.14)	46	91.02 (20.07)	46 (9)	-39.13 (5.75)	7.26 (-11.59, 26.10)	0.4352	0.18 (-0.23, 0.58)	0.3935	
Europe	322	94.13 (22.84)	322 (33)	-37.54 (2.00)	317	93.51 (21.61)	317 (45)	-19.64 (2.06)	-17.90 (-23.63, -12.18)	<.0001	-0.49 (-0.65, -0.34)	<.0001	
IGA													0.1894
3-Moderate	305	93.19 (23.74)	305 (39)	-35.98 (2.23)	313	92.13 (21.22)	313 (48)	-22.67 (2.14)	-13.31 (-19.68, -6.94)	<.0001	-0.35 (-0.50, -0.19)	<.0001	
4-Severe	64	100.94 (24.77)	64 (3)	-40.72 (3.82)	50	99.88 (21.61)	50 (6)	-18.72 (4.48)	-22.01 (-33.55, -10.46)	0.0003	-0.70 (-1.09, -0.32)	0.0003	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of total lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in inflammatory lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	42.88 (12.20)	0	-	363	41.31 (10.96)	0	-
Day 29 ± 5	335	28.00 (15.35)	335	-35.09 (29.54)	310	28.23 (15.30)	310	-31.35 (34.22)
Day 57 ± 7	315	23.10 (15.65)	315	-46.34 (33.12)	289	24.91 (14.36)	289	-39.61 (32.98)
Day 85 ± 10	327	22.07 (15.79)	327	-48.62 (32.95)	309	29.50 (17.79)	309	-28.55 (39.54)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)						
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-46.96 (2.09)	42	363	-29.77 (2.06)	54	-17.19 (-22.87, -11.52)	<.0001	-0.43 (-0.58, -0.29)	<.0001

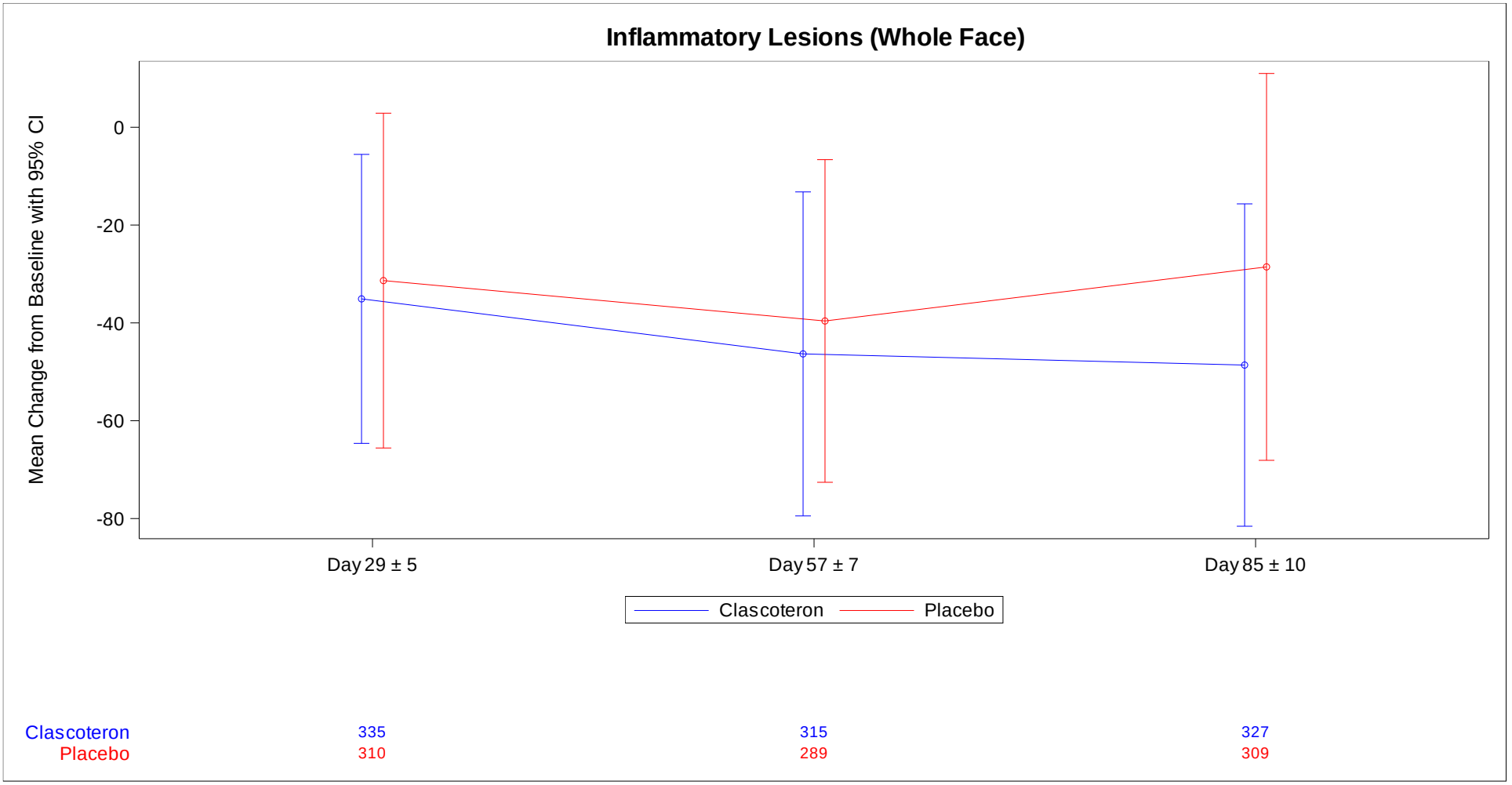
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.8916
9 - <18	172	43.51 (12.71)	172 (14)	-42.56 (2.90)	172	41.49 (11.41)	172 (13)	-24.58 (2.84)	-17.97 (-25.99, -9.96)	<.0001	-0.48 (-0.69, -0.26)	<.0001	
18 - <65	197	42.34 (11.74)	197 (28)	-50.27 (2.78)	191	41.16 (10.57)	191 (41)	-33.08 (2.95)	-17.19 (-25.34, -9.04)	<.0001	-0.43 (-0.63, -0.23)	<.0001	
Gender													0.6871
Male	126	44.16 (12.55)	126 (13)	-44.89 (3.28)	142	42.79 (10.94)	142 (16)	-26.01 (3.09)	-18.88 (-27.89, -9.87)	<.0001	-0.51 (-0.76, -0.27)	<.0001	
Female	243	42.22 (11.99)	243 (29)	-47.55 (2.61)	221	40.37 (10.89)	221 (38)	-31.05 (2.78)	-16.50 (-23.92, -9.08)	<.0001	-0.40 (-0.59, -0.22)	<.0001	
Region													0.0016
USA	47	45.38 (13.54)	47 (9)	-37.48 (5.75)	46	43.17 (10.42)	46 (9)	-44.15 (5.77)	6.67 (-10.04, 23.38)	0.4244	0.17 (-0.24, 0.58)	0.4175	
Europe	322	42.52 (11.97)	322 (33)	-48.01 (2.11)	317	41.04 (11.02)	317 (45)	-26.86 (2.17)	-21.15 (-27.08, -15.22)	<.0001	-0.55 (-0.71, -0.39)	<.0001	
IGA													0.4919
3-Moderate	305	41.79 (11.65)	305 (39)	-46.31 (2.35)	313	39.98 (9.99)	313 (48)	-29.56 (2.29)	-16.76 (-23.27, -10.24)	<.0001	-0.41 (-0.57, -0.25)	<.0001	
4-Severe	64	48.09 (13.46)	64 (3)	-48.00 (4.07)	50	49.68 (13.01)	50 (6)	-26.38 (4.76)	-21.62 (-34.08, -9.15)	0.0009	-0.65 (-1.03, -0.27)	0.0008	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of inflammatory lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in inflammatory lesions count (Nose) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	2.36 (3.03)	0	-	363	2.54 (3.00)	0	-
Day 29 ± 5	335	1.50 (2.06)	214	-36.75 (83.39)	310	1.39 (2.08)	217	-43.01 (76.05)
Day 57 ± 7	315	1.13 (1.71)	202	-53.38 (61.01)	289	1.14 (1.75)	202	-52.20 (67.89)
Day 85 ± 10	327	0.94 (1.44)	207	-58.10 (62.38)	309	1.36 (1.88)	216	-37.76 (105.25)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	232	-58.60 (6.19)	25	254	-43.28 (5.89)	38	-15.32 (-31.77, 1.13)	0.0677	-0.16 (-0.34, 0.02)	0.0739

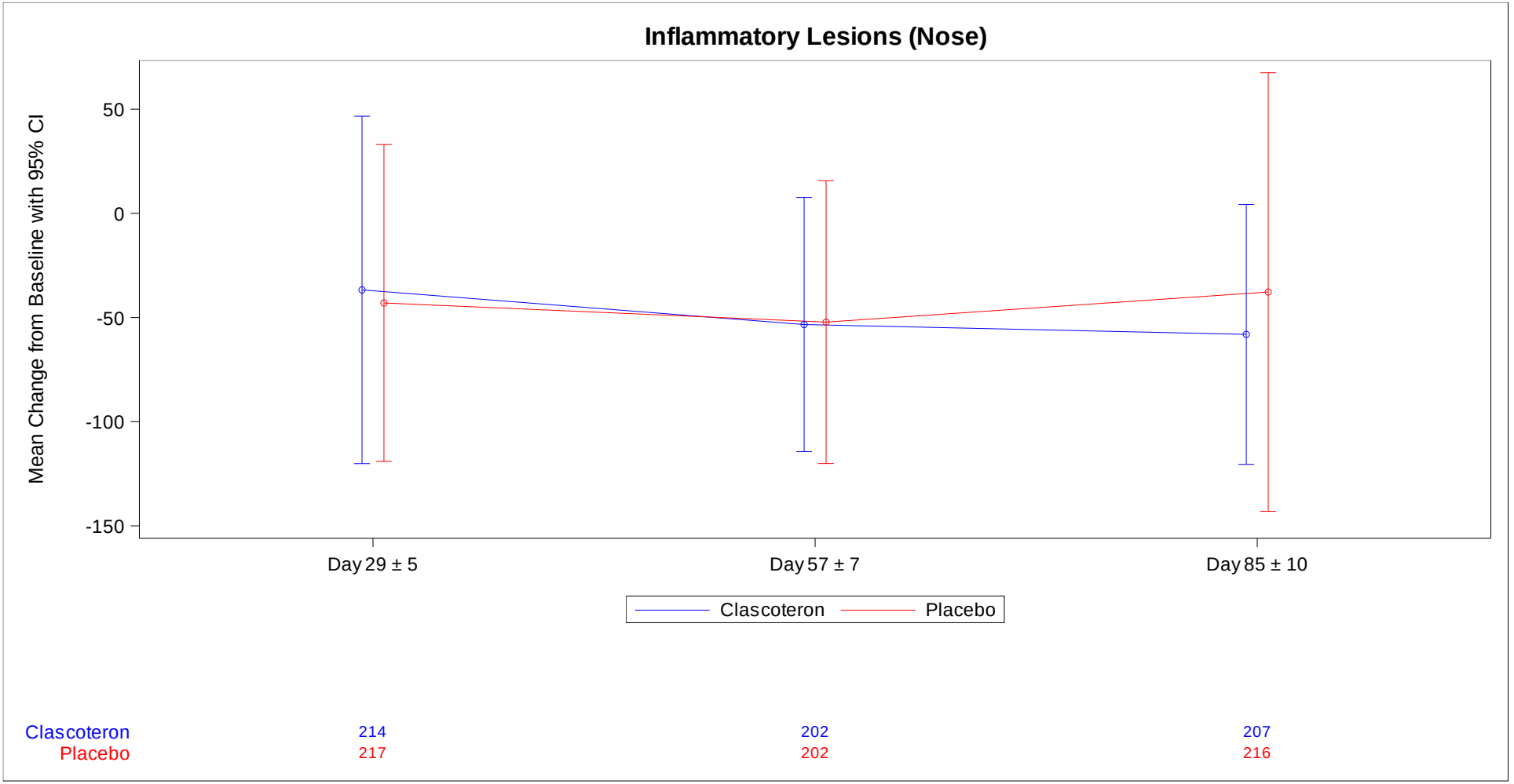
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.5453
9 - <18	172	2.74 (3.44)	113 (9)	-53.56 (9.16)	172	2.92 (3.14)	130 (9)	-32.07 (8.57)	-21.50 (-46.22, 3.23)	0.0880	-0.22 (-0.47, 0.03)	0.0886	
18 - <65	197	2.04 (2.58)	119 (16)	-54.75 (7.74)	191	2.19 (2.82)	124 (29)	-43.25 (6.84)	-11.50 (-33.01, 10.00)	0.2887	-0.14 (-0.39, 0.11)	0.2665	
Gender													0.8752
Male	126	2.48 (2.67)	88 (11)	-47.26 (9.31)	142	3.06 (3.15)	111 (11)	-29.31 (8.24)	-17.94 (-42.59, 6.70)	0.1526	-0.21 (-0.49, 0.08)	0.1515	
Female	243	2.30 (3.20)	144 (14)	-58.83 (7.47)	221	2.20 (2.85)	143 (27)	-43.47 (7.33)	-15.36 (-36.65, 5.94)	0.1562	-0.17 (-0.40, 0.06)	0.1444	
Region													0.0066
USA	47	2.62 (3.95)	31 (4)	-22.32 (11.80)	46	3.00 (3.04)	35 (5)	-49.45 (11.34)	27.13 (-5.68, 59.93)	0.1032	0.40 (-0.09, 0.89)	0.1055	
Europe	322	2.33 (2.87)	201 (21)	-59.18 (6.62)	317	2.47 (2.99)	219 (33)	-35.54 (6.01)	-23.64 (-41.48, -5.81)	0.0096	-0.26 (-0.45, -0.07)	0.0084	
IGA													0.0356
3-Moderate	305	2.23 (2.97)	187 (24)	-50.68 (6.97)	313	2.43 (2.95)	215 (35)	-40.17 (6.19)	-10.51 (-29.31, 8.30)	0.2716	-0.11 (-0.31, 0.08)	0.2592	
4-Severe	64	3.02 (3.24)	45 (1)	-69.62 (10.09)	50	3.24 (3.22)	39 (3)	-21.90 (11.01)	-47.72 (-77.44, -17.99)	0.0020	-0.69 (-1.14, -0.25)	0.0021	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of inflammatory lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in inflammatory lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	40.52 (11.94)	0	-	363	38.77 (10.15)	0	-
Day 29 ± 5	335	26.50 (14.72)	335	-34.59 (30.20)	310	26.83 (14.44)	310	-30.32 (35.31)
Day 57 ± 7	315	21.97 (15.24)	315	-45.72 (34.71)	289	23.77 (13.73)	289	-38.50 (34.37)
Day 85 ± 10	327	21.13 (15.33)	327	-48.09 (33.32)	309	28.15 (16.95)	309	-27.25 (40.98)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-45.95 (2.14)	42	363	-28.31 (2.16)	54	-17.64 (-23.45, -11.83)	<.0001	-0.43 (-0.57, -0.28)	<.0001

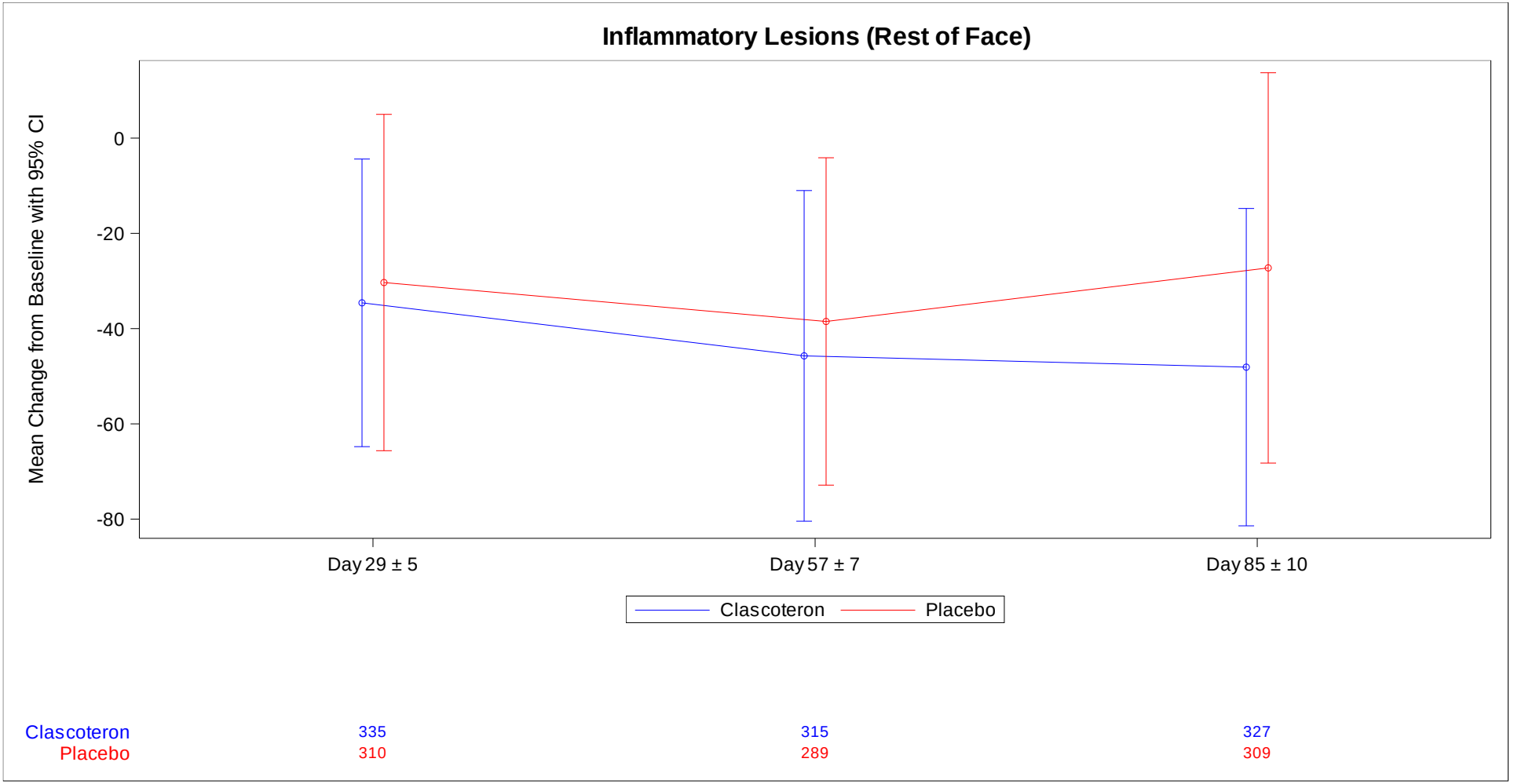
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in inflammatory lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of			
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Age (years)												0.9305
9 - <18	172	40.77 (12.87)	172 (14)	-40.57 (3.28)	172	38.56 (10.21)	172 (13)	-22.60 (3.19)	-17.97 (-26.84, -9.10)	<.0001	-0.42 (-0.64, -0.21)	0.0001
18 - <65	197	40.30 (11.09)	197 (28)	-50.09 (2.69)	191	38.96 (10.12)	191 (41)	-31.59 (2.82)	-18.50 (-26.35, -10.64)	<.0001	-0.48 (-0.68, -0.28)	<.0001
Gender												0.5382
Male	126	41.67 (12.15)	126 (13)	-44.69 (3.38)	142	39.73 (9.87)	142 (16)	-24.22 (3.16)	-20.47 (-29.59, -11.35)	<.0001	-0.54 (-0.78, -0.30)	<.0001
Female	243	39.92 (11.80)	243 (29)	-46.11 (2.80)	221	38.16 (10.30)	221 (38)	-29.37 (2.83)	-16.74 (-24.47, -9.01)	<.0001	-0.39 (-0.57, -0.21)	<.0001
Region												0.0039
USA	47	42.77 (13.86)	47 (9)	-33.38 (8.63)	46	40.17 (9.14)	46 (9)	-44.46 (7.23)	11.08 (-11.83, 33.99)	0.3314	0.20 (-0.21, 0.61)	0.3313
Europe	322	40.19 (11.62)	322 (33)	-47.41 (2.10)	317	38.57 (10.29)	317 (45)	-24.88 (2.20)	-22.54 (-28.52, -16.55)	<.0001	-0.59 (-0.74, -0.43)	<.0001
IGA												0.5332
3-Moderate	305	39.56 (11.34)	305 (39)	-45.21 (2.41)	313	37.55 (9.07)	313 (48)	-27.78 (2.37)	-17.43 (-23.95, -10.91)	<.0001	-0.41 (-0.57, -0.26)	<.0001
4-Severe	64	45.08 (13.64)	64 (3)	-47.17 (4.03)	50	46.44 (12.96)	50 (6)	-25.30 (4.81)	-21.87 (-34.44, -9.30)	0.0009	-0.66 (-1.04, -0.28)	0.0007

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of inflammatory lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in non-inflammatory lesions count (Whole face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	62.81 (21.37)	0	-	363	63.31 (20.52)	0	-
Day 29 ± 5	335	49.49 (27.37)	335	-21.84 (33.78)	310	51.40 (28.12)	310	-18.27 (36.92)
Day 57 ± 7	315	47.11 (29.74)	315	-25.58 (37.23)	289	46.58 (28.09)	289	-25.72 (40.97)
Day 85 ± 10	327	42.25 (29.94)	327	-31.86 (41.48)	309	52.48 (30.44)	309	-15.54 (44.44)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Whole face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)						
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	Difference of LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-29.30 (2.23)	42	363	-15.84 (2.30)	54	-13.46 (-19.81, -7.11)	<.0001	-0.31 (-0.46, -0.16)	<.0001

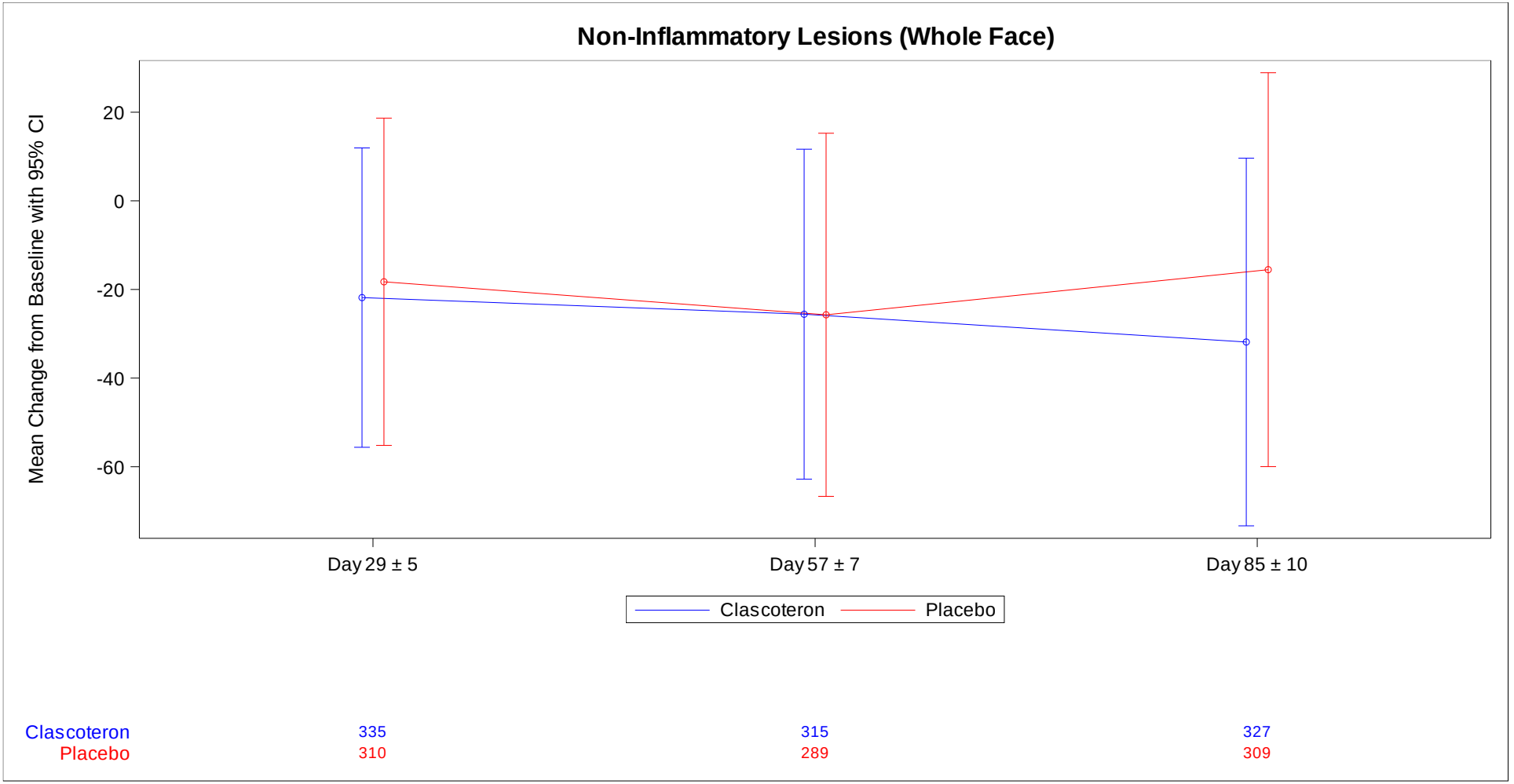
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Whole face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.6789
9 - <18	172	68.11 (21.98)	172 (14)	-24.89 (3.48)	172	66.80 (19.91)	172 (13)	-9.50 (3.52)	-15.40 (-25.08, -5.71)	0.0020	-0.33 (-0.55, -0.12)	0.0020	
18 - <65	197	58.19 (19.75)	197 (28)	-34.85 (3.06)	191	60.17 (20.59)	191 (41)	-22.24 (3.09)	-12.61 (-21.76, -3.47)	0.0074	-0.29 (-0.49, -0.09)	0.0040	
Gender													0.9111
Male	126	65.43 (23.14)	126 (13)	-25.10 (3.77)	142	63.80 (20.30)	142 (16)	-11.86 (3.54)	-13.24 (-23.57, -2.91)	0.0123	-0.31 (-0.55, -0.07)	0.0111	
Female	243	61.46 (20.32)	243 (29)	-32.91 (2.94)	221	63.00 (20.69)	221 (38)	-18.92 (3.01)	-13.99 (-22.36, -5.62)	0.0012	-0.31 (-0.49, -0.13)	0.0010	
Region													0.0144
USA	47	62.06 (24.82)	47 (9)	-27.22 (6.03)	46	59.35 (16.46)	46 (9)	-34.35 (6.62)	7.13 (-11.86, 26.13)	0.4512	0.16 (-0.24, 0.57)	0.4298	
Europe	322	62.92 (20.87)	322 (33)	-30.77 (2.47)	317	63.89 (21.00)	317 (45)	-13.44 (2.43)	-17.32 (-24.21, -10.44)	<.0001	-0.39 (-0.55, -0.24)	<.0001	
IGA													0.4703
3-Moderate	305	62.47 (21.48)	305 (39)	-29.62 (2.63)	313	63.08 (20.90)	313 (48)	-16.48 (2.55)	-13.14 (-20.50, -5.78)	0.0005	-0.29 (-0.45, -0.13)	0.0004	
4-Severe	64	64.45 (20.93)	64 (3)	-33.12 (4.52)	50	64.80 (18.04)	50 (6)	-14.28 (5.35)	-18.84 (-32.72, -4.96)	0.0085	-0.51 (-0.88, -0.13)	0.0082	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of non-inflammatory lesions count (Whole face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in non-inflammatory lesions count (Nose) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	8.80 (9.33)	0	-	363	8.89 (8.69)	0	-
Day 29 ± 5	335	6.47 (8.25)	272	-25.49 (63.94)	310	7.44 (8.63)	261	-14.92 (68.67)
Day 57 ± 7	315	5.69 (7.38)	256	-27.82 (92.27)	289	6.27 (7.38)	243	-13.95 (108.46)
Day 85 ± 10	327	4.65 (6.61)	260	-29.99 (104.91)	309	7.45 (11.39)	256	19.34 (237.50)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Nose) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	293	-27.22 (10.91)	33	298	13.03 (11.06)	42	-40.25 (-69.35, -11.14)	0.0069	-0.21 (-0.37, -0.05)	0.0099

