

APPENDIX I: TABLES, LISTINGS AND FIGURES

Lofarma S.p.A.

**A single arm, open label, dose-escalation study of carbamylated
monomeric grass pollen drops in patients with a history of allergic
rhinoconjunctivitis**

Clinical Study Code: DE_LODRO_GR19

Table of Contents

TABLE 1. DISPOSITION OF PATIENTS (SCREENED, SAFETY, ITT, PP POPULATION)	5
TABLE 2. DISPOSITION OF PATIENTS BY CENTER (SCREENED, SAFETY, ITT, PP POPULATION).....	6
TABLE 3. FREQUENCY OF PATIENTS SCREENING FAILURE (SCREENED, SAFETY, ITT POPULATION).....	7
TABLE 4. PRIMARY REASON FOR DISCONTINUATION (SCREENED, SAFETY, ITT POPULATION).....	8
TABLE 5. FREQUENCY OF THERAPY DISCONTINUATION (SCREENED, SAFETY, ITT, PP POPULATION).....	9
TABLE 6A. DEMOGRAPHICS CHARACTERISTICS (SCREENED POPULATION).....	10
TABLE 6B. DEMOGRAPHICS CHARACTERISTICS (SCREENED POPULATION).....	11
TABLE 7. MEDICAL HISTORY (SCREENED POPULATION).....	12
TABLE 8. FREQUENCY OF PATIENTS WITH AT LEAST ONE PREVIOUS MEDICATION (SCREENED POPULATION).....	13
TABLE 9. FREQUENCY OF PATIENTS WITH AT LEAST ONE CONCOMITANT MEDICATION (SCREENED POPULATION).....	14
TABLE 10. DISPOSITION OF PATIENTS TAKING THE TREATMENT (SCREENED, SAFETY, ITT, PP POPULATION)	15
TABLE 11. ADVERSE EVENTS (SAFETY POPULATION)	16
TABLE 12. FREQUENCY OF ARIA RESULTS (SCREENED POPULATION)	17
TABLE 13. FREQUENCY OF GINA 2018 RESULTS (SCREENED POPULATION).....	19
TABLE 14. FREQUENCY OF PROTOCOL DEVIATIONS (ITT POPULATION).....	21
TABLE 15. FREQUENCY OF MAJOR PROTOCOL DEVIATIONS (ITT POPULATION)	22
TABLE 16. NUMBER OF SOLICITED AES (WHATEVER THE TYPE) (SAFETY POPULATION)	23
TABLE 17. FREQUENCY OF LOCAL REACTIONS AT THE ADMINISTRATION SITE (SAFETY POPULATION).....	24
TABLE 18. FREQUENCY OF LOCAL REACTIONS AT THE ADMINISTRATION SITE BY SEVERITY AT EACH TIME POINT (SAFETY POPULATION)	25
TABLE 19. FREQUENCY OF LOCAL REACTIONS AT THE ADMINISTRATION SITE PER ADMINISTERED DOSE/VOLUME OF SOLUTION (SAFETY POPULATION)	27
TABLE 20. FREQUENCY OF SYSTEMIC REACTIONS (SAFETY POPULATION).....	28
TABLE 21. FREQUENCY OF SYSTEMIC REACTIONS BY SEVERITY GRADE (SAFETY POPULATION).....	29
TABLE 22. FREQUENCY OF SYSTEMIC REACTIONS PER ADMINISTERED DOSE/VOLUME OF SOLUTION (SAFETY POPULATION)	30
TABLE 23. UNSOLICITED ADVERSE EVENTS (SAFETY POPULATION).....	31
TABLE 24. FREQUENCY OF UNSOLICITED ADVERSE EVENTS (SAFETY POPULATION)	32

TABLE 25. VITAL SIGNS (SAFETY, ITT, PP POPULATION)	33
TABLE 26. CHANGE FROM BASELINE IN VITAL SIGNS (SAFETY, ITT, PP POPULATION)	37
TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (SAFETY, ITT, PP POPULATION)	40
TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (SAFETY, ITT, PP POPULATION)	58
TABLE 29. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT (ITT, PP POPULATION)	75
TABLE 30. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT (ITT, PP POPULATION)	80
TABLE 31. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS (ITT, PP POPULATION)	84
TABLE 32. FREQUENCY OF PATIENTS WHO USED RESCUE MEDICATION (ITT, PP POPULATION)	88
TABLE 33. FREQUENCY OF USE OF RESCUE MEDICATION DURING TREATMENT PHASE (ITT, PP POPULATION)	89
TABLE 34. PROPORTION OF PATIENTS WHO REACHED MAXIMUM IMP DOSE (ITT, PP POPULATION)	90
TABLE 35. FREQUENCY OF MAXIMUM IMP DOSE (ITT, PP POPULATION)	91
LISTING 1. SUBJECT DISPOSITION	92
LISTING 2. DISCONTINUED PATIENTS DISPOSITION	94
LISTING 3. DISCONTINUED TREATMENT DISPOSITION	97
LISTING 4. MINOR PROTOCOL DEVIATIONS	106
LISTING 5. MAJOR PROTOCOL DEVIATIONS	110
LISTING 6. DEMOGRAPHIC CHARACTERISTICS	114
LISTING 7. ARIA RESULTS	117
LISTING 8. ASTHMA DIAGNOSIS. GINA 2018 RESULTS	120
LISTING 9. MEDICAL HYSTORY	123
LISTING 10. PREVIOUS MEDICATIONS	126
LISTING 11. CONCOMITANT MEDICATIONS	132
LISTING 12. ADVERSE EVENTS	138
LISTING 13. SOLICITED AES (WHATEVER THE TYPE)	148
LISTING 14. LOCAL REACTIONS AT THE ADMINISTRATION SITE	151
LISTING 15. SYSTEMIC REACTIONS	154
LISTING 16. VITAL SIGNS	157
LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY	171
LISTING 18. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT	214

LISTING 19. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT 222

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC
PATIENTS AND LABORATORY TESTS..... 230

LISTING 21. PATIENTS WHO USED RESCUE MEDICATION..... 249

LISTING 22. PATIENTS WHO REACHED MAXIMUM DOSE OF IMP 254

TABLE 1. DISPOSITION OF PATIENTS (Screened, Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

		Screened	Safety	ITT	PP
Screening	Frequency	39	34	34	7
	%	100.00	100.00	100.00	100.00
V2 - 1st Treatment Visit	Frequency	39	34	34	7
	%	100.00	100.00	100.00	100.00
V3 - 2nd Treatment Visit	Frequency	33	33	33	7
	%	84.62	97.06	97.06	100.00
V4 - 3rd Treatment Visit	Frequency	33	33	33	7
	%	84.62	97.06	97.06	100.00
V5 - 4th Treatment Visit	Frequency	13	13	13	7
	%	33.33	38.24	38.24	100.00
V6 - End of Study/Early Termination Visit	Frequency	39	34	34	7
	%	100.00	100.00	100.00	100.00

TABLE 2. DISPOSITION OF PATIENTS BY CENTER (Screened, Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