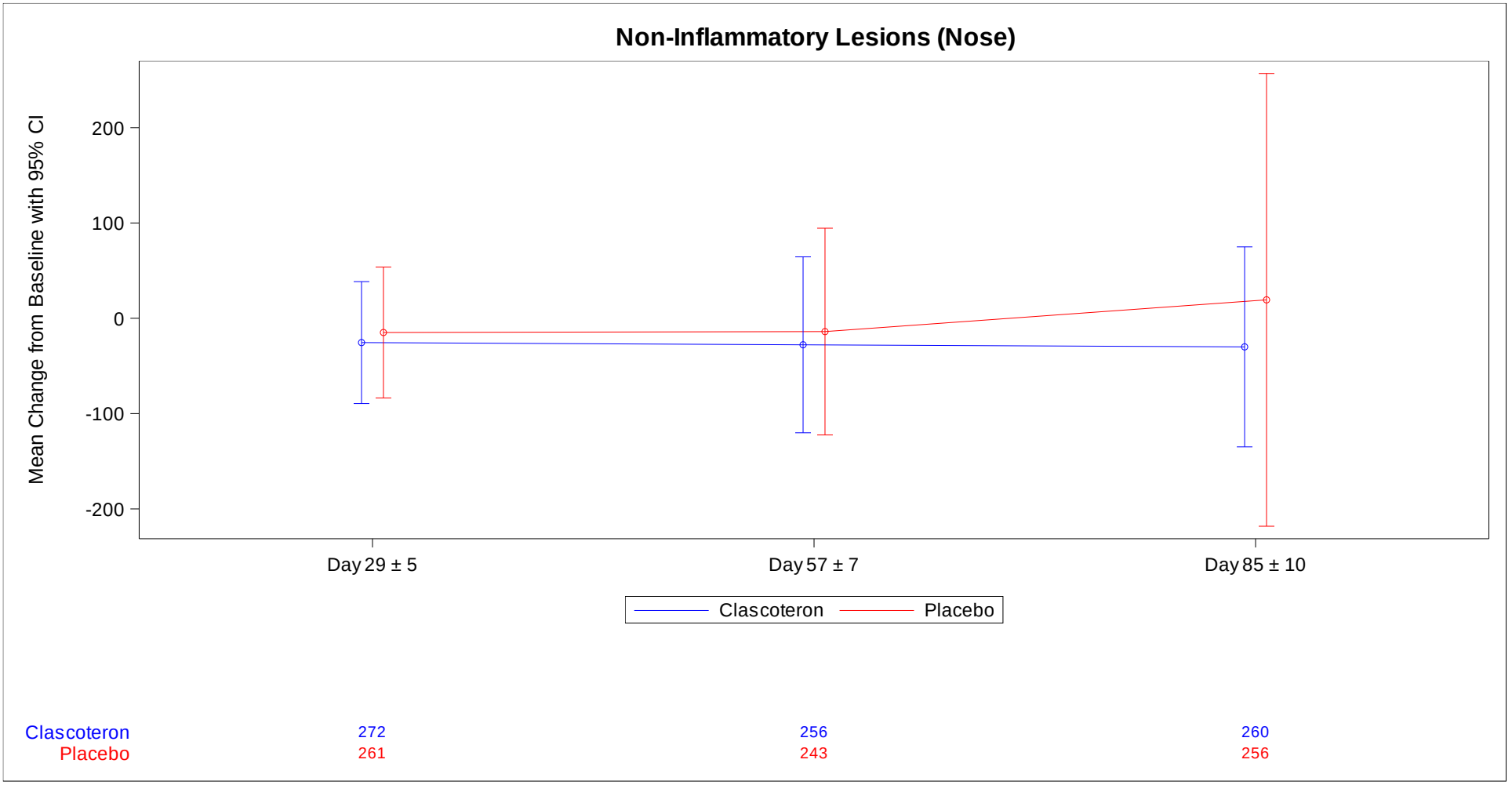
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Nose) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of			
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Age (years)												0.3459
9 - <18	172	9.17 (9.88)	142 (14)	-19.57 (17.59)	172	9.09 (9.12)	143 (8)	40.52 (17.58)	-60.10 (-109.14, -11.05)	0.0165	-0.29 (-0.52, -0.05)	0.0165
18 - <65	197	8.47 (8.85)	151 (19)	-28.40 (11.51)	191	8.72 (8.29)	155 (34)	3.58 (12.11)	-31.98 (-64.40, 0.44)	0.0532	-0.22 (-0.44, 0.01)	0.0572
Gender												0.8858
Male	126	9.43 (9.75)	104 (12)	-20.49 (12.96)	142	9.75 (8.83)	127 (12)	26.81 (12.35)	-47.31 (-83.03, -11.59)	0.0098	-0.35 (-0.61, -0.09)	0.0093
Female	243	8.47 (9.11)	189 (21)	-26.08 (14.82)	221	8.34 (8.57)	171 (30)	17.17 (15.97)	-43.25 (-85.96, -0.55)	0.0472	-0.21 (-0.42, -0.00)	0.0480
Region												0.0173
USA	47	7.55 (7.91)	39 (8)	18.16 (24.63)	46	8.50 (6.81)	42 (6)	-11.06 (25.01)	29.21 (-36.13, 94.56)	0.3738	0.18 (-0.25, 0.62)	0.4117
Europe	322	8.98 (9.52)	254 (25)	-30.70 (11.48)	317	8.95 (8.93)	256 (36)	26.70 (11.61)	-57.39 (-89.35, -25.44)	0.0005	-0.31 (-0.49, -0.14)	0.0005
IGA												0.4846
3-Moderate	305	8.84 (9.09)	240 (32)	-26.79 (12.20)	313	8.50 (8.38)	254 (38)	21.71 (12.04)	-48.50 (-82.00, -15.01)	0.0047	-0.25 (-0.43, -0.08)	0.0049
4-Severe	64	8.59 (10.51)	53 (1)	-10.63 (16.07)	50	11.36 (10.18)	44 (4)	17.24 (18.32)	-27.87 (-75.91, 20.16)	0.2514	-0.23 (-0.63, 0.17)	0.2564

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of non-inflammatory lesions count (Nose) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in non-inflammatory lesions count (Rest of Face) over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	54.02 (19.88)	0	-	363	54.42 (18.61)	0	-
Day 29 ± 5	335	43.02 (24.81)	335	-20.76 (36.67)	310	43.96 (25.59)	310	-18.63 (40.02)
Day 57 ± 7	315	41.42 (27.05)	315	-23.37 (39.67)	289	40.32 (25.40)	289	-25.55 (41.17)
Day 85 ± 10	327	37.60 (27.27)	327	-29.18 (45.03)	309	45.03 (25.53)	309	-15.45 (42.73)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Rest of Face) at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-26.01 (2.41)	42	363	-15.06 (2.37)	54	-10.95 (-17.59, -4.31)	0.0013	-0.24 (-0.38, -0.09)	0.0013

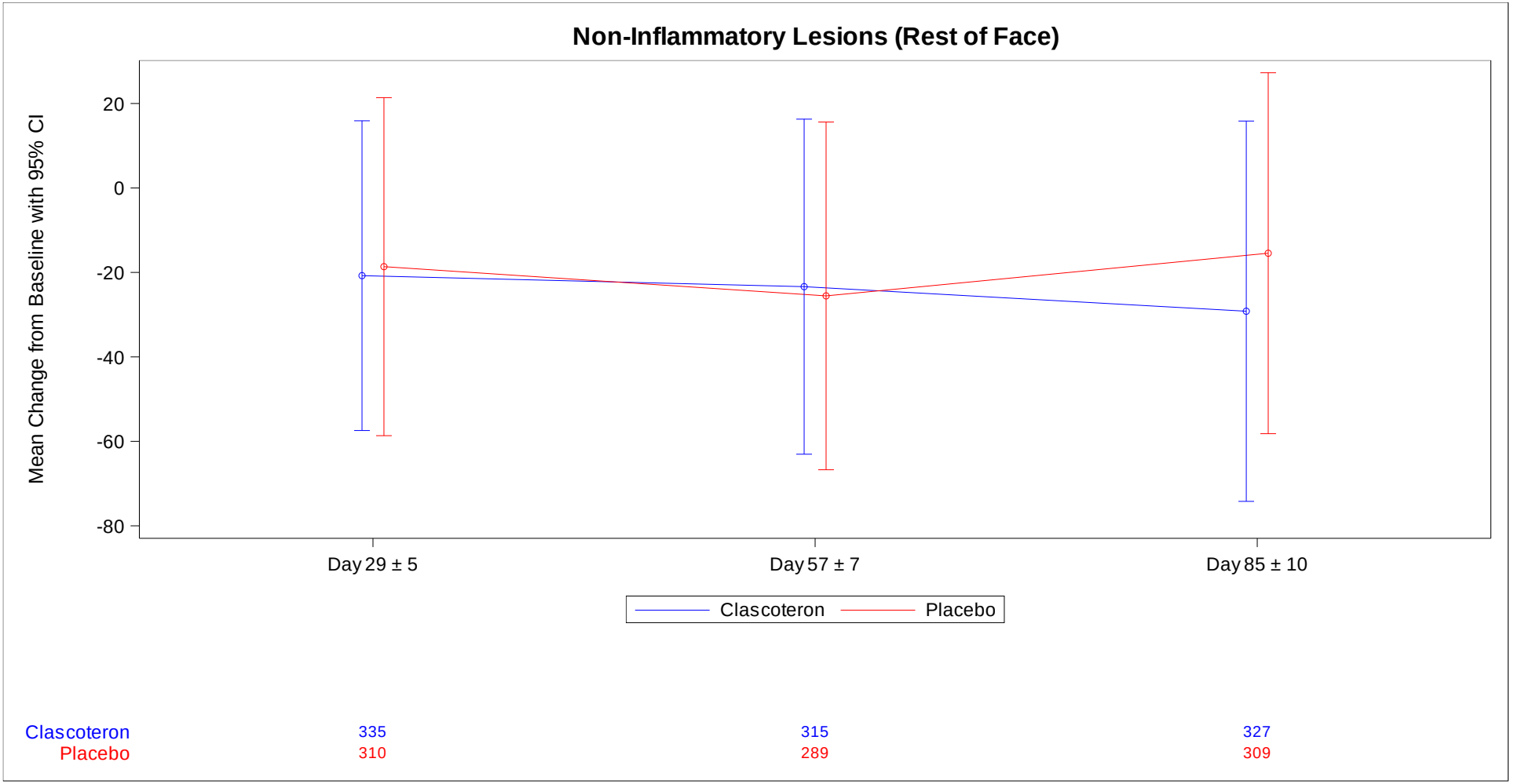
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in non-inflammatory lesions count (Rest of Face) at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)								Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of				
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value	p-Value
Age (years)													0.9054
9 - <18	172	58.94 (20.89)	172 (14)	-22.24 (3.48)	172	57.72 (18.49)	172 (13)	-10.55 (3.41)	-11.68 (-21.38, -1.99)	0.0185	-0.26 (-0.47, -0.05)	0.0172	
18 - <65	197	49.72 (17.93)	197 (28)	-31.42 (3.37)	191	51.46 (18.26)	191 (41)	-20.55 (3.28)	-10.87 (-20.33, -1.40)	0.0247	-0.23 (-0.43, -0.03)	0.0216	
Gender													0.7656
Male	126	56.00 (21.72)	126 (13)	-22.55 (4.23)	142	54.05 (19.43)	142 (16)	-10.28 (4.00)	-12.27 (-23.39, -1.14)	0.0309	-0.26 (-0.50, -0.02)	0.0364	
Female	243	52.99 (18.81)	243 (29)	-29.51 (3.00)	221	54.66 (18.10)	221 (38)	-19.37 (3.07)	-10.15 (-18.70, -1.59)	0.0204	-0.22 (-0.40, -0.04)	0.0187	
Region													0.0221
USA	47	54.51 (24.16)	47 (9)	-24.84 (6.72)	46	50.85 (17.44)	46 (9)	-33.91 (6.87)	9.07 (-10.19, 28.33)	0.3487	0.19 (-0.21, 0.60)	0.3507	
Europe	322	53.94 (19.21)	322 (33)	-27.55 (2.62)	317	54.94 (18.74)	317 (45)	-13.11 (2.57)	-14.45 (-21.76, -7.14)	0.0001	-0.31 (-0.47, -0.16)	<.0001	
IGA													0.1120
3-Moderate	305	53.63 (20.23)	305 (39)	-25.85 (2.79)	313	54.58 (18.94)	313 (48)	-16.52 (2.65)	-9.33 (-17.12, -1.54)	0.0191	-0.20 (-0.35, -0.04)	0.0155	
4-Severe	64	55.86 (18.13)	64 (3)	-33.55 (4.72)	50	53.44 (16.56)	50 (6)	-11.07 (5.54)	-22.48 (-36.98, -7.98)	0.0029	-0.58 (-0.96, -0.20)	0.0025	

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of non-inflammatory lesions count (Rest of Face) over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean values and percent change from Baseline in Investigator´s Global Assessment over time
Intention-to-treat

	Clascoteron (N=369)				Placebo (N=363)			
	Value at timepoint		Percent change from Baseline		Value at timepoint		Percent change from Baseline	
Timepoint	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	369	3.17 (0.38)	0	-	363	3.14 (0.35)	0	-
Day 29 ± 5	335	2.66 (0.63)	335	-16.04 (18.44)	310	2.70 (0.63)	310	-13.84 (18.61)
Day 57 ± 7	315	2.45 (0.67)	315	-22.59 (20.94)	289	2.51 (0.67)	289	-20.07 (20.51)
Day 85 ± 10	328	2.27 (0.87)	328	-28.23 (27.17)	310	2.55 (0.74)	310	-18.52 (23.02)

N=Number of subjects included in the analysis, SD: Standard Deviation.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in Investigator´s Global Assessment at Week 12
Intention-to-treat

	Clascoteron (N=369)			Placebo (N=363)			Difference of			
Timepoint	N	LSMean (SE)	N imputed	N	LSMean (SE)	N imputed	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Day 85 ± 10	369	-27.59 (1.44)	41	363	-19.12 (1.44)	53	-8.48 (-12.42, -4.53)	<.0001	-0.31 (-0.45, -0.16)	<.0001

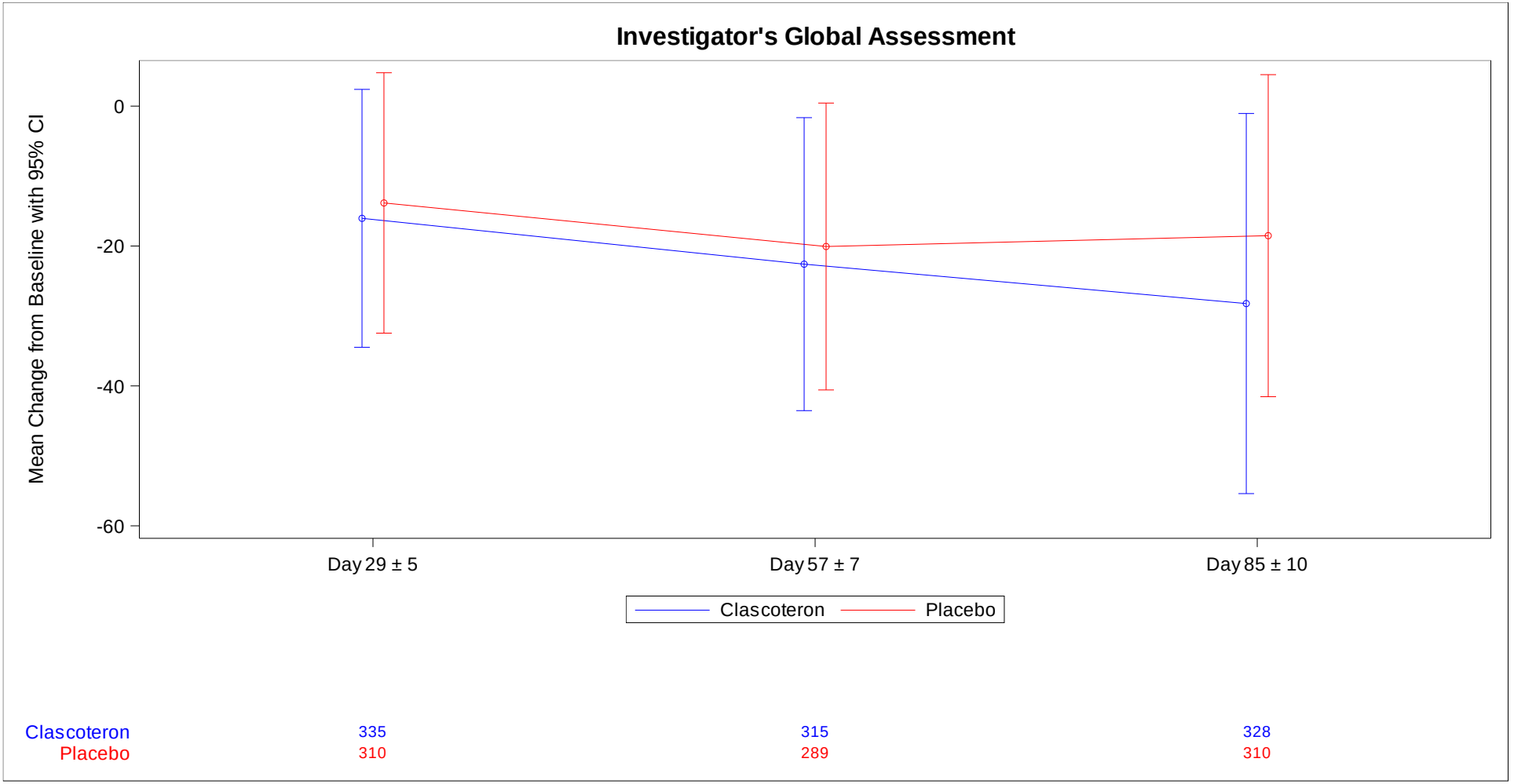
An ANCOVA with treatment and analysis centre as fixed effects and the Baseline value as covariate was used to compare the percent change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
N=Number of subjects included in the analysis, N imputed= Number of imputed values, SE: Standard Error; CI=Confidence Interval

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
ANCOVA analysis of percent change from Baseline in Investigator´s Global Assessment at Week 12 - Subgroup analysis
Intention-to-treat

Subgroup	Clascoteron (N=369)				Placebo (N=363)							Interaction
	Baseline		Percent change from Baseline		Baseline		Percent change from Baseline		Difference of			
Level	N	Mean (SD)	N (imp)	LSMean (SE)	N	Mean (SD)	N (imp)	LSMean (SE)	LSMeans (95% CI)	p-Value	Hedges'g (95% CI)	p-Value
Age (years)												0.6546
9 - <18	172	3.22 (0.42)	172 (14)	-25.45 (2.05)	172	3.14 (0.35)	172 (12)	-15.85 (1.94)	-9.60 (-15.13, -4.08)	0.0007	-0.37 (-0.58, -0.15)	0.0008
18 - <65	197	3.13 (0.34)	197 (27)	-29.62 (1.94)	191	3.14 (0.34)	191 (41)	-21.80 (2.01)	-7.82 (-13.43, -2.21)	0.0067	-0.28 (-0.48, -0.08)	0.0055
Gender												0.3494
Male	126	3.19 (0.39)	126 (12)	-26.85 (2.22)	142	3.20 (0.40)	142 (15)	-15.89 (2.11)	-10.96 (-16.97, -4.96)	0.0004	-0.44 (-0.68, -0.19)	0.0004
Female	243	3.16 (0.37)	243 (29)	-28.14 (1.79)	221	3.10 (0.29)	221 (38)	-20.92 (1.88)	-7.22 (-12.36, -2.07)	0.0062	-0.26 (-0.44, -0.07)	0.0057
Region												0.0046
USA	47	3.19 (0.40)	47 (9)	-20.37 (3.86)	46	3.17 (0.38)	46 (9)	-25.91 (3.96)	5.53 (-5.12, 16.18)	0.3002	0.21 (-0.20, 0.61)	0.3221
Europe	322	3.17 (0.38)	322 (32)	-28.68 (1.47)	317	3.13 (0.34)	317 (44)	-18.03 (1.58)	-10.65 (-14.98, -6.31)	<.0001	-0.39 (-0.55, -0.23)	<.0001
IGA												0.7107
3-Moderate	305	3.00 (0.00)	305 (38)	-26.28 (1.59)	313	3.00 (0.00)	313 (47)	-17.94 (1.55)	-8.34 (-12.69, -3.98)	0.0002	-0.30 (-0.46, -0.14)	0.0002
4-Severe	64	4.00 (0.00)	64 (3)	-34.88 (2.92)	50	4.00 (0.00)	50 (6)	-24.70 (3.32)	-10.18 (-19.05, -1.32)	0.0250	-0.43 (-0.81, -0.06)	0.0237

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
An ANCOVA with treatment as fixed effect and the Baseline value as covariate was used to compare the absolute change from Baseline at Week 12.
Subjects were analyzed according to the treatment they were assigned to (ITT) and missing data was replaced using a multiple imputation (MI) under missing at random (MAR) assumption.
p-Value for interaction from test for heterogeneity of the mean differences in the subgroups using Cochrane`s Q statistic.
N=Number of subjects included in the analysis, SD: standard Deviation, SE: Standard Error; CI=Confidence Interval, IMP = Number of imputed values

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Graphical summary of percent change from baseline of Investigator´s Global Assessment over time
Intention-to-treat



N describes number of patients with non-missing value at the respective timepoint.
N=Number of subjects included in the analysis; CI=Confidence Interval.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events
Safety Analysis Set

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with event, n/N (%)	42/ 369 (11.38)	50/ 363 (13.77)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	0.79 (0.52, 1.19)	
p-value	0.2609	
Odds Ratio (95% CI)	0.80 (0.52, 1.25)	
p-value	0.3297	
Risk Ratio (95% CI)	0.83 (0.56, 1.21)	
p-value	0.3300	
Risk Difference (95% CI)	-0.02 (-0.07, 0.02)	
p-value	0.3290	

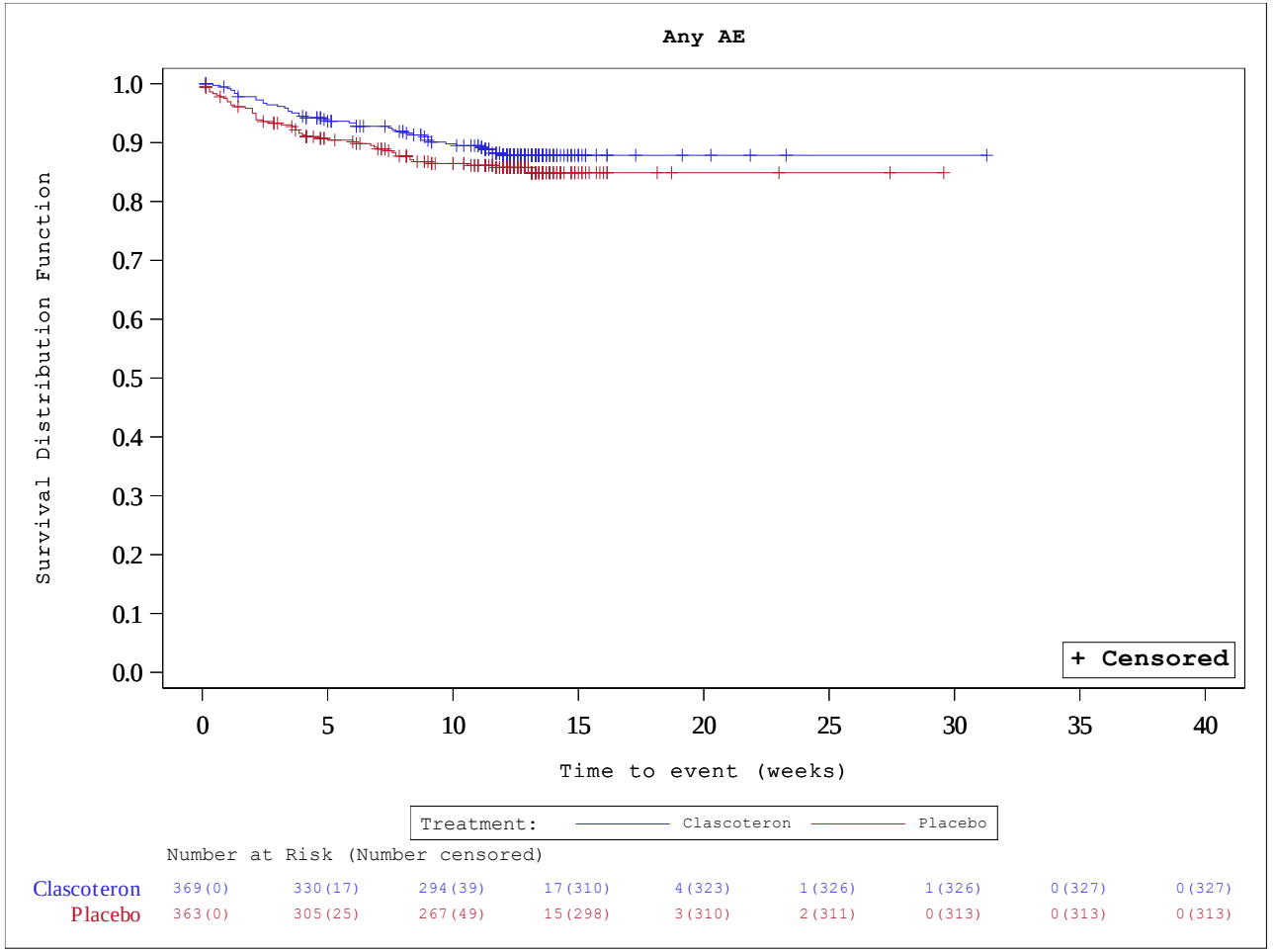
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=369) n/ N (%)	Clascoteron (N=369) Median (95% CI)	Placebo (N=363) n/ N (%)	Placebo (N=363) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							0.1057
9 - <18	17/ 172 (9.88)	NE (NE, NE)	29/ 172 (16.86)	NE (NE, NE)	0.55 (0.30, 1.01)	0.0537	
18 - <65	25/ 197 (12.69)	NE (NE, NE)	21/ 191 (10.99)	NE (NE, NE)	1.11 (0.62, 1.99)	0.7197	
Gender							0.4883
Male	13/ 126 (10.32)	NE (NE, NE)	21/ 142 (14.79)	NE (NE, NE)	0.65 (0.33, 1.30)	0.2267	
Female	29/ 243 (11.93)	NE (NE, NE)	29/ 221 (13.12)	NE (NE, NE)	0.88 (0.53, 1.48)	0.6341	
Region							0.5324
USA	6/ 47 (12.77)	NE (NE, NE)	5/ 46 (10.87)	NE (NE, NE)	1.09 (0.33, 3.58)	0.8835	
Europe	36/ 322 (11.18)	NE (NE, NE)	45/ 317 (14.20)	NE (NE, NE)	0.75 (0.49, 1.17)	0.2061	
IGA							0.9151
3-Moderate	35/ 305 (11.48)	NE (NE, NE)	44/ 313 (14.06)	NE (NE, NE)	0.79 (0.50, 1.23)	0.2874	
4-Severe	7/ 64 (10.94)	NE (NE, NE)	6/ 50 (12.00)	NE (NE, NE)	0.86 (0.29, 2.55)	0.7816	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events excluding disease-related events
Safety Analysis Set