			Screened	Safety	ITT	PP
Screening	Chiaravalle Centrale	Frequency	25	20	20	.
		%	64.10	58.82	58.82	.
	TROPEA	Frequency	14	14	14	7
		%	35.90	41.18	41.18	100.00
V2 - 1st Treatment Visit	Chiaravalle Centrale	Frequency	25	20	20	.
		%	64.10	58.82	58.82	.
	TROPEA	Frequency	14	14	14	7
		%	35.90	41.18	41.18	100.00
V3 - 2nd Treatment Visit	Chiaravalle Centrale	Frequency	20	20	20	.
		%	51.28	58.82	58.82	.
	TROPEA	Frequency	13	13	13	7
		%	33.33	38.24	38.24	100.00
V4 - 3rd Treatment Visit	Chiaravalle Centrale	Frequency	20	20	20	.
		%	51.28	58.82	58.82	.
	TROPEA	Frequency	13	13	13	7
		%	33.33	38.24	38.24	100.00
V5 - 4th Treatment Visit	Chiaravalle Centrale	Frequency
		%
	TROPEA	Frequency	13	13	13	7
		%	33.33	38.24	38.24	100.00
V6 - End of Study/Early Termination Visit	Chiaravalle Centrale	Frequency	25	20	20	.
		%	64.10	58.82	58.82	.
	TROPEA	Frequency	14	14	14	7
		%	35.90	41.18	41.18	100.00

TABLE 3. FREQUENCY OF PATIENTS SCREENING FAILURE (Screened, Safety, ITT Population)
10:22 Monday, July 27, 2020

Eligible?		Screened	Safety	ITT
No	Frequency	.	.	.
	%	.	.	.
Yes	Frequency	39	34	34
	%	100.00	100.00	100.00

TABLE 4. PRIMARY REASON FOR DISCONTINUATION (Screened, Safety, ITT Population)
 10:22 Monday, July 27, 2020

Study completed?	Cause of end of study		Screened	Safety	ITT
No	Investigator's decision	Frequency	2	.	.
		%	5.13	.	.
	Other	Frequency	1	1	1
		%	2.56	2.94	2.94
	Withdrawal of consent	Frequency	3	.	.
%		7.69	.	.	
Yes	//	Frequency	33	33	33
		%	84.62	97.06	97.06

TABLE 5. FREQUENCY OF THERAPY DISCONTINUATION (Screened, Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Diary completed?	Drug discontinued?		Screened	Safety	ITT	PP
V3 - 2nd Treatment Visit	No	//	Frequency	15	10	10	.
			%	38.46	29.41	29.41	.
	Yes	No	Frequency	23	23	23	6
			%	58.97	67.65	67.65	85.71
	Yes	Frequency	1	1	1	1	
			%	2.56	2.94	2.94	14.29
V4 - 3rd Treatment Visit	No	//	Frequency	13	8	8	.
			%	33.33	23.53	23.53	.
	Yes	No	Frequency	25	25	25	7
			%	64.10	73.53	73.53	100.00
	Yes	Frequency	1	1	1	.	
			%	2.56	2.94	2.94	.
V5 - 4th Treatment Visit	No	//	Frequency	15	10	10	2
			%	38.46	29.41	29.41	28.57
	Yes	No	Frequency	24	24	24	5
			%	61.54	70.59	70.59	71.43
	Yes	Frequency	
			%
V6 - End of study/Early termination Visit	No	//	Frequency	18	13	13	5
			%	46.15	38.24	38.24	71.43
	Yes	No	Frequency	21	21	21	2
			%	53.85	61.76	61.76	28.57
	Yes	Frequency	
			%
Unscheduled Visit	No	//	Frequency
			%
	Yes	No	Frequency	1	1	1	1
			%	2.56	2.94	2.94	14.29
	Yes	Frequency	
			%

TABLE 6A. DEMOGRAPHICS CHARACTERISTICS (Screened Population)
 10:22 Monday, July 27, 2020

Variables		Screened
AGE (year)	N	39
	MEAN	32.31
	MEDIAN	29.00
	STD	11.10
	MIN	19.00
	MAX	60.00
HEIGHT (cm)	N	39
	MEAN	167.00
	MEDIAN	170.00
	STD	13.27
	MIN	106.00
	MAX	185.00
WEIGHT (kg)	N	39
	MEAN	72.23
	MEDIAN	70.00
	STD	15.68
	MIN	43.00
	MAX	109.00

CONFIDENTIAL

TABLE 6B. DEMOGRAPHICS CHARACTERISTICS (Screened Population)
10:22 Monday, July 27, 2020

Variables			Screened
Gender	Female	Frequency	16
		%	41.03
	Male	Frequency	23
		%	58.97
Race	Caucasian	Frequency	39
		%	100.00

TABLE 7. MEDICAL HISTORY (Screened Population)
 10:22 Monday, July 27, 2020

Medical History	System	PT Name	PT Code		Screened
No	//	//	//	Frequency %	36 92.31
Yes	Cardiovascular	Hypertension	10020772	Frequency %	2 5.13
	Metabolic	Diabetes mellitus	10012601	Frequency %	1 2.56
	Respiratory	Sleep apnoea syndrome	10040979	Frequency %	1 2.56

TABLE 8. FREQUENCY OF PATIENTS WITH AT LEAST ONE PREVIOUS MEDICATION (Screened Population)
 10:22 Monday, July 27, 2020

Previous Medication	ATC Code		Screened
No	//	Frequency %	35 89.74
Yes	A10BA02	Frequency %	1 2.56
	C08CA01	Frequency %	1 2.56
	C09AA04	Frequency %	1 2.56
	C09BX01	Frequency %	1 2.56
	R03AK11	Frequency %	1 2.56
	R06AX29	Frequency %	1 2.56

TABLE 9. FREQUENCY OF PATIENTS WITH AT LEAST ONE CONCOMITANT MEDICATION (Screened Population)
10:22 Monday, July 27, 2020

Concomitant Medication	ATC Code		Screened
No	//	Frequency %	33 84.62
Yes	R01AD09	Frequency %	1 2.56
	R03BA05	Frequency %	1 2.56
	R03DC03	Frequency %	1 2.56
	R06AX22	Frequency %	1 2.56
	R06AX28	Frequency %	1 2.56
	R06AX29	Frequency %	3 7.69

TABLE 10. DISPOSITION OF PATIENTS TAKING THE TREATMENT (Screened, Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

			Screened	Safety	ITT	PP
V2 - 1st Treatment Visit	1st Administration	Frequency	34	34	34	7
		%	87.18	100.00	100.00	100.00
	2nd Administration	Frequency	34	34	34	7
		%	87.18	100.00	100.00	100.00
V3 - 2nd Treatment Visit	1st Administration	Frequency	33	33	33	7
		%	84.62	97.06	97.06	100.00
	2nd Administration	Frequency	33	33	33	7
		%	84.62	97.06	97.06	100.00
V4 - 3rd Treatment Visit	1st Administration	Frequency	33	33	33	7
		%	84.62	97.06	97.06	100.00
V5 - 4th Treatment Visit	1st Administration	Frequency	13	13	13	7
		%	33.33	38.24	38.24	100.00

TABLE 11. ADVERSE EVENTS (Safety Population)
10:22 Monday, July 27, 2020

Adverse event?	Where AE occurred	Type		Safety
No	//	//	Frequency	22
			%	64.71
Yes	At site	Solicited Local AEs	Frequency	4
			%	11.76
		Solicited Systemic AEs	Frequency	2
			%	5.88
		Unknown	Frequency	.
			%	.
	At home	Solicited Local AEs	Frequency	.
			%	.
		Solicited Systemic AEs	Frequency	.
			%	.
Unknown		Frequency	1	
		%	2.94	
	Unsolicited AEs	Frequency	8	
		%	23.53	

TABLE 12. FREQUENCY OF ARIA RESULTS (Screened Population)
10:22 Monday, July 27, 2020

ARIA Results			Screened
Are the rhinitis symptoms troublesome?	No	Frequency	2
		%	5.13
	Yes	Frequency	37
		%	94.87
Do the rhinitis symptoms cause impairment at work or at school?	No	Frequency	3
		%	7.69
	Yes	Frequency	36
		%	92.31
Do the rhinitis symptoms cause impairment of the patient daily activities in sports at leisure?	No	Frequency	2
		%	5.13
	Yes	Frequency	37
		%	94.87
Do the rhinitis symptoms disturb the patient sleep?	No	Frequency	2
		%	5.13
	Yes	Frequency	37
		%	94.87
Frequency and duration of occurrence of rhinitis	Intermittent (symptoms are present < 4 days a week or for < 4 weeks in the year)	Frequency	2

TABLE 12. FREQUENCY OF ARIA RESULTS (Screened Population)
10:22 Monday, July 27, 2020

ARIA Results			Screened
Frequency and duration of occurrence of rhinitis	Intermittent	%	5.13
	(symptoms are present < 4 days a week or for < 4 weeks in the year)		
	Persistent	Frequency	37
	(symptoms are present > 4 days a week and for > 4 weeks in the year)		
		%	94.87
Previous anaphylaxis episodes?	No	Frequency	39
		%	100.00
	Yes	Frequency	.
		%	.

TABLE 13. FREQUENCY OF GINA 2018 RESULTS (Screened Population)
10:22 Monday, July 27, 2020

Has the patient asthma?	GINA 2018 Results			Screened
No	//	//	Frequency %	32 82.05
Yes	Daytime asthma symptoms more than twice a week?	No	Frequency	7
			%	17.95
	Yes		Frequency	.
			%	.
	Any night walking due to asthma?	No	Frequency	7
			%	17.95
Yes		Frequency	.	
		%	.	
Reliever needed for symptoms more than twice/week ?	No	Frequency	7	
		%	17.95	
Yes		Frequency	.	
		%	.	

TABLE 13. FREQUENCY OF GINA 2018 RESULTS (Screened Population)
10:22 Monday, July 27, 2020

Has the patient asthma?	GINA 2018 Results		Screened	
Yes	Any activity limitation due to asthma?	No	Frequency	7
			%	17.95
	Current control status	Yes	Frequency	.
			%	.
		Partially controlled	Frequency	.
			%	.
Uncontrolled	Frequency	.		
	%	.		
	Well controlled	Frequency	7	
		%	17.95	

TABLE 14. FREQUENCY OF PROTOCOL DEVIATIONS (ITT Population)
10:22 Monday, July 27, 2020

Type of PD	N° PD		ITT
Minor PD	0	Frequency %	6 17.65
	1	Frequency %	1 2.94
	2	Frequency %	2 5.88
	3	Frequency %	4 11.76
	4	Frequency %	1 2.94
	6	Frequency %	19 55.88
	9	Frequency %	1 2.94
	>=1	Frequency %	28 82.35
Major PD	0	Frequency %	8 23.53
	1	Frequency %	25 73.53
	2	Frequency %	1 2.94
	>=1	Frequency %	26 76.47

TABLE 15. FREQUENCY OF MAJOR PROTOCOL DEVIATIONS (ITT Population)
10:22 Monday, July 27, 2020

Deviation category		ITT
Patients of Chiaravalle Centrale	Frequency	20
	%	58.82
More than 10 days over the expected visit	Frequency	1
	%	2.94
Use of not allowed drugs and procedures	Frequency	6
	%	17.65
Treatment permanently discontinued	Frequency	.
	%	.
No dose of the study treatment taken	Frequency	.
	%	.

TABLE 16. NUMBER OF SOLICITED AEs (WHATEVER THE TYPE) (Safety Population)
 10:22 Monday, July 27, 2020

Solicited AEs?	Type		Safety
No	//	Frequency	28
		%	82.35
Yes	Solicited Local AEs	Frequency	4
		%	11.76
	Solicited Systemic AEs	Frequency	2
		%	5.88

TABLE 17. FREQUENCY OF LOCAL REACTIONS AT THE ADMINISTRATION SITE (Safety Population)
10:22 Monday, July 27, 2020

Number of Local Reactions		Safety
0	Frequency	30
	%	88.24
1	Frequency	4
	%	11.76

TABLE 18. FREQUENCY OF LOCAL REACTIONS AT THE ADMINISTRATION SITE BY SEVERITY AT EACH TIME POINT (Safety Population)
10:22 Monday, July 27, 2020

Visit	Severity of Local Reactions		Safety
V2	Mild (1)	Frequency %	1 25.00
	Moderate (2)	Frequency %	. .
	Severe (3)	Frequency %	. .
	Unknown	Frequency %	. .
V3	Moderate (2)	Frequency %	. .
	Severe (3)	Frequency %	. .
	Unknown	Frequency %	. .
V4	Mild (1)	Frequency %	1 25.00
	Moderate (2)	Frequency %	. .
	Severe (3)	Frequency %	. .
	Unknown	Frequency %	. .
V5	Mild (1)	Frequency %	2 50.00

TABLE 18. FREQUENCY OF LOCAL REACTIONS AT THE ADMINISTRATION SITE BY SEVERITY AT EACH TIME POINT (Safety Population)
10:22 Monday, July 27, 2020

Visit	Severity of Local Reactions		Safety
V5	Moderate (2)	Frequency %	. .
	Severe (3)	Frequency %	. .
	Unknown	Frequency %	. .
Unscheduled Visit	Mild (1)	Frequency %	. .
	Moderate (2)	Frequency %	. .
	Severe (3)	Frequency %	. .
	Unknown	Frequency %	. .

TABLE 19. FREQUENCY OF LOCAL REACTIONS AT THE ADMINISTRATION SITE PER ADMINISTERED DOSE/VOLUME OF SOLUTION (Safety Population)
 10:22 Monday, July 27, 2020

Dose		Safety
2000	% Frequency	. .
5000	Frequency %	1 25.00
10000	% Frequency	. .
15000	% Frequency	. .
25000	Frequency %	1 25.00
50000	Frequency %	2 50.00

TABLE 20. FREQUENCY OF SYSTEMIC REACTIONS (Safety Population)
10:22 Monday, July 27, 2020

Number of Systemic Reactions		Safety
0	Frequency	32
	%	94.12
1	Frequency	2
	%	5.88

TABLE 21. FREQUENCY OF SYSTEMIC REACTIONS BY SEVERITY GRADE (Safety Population)
10:22 Monday, July 27, 2020

Severity of Systemic Reactions		Safety
Grade I	Frequency	2
	%	100.00
Grade II	Frequency	.
	%	.
Grade III	Frequency	.
	%	.
Grade IV	Frequency	.
	%	.
Grade V	Frequency	.
	%	.
Unknown Grade	Frequency	.
	%	.

TABLE 22. FREQUENCY OF SYSTEMIC REACTIONS PER ADMINISTERED DOSE/VOLUME OF SOLUTION (Safety Population)
 10:22 Monday, July 27, 2020

Dose		Safety
2000	Frequency	1
	%	50.00
	Frequency	.
	%	.
5000	Frequency	1
	%	50.00
10000	Frequency	.
	%	.
15000	Frequency	.
	%	.
25000	Frequency	.
	%	.
50000	Frequency	.
	%	.