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with event, n/N (%)	41/ 369 (11.11)	47/ 363 (12.95)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	0.82 (0.54, 1.25)	
p-value	0.3533	
Odds Ratio (95% CI)	0.84 (0.54, 1.31)	
p-value	0.4453	
Risk Ratio (95% CI)	0.86 (0.58, 1.27)	
p-value	0.4455	
Risk Difference (95% CI)	-0.02 (-0.07, 0.03)	
p-value	0.4450	

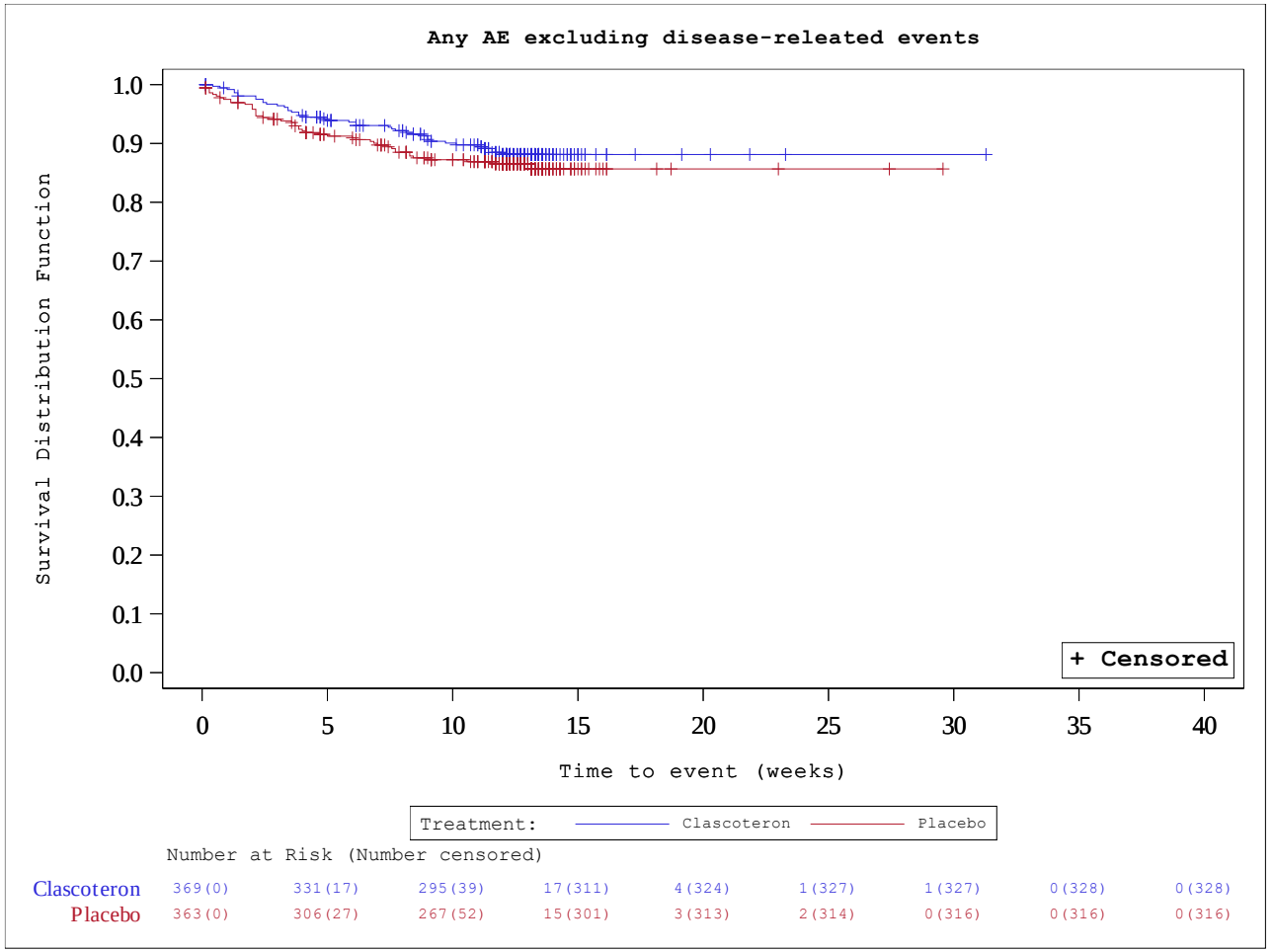
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events excluding disease-related events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=369) n/ N (%)	Clascoteron (N=369) Median (95% CI)	Placebo (N=363) n/ N (%)	Placebo (N=363) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							0.0599
9 - <18	16/ 172 (9.30)	NE (NE, NE)	28/ 172 (16.28)	NE (NE, NE)	0.54 (0.29, 0.99)	0.0478	
18 - <65	25/ 197 (12.69)	NE (NE, NE)	19/ 191 (9.95)	NE (NE, NE)	1.23 (0.68, 2.24)	0.4907	
Gender							0.3589
Male	12/ 126 (9.52)	NE (NE, NE)	20/ 142 (14.08)	NE (NE, NE)	0.63 (0.31, 1.29)	0.2037	
Female	29/ 243 (11.93)	NE (NE, NE)	27/ 221 (12.22)	NE (NE, NE)	0.95 (0.56, 1.61)	0.8488	
Region							0.5786
USA	6/ 47 (12.77)	NE (NE, NE)	5/ 46 (10.87)	NE (NE, NE)	1.09 (0.33, 3.58)	0.8835	
Europe	35/ 322 (10.87)	NE (NE, NE)	42/ 317 (13.25)	NE (NE, NE)	0.79 (0.50, 1.23)	0.2910	
IGA							0.9731
3-Moderate	34/ 305 (11.15)	NE (NE, NE)	41/ 313 (13.10)	NE (NE, NE)	0.82 (0.52, 1.29)	0.3886	
4-Severe	7/ 64 (10.94)	NE (NE, NE)	6/ 50 (12.00)	NE (NE, NE)	0.86 (0.29, 2.55)	0.7816	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events excluding disease-related events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Seroius Adverse Events
Safety Analysis Set

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with event, n/N (%)	0/ 369 (0.00)	1/ 363 (0.28)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	
Odds Ratio (95% CI)	0.33 (0.01, 8.05)	
p-value	0.4941	
Risk Ratio (95% CI)	0.33 (0.01, 8.02)	
p-value	0.4943	
Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
p-value	0.3166	

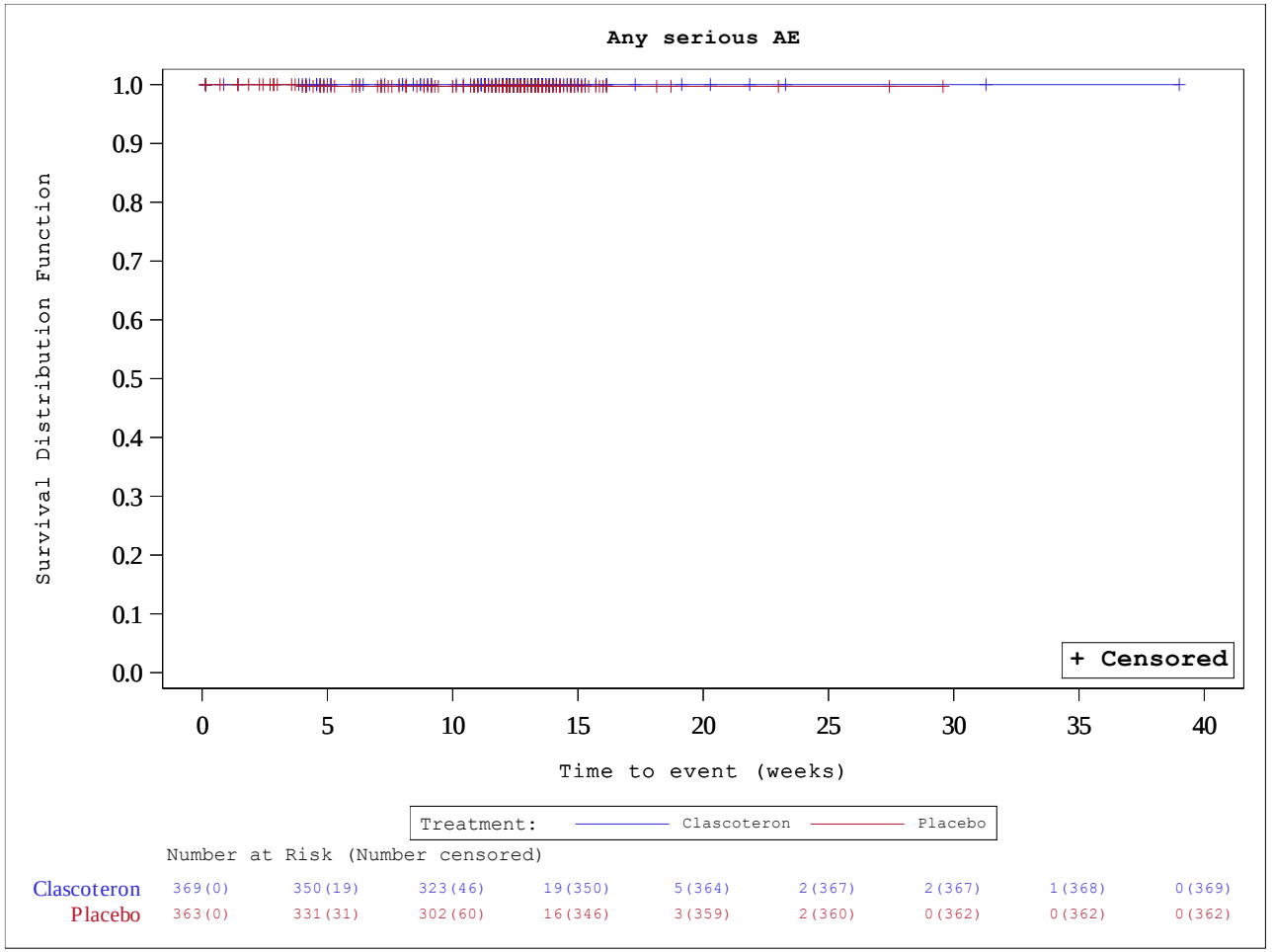
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Seroius Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=369) n/ N (%)	Clascoteron (N=369) Median (95% CI)	Placebo (N=363) n/ N (%)	Placebo (N=363) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	0/ 172 (0.00)	NE (NE, NE)	1/ 172 (0.58)	NE (NE, NE)			
18 - <65	0/ 197 (0.00)	NE (NE, NE)	0/ 191 (0.00)	NE (NE, NE)			
Gender							
Male	0/ 126 (0.00)	NE (NE, NE)	1/ 142 (0.70)	NE (NE, NE)			
Female	0/ 243 (0.00)	NE (NE, NE)	0/ 221 (0.00)	NE (NE, NE)			
Region							
USA	0/ 47 (0.00)	NE (NE, NE)	0/ 46 (0.00)	NE (NE, NE)			
Europe	0/ 322 (0.00)	NE (NE, NE)	1/ 317 (0.32)	NE (NE, NE)			
IGA							
3-Moderate	0/ 305 (0.00)	NE (NE, NE)	1/ 313 (0.32)	NE (NE, NE)			
4-Severe	0/ 64 (0.00)	NE (NE, NE)	0/ 50 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Seroius Adverse Events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Seroius Adverse Events excluding disease-related events
Safety Analysis Set

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with event, n/N (%)	0/ 369 (0.00)	1/ 363 (0.28)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	
Odds Ratio (95% CI)	0.33 (0.01, 8.05)	
p-value	0.4941	
Risk Ratio (95% CI)	0.33 (0.01, 8.02)	
p-value	0.4943	
Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
p-value	0.3166	

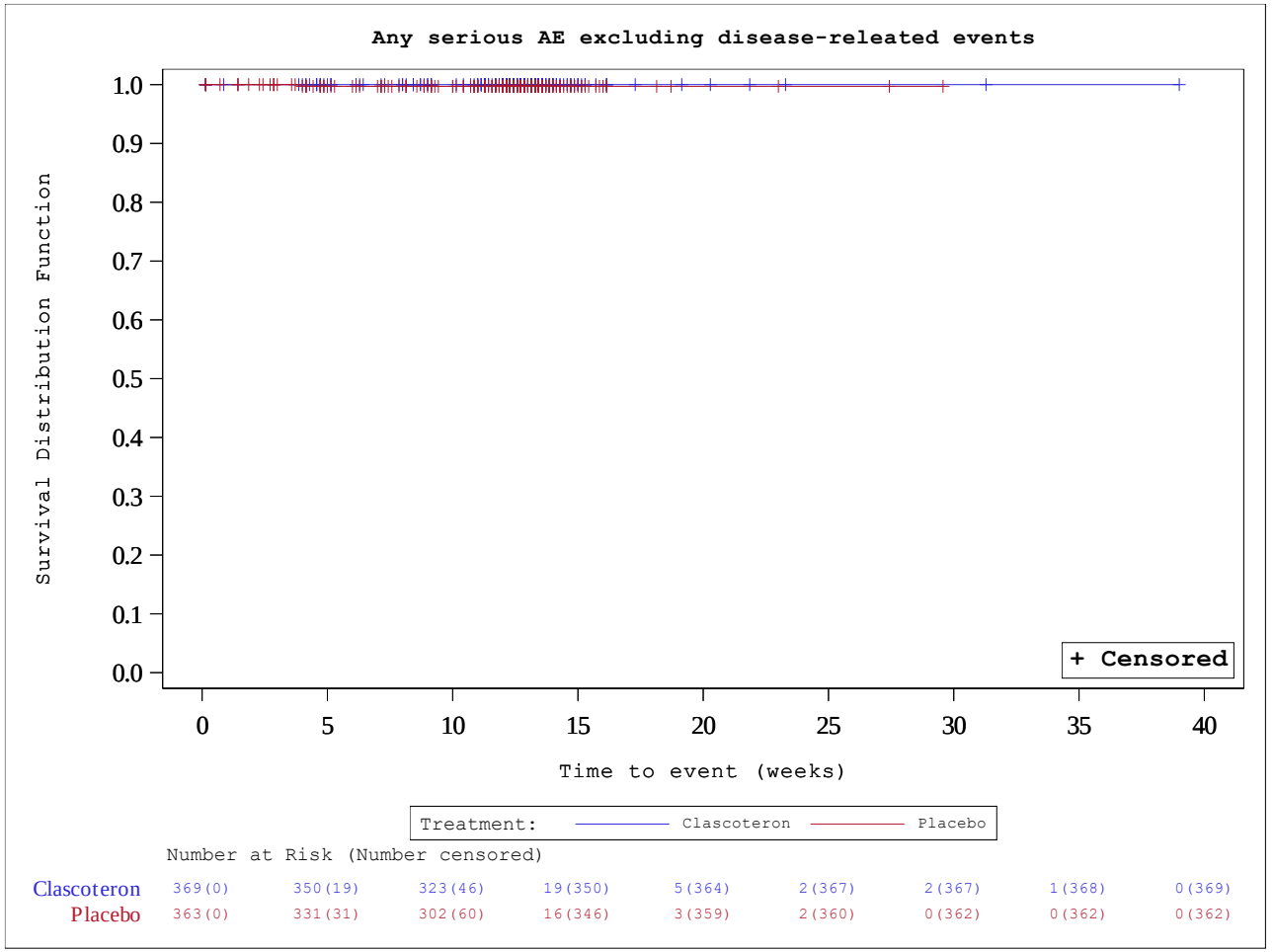
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Seroius Adverse Events excluding disease-related events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=369) n/ N (%)	Clascoteron (N=369) Median (95% CI)	Placebo (N=363) n/ N (%)	Placebo (N=363) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	0/ 172 (0.00)	NE (NE, NE)	1/ 172 (0.58)	NE (NE, NE)			
18 - <65	0/ 197 (0.00)	NE (NE, NE)	0/ 191 (0.00)	NE (NE, NE)			
Gender							
Male	0/ 126 (0.00)	NE (NE, NE)	1/ 142 (0.70)	NE (NE, NE)			
Female	0/ 243 (0.00)	NE (NE, NE)	0/ 221 (0.00)	NE (NE, NE)			
Region							
USA	0/ 47 (0.00)	NE (NE, NE)	0/ 46 (0.00)	NE (NE, NE)			
Europe	0/ 322 (0.00)	NE (NE, NE)	1/ 317 (0.32)	NE (NE, NE)			
IGA							
3-Moderate	0/ 305 (0.00)	NE (NE, NE)	1/ 313 (0.32)	NE (NE, NE)			
4-Severe	0/ 64 (0.00)	NE (NE, NE)	0/ 50 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Seroius Adverse Events excluding disease-related events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events
Safety Analysis Set

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with event, n/N (%)	0/ 369 (0.00)	1/ 363 (0.28)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	
Odds Ratio (95% CI)	0.33 (0.01, 8.05)	
p-value	0.4941	
Risk Ratio (95% CI)	0.33 (0.01, 8.02)	
p-value	0.4943	
Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
p-value	0.3166	

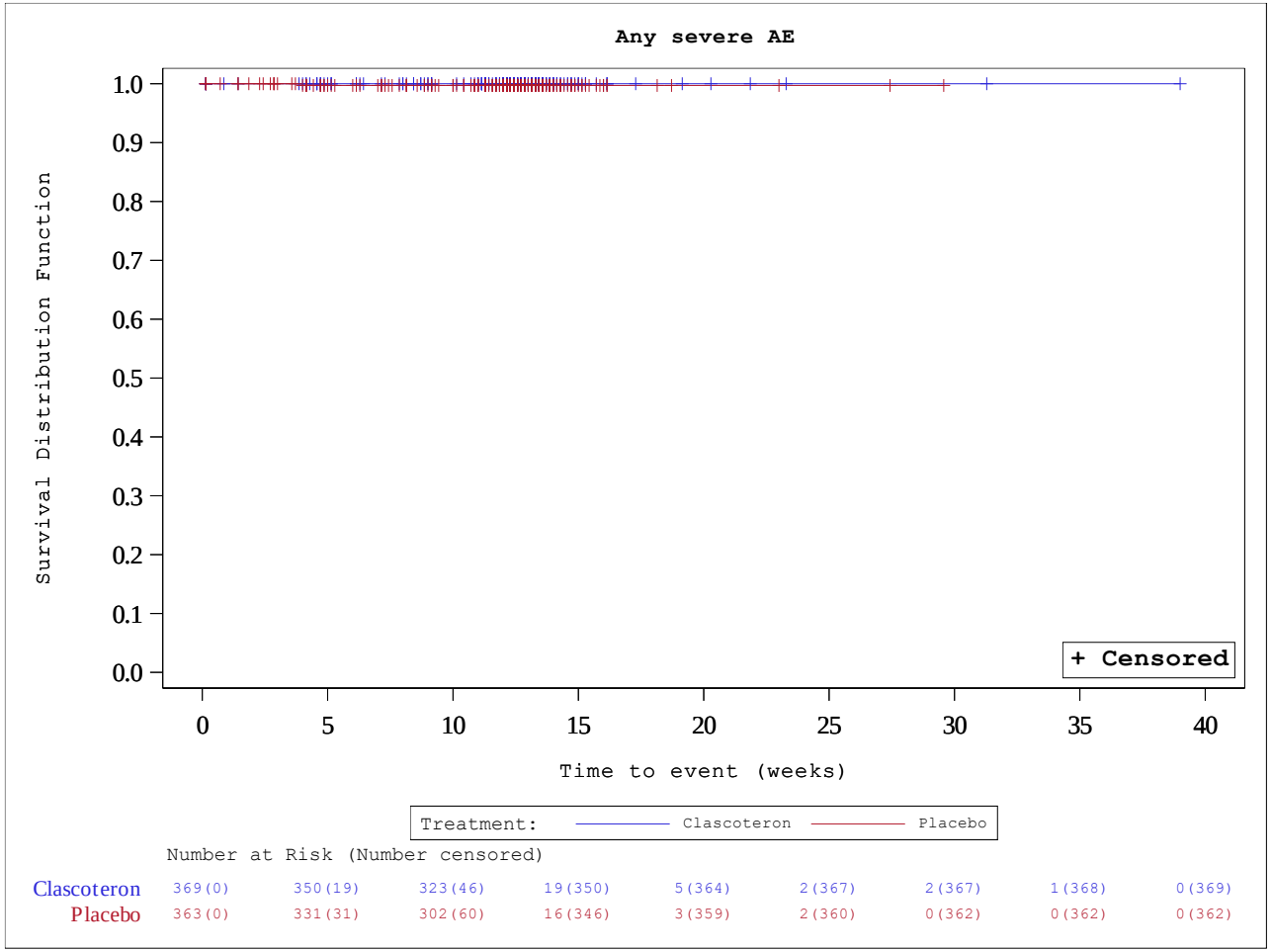
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=369) n/ N (%)	Clascoteron (N=369) Median (95% CI)	Placebo (N=363) n/ N (%)	Placebo (N=363) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	0/ 172 (0.00)	NE (NE, NE)	1/ 172 (0.58)	NE (NE, NE)			
18 - <65	0/ 197 (0.00)	NE (NE, NE)	0/ 191 (0.00)	NE (NE, NE)			
Gender							
Male	0/ 126 (0.00)	NE (NE, NE)	1/ 142 (0.70)	NE (NE, NE)			
Female	0/ 243 (0.00)	NE (NE, NE)	0/ 221 (0.00)	NE (NE, NE)			
Region							
USA	0/ 47 (0.00)	NE (NE, NE)	0/ 46 (0.00)	NE (NE, NE)			
Europe	0/ 322 (0.00)	NE (NE, NE)	1/ 317 (0.32)	NE (NE, NE)			
IGA							
3-Moderate	0/ 305 (0.00)	NE (NE, NE)	1/ 313 (0.32)	NE (NE, NE)			
4-Severe	0/ 64 (0.00)	NE (NE, NE)	0/ 50 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Severe Adverse Events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events excluding disease-related events
Safety Analysis Set

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with event, n/N (%)	0/ 369 (0.00)	1/ 363 (0.28)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	
Odds Ratio (95% CI)	0.33 (0.01, 8.05)	
p-value	0.4941	
Risk Ratio (95% CI)	0.33 (0.01, 8.02)	
p-value	0.4943	
Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
p-value	0.3166	

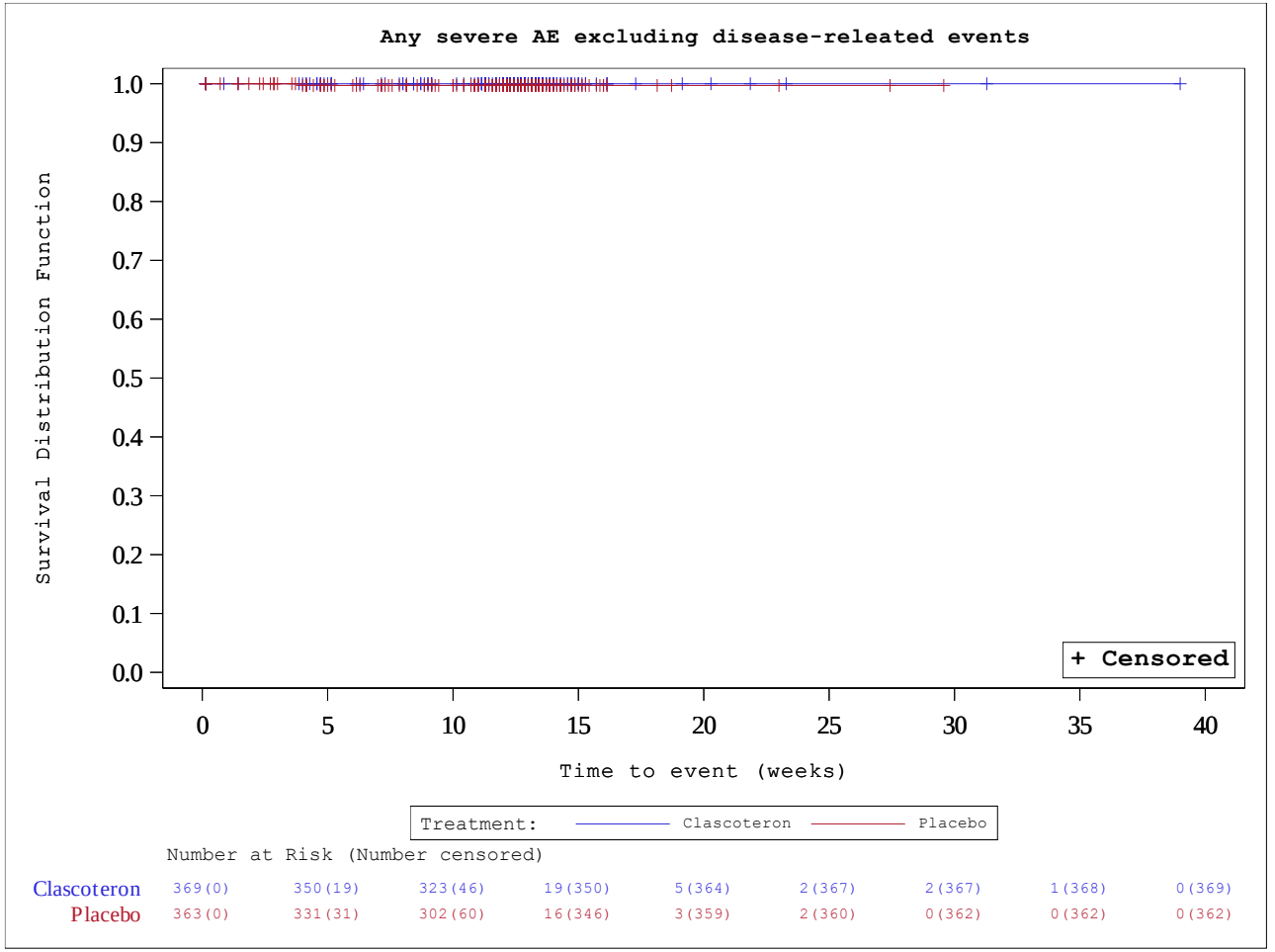
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Severe Adverse Events excluding disease-related events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=369) n/ N (%)	Clascoteron (N=369) Median (95% CI)	Placebo (N=363) n/ N (%)	Placebo (N=363) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	0/ 172 (0.00)	NE (NE, NE)	1/ 172 (0.58)	NE (NE, NE)			
18 - <65	0/ 197 (0.00)	NE (NE, NE)	0/ 191 (0.00)	NE (NE, NE)			
Gender							
Male	0/ 126 (0.00)	NE (NE, NE)	1/ 142 (0.70)	NE (NE, NE)			
Female	0/ 243 (0.00)	NE (NE, NE)	0/ 221 (0.00)	NE (NE, NE)			
Region							
USA	0/ 47 (0.00)	NE (NE, NE)	0/ 46 (0.00)	NE (NE, NE)			
Europe	0/ 322 (0.00)	NE (NE, NE)	1/ 317 (0.32)	NE (NE, NE)			
IGA							
3-Moderate	0/ 305 (0.00)	NE (NE, NE)	1/ 313 (0.32)	NE (NE, NE)			
4-Severe	0/ 64 (0.00)	NE (NE, NE)	0/ 50 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Severe Adverse Events excluding disease-related events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment
Safety Analysis Set

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with event, n/N (%)	2/ 369 (0.54)	8/ 363 (2.20)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	0.24 (0.05, 1.14)	
p-value	0.0727	
Odds Ratio (95% CI)	0.24 (0.05, 1.15)	
p-value	0.0738	
Risk Ratio (95% CI)	0.25 (0.05, 1.15)	
p-value	0.0747	
Risk Difference (95% CI)	-0.02 (-0.03, 0.00)	
p-value	0.0533	

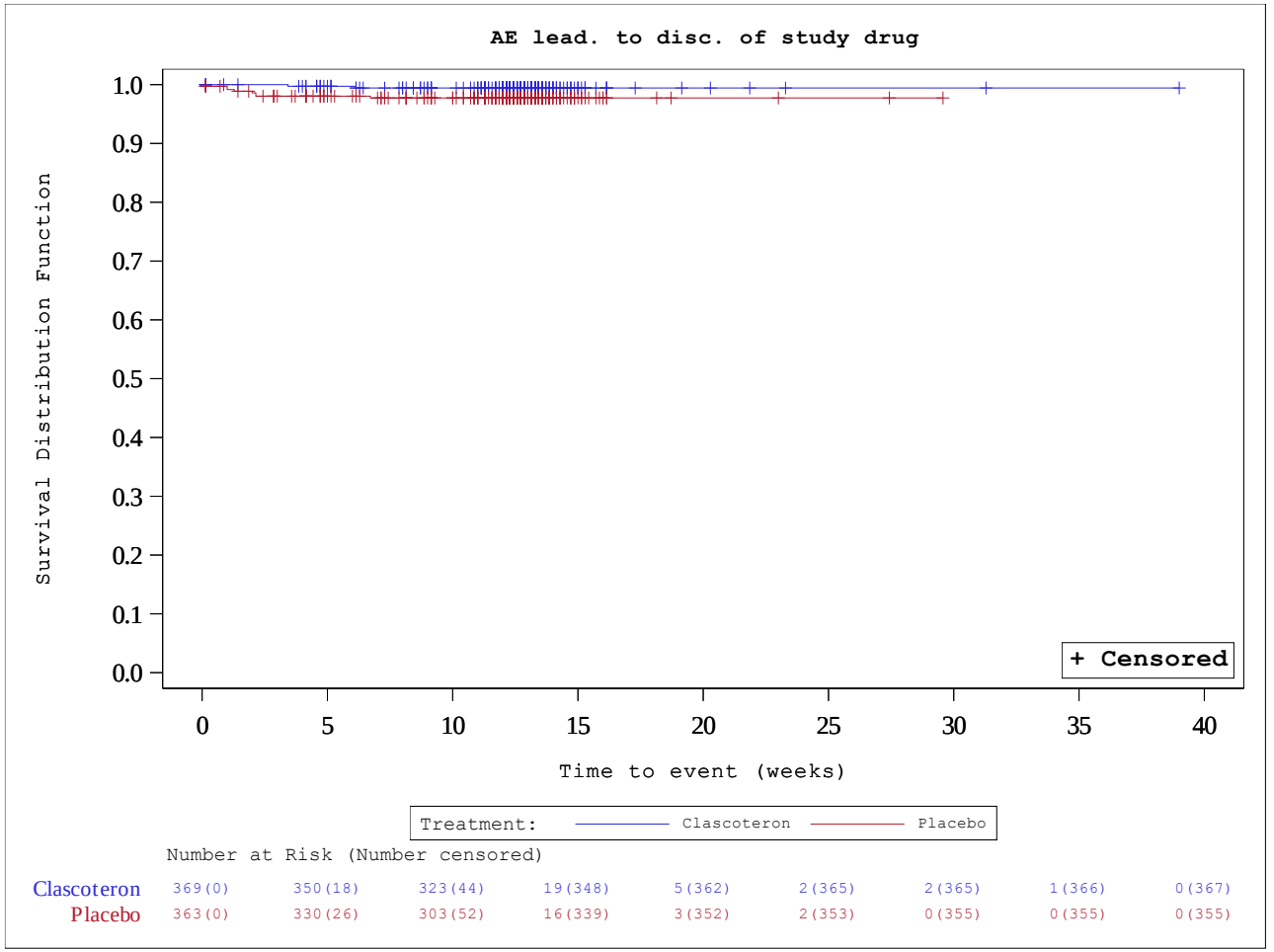
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=369) n/ N (%)	Clascoteron (N=369) Median (95% CI)	Placebo (N=363) n/ N (%)	Placebo (N=363) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	1/ 172 (0.58)	NE (NE, NE)	3/ 172 (1.74)	NE (NE, NE)			
18 - <65	1/ 197 (0.51)	NE (NE, NE)	5/ 191 (2.62)	NE (NE, NE)			
Gender							
Male	1/ 126 (0.79)	NE (NE, NE)	4/ 142 (2.82)	NE (NE, NE)			
Female	1/ 243 (0.41)	NE (NE, NE)	4/ 221 (1.81)	NE (NE, NE)			
Region							0.9997
USA	0/ 47 (0.00)	NE (NE, NE)	0/ 46 (0.00)	NE (NE, NE)	NE (NE, NE)	NE	
Europe	2/ 322 (0.62)	NE (NE, NE)	8/ 317 (2.52)	NE (NE, NE)	0.24 (0.05, 1.14)	0.0728	
IGA							
3-Moderate	1/ 305 (0.33)	NE (NE, NE)	8/ 313 (2.56)	NE (NE, NE)			
4-Severe	1/ 64 (1.56)	NE (NE, NE)	0/ 50 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events leading to discontinuation of study treatment
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment excluding disease-related events
Safety Analysis Set

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with event, n/N (%)	2/ 369 (0.54)	5/ 363 (1.38)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	0.39 (0.07, 1.99)	
p-value	0.2560	
Odds Ratio (95% CI)	0.39 (0.08, 2.02)	
p-value	0.2625	
Risk Ratio (95% CI)	0.39 (0.08, 2.02)	
p-value	0.2631	
Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
p-value	0.2468	

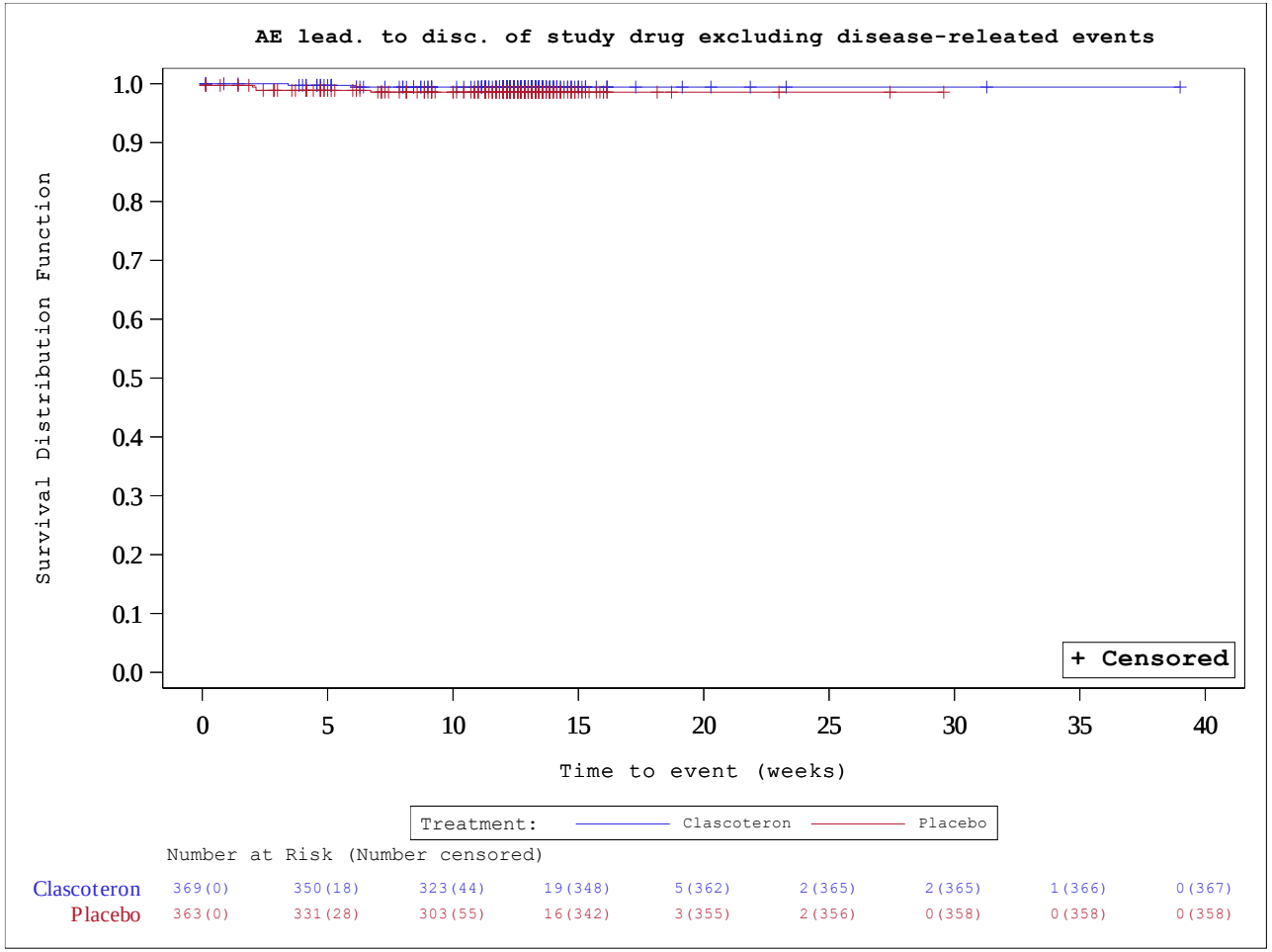
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study treatment excluding disease-related events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=369) n/ N (%)	Clascoteron (N=369) Median (95% CI)	Placebo (N=363) n/ N (%)	Placebo (N=363) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	1/ 172 (0.58)	NE (NE, NE)	2/ 172 (1.16)	NE (NE, NE)			
18 - <65	1/ 197 (0.51)	NE (NE, NE)	3/ 191 (1.57)	NE (NE, NE)			
Gender							
Male	1/ 126 (0.79)	NE (NE, NE)	3/ 142 (2.11)	NE (NE, NE)			
Female	1/ 243 (0.41)	NE (NE, NE)	2/ 221 (0.90)	NE (NE, NE)			
Region							
USA	0/ 47 (0.00)	NE (NE, NE)	0/ 46 (0.00)	NE (NE, NE)			
Europe	2/ 322 (0.62)	NE (NE, NE)	5/ 317 (1.58)	NE (NE, NE)			
IGA							
3-Moderate	1/ 305 (0.33)	NE (NE, NE)	5/ 313 (1.60)	NE (NE, NE)			
4-Severe	1/ 64 (1.56)	NE (NE, NE)	0/ 50 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events leading to discontinuation of study treatment excluding disease-related events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study
Safety Analysis Set

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with event, n/N (%)	2/ 369 (0.54)	8/ 363 (2.20)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	0.24 (0.05, 1.14)	
p-value	0.0729	
Odds Ratio (95% CI)	0.24 (0.05, 1.15)	
p-value	0.0738	
Risk Ratio (95% CI)	0.25 (0.05, 1.15)	
p-value	0.0747	
Risk Difference (95% CI)	-0.02 (-0.03, 0.00)	
p-value	0.0533	

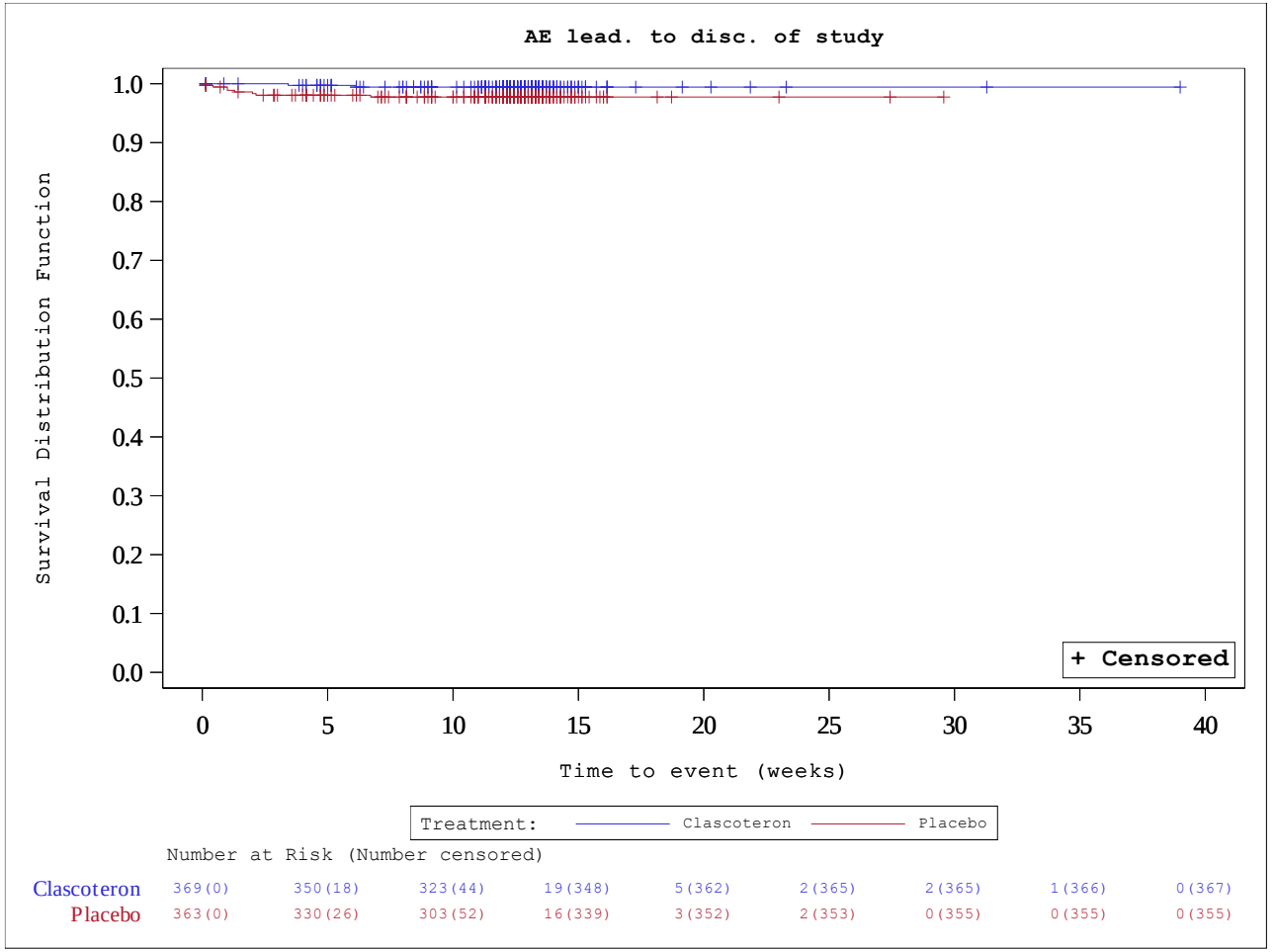
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=369) n/ N (%)	Clascoteron (N=369) Median (95% CI)	Placebo (N=363) n/ N (%)	Placebo (N=363) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	1/ 172 (0.58)	NE (NE, NE)	3/ 172 (1.74)	NE (NE, NE)			
18 - <65	1/ 197 (0.51)	NE (NE, NE)	5/ 191 (2.62)	NE (NE, NE)			
Gender							
Male	1/ 126 (0.79)	NE (NE, NE)	3/ 142 (2.11)	NE (NE, NE)			
Female	1/ 243 (0.41)	NE (NE, NE)	5/ 221 (2.26)	NE (NE, NE)			
Region							0.9997
USA	0/ 47 (0.00)	NE (NE, NE)	0/ 46 (0.00)	NE (NE, NE)	NE (NE, NE)	NE	
Europe	2/ 322 (0.62)	NE (NE, NE)	8/ 317 (2.52)	NE (NE, NE)	0.24 (0.05, 1.14)	0.0730	
IGA							
3-Moderate	1/ 305 (0.33)	NE (NE, NE)	8/ 313 (2.56)	NE (NE, NE)			
4-Severe	1/ 64 (1.56)	NE (NE, NE)	0/ 50 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events leading to discontinuation of study
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study excluding disease-related events
Safety Analysis Set

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with event, n/N (%)	2/ 369 (0.54)	5/ 363 (1.38)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	0.39 (0.08, 2.00)	
p-value	0.2568	
Odds Ratio (95% CI)	0.39 (0.08, 2.02)	
p-value	0.2625	
Risk Ratio (95% CI)	0.39 (0.08, 2.02)	
p-value	0.2631	
Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
p-value	0.2468	

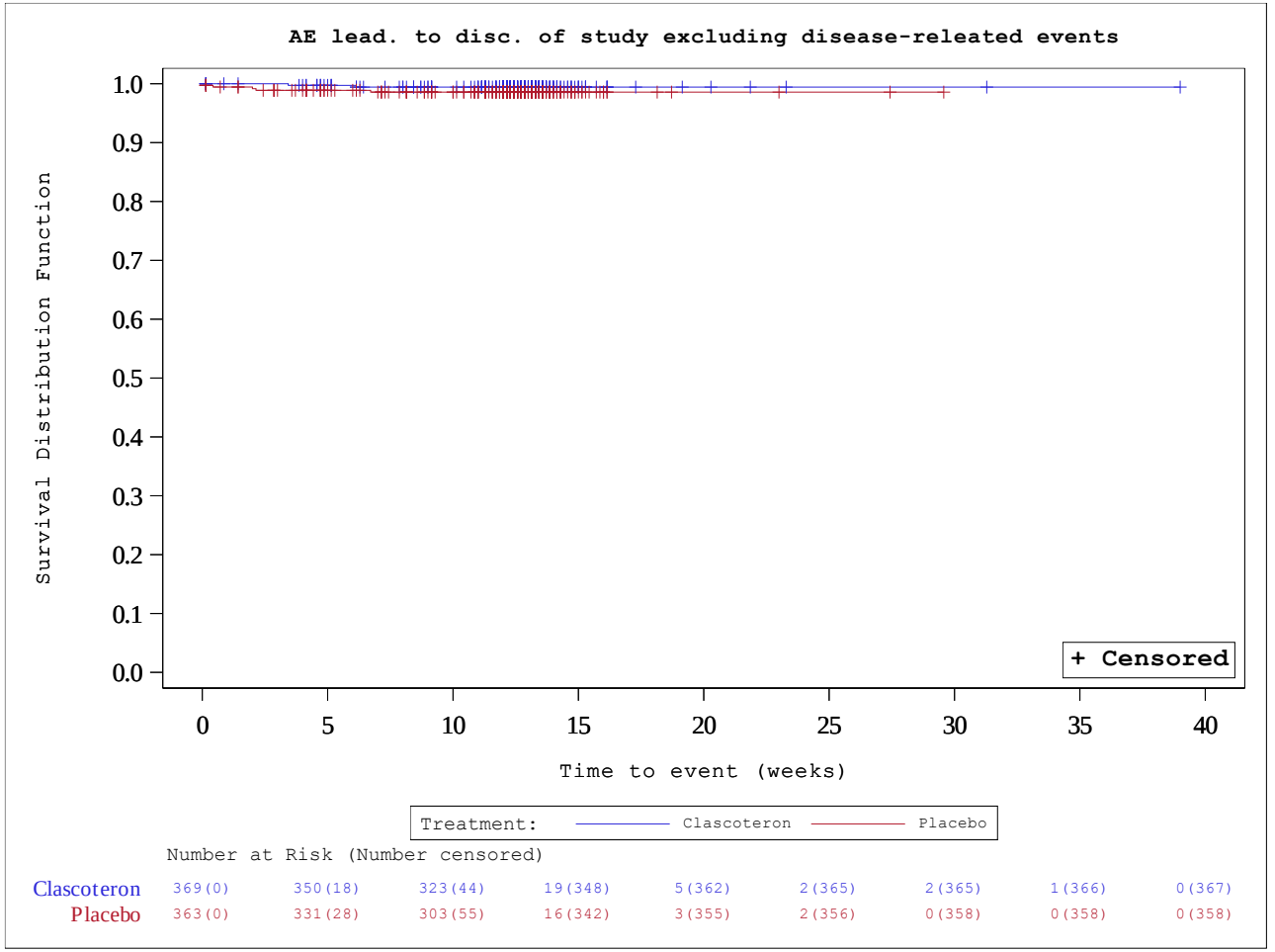
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to discontinuation of study excluding disease-related events - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=369) n/ N (%)	Clascoteron (N=369) Median (95% CI)	Placebo (N=363) n/ N (%)	Placebo (N=363) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	1/ 172 (0.58)	NE (NE, NE)	2/ 172 (1.16)	NE (NE, NE)			
18 - <65	1/ 197 (0.51)	NE (NE, NE)	3/ 191 (1.57)	NE (NE, NE)			
Gender							
Male	1/ 126 (0.79)	NE (NE, NE)	2/ 142 (1.41)	NE (NE, NE)			
Female	1/ 243 (0.41)	NE (NE, NE)	3/ 221 (1.36)	NE (NE, NE)			
Region							
USA	0/ 47 (0.00)	NE (NE, NE)	0/ 46 (0.00)	NE (NE, NE)			
Europe	2/ 322 (0.62)	NE (NE, NE)	5/ 317 (1.58)	NE (NE, NE)			
IGA							
3-Moderate	1/ 305 (0.33)	NE (NE, NE)	5/ 313 (1.60)	NE (NE, NE)			
4-Severe	1/ 64 (1.56)	NE (NE, NE)	0/ 50 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with Adverse Events leading to discontinuation of study excluding disease-related events
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to death
Safety Analysis Set

	Clascoteron (N=369)	Placebo (N=363)
Number of subjects with event, n/N (%)	0/ 369 (0.00)	0/ 363 (0.00)
Kaplan-Meier estimates of Time to Event (weeks)		
25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis Clascoteron vs. Placebo		
Hazard Ratio (95% CI)	NE	
p-value	NE	
Odds Ratio (95% CI)	NE	
p-value	NE	
Risk Ratio (95% CI)	NE	
p-value	NE	
Risk Difference (95% CI)	NE	
p-value	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; HR= Hazard Ratio NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with Adverse Events leading to death - Subgroup analysis
Safety Analysis Set

Subgroup Level	Clascoteron (N=369) n/ N (%)	Clascoteron (N=369) Median (95% CI)	Placebo (N=363) n/ N (%)	Placebo (N=363) Median (95% CI)	Hazard Ratio (95% CI)	p-Value	Interaction p-Value
Age (years)							
9 - <18	0/ 172 (0.00)	NE (NE, NE)	0/ 172 (0.00)	NE (NE, NE)			
18 - <65	0/ 197 (0.00)	NE (NE, NE)	0/ 191 (0.00)	NE (NE, NE)			
Gender							
Male	0/ 126 (0.00)	NE (NE, NE)	0/ 142 (0.00)	NE (NE, NE)			
Female	0/ 243 (0.00)	NE (NE, NE)	0/ 221 (0.00)	NE (NE, NE)			
Region							
USA	0/ 47 (0.00)	NE (NE, NE)	0/ 46 (0.00)	NE (NE, NE)			
Europe	0/ 322 (0.00)	NE (NE, NE)	0/ 317 (0.00)	NE (NE, NE)			
IGA							
3-Moderate	0/ 305 (0.00)	NE (NE, NE)	0/ 313 (0.00)	NE (NE, NE)			
4-Severe	0/ 64 (0.00)	NE (NE, NE)	0/ 50 (0.00)	NE (NE, NE)			

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval;NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	3/ 369 (0.81)	13/ 363 (3.58)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	0.22 (0.06, 0.78)	
	p-value	0.0187	
	Odds Ratio (95% CI)	0.22 (0.06, 0.78)	
	p-value	0.0191	
	Risk Ratio (95% CI)	0.23 (0.07, 0.79)	
	p-value	0.0198	
	Risk Difference (95% CI)	-0.03 (-0.05, -0.01)	
	p-value	0.0105	