TABLE 23. UNSOLICITED ADVERSE EVENTS (Safety Population)
10:22 Monday, July 27, 2020

Unsolicited AEs?	Type	SOC	SOC Code	PT	PT Code		Safety
No	//	//	//	//	//	Frequency	27
						%	79.41
Yes	Unsolicited AEs	Eye disorders	10015919	Conjunctival hyperaemia	10051625	Frequency	1
						%	2.94
		Gastrointestinal disorders	10017947	Oral pruritus	10052894	Frequency	1
						%	2.94
		Psychiatric disorders	10037175	Somnolence	10041349	Frequency	1
						%	2.94
		Respiratory, thoracic and mediastinal disorders	10038738	Cough	10011224	Frequency	1
						%	2.94
				Nasal obstruction	10028748	Frequency	1
						%	2.94
				Sneezing	10041232	Frequency	2
						%	5.88
		Skin and subcutaneous tissue disorders	10040785	Lip swelling	10024570	Frequency	1
						%	2.94

TABLE 24. FREQUENCY OF UNSOLICITED ADVERSE EVENTS (Safety Population)
10:22 Monday, July 27, 2020

Number of Unsolicited AEs		Safety
0	Frequency	27
	%	79.41
1	Frequency	6
	%	17.65
2	Frequency	1
	%	2.94

TABLE 25. VITAL SIGNS (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Variables		Safety	ITT	PP
Screening	DBP (mmHg)	N	23	23	3
		MEAN	68.70	68.70	70.00
		MEDIAN	70.00	70.00	70.00
		STD	7.57	7.57	0.00
		MIN	60.00	60.00	70.00
		MAX	80.00	80.00	70.00
	HR (beats/m in)	N	23	23	3
		MEAN	72.83	72.83	71.33
		MEDIAN	72.00	72.00	72.00
		STD	9.01	9.01	3.06
		MIN	60.00	60.00	68.00
		MAX	95.00	95.00	74.00
	SBP (mmHg)	N	23	23	3
		MEAN	111.74	111.74	118.33
		MEDIAN	110.00	110.00	120.00
		STD	9.96	9.96	7.64
		MIN	90.00	90.00	110.00
		MAX	130.00	130.00	125.00
V2 - 1st Treatment Visit	DBP (mmHg)	N	20	20	0
		MEAN	69.00	69.00	.
		MEDIAN	70.00	70.00	.
		STD	7.88	7.88	.
		MIN	60.00	60.00	.
		MAX	80.00	80.00	.
	HR (beats/m in)	N	20	20	0
		MEAN	74.90	74.90	.
		MEDIAN	77.00	77.00	.
		STD	5.60	5.60	.
		MIN	60.00	60.00	.
		MAX	82.00	82.00	.

TABLE 25. VITAL SIGNS (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Variables		Safety	ITT	PP
V2 - 1st Treatment Visit	SBP (mmHg)	N	20	20	0
		MEAN	121.00	121.00	.
		MEDIAN	120.00	120.00	.
		STD	8.68	8.68	.
		MIN	105.00	105.00	.
		MAX	130.00	130.00	.
V3 - 2nd Treatment Visit	DBP (mmHg)	N	20	20	0
		MEAN	72.50	72.50	.
		MEDIAN	70.00	70.00	.
		STD	7.16	7.16	.
		MIN	60.00	60.00	.
		MAX	80.00	80.00	.
	HR (beats/min)	N	20	20	0
		MEAN	75.90	75.90	.
		MEDIAN	76.00	76.00	.
		STD	6.47	6.47	.
		MIN	68.00	68.00	.
		MAX	96.00	96.00	.
	SBP (mmHg)	N	20	20	0
		MEAN	117.00	117.00	.
		MEDIAN	110.00	110.00	.
STD		12.50	12.50	.	
MIN		100.00	100.00	.	
MAX		140.00	140.00	.	
V4 - 3rd Treatment Visit	DBP (mmHg)	N	23	23	1
		MEAN	66.09	66.09	60.00
		MEDIAN	60.00	60.00	60.00
		STD	7.22	7.22	.
		MIN	60.00	60.00	60.00

TABLE 25. VITAL SIGNS (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Variables		Safety	ITT	PP	
V4 - 3rd Treatment Visit	DBP (mmHg)	MAX	80.00	80.00	60.00	
		HR (beats/min)	N	23	23	1
			MEAN	74.61	74.61	74.00
			MEDIAN	74.00	74.00	74.00
			STD	4.20	4.20	.
			MIN	68.00	68.00	74.00
			MAX	82.00	82.00	74.00
	SBP (mmHg)	N	23	23	1	
		MEAN	119.13	119.13	110.00	
		MEDIAN	120.00	120.00	110.00	
		STD	7.33	7.33	.	
		MIN	110.00	110.00	110.00	
		MAX	130.00	130.00	110.00	
	V5 - 4th Treatment Visit	DBP (mmHg)	N	9	9	5
			MEAN	72.22	72.22	74.00
MEDIAN			70.00	70.00	70.00	
STD			6.18	6.18	8.22	
MIN			65.00	65.00	65.00	
MAX			85.00	85.00	85.00	
HR (beats/min)		N	9	9	5	
		MEAN	71.89	71.89	70.00	
		MEDIAN	70.00	70.00	70.00	
		STD	4.54	4.54	3.74	
		MIN	66.00	66.00	66.00	
		MAX	78.00	78.00	76.00	
SBP (mmHg)		N	9	9	5	
		MEAN	118.89	118.89	120.00	
		MEDIAN	120.00	120.00	120.00	
	STD	10.54	10.54	14.14		

TABLE 25. VITAL SIGNS (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Variables		Safety	ITT	PP
V5 - 4th Treatment Visit	SBP (mmHg)	MIN	100.00	100.00	100.00
		MAX	140.00	140.00	140.00
V6 - End of Study/Early Termination Visit	DBP (mmHg)	N	33	33	7
		MEAN	70.06	70.06	72.86
		MEDIAN	70.00	70.00	70.00
		STD	8.41	8.41	5.67
		MIN	60.00	60.00	65.00
		MAX	87.00	87.00	80.00
	HR (beats/min)	N	33	33	7
		MEAN	71.45	71.45	72.57
		MEDIAN	70.00	70.00	72.00
		STD	4.25	4.25	3.78
		MIN	66.00	66.00	68.00
		MAX	84.00	84.00	78.00
	SBP (mmHg)	N	33	33	7
		MEAN	121.21	121.21	122.86
MEDIAN		120.00	120.00	120.00	
STD		9.44	9.44	8.59	
MIN		100.00	100.00	115.00	
MAX		140.00	140.00	140.00	

TABLE 26. CHANGE FROM BASELINE IN VITAL SIGNS (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Variables		Safety	ITT	PP
V2 - 1st Treatment Visit	DBP (mmHg)	N	20	20	0
		MEAN	0.50	0.50	.
		MEDIAN	0.00	0.00	.
		STD	7.59	7.59	.
		MIN	-10.00	-10.00	.
		MAX	10.00	10.00	.
	HR (beats/min)	N	20	20	0
		MEAN	1.85	1.85	.
		MEDIAN	2.00	2.00	.
		STD	10.43	10.43	.
		MIN	-27.00	-27.00	.
		MAX	20.00	20.00	.
	SBP (mmHg)	N	20	20	0
		MEAN	10.25	10.25	.
		MEDIAN	10.00	10.00	.
STD		10.45	10.45	.	
MIN		-5.00	-5.00	.	
MAX		40.00	40.00	.	
V3 - 2nd Treatment Visit	DBP (mmHg)	N	20	20	0
		MEAN	4.00	4.00	.
		MEDIAN	5.00	5.00	.
		STD	8.21	8.21	.
		MIN	-10.00	-10.00	.
		MAX	20.00	20.00	.
	HR (beats/min)	N	20	20	0
		MEAN	2.85	2.85	.
		MEDIAN	4.00	4.00	.
		STD	13.06	13.06	.
		MIN	-27.00	-27.00	.
		MAX	24.00	24.00	.