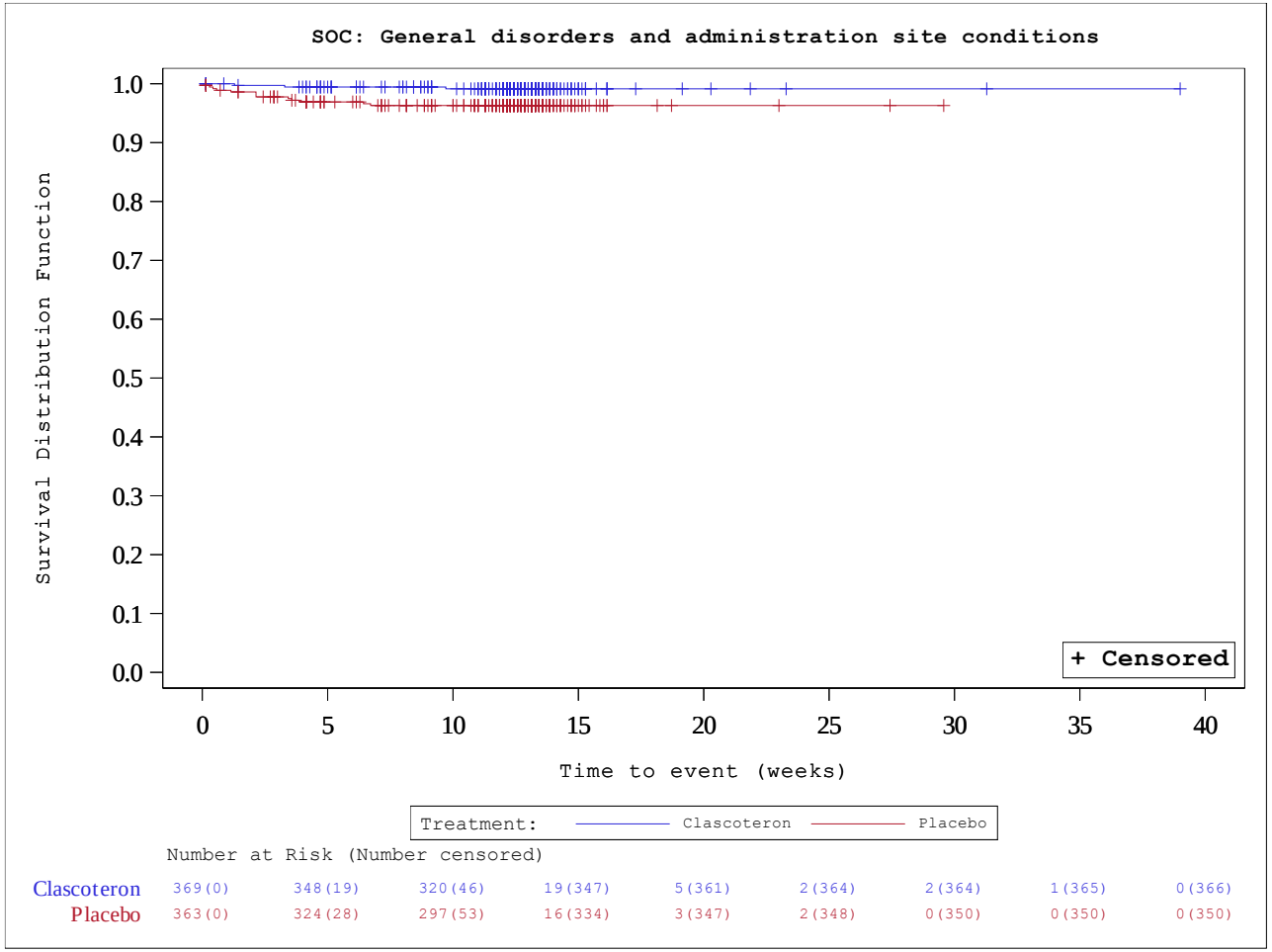
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: Infections and infestations	Number of subjects with event, n/N (%)	19/ 369 (5.15)	18/ 363 (4.96)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	1.00 (0.53, 1.91)	
	p-value	0.9907	
	Odds Ratio (95% CI)	1.04 (0.54, 2.02)	
	p-value	0.9064	
	Risk Ratio (95% CI)	1.04 (0.55, 1.95)	
	p-value	0.9064	
	Risk Difference (95% CI)	0.00 (-0.03, 0.03)	
	p-value	0.9064	

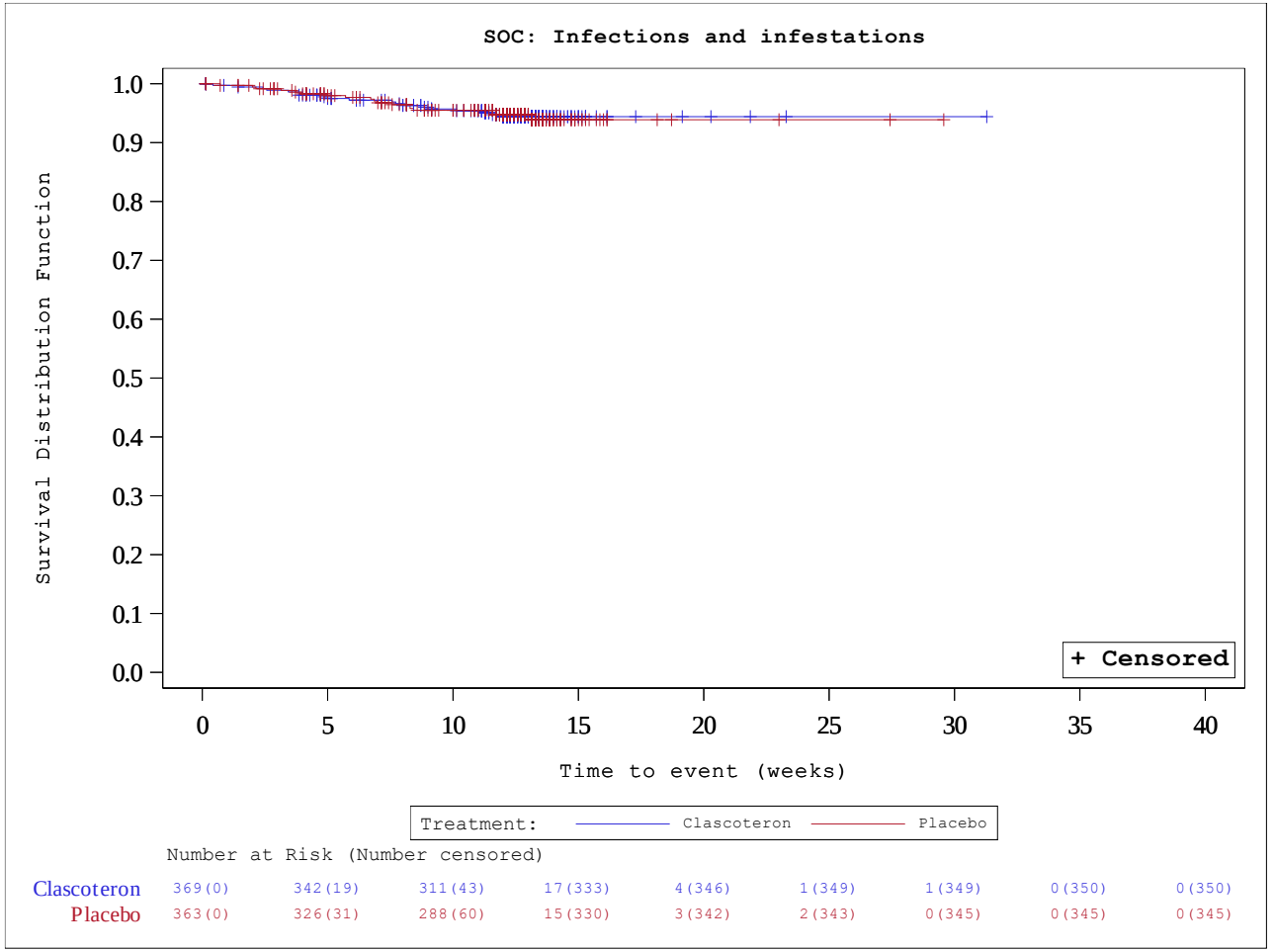
Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
&set.



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm)
&set.



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) - Subgroup analysis
Safety Analysis Set

	Subgroup	Clascoteron (N=369)		Placebo (N=363)				Interaction
	Level	n/ N (%)	Median (95% CI)	n/ N (%)	Median (95% CI)	Hazard Ratio (95% CI)	p-Value	p-Value
SOC: General disorders and administration site conditions	Age (years)							0.9899
	9 - <18	0/ 172 (0.00)	NE (NE, NE)	4/ 172 (2.33)	NE (NE, NE)	NE (NE, NE)	NE	
	18 - <65	3/ 197 (1.52)	NE (NE, NE)	9/ 191 (4.71)	NE (NE, NE)	0.31 (0.08, 1.16)	0.0820	
	Gender							0.9904
	Male	0/ 126 (0.00)	NE (NE, NE)	5/ 142 (3.52)	NE (NE, NE)	NE (NE, NE)	NE	
	Female	3/ 243 (1.23)	NE (NE, NE)	8/ 221 (3.62)	NE (NE, NE)	0.33 (0.09, 1.26)	0.1051	
	Region							0.9996
	USA	0/ 47 (0.00)	NE (NE, NE)	0/ 46 (0.00)	NE (NE, NE)	NE (NE, NE)	NE	
	Europe	3/ 322 (0.93)	NE (NE, NE)	13/ 317 (4.10)	NE (NE, NE)	0.22 (0.06, 0.78)	0.0188	
	IGA							0.9898
	3-Moderate	2/ 305 (0.66)	NE (NE, NE)	13/ 313 (4.15)	NE (NE, NE)	0.15 (0.03, 0.68)	0.0140	
	4-Severe	1/ 64 (1.56)	NE (NE, NE)	0/ 50 (0.00)	NE (NE, NE)	NE (NE, NE)	NE	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.
Subgroup analysis only for SOC / PT with significant overall treatment effect based on Hazard Ratio (alpha=0.05).
Quartiles based on Kaplan-Meier estimates. Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate..
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Serious Adverse Event by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

---- NO OBSERVATION FOR THE REPORT ----

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Severe Adverse Event (CTCAE Grade >=3) by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm)
Safety Analysis Set

---- NO OBSERVATION FOR THE REPORT ----

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: General disorders and administration site conditions	Number of subjects with event, n/N (%)	0/ 369 (0.00)	4/ 363 (1.10)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.11 (0.01, 2.02)	
	p-value	0.1361	
	Risk Ratio (95% CI)	0.11 (0.01, 2.02)	
	p-value	0.1371	
	Risk Difference (95% CI)	-0.01 (-0.02, -0.00)	
	p-value	0.0443	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: General disorders and administration site conditions, PT: Application site erythema	Number of subjects with event, n/N (%)	0/ 369 (0.00)	2/ 363 (0.55)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.20 (0.01, 4.09)	
	p-value	0.2929	
	Risk Ratio (95% CI)	0.20 (0.01, 4.08)	
	p-value	0.2934	
	Risk Difference (95% CI)	-0.01 (-0.01, 0.00)	
	p-value	0.1562	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: General disorders and administration site conditions, PT: Application site nodule	Number of subjects with event, n/N (%)	0/ 369 (0.00)	1/ 363 (0.28)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.33 (0.01, 8.05)	
	p-value	0.4941	
	Risk Ratio (95% CI)	0.33 (0.01, 8.02)	
	p-value	0.4943	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: General disorders and administration site conditions, PT: Application site pain	Number of subjects with event, n/N (%)	0/ 369 (0.00)	1/ 363 (0.28)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.33 (0.01, 8.05)	
	p-value	0.4941	
	Risk Ratio (95% CI)	0.33 (0.01, 8.02)	
	p-value	0.4943	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: General disorders and administration site conditions, PT: Application site pruritus	Number of subjects with event, n/N (%)	0/ 369 (0.00)	2/ 363 (0.55)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.20 (0.01, 4.09)	
	p-value	0.2929	
	Risk Ratio (95% CI)	0.20 (0.01, 4.08)	
	p-value	0.2934	
	Risk Difference (95% CI)	-0.01 (-0.01, 0.00)	
	p-value	0.1562	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with event, n/N (%)	2/ 369 (0.54)	4/ 363 (1.10)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	0.49 (0.09, 2.65)	
	p-value	0.4044	
	Odds Ratio (95% CI)	0.49 (0.09, 2.69)	
	p-value	0.4106	
	Risk Ratio (95% CI)	0.49 (0.09, 2.67)	
	p-value	0.4109	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.01)	
	p-value	0.4020	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: Skin and subcutaneous tissue disorders, PT: Acne	Number of subjects with event, n/N (%)	0/ 369 (0.00)	3/ 363 (0.83)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.14 (0.01, 2.71)	
	p-value	0.1930	
	Risk Ratio (95% CI)	0.14 (0.01, 2.71)	
	p-value	0.1938	
	Risk Difference (95% CI)	-0.01 (-0.02, 0.00)	
	p-value	0.0820	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: Skin and subcutaneous tissue disorders, PT: Dermatitis contact	Number of subjects with event, n/N (%)	1/ 369 (0.27)	0/ 363 (0.00)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	2.96 (0.12, 72.88)	
	p-value	0.5069	
	Risk Ratio (95% CI)	2.95 (0.12, 72.21)	
	p-value	0.5071	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3167	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: Skin and subcutaneous tissue disorders, PT: Hair colour changes	Number of subjects with event, n/N (%)	1/ 369 (0.27)	0/ 363 (0.00)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	2.96 (0.12, 72.88)	
	p-value	0.5069	
	Risk Ratio (95% CI)	2.95 (0.12, 72.21)	
	p-value	0.5071	
	Risk Difference (95% CI)	0.00 (-0.00, 0.01)	
	p-value	0.3167	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Analysis of Proportion of patients with frequent Adverse Event leading to discontinuation by SOC and PT
Safety Analysis Set

SOC / PT		Clascoteron (N=369)	Placebo (N=363)
SOC: Skin and subcutaneous tissue disorders, PT: Skin irritation	Number of subjects with event, n/N (%)	0/ 369 (0.00)	1/ 363 (0.28)
	Kaplan-Meier estimates of Time to Event (weeks)		
	25%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	75%-ile (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis Clascoteron vs. Placebo		
	Hazard Ratio (95% CI)	NE	
	p-value	NE	
	Odds Ratio (95% CI)	0.33 (0.01, 8.05)	
	p-value	0.4941	
	Risk Ratio (95% CI)	0.33 (0.01, 8.02)	
	p-value	0.4943	
	Risk Difference (95% CI)	-0.00 (-0.01, 0.00)	
	p-value	0.3166	

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
Quartiles based on Kaplan-Meier estimates.
Hazard ratio and p-Value based on Cox proportional hazards model with treatment as covariate.;
n=Number of patients with event; N=Number of patients included in the analysis; CI=Confidence Interval; NE=Not estimable.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
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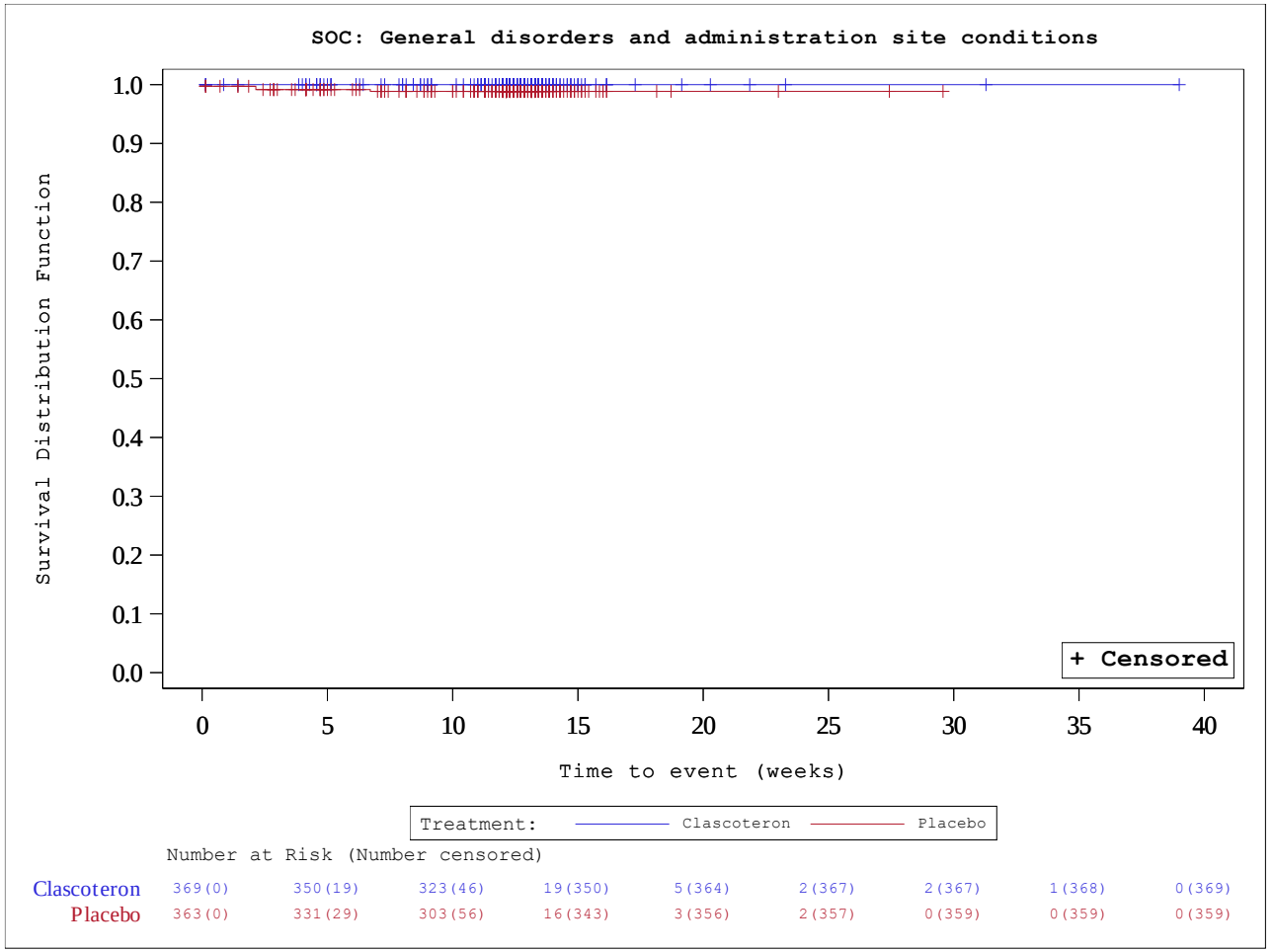

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
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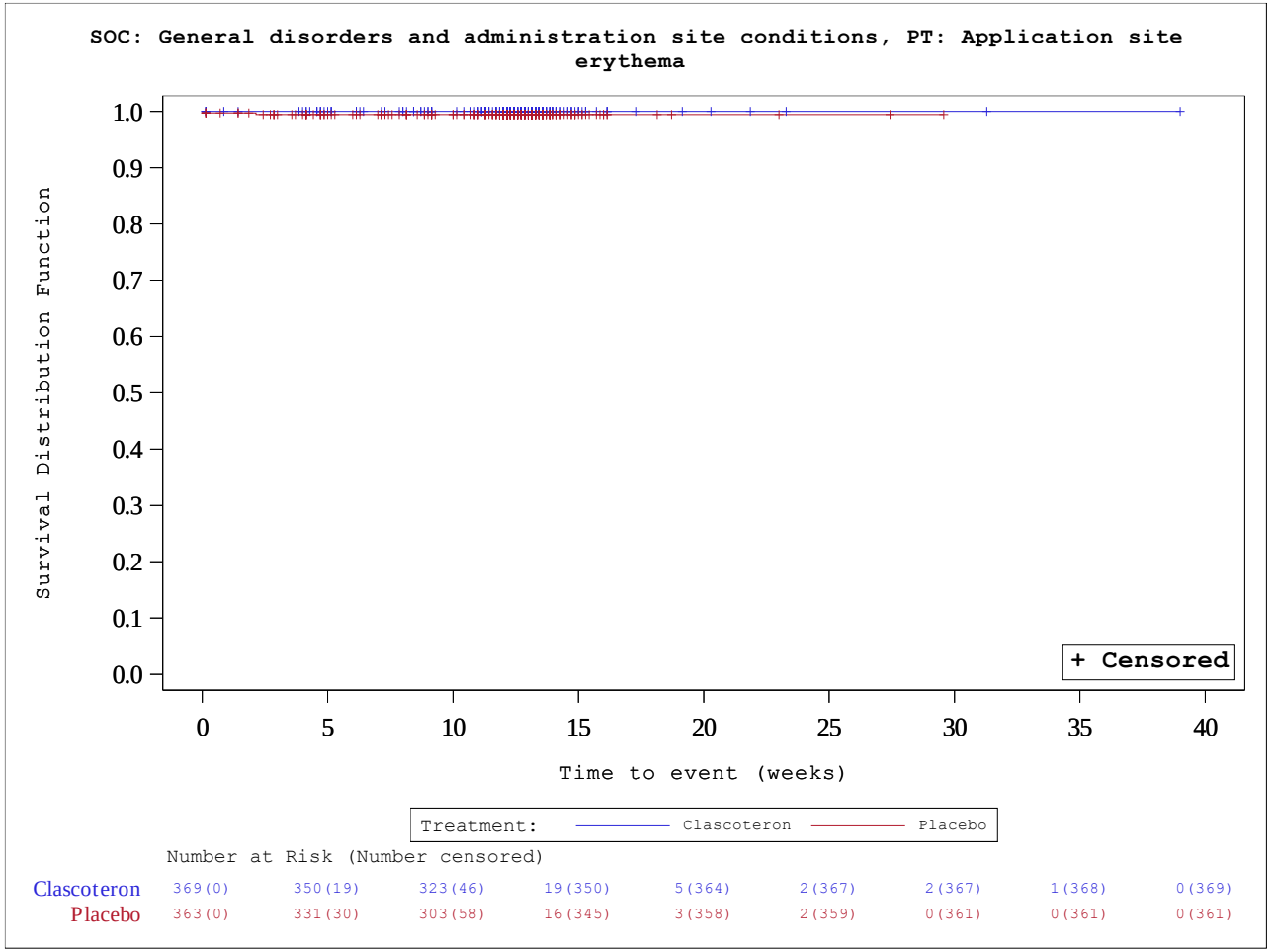

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
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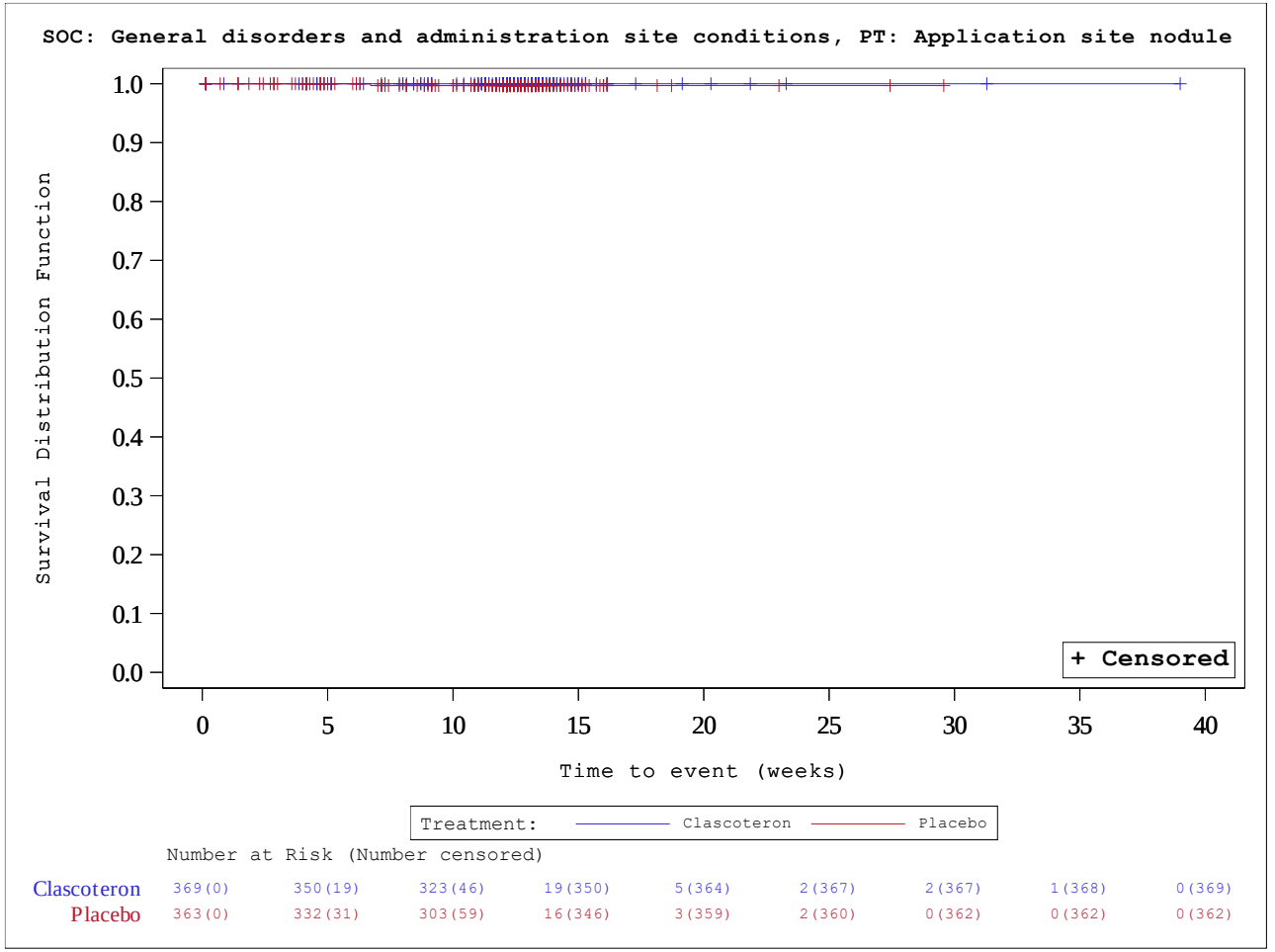

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
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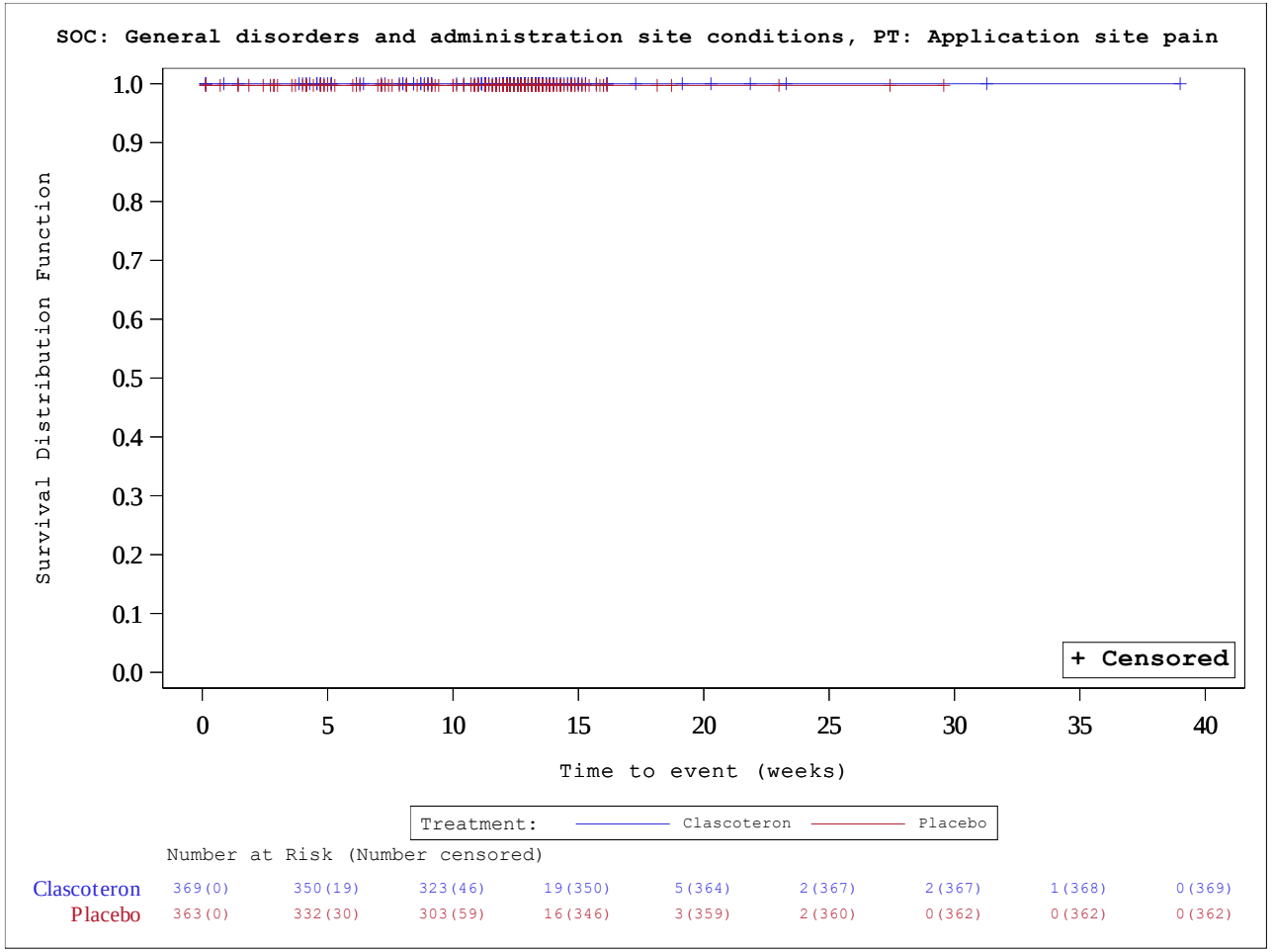