TABLE 26. CHANGE FROM BASELINE IN VITAL SIGNS (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Variables		Safety	ITT	PP
V3 - 2nd Treatment Visit	SBP (mmHg)	N	20	20	0
		MEAN	6.25	6.25	.
		MEDIAN	10.00	10.00	.
		STD	9.16	9.16	.
		MIN	-10.00	-10.00	.
		MAX	20.00	20.00	.
V4 - 3rd Treatment Visit	DBP (mmHg)	N	20	20	0
		MEAN	-2.00	-2.00	.
		MEDIAN	0.00	0.00	.
		STD	8.94	8.94	.
		MIN	-20.00	-20.00	.
		MAX	10.00	10.00	.
	HR (beats/min)	N	20	20	0
		MEAN	1.65	1.65	.
		MEDIAN	4.00	4.00	.
		STD	11.65	11.65	.
		MIN	-27.00	-27.00	.
		MAX	18.00	18.00	.
	SBP (mmHg)	N	20	20	0
		MEAN	9.25	9.25	.
		MEDIAN	10.00	10.00	.
		STD	9.77	9.77	.
		MIN	-10.00	-10.00	.
		MAX	30.00	30.00	.
V5 - 4th Treatment Visit	DBP (mmHg)	N	2	2	2
		MEAN	5.00	5.00	5.00
		MEDIAN	5.00	5.00	5.00
		STD	7.07	7.07	7.07
		MIN	0.00	0.00	0.00
		MAX	10.00	10.00	10.00

TABLE 26. CHANGE FROM BASELINE IN VITAL SIGNS (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Variables		Safety	ITT	PP	
V5 - 4th Treatment Visit	HR (beats/min)	N	2	2	2	
		MEAN	-2.00	-2.00	-2.00	
		MEDIAN	-2.00	-2.00	-2.00	
		STD	5.66	5.66	5.66	
		MIN	-6.00	-6.00	-6.00	
		MAX	2.00	2.00	2.00	
	SBP (mmHg)	N	2	2	2	
		MEAN	5.00	5.00	5.00	
		MEDIAN	5.00	5.00	5.00	
		STD	7.07	7.07	7.07	
		MIN	0.00	0.00	0.00	
		MAX	10.00	10.00	10.00	
	V6 - End of Study/Early Termination Visit	DBP (mmHg)	N	23	23	3
			MEAN	0.74	0.74	3.33
			MEDIAN	0.00	0.00	0.00
STD			9.24	9.24	5.77	
MIN			-10.00	-10.00	0.00	
MAX			20.00	20.00	10.00	
HR (beats/min)		N	23	23	3	
		MEAN	-1.35	-1.35	2.00	
		MEDIAN	0.00	0.00	4.00	
		STD	10.65	10.65	5.29	
		MIN	-27.00	-27.00	-4.00	
		MAX	14.00	14.00	6.00	
SBP (mmHg)		N	23	23	3	
		MEAN	9.57	9.57	5.00	
		MEDIAN	10.00	10.00	0.00	
	STD	11.07	11.07	8.66		
	MIN	-10.00	-10.00	0.00		
	MAX	40.00	40.00	15.00		

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
Screening	Asthma Test	FEV1 predicted(%)	N	4	4	0
			MEAN	113.50	113.50	.
			MEDIAN	109.00	109.00	.
			STD	19.76	19.76	.
			MIN	95.00	95.00	.
			MAX	141.00	141.00	.
		FEV1 (l)	N	4	4	0
			MEAN	3.84	3.84	.
			MEDIAN	3.80	3.80	.
			STD	0.64	0.64	.
			MIN	3.09	3.09	.
			MAX	4.65	4.65	.
		FVC predicted(%)	N	4	4	0
			MEAN	115.50	115.50	.
			MEDIAN	109.50	109.50	.
			STD	25.88	25.88	.
			MIN	91.00	91.00	.
			MAX	152.00	152.00	.
		FVC (l)	N	4	4	0
			MEAN	4.53	4.53	.
			MEDIAN	4.56	4.56	.
			STD	0.67	0.67	.
			MIN	3.72	3.72	.
			MAX	5.29	5.29	.
		PEF predicted(%)	N	4	4	0
			MEAN	98.75	98.75	.
			MEDIAN	106.00	106.00	.
			STD	17.44	17.44	.
			MIN	73.00	73.00	.
			MAX	110.00	110.00	.

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
Screening	Asthma Test	PEF (l/s)	N	4	4	0
			MEAN	7.98	7.98	.
			MEDIAN	8.41	8.41	.
			STD	2.47	2.47	.
			MIN	4.92	4.92	.
			MAX	10.20	10.20	.
V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
STD	.		.	.		
MIN	.		.	.		
MAX	.		.	.		

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	PEF predicted(%)	N	4	4	0
			MEAN	82.75	82.75	.
		MEDIAN	88.00	88.00	.	
		STD	21.75	21.75	.	
		MIN	52.00	52.00	.	
		MAX	103.00	103.00	.	
		PEF (l/s)	N	4	4	0
			MEAN	6.43	6.43	.
			MEDIAN	6.20	6.20	.
			STD	1.41	1.41	.
	MIN		5.00	5.00	.	
	MAX		8.30	8.30	.	
	Asthma Test Prior to 2nd Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (l)	N	0	0	0
			MEAN	.	.	.
MEDIAN			.	.	.	
STD			.	.	.	
FVC predicted(%)	N	0	0	0		
	MEAN	.	.	.		
	STD	.	.	.		

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	FVC predicted(%)	MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	81.25	81.25	.
			MEDIAN	80.00	80.00	.
			STD	18.68	18.68	.
			MIN	62.00	62.00	.
			MAX	103.00	103.00	.
		PEF (l/s)	N	4	4	0
	MEAN		6.45	6.45	.	
	MEDIAN		6.65	6.65	.	
	STD		1.69	1.69	.	
	MIN		4.20	4.20	.	
	MAX		8.30	8.30	.	
	Asthma Test After 2nd Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
STD			.	.	.	
MIN			.	.	.	
MAX			.	.	.	
FEV1 (l)		N	0	0	0	
		MEAN	.	.	.	
		MEDIAN	.	.	.	

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	FEV1 (l)	STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	79.75	79.75	.
			MEDIAN	82.00	82.00	.
			STD	21.98	21.98	.
			MIN	52.00	52.00	.
MAX	103.00		103.00	.		
PEF (l/s)	N	4	4	0		
	MEAN	6.23	6.23	.		
	MEDIAN	5.80	5.80	.		
	STD	1.58	1.58	.		
	MIN	5.00	5.00	.		
	MAX	8.30	8.30	.		
V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	FEV1 predicted(%)	N	0	0	0

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP	
V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	FEV1 predicted(%)	MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
			MIN	.	.	.	
			MAX	.	.	.	
		FEV1 (l)	N	0	0	0	
			MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
			MIN	.	.	.	
		FVC predicted(%)	N	0	0	0	
			MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
			MIN	.	.	.	
		FVC (l)	N	0	0	0	
			MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
			MIN	.	.	.	
		PEF predicted(%)	N	4	4	0	
			MEAN	80.00	80.00	.	
			MEDIAN	73.50	73.50	.	
			STD	15.43	15.43	.	
			MIN	70.00	70.00	.	
				MAX	103.00	103.00	.

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP	
V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	PEF(1/s)	N	4	4	0	
			MEAN	6.23	6.23	.	
		MEDIAN	6.60	6.60	.		
		STD	0.82	0.82	.		
		MIN	5.00	5.00	.		
		MAX	6.70	6.70	.		
		Asthma Test Prior to 2nd Administration	FEV1 predicted(%)	N	0	0	0
				MEAN	.	.	.
			MEDIAN	.	.	.	
			STD	.	.	.	
	MIN		.	.	.		
	FEV1 (l)	N	0	0	0		
		MEAN	.	.	.		
		MEDIAN	.	.	.		
		STD	.	.	.		
		MIN	.	.	.		
	FVC predicted(%)	N	0	0	0		
		MEAN	.	.	.		
		MEDIAN	.	.	.		
		STD	.	.	.		
MIN		.	.	.			
FVC (l)	N	0	0	0			
	MEAN	.	.	.			
	MEDIAN	.	.	.			
	STD	.	.	.			
	MIN	.	.	.			

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	FVC(l)	MAX	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	75.25	75.25	.
			MEDIAN	73.00	73.00	.
			STD	21.00	21.00	.
			MIN	52.00	52.00	.
			MAX	103.00	103.00	.
		PEF(l/s)	N	4	4	0
			MEAN	5.80	5.80	.
			MEDIAN	5.80	5.80	.
			STD	0.92	0.92	.
			MIN	5.00	5.00	.
			MAX	6.60	6.60	.
	Asthma Test After 2nd Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
		MAX	.	.	.	
		FEV1(l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
MIN	.		.	.		
FVC predicted(%)	N	0	0	0		
	MEAN	.	.	.		
		MEDIAN	.	.	.	

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	FVC predicted(%)	STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	75.25	75.25	.
			MEDIAN	73.00	73.00	.
			STD	21.00	21.00	.
			MIN	52.00	52.00	.
			MAX	103.00	103.00	.
		PEF (l/s)	N	4	4	0
			MEAN	5.80	5.80	.
			MEDIAN	5.80	5.80	.
			STD	0.92	0.92	.
			MIN	5.00	5.00	.
MAX	6.60		6.60	.		
V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (l)	N	0	0	0
			MEAN	.	.	.

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	FEV1 (l)	MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	78.00	78.00	.
			MEDIAN	80.00	80.00	.
			STD	23.62	23.62	.
			MIN	49.00	49.00	.
			MAX	103.00	103.00	.
		PEF (l/s)	N	4	4	0
			MEAN	6.20	6.20	.
			MEDIAN	6.60	6.60	.
			STD	2.09	2.09	.
			MIN	3.30	3.30	.
			MAX	8.30	8.30	.

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (1)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (1)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
MAX	.		.	.		
PEF predicted(%)	N	4	4	0		
	MEAN	72.25	72.25	.		
	MEDIAN	67.00	67.00	.		
	STD	22.07	22.07	.		
	MIN	52.00	52.00	.		
	MAX	103.00	103.00	.		

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	PEF(1/s)	N	4	4	0
			MEAN	5.60	5.60	.
			MEDIAN	5.80	5.80	.
			STD	1.20	1.20	.
			MIN	4.20	4.20	.
			MAX	6.60	6.60	.
V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (1)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
FVC (1)	N	0	0	0		
	MEAN	.	.	.		
	MEDIAN	.	.	.		
	STD	.	.	.		
	MIN	.	.	.		
	MAX	.	.	.		

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	PEF predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF (l/s)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
	Asthma Test After 1st Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
FVC predicted(%)	N	0	0	0		
	MEAN	.	.	.		
	MEDIAN	.	.	.		
	STD	.	.	.		

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V5 - 4th Treatment Visit	Asthma Test After 1st Administration	FVC predicted(%)	MAX	.	.	.
			FVC (l)	N	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF (l/s)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
MAX	.		.	.		
V6 - End of Study/Early Termination Visit	Asthma Test	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V6 - End of Study/Early Termination Visit	Asthma Test	FEV1 (l)	MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	80.75	80.75	.
			MEDIAN	84.00	84.00	.
			STD	21.30	21.30	.
			MIN	52.00	52.00	.
			MAX	103.00	103.00	.
PEF (l/s)	N	4	4	0		
	MEAN	6.23	6.23	.		
	MEDIAN	6.20	6.20	.		
	STD	1.07	1.07	.		
	MIN	5.00	5.00	.		
	MAX	7.50	7.50	.		
Unscheduled Visit	Asthma Test Prior to Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
Unscheduled Visit	Asthma Test Prior to Administration	FEV1 predicted(%)	MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
MAX	.		.	.		
PEF (l/s)	N	0	0	0		
	MEAN	.	.	.		

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
Unscheduled Visit	Asthma Test Prior to Administration	PEF(1/s)	MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
	Asthma Test After the Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (1)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
	FVC predicted(%)	N	0	0	0	
		MEAN	.	.	.	
		MEDIAN	.	.	.	
		STD	.	.	.	
		MIN	.	.	.	
		MAX	.	.	.	
	FVC (1)	N	0	0	0	
		MEAN	.	.	.	
MEDIAN		.	.	.		
STD		.	.	.		
MIN		.	.	.		
MAX		.	.	.		
PEF predicted(%)	N	0	0	0		

TABLE 27. PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP	
Unscheduled Visit	Asthma Test After the Administration	PEF predicted(%)	MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
			MIN	.	.	.	
			MAX	.	.	.	
		PEF (l/s)	N	0	0	0	
			MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
			MIN	.	.	.	
				MAX	.	.	.

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
		MAX	.	.	.	
		FEV1 (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
		MAX	.	.	.	
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
		MAX	.	.	.	
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
		MAX	.	.	.	
		PEF predicted(%)	N	4	4	0
MEAN	-16.00		-16.00	.		
MEDIAN	-13.00		-13.00	.		
STD	26.97		26.97	.		
MIN	-51.00		-51.00	.		

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP		
V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	PEF predicted(%)	MAX	13.00	13.00	.		
			PEF (l/s)	N	4	4	0	
				MEAN	-1.56	-1.56	.	
				MEDIAN	-1.17	-1.17	.	
				STD	2.42	2.42	.	
				MIN	-4.76	-4.76	.	
				MAX	0.88	0.88	.	
			Asthma Test Prior to 2nd Administration	FEV1 predicted(%)	N	0	0	0
					MEAN	.	.	.
				MEDIAN	.	.	.	
		STD		.	.	.		
		MIN		.	.	.		
			MAX	.	.	.		
			FEV1 (l)	N	0	0	0	
				MEAN	.	.	.	
			MEDIAN	.	.	.		
			STD	.	.	.		
			MIN	.	.	.		
			MAX	.	.	.		
			FVC predicted(%)	N	0	0	0	
	MEAN			.	.	.		
	MEDIAN		.	.	.			
	STD		.	.	.			
	MIN		.	.	.			
		MAX	.	.	.			
		FVC (l)	N	0	0	0		
			MEAN	.	.	.		
			MEDIAN	.	.	.		

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	FVC(1)	STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	-17.50	-17.50	.
			MEDIAN	-15.50	-15.50	.
			STD	11.85	11.85	.
			MIN	-33.00	-33.00	.
			MAX	-6.00	-6.00	.
			PEF (l/s)	N	4	4
	MEAN	-1.53		-1.53	.	
	MEDIAN	-1.31		-1.31	.	
	STD	1.20		1.20	.	
	MIN	-3.06		-3.06	.	
	MAX	-0.45		-0.45	.	
	Asthma Test After 2nd Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
FEV1 (l)		N	0	0	0	
		MEAN	.	.	.	
		MEDIAN	.	.	.	
		STD	.	.	.	
		MIN	.	.	.	
FVC predicted(%)	N	0	0	0		

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	FVC predicted(%)	MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	-19.00	-19.00	.
			MEDIAN	-13.00	-13.00	.
			STD	23.05	23.05	.
			MIN	-51.00	-51.00	.
		PEF (l/s)	N	4	4	0
			MEAN	-1.76	-1.76	.
			MEDIAN	-1.17	-1.17	.
			STD	2.17	2.17	.
			MIN	-4.76	-4.76	.
V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
		MAX	.	.	.	