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
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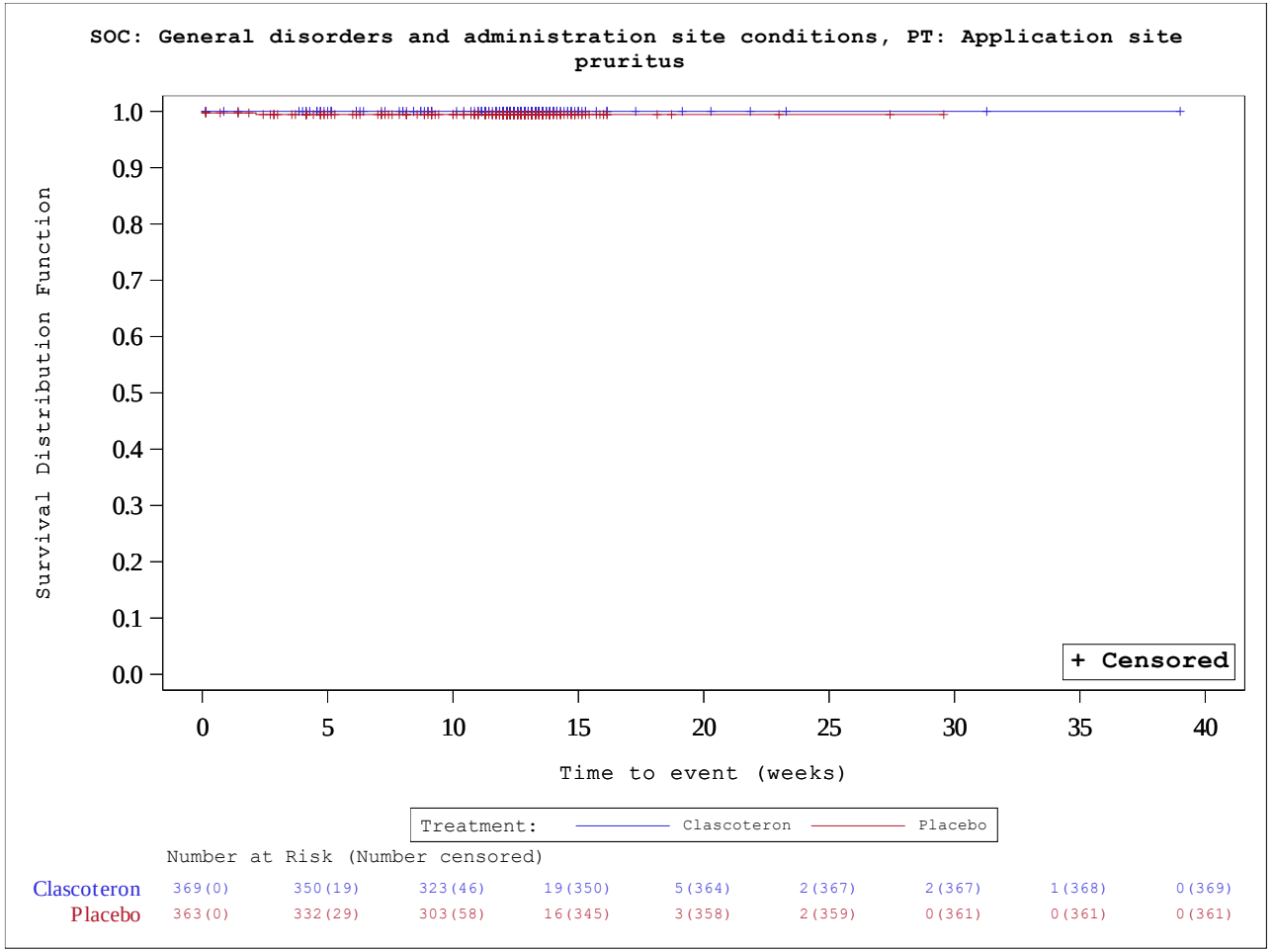

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
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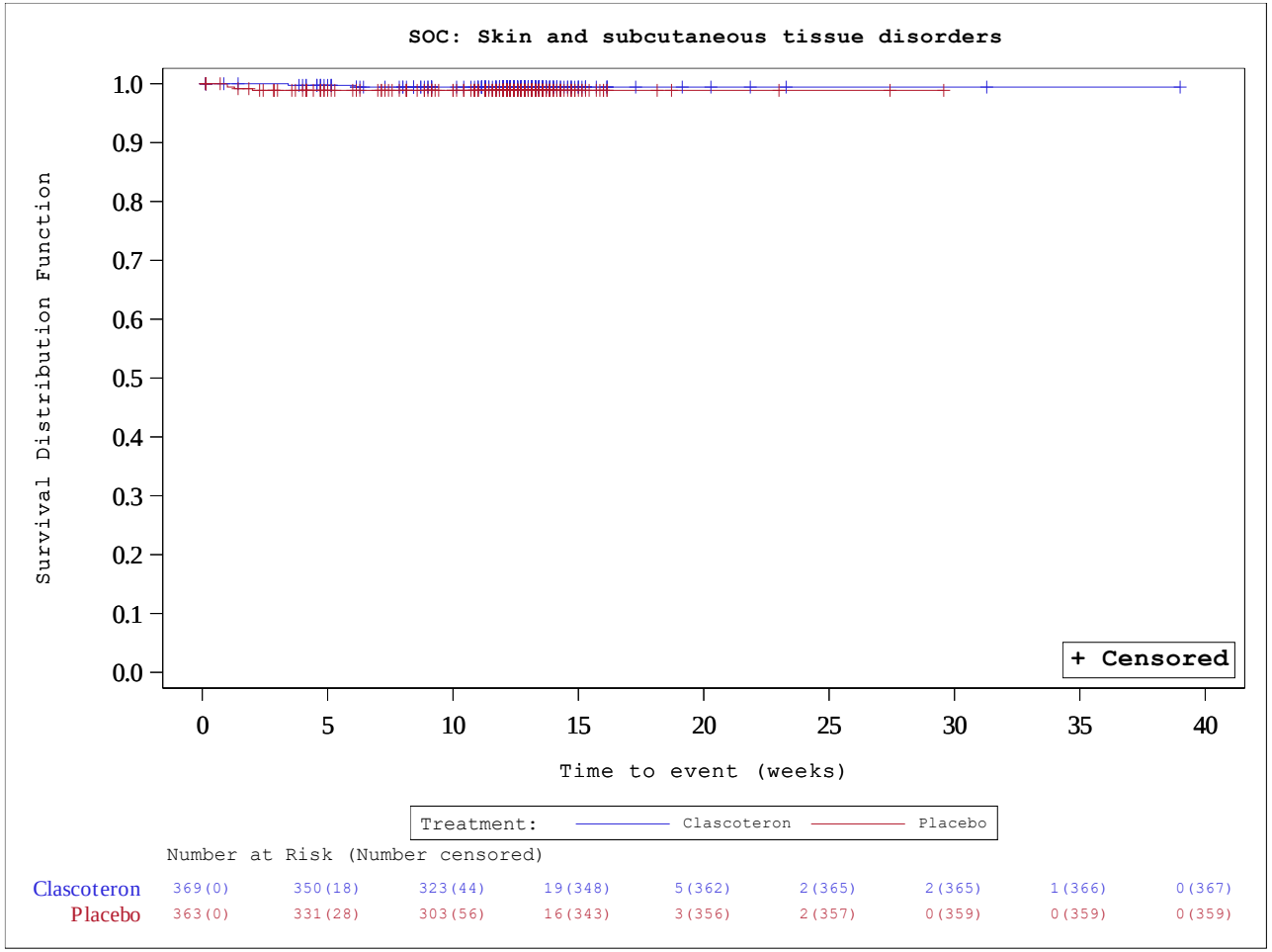

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
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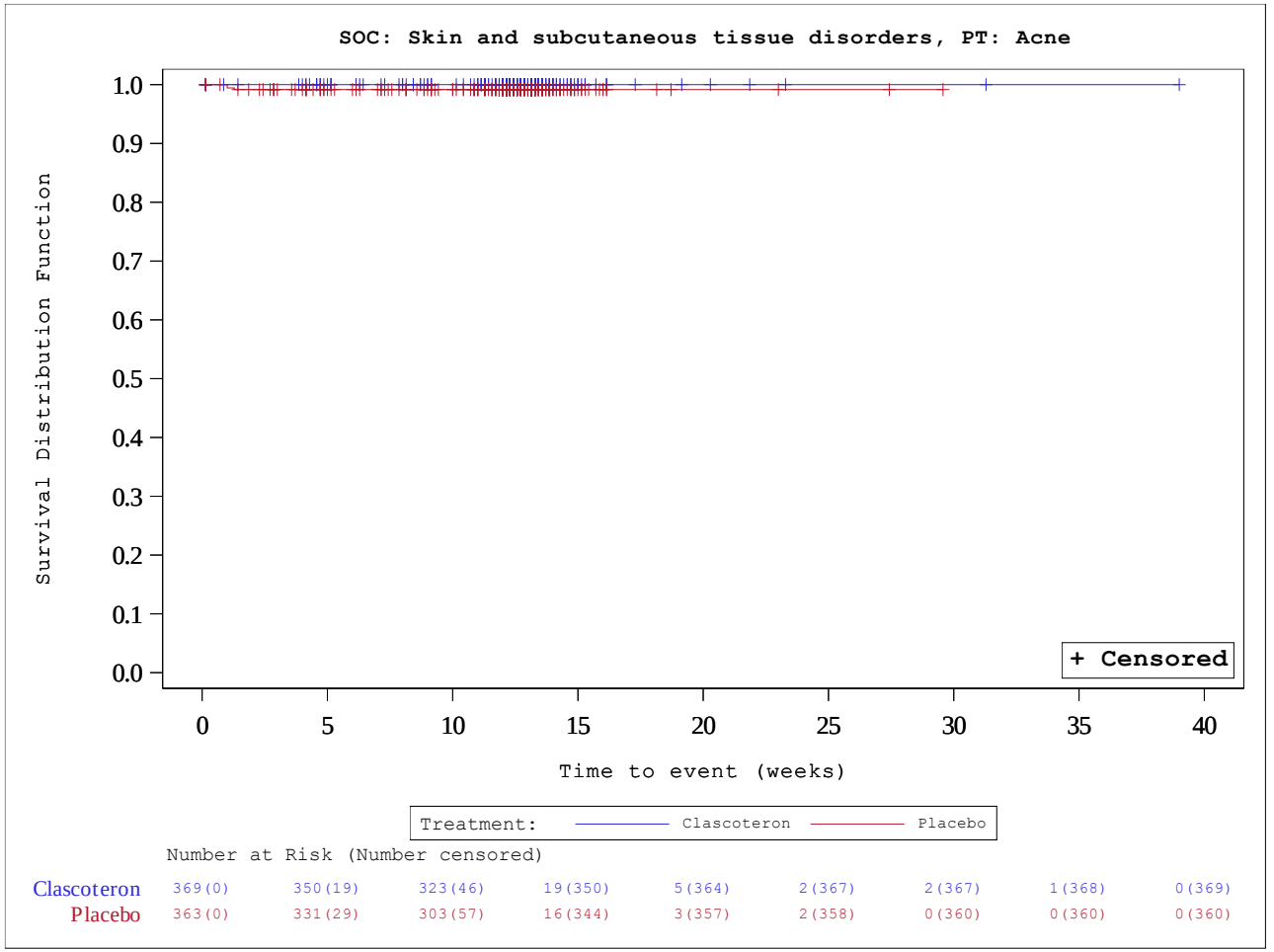

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
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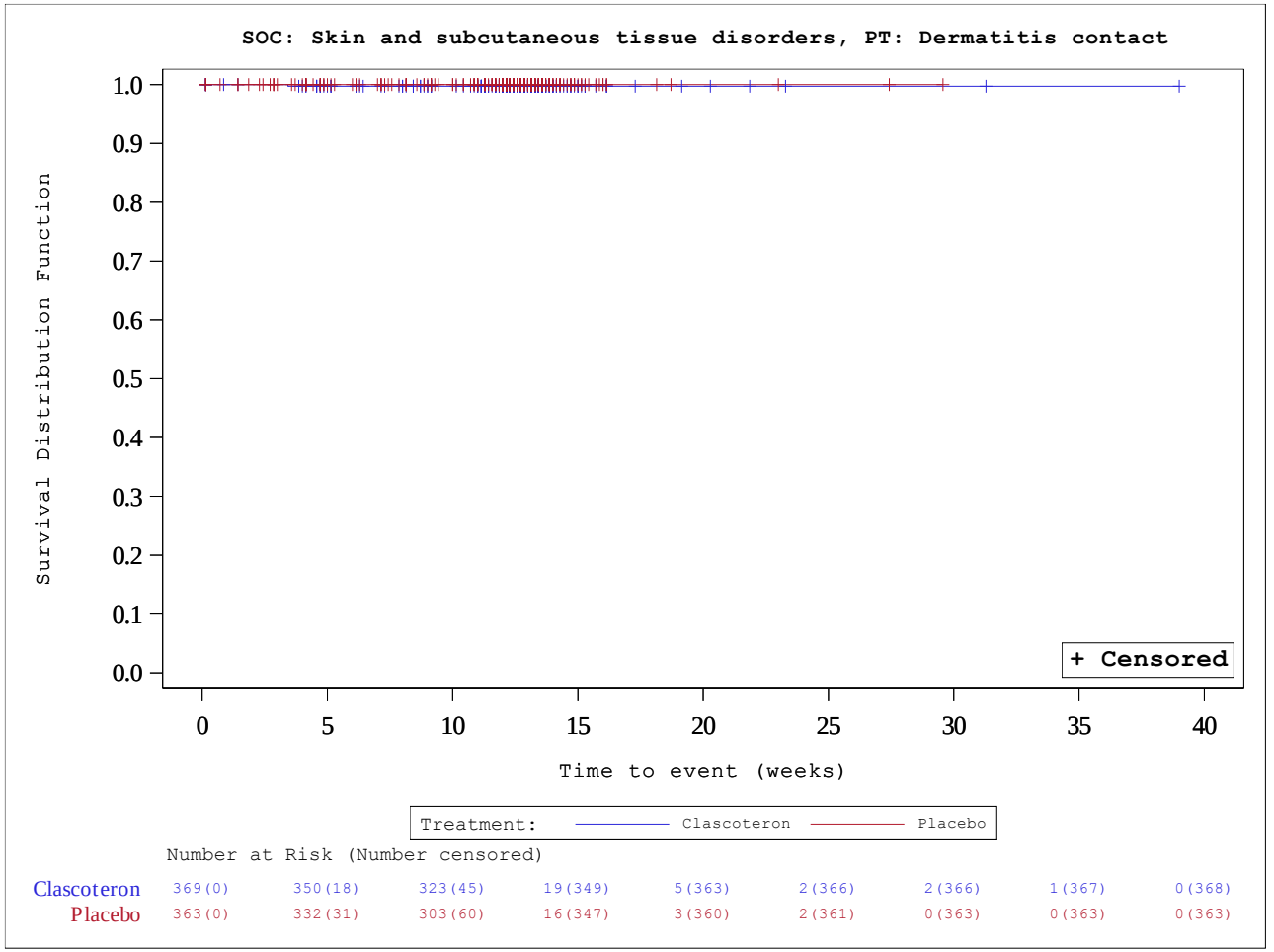

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
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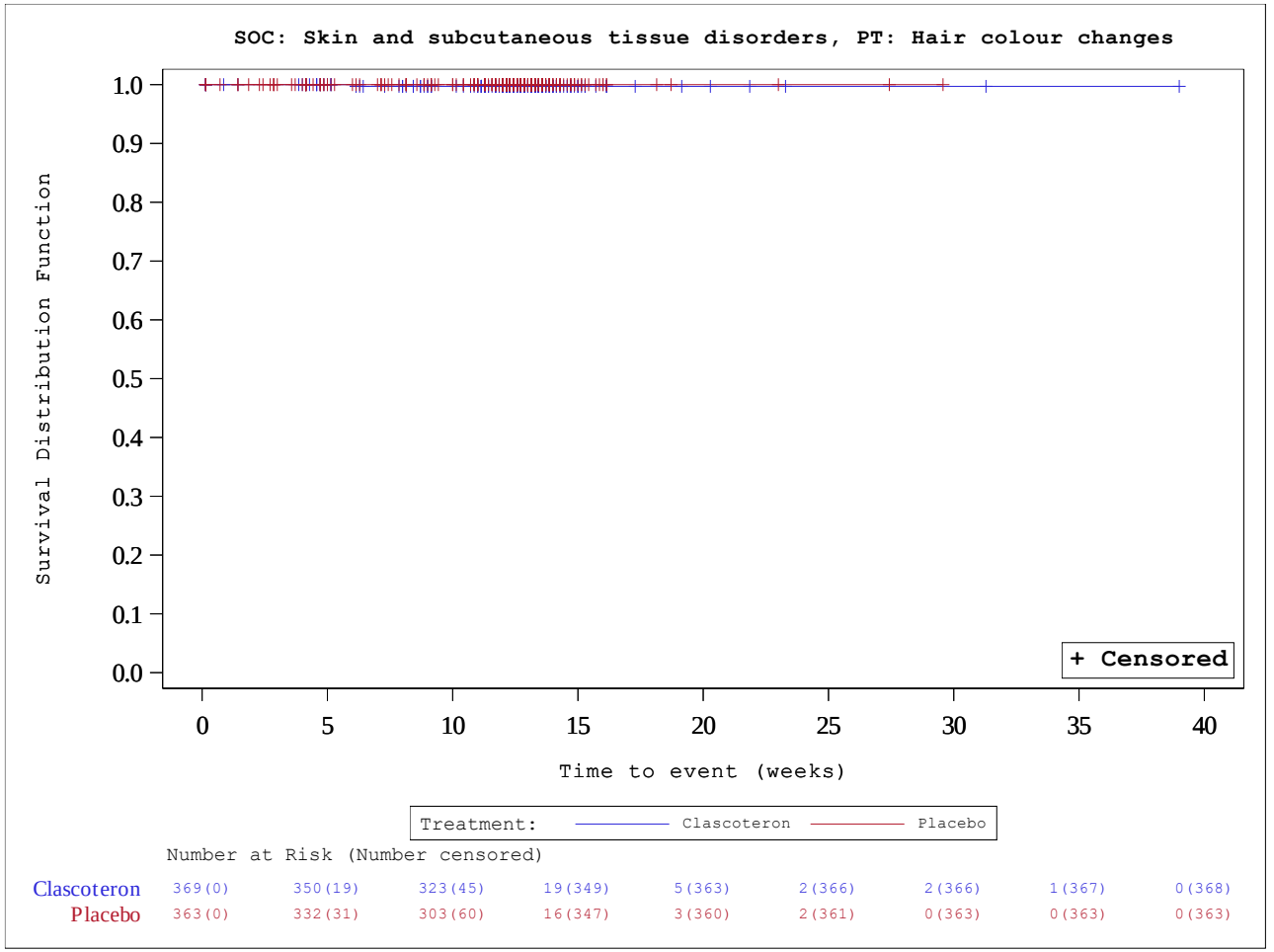
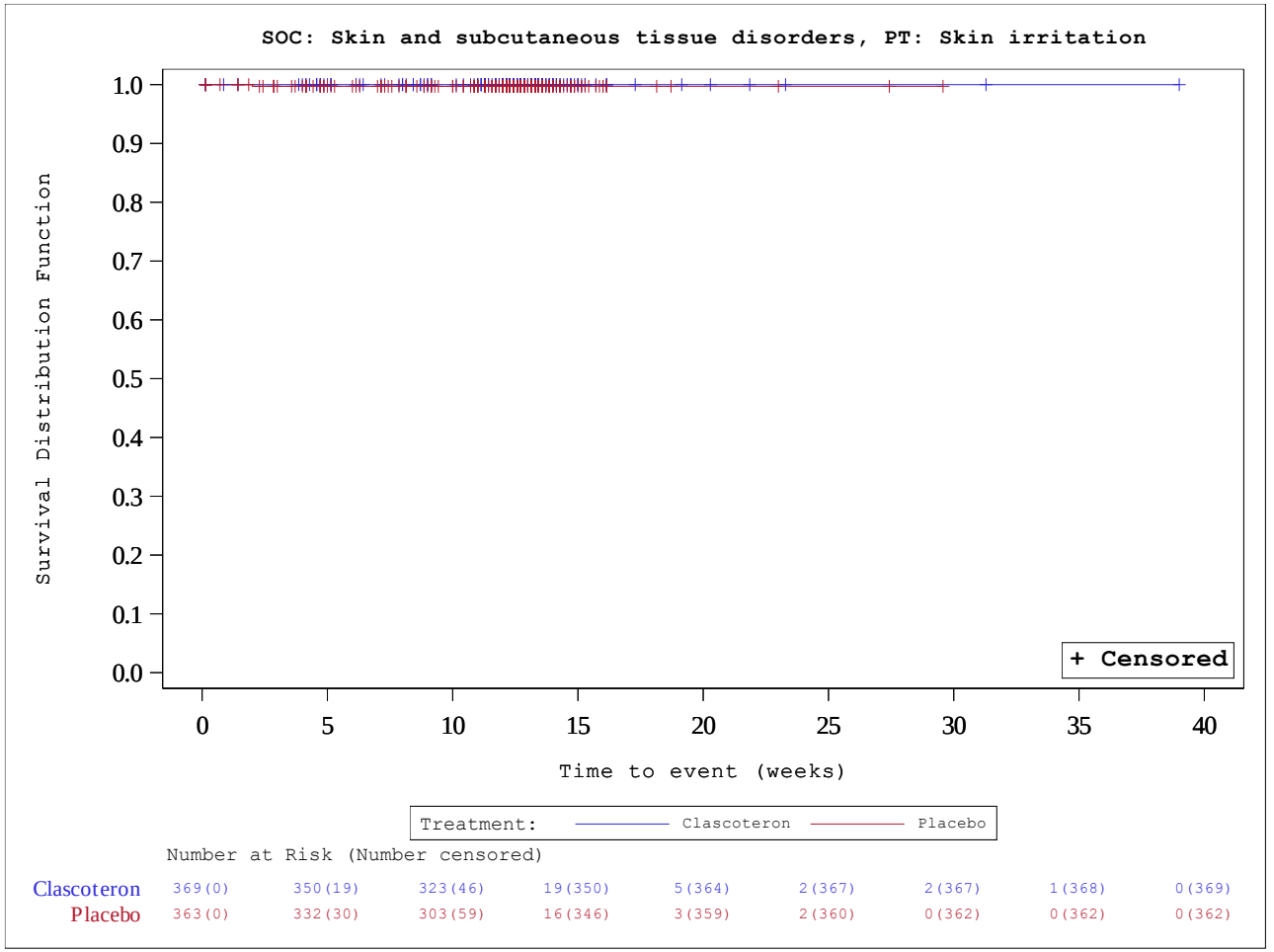


Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Kaplan-Meier Plot of patients with frequent Adverse Event leading to discontinuation by SOC and PT
&set.