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	FEV1 (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	-18.75	-18.75	.
			MEDIAN	-19.50	-19.50	.
			STD	19.05	19.05	.
			MIN	-37.00	-37.00	.
			MAX	1.00	1.00	.
		PEF (l/s)	N	4	4	0
			MEAN	-1.76	-1.76	.
			MEDIAN	-1.76	-1.76	.
			STD	1.84	1.84	.
MIN	-3.60		-3.60	.		
MAX	0.08		0.08	.		

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
STD	.		.	.		
MIN	.		.	.		
MAX	.		.	.		
PEF predicted(%)	N	4	4	0		
	MEAN	-23.50	-23.50	.		
	MEDIAN	-22.00	-22.00	.		
	STD	24.99	24.99	.		
	MIN	-51.00	-51.00	.		

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP		
V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	PEF predicted(%)	MAX	1.00	1.00	.		
			PEF (l/s)	N	4	4	0	
				MEAN	-2.18	-2.18	.	
				MEDIAN	-2.03	-2.03	.	
				STD	2.36	2.36	.	
				MIN	-4.76	-4.76	.	
				MAX	0.08	0.08	.	
			Asthma Test After 2nd Administration	FEV1 predicted(%)	N	0	0	0
					MEAN	.	.	.
					MEDIAN	.	.	.
					STD	.	.	.
		MIN			.	.	.	
		MAX			.	.	.	
			FEV1 (l)	N	0	0	0	
				MEAN	.	.	.	
				MEDIAN	.	.	.	
				STD	.	.	.	
				MIN	.	.	.	
				MAX	.	.	.	
			FVC predicted(%)	N	0	0	0	
				MEAN	.	.	.	
				MEDIAN	.	.	.	
				STD	.	.	.	
	MIN			.	.	.		
	MAX			.	.	.		
		FVC (l)	N	0	0	0		
			MEAN	.	.	.		
			MEDIAN	.	.	.		
			STD	.	.	.		

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	FVC (l)	MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	-23.50	-23.50	.
			MEDIAN	-22.00	-22.00	.
			STD	24.99	24.99	.
			MIN	-51.00	-51.00	.
			MAX	1.00	1.00	.
		PEF (l/s)	N	4	4	0
			MEAN	-2.18	-2.18	.
			MEDIAN	-2.03	-2.03	.
			STD	2.36	2.36	.
			MIN	-4.76	-4.76	.
			MAX	0.08	0.08	.
V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	FVC predicted(%)	MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	-20.75	-20.75	.
			MEDIAN	-22.00	-22.00	.
			STD	11.24	11.24	.
			MIN	-33.00	-33.00	.
	MAX		-6.00	-6.00	.	
	PEF (l/s)	N	4	4	0	
		MEAN	-1.78	-1.78	.	
		MEDIAN	-1.76	-1.76	.	
		STD	1.11	1.11	.	
		MIN	-3.16	-3.16	.	
		MAX	-0.45	-0.45	.	
	Asthma Test After 1st Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
MAX			.	.	.	
FEV1 (l)		N	0	0	0	

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP	
V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	FEV1 (l)	MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
			MIN	.	.	.	
			MAX	.	.	.	
		FVC predicted(%)	N	0	0	0	
			MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
			MIN	.	.	.	
		FVC (l)	N	0	0	0	
			MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
			MIN	.	.	.	
		PEF predicted(%)	N	4	4	0	
			MEAN	-26.50	-26.50	.	
			MEDIAN	-24.50	-24.50	.	
			STD	21.55	21.55	.	
			MIN	-51.00	-51.00	.	
		PEF (l/s)	N	4	4	0	
			MEAN	-2.38	-2.38	.	
			MEDIAN	-2.16	-2.16	.	
			STD	2.13	2.13	.	
			MIN	-4.76	-4.76	.	
				MAX	-0.45	-0.45	.

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (1)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (1)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
STD	.		.	.		
MIN	.		.	.		
MAX	.		.	.		

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP	
V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	PEF(l/s)	N	0	0	0	
			MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
			MIN	.	.	.	
			MAX	.	.	.	
		Asthma Test After 1st Administration	FEV1 predicted(%)	N	0	0	0
				MEAN	.	.	.
				MEDIAN	.	.	.
				STD	.	.	.
	FEV1 (l)	N	N	0	0	0	
			MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
			MIN	.	.	.	
			MAX	.	.	.	
	FVC predicted(%)	N	N	0	0	0	
			MEAN	.	.	.	
			MEDIAN	.	.	.	
			STD	.	.	.	
MIN			.	.	.		
MAX			.	.	.		
FVC (l)	N	N	0	0	0		
		MEAN	.	.	.		
		MEDIAN	.	.	.		
		STD	.	.	.		

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V5 - 4th Treatment Visit	Asthma Test After 1st Administration	FVC (l)	MAX	.	.	.
		PEF predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF (l/s)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		V6 - End of Study/Early Termination Visit	Asthma Test	FEV1 predicted(%)	N	0
MEAN	.				.	.
MEDIAN	.				.	.
STD	.				.	.
MIN	.				.	.
MAX	.				.	.
FEV1 (l)	N			0	0	0
	MEAN			.	.	.
	MEDIAN			.	.	.
	STD			.	.	.
	MIN			.	.	.
	MAX			.	.	.
FVC predicted(%)	N			0	0	0
	MEAN			.	.	.
	MEDIAN	.	.	.		

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
V6 - End of Study/Early Termination Visit	Asthma Test	FVC predicted(%)	STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	4	4	0
			MEAN	-18.00	-18.00	.
			MEDIAN	-17.50	-17.50	.
			STD	28.15	28.15	.
			MIN	-51.00	-51.00	.
			MAX	14.00	14.00	.
		PEF (l/s)	N	4	4	0
			MEAN	-1.76	-1.76	.
			MEDIAN	-1.58	-1.58	.
			STD	2.49	2.49	.
			MIN	-4.76	-4.76	.
MAX	0.88		0.88	.		
Unscheduled Visit	Asthma Test Prior to Administration	FEV1 predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (l)	N	0	0	0
			MEAN	.	.	.

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
Unscheduled Visit	Asthma Test Prior to Administration	FEV1 (l)	MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
	MIN		.	.	.	
	MAX		.	.	.	
	PEF predicted(%)	N	0	0	0	
		MEAN	.	.	.	
		MEDIAN	.	.	.	
		STD	.	.	.	
		MIN	.	.	.	
		MAX	.	.	.	
	PEF (l/s)	N	0	0	0	
		MEAN	.	.	.	
		MEDIAN	.	.	.	
		STD	.	.	.	
		MIN	.	.	.	
MAX		.	.	.		
	Asthma Test After the Administration	FEV1 predicted(%)	N	0	0	0

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
Unscheduled Visit	Asthma Test After the Administration	FEV1 predicted(%)	MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.
		FEV1 (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MAX	.	.	.
		FVC predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MAX	.	.	.
		FVC (l)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MAX	.	.	.
		PEF predicted(%)	N	0	0	0
			MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MAX	.	.	.
		PEF (l/s)	N	0	0	0

TABLE 28. CHANGE FROM BASELINE IN PULMONARY FUNCTION IN ASHTMATIC PATIENTS ONLY (Safety, ITT, PP Population)
10:22 Monday, July 27, 2020

Visit	Administration	Variables		Safety	ITT	PP
Unscheduled Visit	Asthma Test After the Administration	PEF(l/s)	MEAN	.	.	.
			MEDIAN	.	.	.
			STD	.	.	.
			MIN	.	.	.
			MAX	.	.	.