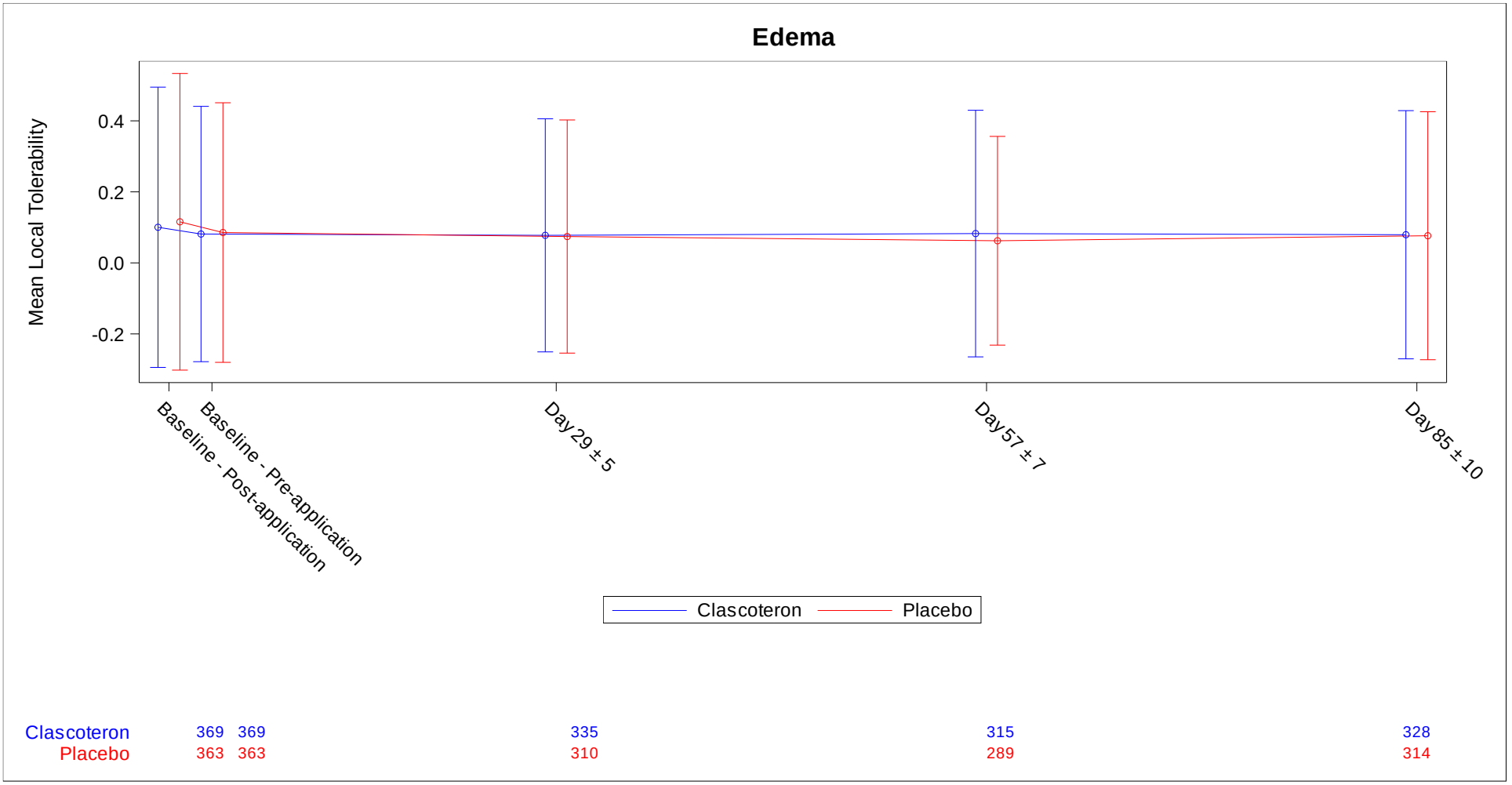
Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Edema
Safety Analysis Set

		Clascoteron (N=369) n (%)	Placebo (N=363) n (%)
Baseline - Pre-application	0-None	342 (92.7)	334 (92.0)
	1-Minimal	19 (5.1)	16 (4.4)
	2-Mild	6 (1.6)	13 (3.6)
	3-Moderate	2 (0.5)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	347 (94.0)	342 (94.2)
	1-Minimal	16 (4.3)	11 (3.0)
	2-Mild	4 (1.1)	10 (2.8)
	3-Moderate	2 (0.5)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	314 (85.1)	293 (80.7)
	1-Minimal	17 (4.6)	11 (3.0)
	2-Mild	3 (0.8)	6 (1.7)
	3-Moderate	1 (0.3)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	34 (9.2)	53 (14.6)
Day 57 ± 7	0-None	295 (79.9)	275 (75.8)
	1-Minimal	15 (4.1)	10 (2.8)
	2-Mild	4 (1.1)	4 (1.1)
	3-Moderate	1 (0.3)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	54 (14.6)	74 (20.4)
Day 85 ± 10	0-None	310 (84.0)	297 (81.8)
	1-Minimal	10 (2.7)	11 (3.0)
	2-Mild	8 (2.2)	5 (1.4)
	3-Moderate	0 (0.0)	1 (0.3)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	41 (11.1)	49 (13.5)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Edema
Safety Analysis Set

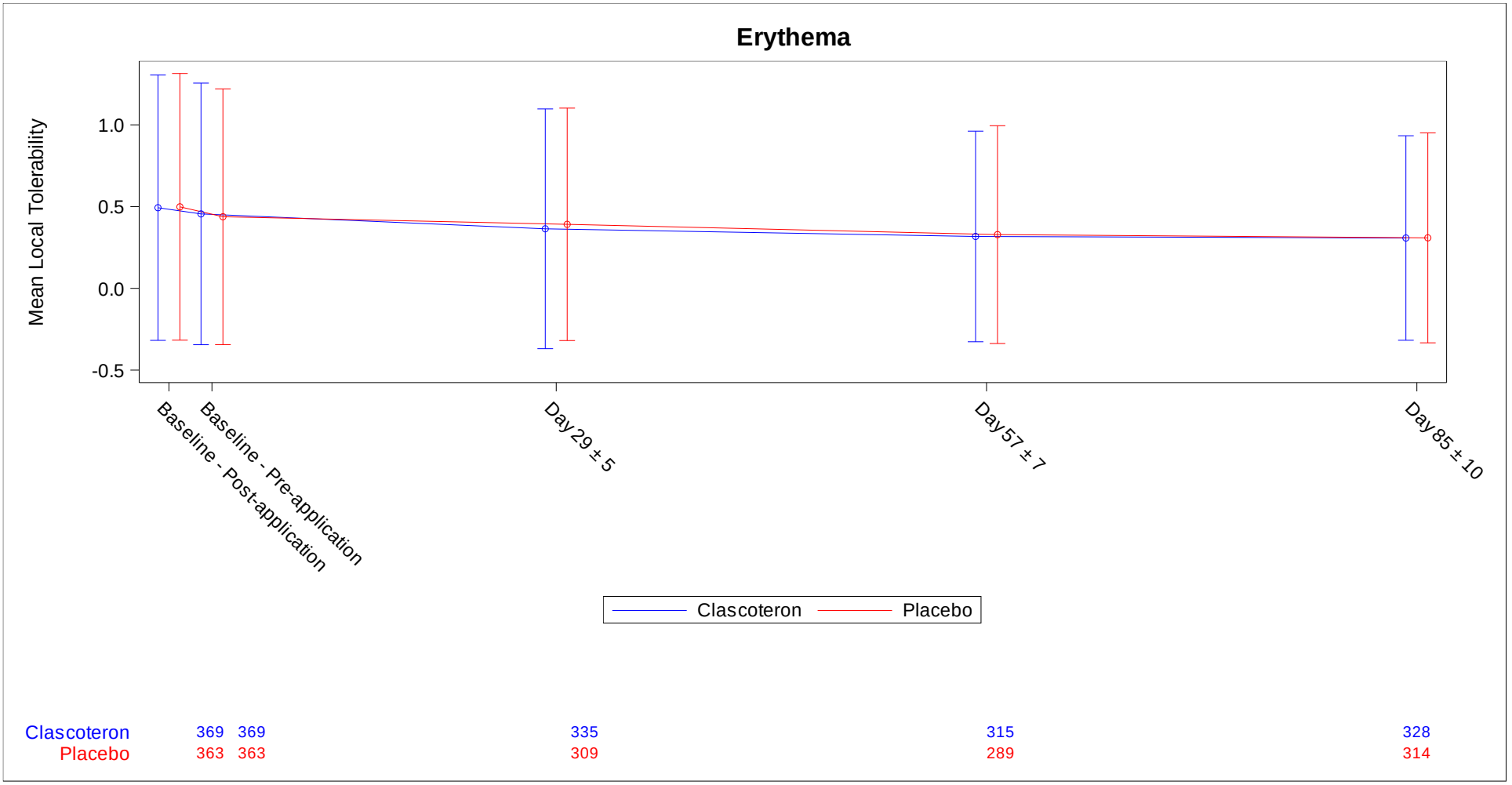


InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Erythema
Safety Analysis Set

		Clascoteron (N=369) n (%)	Placebo (N=363) n (%)
Baseline - Pre-application	0-None	246 (66.7)	243 (66.9)
	1-Minimal	79 (21.4)	72 (19.8)
	2-Mild	30 (8.1)	36 (9.9)
	3-Moderate	13 (3.5)	11 (3.0)
	4-Severe	1 (0.3)	1 (0.3)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	259 (70.2)	258 (71.1)
	1-Minimal	65 (17.6)	62 (17.1)
	2-Mild	33 (8.9)	33 (9.1)
	3-Moderate	11 (3.0)	9 (2.5)
	4-Severe	1 (0.3)	1 (0.3)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	255 (69.1)	223 (61.4)
	1-Minimal	47 (12.7)	57 (15.7)
	2-Mild	24 (6.5)	23 (6.3)
	3-Moderate	9 (2.4)	6 (1.7)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	34 (9.2)	54 (14.9)
Day 57 ± 7	0-None	241 (65.3)	222 (61.2)
	1-Minimal	53 (14.4)	43 (11.8)
	2-Mild	16 (4.3)	20 (5.5)
	3-Moderate	5 (1.4)	4 (1.1)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	54 (14.6)	74 (20.4)
Day 85 ± 10	0-None	253 (68.6)	243 (66.9)
	1-Minimal	52 (14.1)	50 (13.8)
	2-Mild	20 (5.4)	16 (4.4)
	3-Moderate	3 (0.8)	5 (1.4)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	41 (11.1)	49 (13.5)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Erythema
Safety Analysis Set



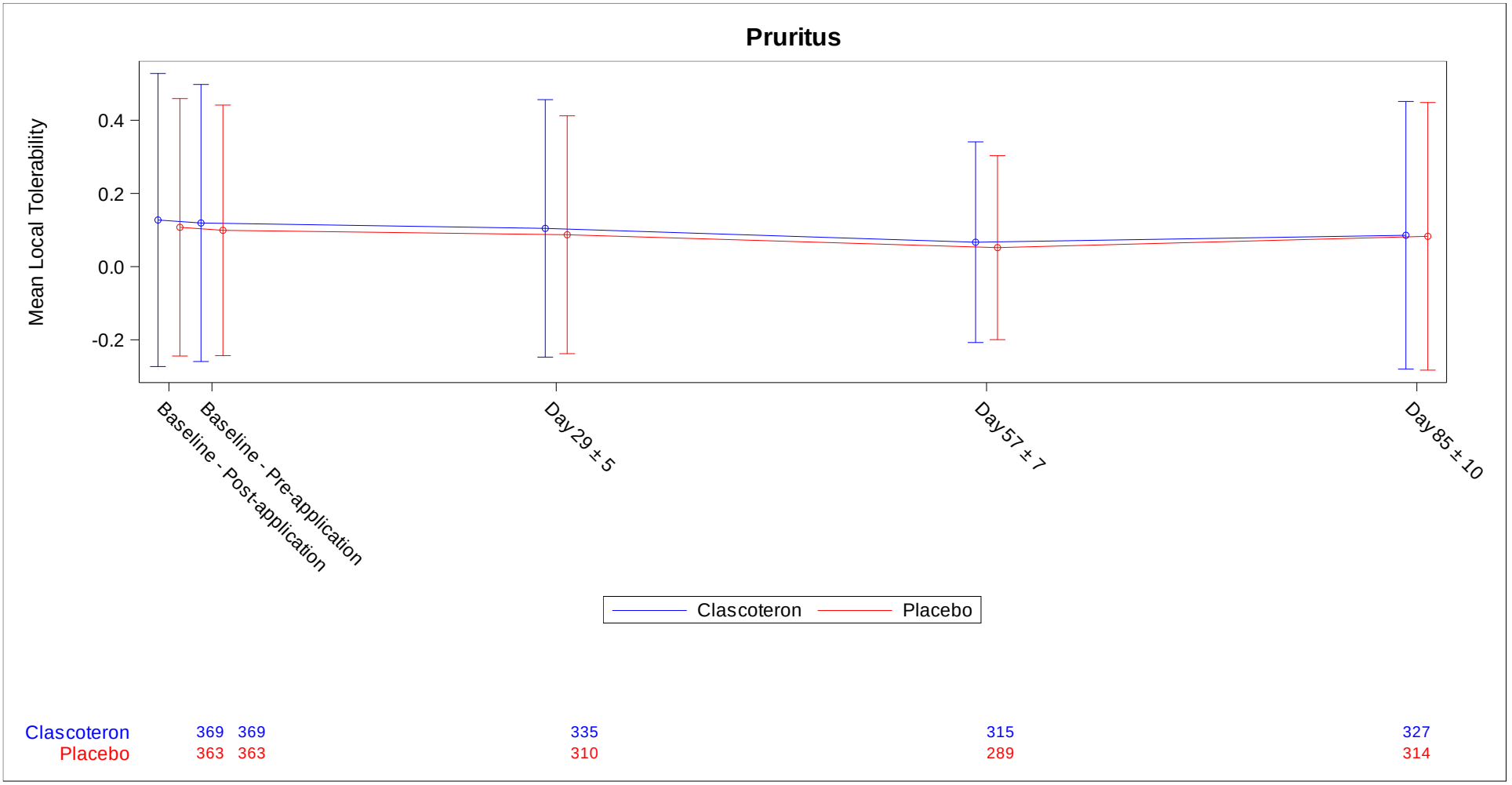
Clascoteron	369	369	335	315	328
Placebo	363	363	309	289	314

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Pruritus
Safety Analysis Set

		Clascoteron (N=369) n (%)	Placebo (N=363) n (%)
Baseline - Pre-application	0-None	331 (89.7)	329 (90.6)
	1-Mild	29 (7.9)	29 (8.0)
	2-Moderate	9 (2.4)	5 (1.4)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	332 (90.0)	332 (91.5)
	1-Mild	30 (8.1)	26 (7.2)
	2-Moderate	7 (1.9)	5 (1.4)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	305 (82.7)	287 (79.1)
	1-Mild	25 (6.8)	19 (5.2)
	2-Moderate	5 (1.4)	4 (1.1)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	34 (9.2)	53 (14.6)
Day 57 ± 7	0-None	296 (80.2)	276 (76.0)
	1-Mild	17 (4.6)	11 (3.0)
	2-Moderate	2 (0.5)	2 (0.6)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	54 (14.6)	74 (20.4)
Day 85 ± 10	0-None	307 (83.2)	296 (81.5)
	1-Mild	13 (3.5)	11 (3.0)
	2-Moderate	6 (1.6)	6 (1.7)
	3-Severe	1 (0.3)	1 (0.3)
	Not Done	42 (11.4)	49 (13.5)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Pruritus
Safety Analysis Set



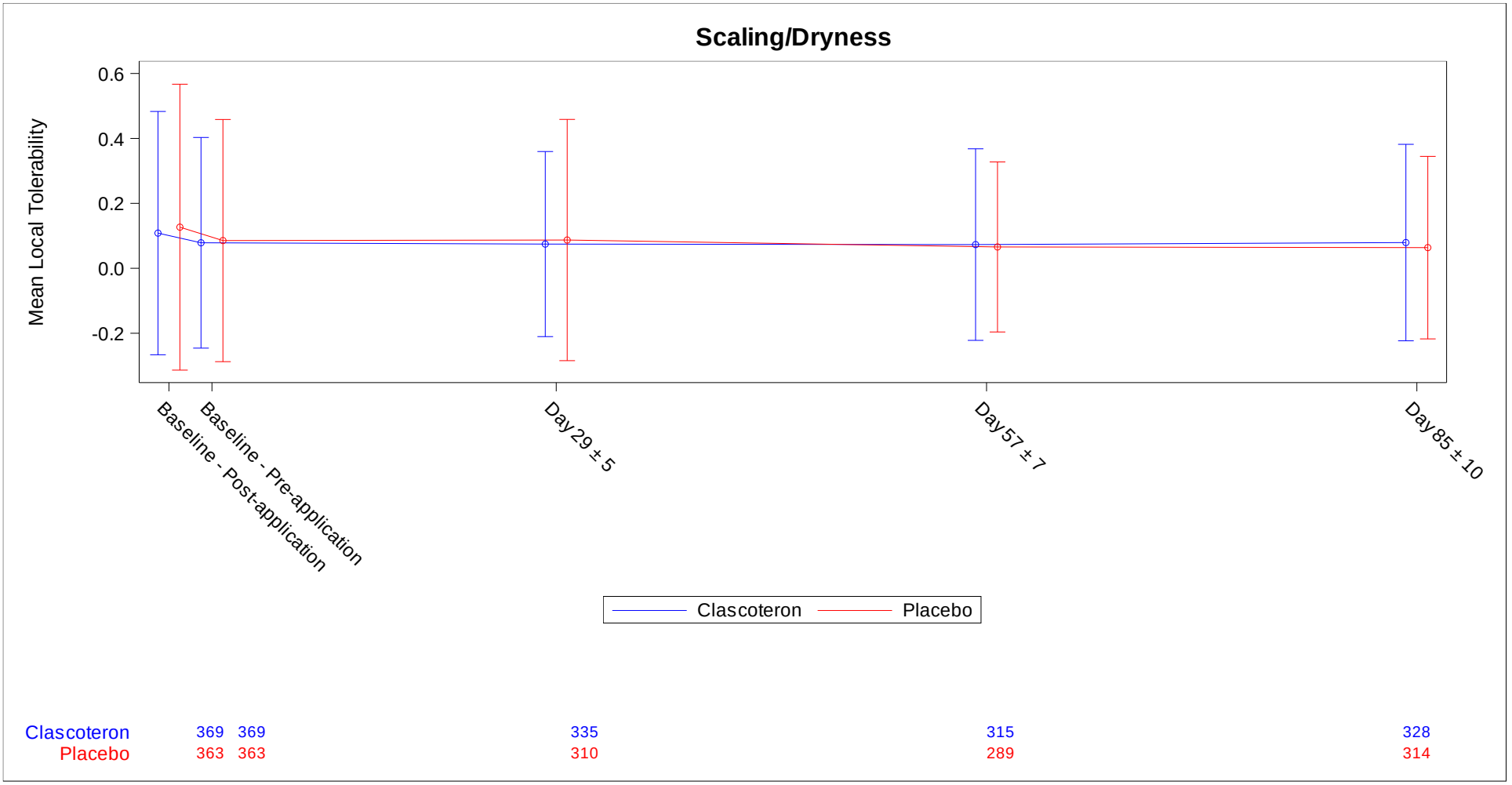
Clascoteron	369	369	335	315	327
Placebo	363	363	310	289	314

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Scaling/Dryness
Safety Analysis Set

		Clascoteron (N=369) n (%)	Placebo (N=363) n (%)
Baseline - Pre-application	0-None	337 (91.3)	330 (90.9)
	1-Minimal	24 (6.5)	22 (6.1)
	2-Mild	8 (2.2)	9 (2.5)
	3-Moderate	0 (0.0)	2 (0.6)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	346 (93.8)	341 (93.9)
	1-Minimal	17 (4.6)	15 (4.1)
	2-Mild	6 (1.6)	5 (1.4)
	3-Moderate	0 (0.0)	2 (0.6)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	312 (84.6)	290 (79.9)
	1-Minimal	21 (5.7)	15 (4.1)
	2-Mild	2 (0.5)	3 (0.8)
	3-Moderate	0 (0.0)	2 (0.6)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	34 (9.2)	53 (14.6)
Day 57 ± 7	0-None	295 (79.9)	271 (74.7)
	1-Minimal	17 (4.6)	17 (4.7)
	2-Mild	3 (0.8)	1 (0.3)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	54 (14.6)	74 (20.4)
Day 85 ± 10	0-None	305 (82.7)	297 (81.8)
	1-Minimal	20 (5.4)	14 (3.9)
	2-Mild	3 (0.8)	3 (0.8)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	41 (11.1)	49 (13.5)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Scaling/Dryness
Safety Analysis Set



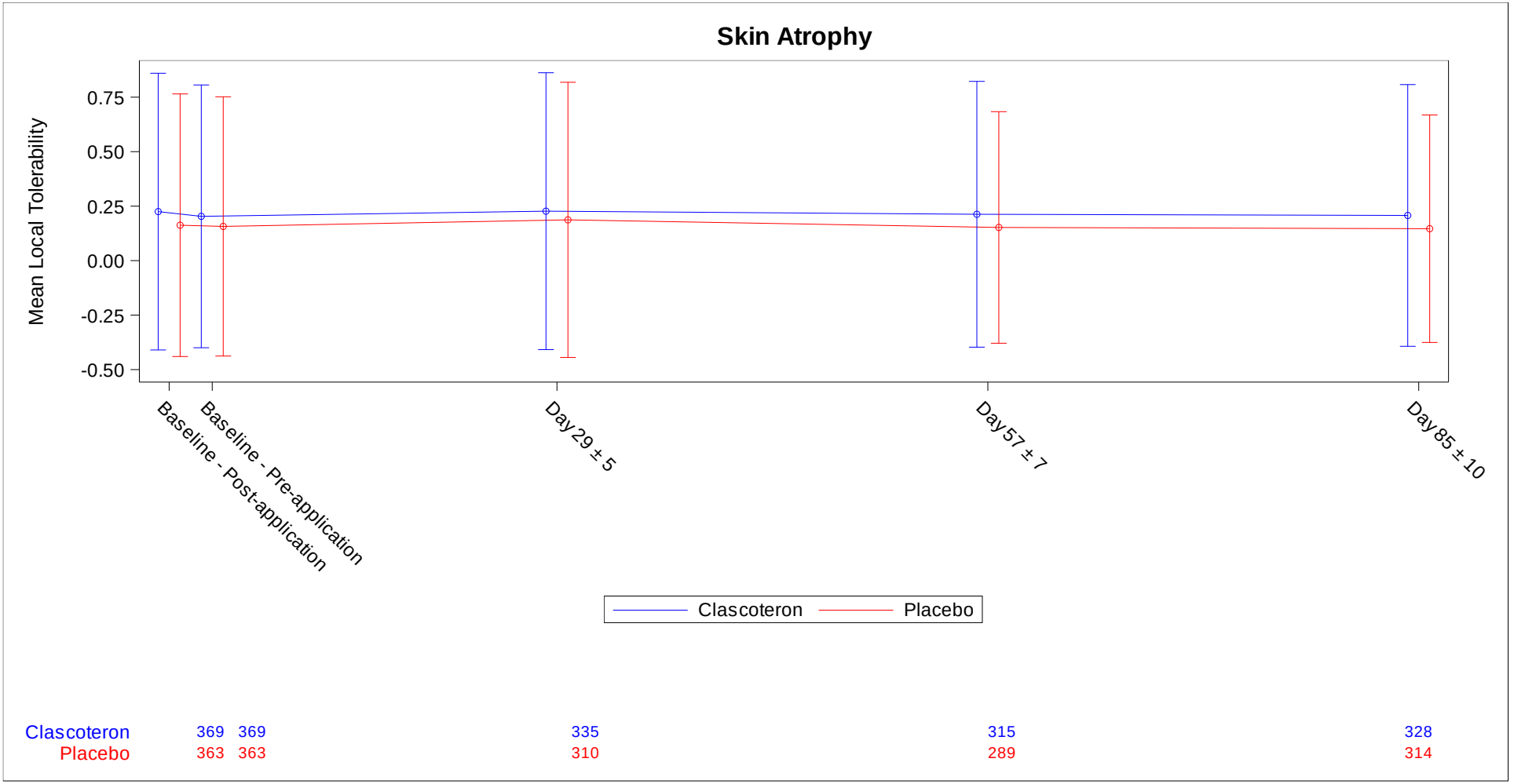
Clascoteron	369	369	335	315	328
Placebo	363	363	310	289	314

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Skin Atrophy
Safety Analysis Set

		Clascoteron (N=369) n (%)	Placebo (N=363) n (%)
Baseline - Pre-application	0-None	317 (85.9)	330 (90.9)
	1-Trace	30 (8.1)	18 (5.0)
	2-Mild	15 (4.1)	8 (2.2)
	3-Moderate	5 (1.4)	3 (0.8)
	4-Severe	2 (0.5)	4 (1.1)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	321 (87.0)	331 (91.2)
	1-Trace	29 (7.9)	18 (5.0)
	2-Mild	13 (3.5)	7 (1.9)
	3-Moderate	4 (1.1)	3 (0.8)
	4-Severe	2 (0.5)	4 (1.1)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	287 (77.8)	276 (76.0)
	1-Trace	28 (7.6)	20 (5.5)
	2-Mild	14 (3.8)	8 (2.2)
	3-Moderate	4 (1.1)	2 (0.6)
	4-Severe	2 (0.5)	4 (1.1)
	Not Done	34 (9.2)	53 (14.6)
Day 57 ± 7	0-None	271 (73.4)	261 (71.9)
	1-Trace	28 (7.6)	17 (4.7)
	2-Mild	11 (3.0)	7 (1.9)
	3-Moderate	3 (0.8)	3 (0.8)
	4-Severe	2 (0.5)	1 (0.3)
	Not Done	54 (14.6)	74 (20.4)
Day 85 ± 10	0-None	283 (76.7)	284 (78.2)
	1-Trace	29 (7.9)	20 (5.5)
	2-Mild	11 (3.0)	5 (1.4)
	3-Moderate	3 (0.8)	4 (1.1)
	4-Severe	2 (0.5)	1 (0.3)
	Not Done	41 (11.1)	49 (13.5)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Skin Atrophy
Safety Analysis Set



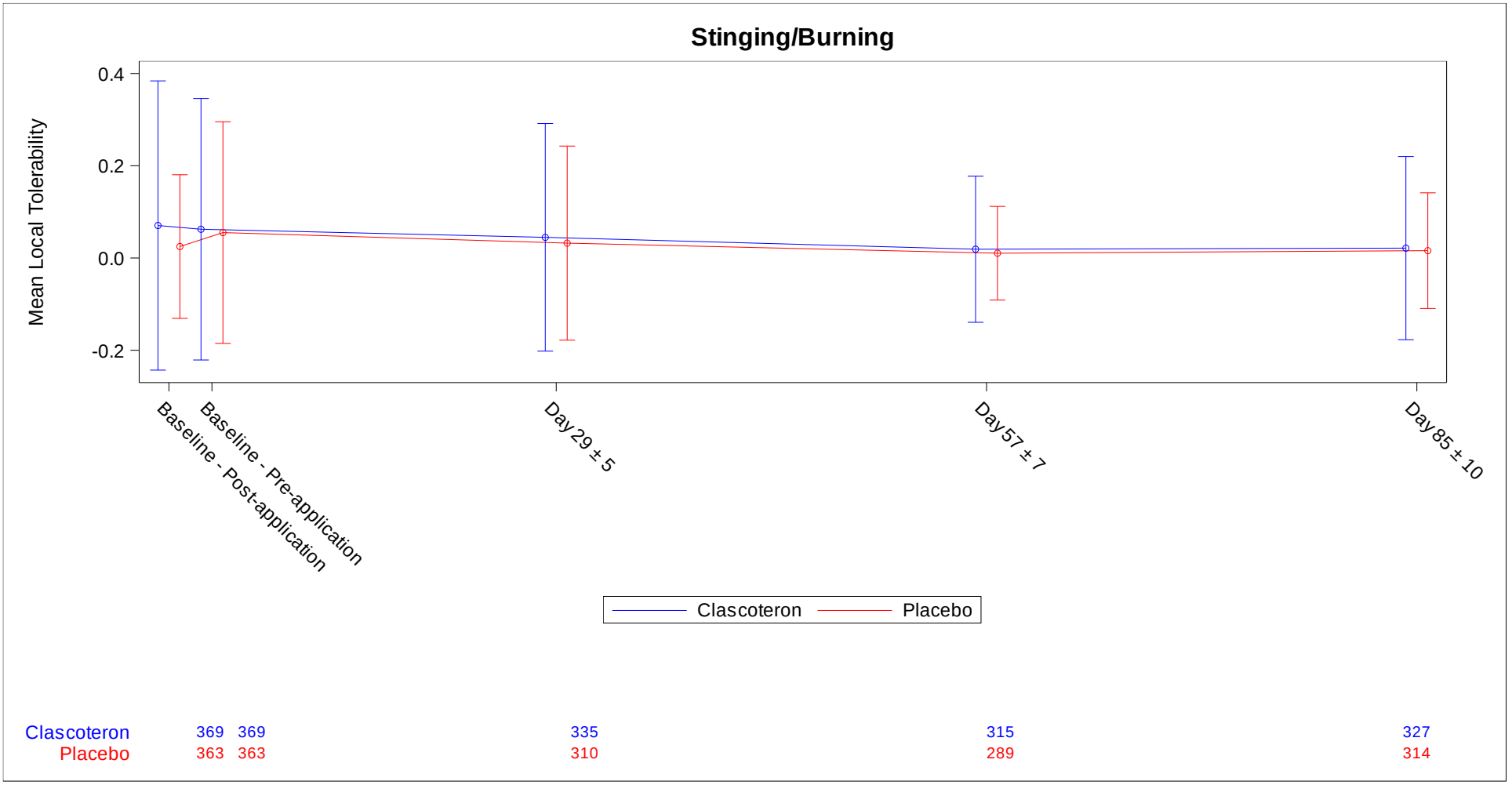
Clascoteron	369	369	335	315	328
Placebo	363	363	310	289	314

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Stinging/Burning
Safety Analysis Set

		Clascoteron (N=369) n (%)	Placebo (N=363) n (%)
Baseline - Pre-application	0-None	348 (94.3)	354 (97.5)
	1-Minimal	17 (4.6)	9 (2.5)
	2-Moderate	3 (0.8)	0 (0.0)
	3-Severe	1 (0.3)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	349 (94.6)	344 (94.8)
	1-Minimal	18 (4.9)	18 (5.0)
	2-Moderate	1 (0.3)	1 (0.3)
	3-Severe	1 (0.3)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	323 (87.5)	302 (83.2)
	1-Minimal	9 (2.4)	6 (1.7)
	2-Moderate	3 (0.8)	2 (0.6)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	34 (9.2)	53 (14.6)
Day 57 ± 7	0-None	310 (84.0)	286 (78.8)
	1-Minimal	4 (1.1)	3 (0.8)
	2-Moderate	1 (0.3)	0 (0.0)
	3-Severe	0 (0.0)	0 (0.0)
	Not Done	54 (14.6)	74 (20.4)
Day 85 ± 10	0-None	322 (87.3)	309 (85.1)
	1-Minimal	4 (1.1)	5 (1.4)
	2-Moderate	0 (0.0)	0 (0.0)
	3-Severe	1 (0.3)	0 (0.0)
	Not Done	42 (11.4)	49 (13.5)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Stinging/Burning
Safety Analysis Set



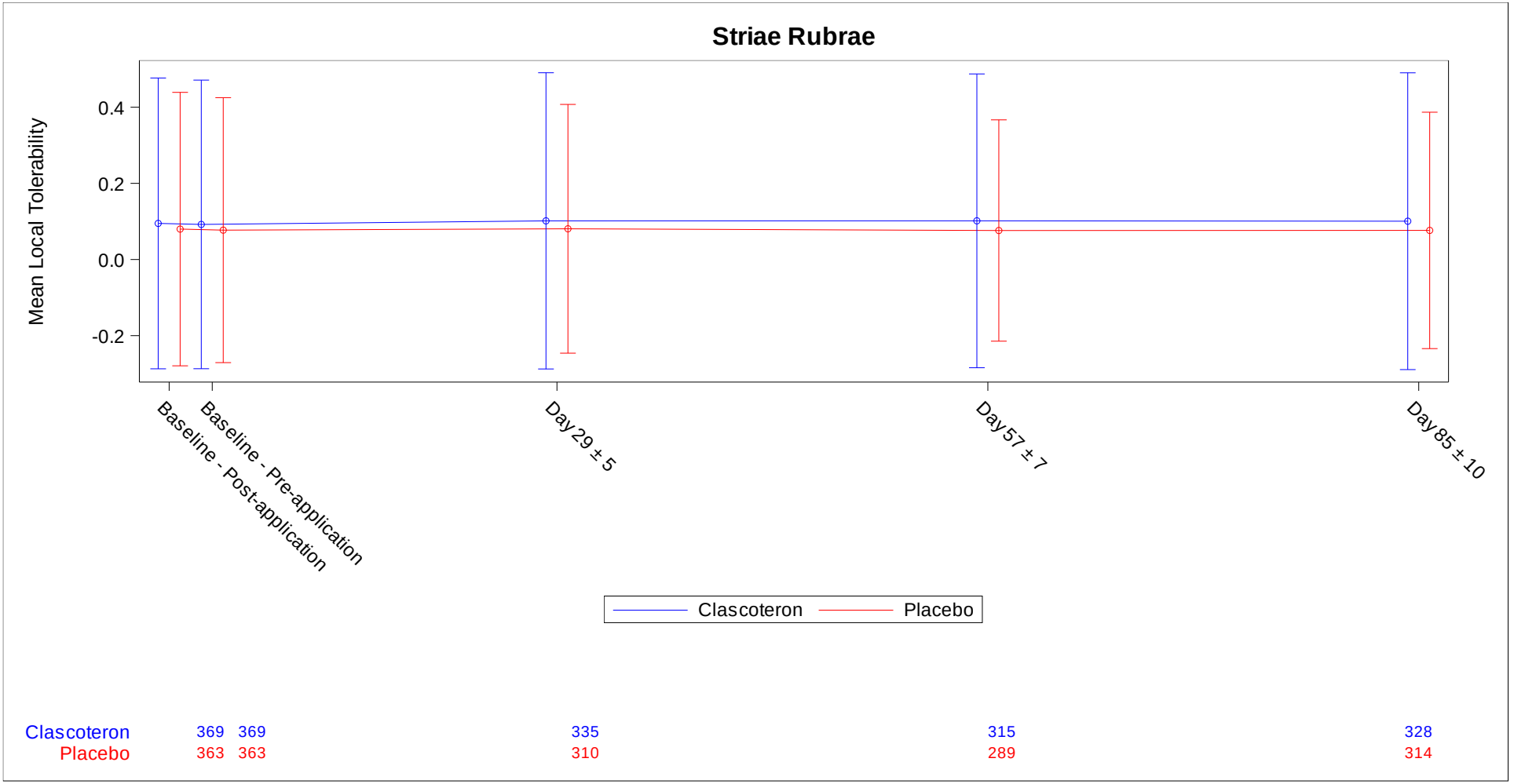
Clascoteron	369	369	335	315	327
Placebo	363	363	310	289	314

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Striae Rubrae
Safety Analysis Set

		Clascoteron (N=369) n (%)	Placebo (N=363) n (%)
Baseline - Pre-application	0-None	344 (93.2)	342 (94.2)
	1-Trace	16 (4.3)	15 (4.1)
	2-Mild	8 (2.2)	4 (1.1)
	3-Moderate	1 (0.3)	2 (0.6)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	345 (93.5)	342 (94.2)
	1-Trace	15 (4.1)	16 (4.4)
	2-Mild	8 (2.2)	3 (0.8)
	3-Moderate	1 (0.3)	2 (0.6)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	310 (84.0)	289 (79.6)
	1-Trace	17 (4.6)	18 (5.0)
	2-Mild	7 (1.9)	2 (0.6)
	3-Moderate	1 (0.3)	1 (0.3)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	34 (9.2)	53 (14.6)
Day 57 ± 7	0-None	291 (78.9)	269 (74.1)
	1-Trace	17 (4.6)	18 (5.0)
	2-Mild	6 (1.6)	2 (0.6)
	3-Moderate	1 (0.3)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	54 (14.6)	74 (20.4)
Day 85 ± 10	0-None	305 (82.7)	293 (80.7)
	1-Trace	13 (3.5)	19 (5.2)
	2-Mild	10 (2.7)	1 (0.3)
	3-Moderate	0 (0.0)	1 (0.3)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	41 (11.1)	49 (13.5)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Striae Rubrae
Safety Analysis Set



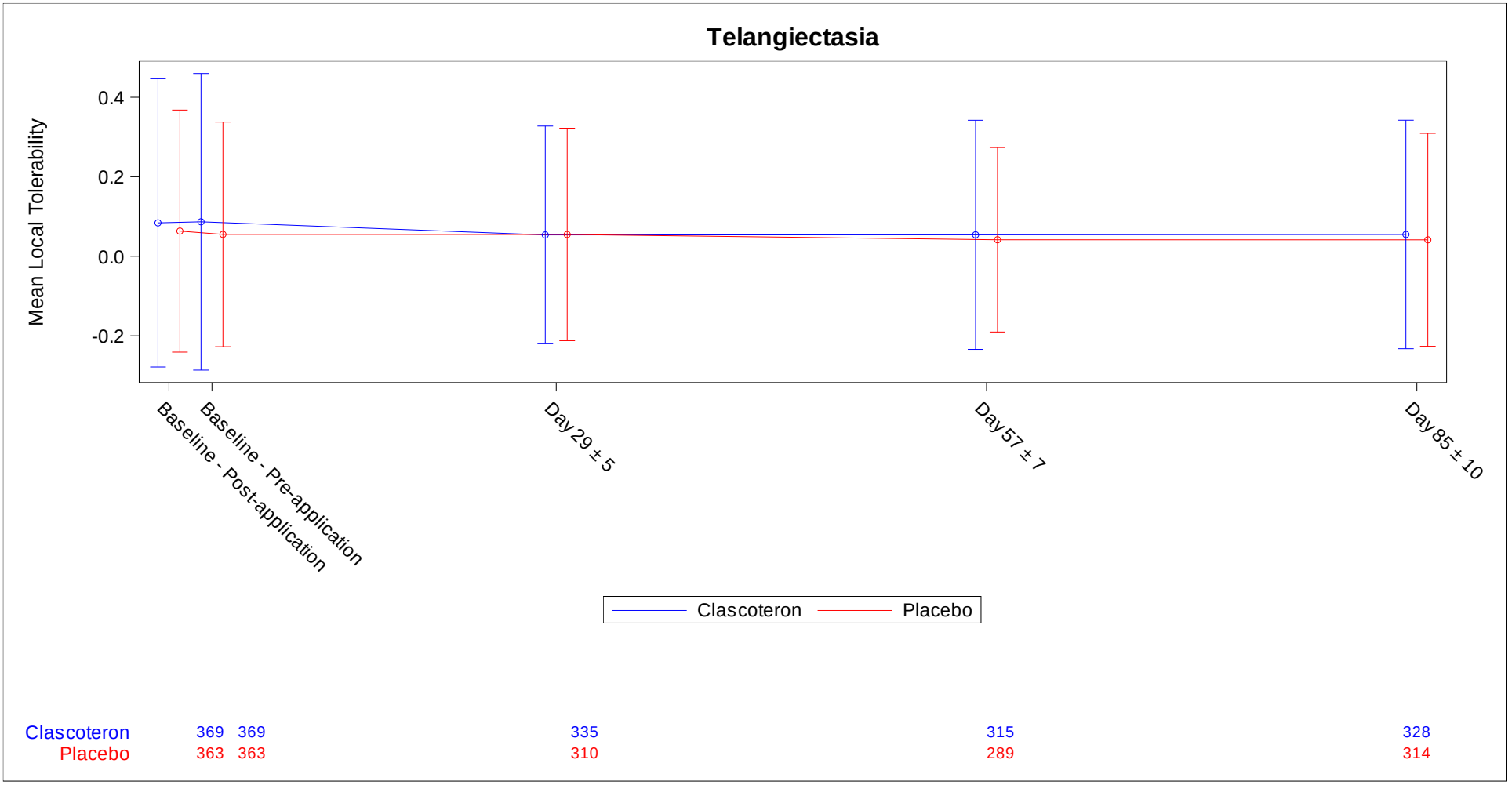
Clascoteron	369	369	335	315	328
Placebo	363	363	310	289	314

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Number and Proportion of Patients with local skin reactions - Telangiectasia
Safety Analysis Set

		Clascoteron (N=369) n (%)	Placebo (N=363) n (%)
Baseline - Pre-application	0-None	346 (93.8)	346 (95.3)
	1-Trace	17 (4.6)	11 (3.0)
	2-Mild	4 (1.1)	6 (1.7)
	3-Moderate	2 (0.5)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Baseline - Post-application	0-None	346 (93.8)	348 (95.9)
	1-Trace	16 (4.3)	10 (2.8)
	2-Mild	5 (1.4)	5 (1.4)
	3-Moderate	2 (0.5)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	0 (0.0)	0 (0.0)
Day 29 ± 5	0-None	321 (87.0)	296 (81.5)
	1-Trace	10 (2.7)	11 (3.0)
	2-Mild	4 (1.1)	3 (0.8)
	3-Moderate	0 (0.0)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	34 (9.2)	53 (14.6)
Day 57 ± 7	0-None	302 (81.8)	279 (76.9)
	1-Trace	10 (2.7)	8 (2.2)
	2-Mild	2 (0.5)	2 (0.6)
	3-Moderate	1 (0.3)	0 (0.0)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	54 (14.6)	74 (20.4)
Day 85 ± 10	0-None	315 (85.4)	305 (84.0)
	1-Trace	8 (2.2)	6 (1.7)
	2-Mild	5 (1.4)	2 (0.6)
	3-Moderate	0 (0.0)	1 (0.3)
	4-Severe	0 (0.0)	0 (0.0)
	Not Done	41 (11.1)	49 (13.5)

Analysis based on Treatment-Emergent Adverse Events (TEAEs).
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
The number and the proportion of subjects for each classification level are reported

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Mean tolerability of local skin reactions - Telangiectasia
Safety Analysis Set



InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Summary of on treatment/follow-up medications
Safety Analysis Set

Medication Class Standardised Medication Name	Clascoteron (N=369)	Placebo (N=363)
PENICILLINS WITH EXTENDED SPECTRUM	8 (2.17 %)	2 (0.55 %)
DUOMOX	4 (1.08 %)	0 (0.00 %)
AMOXICILLIN	2 (0.54 %)	1 (0.28 %)
AMOTAKS	2 (0.54 %)	0 (0.00 %)
OSPAMOX	0 (0.00 %)	1 (0.28 %)
PROPIONIC ACID DERIVATIVES	2 (0.54 %)	7 (1.93 %)
IBUPROFEN	0 (0.00 %)	5 (1.38 %)
BRUFEN	1 (0.27 %)	0 (0.00 %)
IBUPROFENUM	0 (0.00 %)	1 (0.28 %)
KETONAL	0 (0.00 %)	1 (0.28 %)
NAPROXEN	1 (0.27 %)	0 (0.00 %)
ANILIDES	5 (1.36 %)	1 (0.28 %)
PARACETAMOL	4 (1.08 %)	0 (0.00 %)
GRIPEX	0 (0.00 %)	1 (0.28 %)
THERAFLU	1 (0.27 %)	0 (0.00 %)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	3 (0.81 %)	3 (0.83 %)
AUGMENTIN	2 (0.54 %)	2 (0.55 %)
AMOXICILINA + ACIDO CLAVULANICO	1 (0.27 %)	0 (0.00 %)
PANKLAV	0 (0.00 %)	1 (0.28 %)
ANTISEPTICS	2 (0.54 %)	3 (0.83 %)
GARDIMAX MEDICA	0 (0.00 %)	1 (0.28 %)
HASCOSEPT	1 (0.27 %)	0 (0.00 %)
OROFAR MAX	1 (0.27 %)	0 (0.00 %)
SEPTOLETE	0 (0.00 %)	1 (0.28 %)
SEPTOLETE PLUS	0 (0.00 %)	1 (0.28 %)
UNIBEN	0 (0.00 %)	1 (0.28 %)
MACROLIDES	2 (0.54 %)	3 (0.83 %)
SUMAMED	0 (0.00 %)	3 (0.83 %)
AZITHROMYCIN	1 (0.27 %)	0 (0.00 %)
AZITHROMYCINE	1 (0.27 %)	0 (0.00 %)
PIPERAZINE DERIVATIVES	2 (0.54 %)	3 (0.83 %)
ZYRTEC	1 (0.27 %)	2 (0.55 %)
LEVOCETIRIZINE	1 (0.27 %)	0 (0.00 %)
XYZAL	0 (0.00 %)	1 (0.28 %)
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	3 (0.81 %)	2 (0.55 %)
DROSPIRENONE AND ETHINYL ESTRADIOL	1 (0.27 %)	1 (0.28 %)
BELARA	1 (0.27 %)	0 (0.00 %)
MADINETTE	0 (0.00 %)	1 (0.28 %)
VIBIN MINI	1 (0.27 %)	0 (0.00 %)
SALICYLIC ACID AND DERIVATIVES	4 (1.08 %)	1 (0.28 %)
ASPIRIN	1 (0.27 %)	1 (0.28 %)
POLOPIRYNA MAX	1 (0.27 %)	0 (0.00 %)
POLOPIRYNA S	1 (0.27 %)	0 (0.00 %)
SCORBOLAMID	1 (0.27 %)	0 (0.00 %)
ANESTHETICS, LOCAL	1 (0.27 %)	3 (0.83 %)
STREPSILS	1 (0.27 %)	3 (0.83 %)
GLUCOCORTICOIDS	2 (0.54 %)	2 (0.55 %)
PREDNISONE	1 (0.27 %)	1 (0.28 %)

The number and the proportion of subjects with any on treatment/follow-up medication for each classification level are reported.
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall.
WHO Drug Dictionary 2015 SEP B2.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Summary of on treatment/follow-up medications
Safety Analysis Set

Medication Class Standardised Medication Name	Clascoteron (N=369)	Placebo (N=363)
DECADRON	0 (0.00 %)	1 (0.28 %)
KENALOG	1 (0.27 %)	0 (0.00 %)
METMIN	0 (0.00 %)	1 (0.28 %)
PAPAVERINE AND DERIVATIVES	2 (0.54 %)	2 (0.55 %)
DROTAVERINE HYDROCHLORIDE	1 (0.27 %)	1 (0.28 %)
NO-SPA	1 (0.27 %)	1 (0.28 %)
ANTIINFECTIVES FOR TREATMENT OF ACNE	1 (0.27 %)	2 (0.55 %)
CLINDACNE	1 (0.27 %)	0 (0.00 %)
DUAC	0 (0.00 %)	1 (0.28 %)
ISOTREXIN	0 (0.00 %)	1 (0.28 %)
NATURAL OPIUM ALKALOIDS	1 (0.27 %)	2 (0.55 %)
PAINBREAK	1 (0.27 %)	1 (0.28 %)
ACETAMINOPHEN W/HYDROCODONE	0 (0.00 %)	1 (0.28 %)
OPIUM ALKALOIDS AND DERIVATIVES	2 (0.54 %)	1 (0.28 %)
DEXTROMETHORPHAN HYDROBROMIDE	0 (0.00 %)	1 (0.28 %)
DEXTROMETORFANO BROMHIDRATO	1 (0.27 %)	0 (0.00 %)
HYDROBROMIDE DEXTROMETHORPHAN	1 (0.27 %)	0 (0.00 %)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	1 (0.27 %)	2 (0.55 %)
AERIUS	1 (0.27 %)	0 (0.00 %)
ATARAX	0 (0.00 %)	1 (0.28 %)
CLARITINE	0 (0.00 %)	1 (0.28 %)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	1 (0.27 %)	2 (0.55 %)
NIMESIL	0 (0.00 %)	1 (0.28 %)
UNIBEN	0 (0.00 %)	1 (0.28 %)
ZYX	1 (0.27 %)	0 (0.00 %)
OTHER ANTIVIRALS	1 (0.27 %)	2 (0.55 %)
GROPRINOSIN	1 (0.27 %)	1 (0.28 %)
NEOSINE	0 (0.00 %)	1 (0.28 %)
ANTIDIARRHEAL MICROORGANISMS	1 (0.27 %)	1 (0.28 %)
LACIDOFIL	1 (0.27 %)	1 (0.28 %)
BIOFLAVONOIDS	1 (0.27 %)	1 (0.28 %)
CERUTIN	0 (0.00 %)	1 (0.28 %)
RUTINOSCORBIN	1 (0.27 %)	0 (0.00 %)
OTHER COLD PREPARATIONS	1 (0.27 %)	1 (0.28 %)
HALLS	0 (0.00 %)	1 (0.28 %)
SINUPRET	1 (0.27 %)	0 (0.00 %)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	1 (0.27 %)	1 (0.28 %)
EURESPAL	1 (0.27 %)	1 (0.28 %)
PREGNADIEN DERIVATIVES	1 (0.27 %)	1 (0.28 %)
DUPHASTON	1 (0.27 %)	0 (0.00 %)
LUTENYL	0 (0.00 %)	1 (0.28 %)
PROTON PUMP INHIBITORS	1 (0.27 %)	1 (0.28 %)
CONTROLOC	1 (0.27 %)	1 (0.28 %)
SECOND-GENERATION CEPHALOSPORINS	1 (0.27 %)	1 (0.28 %)
ZAMUR	1 (0.27 %)	0 (0.00 %)

The number and the proportion of subjects with any on treatment/follow-up medication for each classification level are reported.
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall.
WHO Drug Dictionary 2015 SEP B2.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Summary of on treatment/follow-up medications
Safety Analysis Set

Medication Class Standardised Medication Name	Clascoteron (N=369)	Placebo (N=363)
ZINNAT	0 (0.00 %)	1 (0.28 %)
SYMPATHOMIMETICS	1 (0.27 %)	1 (0.28 %)
CIRRUS	0 (0.00 %)	1 (0.28 %)
DISOPHROL	1 (0.27 %)	0 (0.00 %)
TETRACYCLINES	0 (0.00 %)	2 (0.55 %)
DAMELIUM	0 (0.00 %)	1 (0.28 %)
DOXICICLINA	0 (0.00 %)	1 (0.28 %)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	0 (0.00 %)	2 (0.55 %)
HERBAL EXTRACT NOS	0 (0.00 %)	1 (0.28 %)
HERBAL PREPARATION	0 (0.00 %)	1 (0.28 %)
AMINOALKYL ETHERS	1 (0.27 %)	0 (0.00 %)
BENADRYL	1 (0.27 %)	0 (0.00 %)
ANGIOTENSIN II ANTAGONISTS, PLAIN	1 (0.27 %)	0 (0.00 %)
KARBIS	1 (0.27 %)	0 (0.00 %)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT	0 (0.00 %)	1 (0.28 %)
MOUTH WASH	0 (0.00 %)	1 (0.28 %)
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS	1 (0.27 %)	0 (0.00 %)
BUSCOPAN	1 (0.27 %)	0 (0.00 %)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS	0 (0.00 %)	1 (0.28 %)
SMECTA	0 (0.00 %)	1 (0.28 %)
CORTICOSTEROIDS	0 (0.00 %)	1 (0.28 %)
FLONASE	0 (0.00 %)	1 (0.28 %)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	1 (0.27 %)	0 (0.00 %)
HYDROCORTISONE BUTYRATE	1 (0.27 %)	0 (0.00 %)
CORTICOSTEROIDS, POTENT (GROUP III)	0 (0.00 %)	1 (0.28 %)
ADVANTAN	0 (0.00 %)	1 (0.28 %)
CORTICOSTEROIDS, VERY POTENT (GROUP IV)	0 (0.00 %)	1 (0.28 %)
CLOBETASOL	0 (0.00 %)	1 (0.28 %)
CORTICOSTEROIDS, WEAK (GROUP I)	0 (0.00 %)	1 (0.28 %)
TOPICORT	0 (0.00 %)	1 (0.28 %)
EXPECTORANTS	1 (0.27 %)	0 (0.00 %)
TUSSIN	1 (0.27 %)	0 (0.00 %)
FLUOROQUINOLONES	1 (0.27 %)	0 (0.00 %)
CIPRONEX	1 (0.27 %)	0 (0.00 %)
IMIDAZOLE AND TRIAZOLE DERIVATIVES	1 (0.27 %)	0 (0.00 %)
CLOTRIMAZOLUM	1 (0.27 %)	0 (0.00 %)
IMIDAZOLE DERIVATIVES	1 (0.27 %)	0 (0.00 %)
CLOTRIMAZOLUM	1 (0.27 %)	0 (0.00 %)
IRON IN OTHER COMBINATIONS	0 (0.00 %)	1 (0.28 %)
HEMOFER	0 (0.00 %)	1 (0.28 %)

The number and the proportion of subjects with any on treatment/follow-up medication for each classification level are reported.
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall.
WHO Drug Dictionary 2015 SEP B2.

InfectoPharm
Study CB-03-01/26 - Datacut: 21FEB2018
CB-03-01/26 - Clascoteron vs. Placebo
Summary of on treatment/follow-up medications
Safety Analysis Set

Medication Class Standardised Medication Name	Clascoteron (N=369)	Placebo (N=363)
IRRIGATING SOLUTIONS	0 (0.00 %)	1 (0.28 %)
IRRIGATING SOLUTIONS	0 (0.00 %)	1 (0.28 %)
LINCOSAMIDES	0 (0.00 %)	1 (0.28 %)
DALACIN C	0 (0.00 %)	1 (0.28 %)
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	1 (0.27 %)	0 (0.00 %)
ESTROFEM	1 (0.27 %)	0 (0.00 %)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	0 (0.00 %)	1 (0.28 %)
FIORDA	0 (0.00 %)	1 (0.28 %)
OPIUM DERIVATIVES AND EXPECTORANTS	0 (0.00 %)	1 (0.28 %)
GRIPEX	0 (0.00 %)	1 (0.28 %)
OTHER CENTRALLY ACTING AGENTS	0 (0.00 %)	1 (0.28 %)
MYDOCALM	0 (0.00 %)	1 (0.28 %)
OTHER CICATRIZANTS	0 (0.00 %)	1 (0.28 %)
BEPANTHEN	0 (0.00 %)	1 (0.28 %)
OTHER ECTOPARASITICIDES, INCL. SCABICIDES	0 (0.00 %)	1 (0.28 %)
HEDRIN	0 (0.00 %)	1 (0.28 %)
OTHER INTESTINAL ADSORBENTS	1 (0.27 %)	0 (0.00 %)
DIOSMECTITE	1 (0.27 %)	0 (0.00 %)
OTHER THROAT PREPARATIONS	1 (0.27 %)	0 (0.00 %)
LARYNG UP	1 (0.27 %)	0 (0.00 %)
OXICAMS	1 (0.27 %)	0 (0.00 %)
AGLAN	1 (0.27 %)	0 (0.00 %)
PREGNEN (4) DERIVATIVES	0 (0.00 %)	1 (0.28 %)
PROGESTERONE	0 (0.00 %)	1 (0.28 %)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	0 (0.00 %)	1 (0.28 %)
ESCITIL	0 (0.00 %)	1 (0.28 %)
SILICONE PRODUCTS	1 (0.27 %)	0 (0.00 %)
MOISTURIZING SKIN PROTECTING	1 (0.27 %)	0 (0.00 %)
SPECIFIC ANTIRHEUMATIC AGENTS	1 (0.27 %)	0 (0.00 %)
COLLAGEN	1 (0.27 %)	0 (0.00 %)
THYROID HORMONES	0 (0.00 %)	1 (0.28 %)
EUTHYROX	0 (0.00 %)	1 (0.28 %)
VITAMINS WITH MINERALS	0 (0.00 %)	1 (0.28 %)
ELEVIT	0 (0.00 %)	1 (0.28 %)

The number and the proportion of subjects with any on treatment/follow-up medication for each classification level are reported.
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall.
WHO Drug Dictionary 2015 SEP B2.