TABLE 29. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT (ITT, PP Population)
10:22 Monday, July 27, 2020

Variables		ITT	PP
ALT (UI/l)	N	34	7
	MEAN	22.00	23.71
	MEDIAN	21.00	26.00
	STD	10.52	11.35
	MIN	8.00	8.00
	MAX	44.00	38.00
AST (UI/l)	N	34	7
	MEAN	20.21	23.14
	MEDIAN	18.00	18.00
	STD	8.48	15.16
	MIN	11.00	11.00
	MAX	55.00	55.00
Albumin (g/dl)	N	34	7
	MEAN	4.65	4.61
	MEDIAN	4.70	4.50
	STD	0.29	0.36
	MIN	4.10	4.20
	MAX	5.10	5.10
Basophils (10 ⁹)	N	34	7
	MEAN	0.10	0.09
	MEDIAN	0.08	0.10
	STD	0.20	0.04
	MIN	0.00	0.00
	MAX	1.20	0.10
Calcium Total Protein (mg/dl)	N	34	7
	MEAN	9.37	9.43
	MEDIAN	9.33	9.40
	STD	0.29	0.24
	MIN	8.87	9.20
	MAX	9.90	9.90
Chloride (mmol/L)	N	34	7

TABLE 29. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT (ITT, PP Population)
10:22 Monday, July 27, 2020

Variables		ITT	PP
Chloride (mmol/L)	MEAN	101.62	103.00
	MEDIAN	102.00	103.00
	STD	2.28	1.00
	MIN	95.00	101.00
	MAX	106.00	104.00
Creatinine (mg/dl)	N	34	7
	MEAN	0.78	0.80
	MEDIAN	0.80	0.80
	STD	0.14	0.14
	MIN	0.50	0.60
Eosinophils (10 ⁹)	MAX	1.02	1.00
	N	34	7
	MEAN	0.24	0.19
	MEDIAN	0.20	0.20
	STD	0.16	0.09
GGT (UI/l)	MIN	0.06	0.10
	MAX	0.55	0.30
	N	34	7
	MEAN	18.15	24.00
	MEDIAN	14.00	14.00
Grass pollen specific IgE (UI/l)	STD	14.23	22.33
	MIN	3.00	3.00
	MAX	57.00	57.00
	N	34	7
	MEAN	22.41	5.41
Haematocrit (%)	MEDIAN	5.27	2.87
	STD	30.57	7.10
	MIN	1.12	2.36
	MAX	100.00	21.50
	N	34	7
Haematocrit (%)	MEAN	42.60	41.46
	MEDIAN	43.15	42.10

TABLE 29. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT (ITT, PP Population)
10:22 Monday, July 27, 2020

Variables		ITT	PP
Haematocrit (%)	STD	4.31	3.77
	MIN	33.20	36.10
	MAX	50.30	45.90
Haemoglobin (g/dl)	N	34	7
	MEAN	14.71	14.71
	MEDIAN	15.00	14.50
	STD	1.64	1.26
	MIN	11.30	12.80
	MAX	17.50	16.50
Lymphocytes (10 ⁹)	N	34	7
	MEAN	2.40	2.00
	MEDIAN	2.40	1.90
	STD	0.77	0.68
	MIN	1.00	1.00
	MAX	4.60	3.10
Monocytes (10 ⁹)	N	34	7
	MEAN	0.59	0.54
	MEDIAN	0.57	0.60
	STD	0.22	0.18
	MIN	0.29	0.30
	MAX	1.19	0.80
Neutrophils (10 ⁹)	N	34	7
	MEAN	3.95	3.79
	MEDIAN	3.80	3.80
	STD	1.35	0.87
	MIN	1.93	2.70
	MAX	7.90	4.80
Platelets (10 ³ /ul)	N	34	7
	MEAN	239.15	212.00
	MEDIAN	239.00	232.00
	STD	58.70	37.63
	MIN	125.00	163.00
	MAX	382.00	256.00

TABLE 29. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT (ITT, PP Population)
10:22 Monday, July 27, 2020

Variables		ITT	PP
Potassium(mEq/l)	N	34	7
	MEAN	4.46	4.49
	MEDIAN	4.45	4.50
	STD	0.43	0.29
	MIN	3.70	4.10
	MAX	5.60	4.90
RBC (10 ³ /ul)	N	34	7
	MEAN	5.10	4.78
	MEDIAN	5.21	4.73
	STD	0.55	0.48
	MIN	3.68	4.17
	MAX	6.22	5.48
Sodium (mEq/l)	N	34	7
	MEAN	140.82	139.71
	MEDIAN	141.00	140.00
	STD	1.55	2.29
	MIN	136.00	136.00
	MAX	144.00	143.00
Total bilirubin(mg/dl)	N	34	7
	MEAN	0.51	0.51
	MEDIAN	0.50	0.50
	STD	0.24	0.20
	MIN	0.13	0.30
	MAX	1.35	0.90
Urea (mmol/L)	N	34	7
	MEAN	33.06	28.86
	MEDIAN	32.50	28.00
	STD	8.29	7.40
	MIN	19.00	19.00
	MAX	54.00	42.00
WBC (10 ³ /ul)	N	34	7
	MEAN	7.24	6.58

TABLE 29. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT (ITT, PP Population)
10:22 Monday, July 27, 2020

Variables		ITT	PP
WBC (10 ³ /ul)	MEDIAN	7.02	6.60
	STD	1.85	1.22
	MIN	3.88	4.86
	MAX	12.16	7.82

TABLE 30. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT (ITT, PP Population)
10:22 Monday, July 27, 2020

Variables		ITT	PP
ALT (UI/l)	N	33	7
	MEAN	21.67	27.14
	MEDIAN	19.00	25.00
	STD	9.68	11.36
	MIN	8.00	11.00
	MAX	44.00	40.00
AST (UI/l)	N	33	7
	MEAN	20.27	25.29
	MEDIAN	18.00	19.00
	STD	8.19	13.66
	MIN	11.00	15.00
	MAX	54.00	54.00
Albumin (g/dl)	N	33	7
	MEAN	4.56	4.61
	MEDIAN	4.60	4.70
	STD	0.29	0.37
	MIN	4.00	4.10
	MAX	5.10	5.10
Basophils (10 ⁹)	N	33	7
	MEAN	0.27	0.46
	MEDIAN	0.07	0.10
	STD	0.81	0.90
	MIN	0.02	0.10
	MAX	4.10	2.50
Calcium Total Protein (mg/dl)	N	33	7
	MEAN	9.28	9.36
	MEDIAN	9.35	9.40
	STD	0.33	0.21
	MIN	8.42	9.10
	MAX	9.86	9.70
Chloride (mmol/L)	N	33	7

TABLE 30. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT (ITT, PP Population)
10:22 Monday, July 27, 2020

Variables		ITT	PP
Chloride (mmol/L)	MEAN	101.76	102.14
	MEDIAN	102.00	102.00
	STD	2.11	1.86
	MIN	96.00	100.00
	MAX	106.00	106.00
Creatinine (mg/dl)	N	33	7
	MEAN	0.82	0.84
	MEDIAN	0.80	0.90
	STD	0.17	0.17
	MIN	0.50	0.50
Eosinophils (10 ⁹)	MAX	1.30	1.00
	N	33	7
	MEAN	0.30	0.31
	MEDIAN	0.22	0.30
	STD	0.16	0.13
GGT (UI/l)	MIN	0.06	0.10
	MAX	0.60	0.50
	N	33	7
	MEAN	16.85	19.57
	MEDIAN	14.00	12.00
Haematocrit (%)	STD	11.32	18.08
	MIN	3.00	3.00
	MAX	56.00	56.00
	N	33	7
	MEAN	42.11	40.49
Haemoglobin (g/dl)	MEDIAN	43.40	39.70
	STD	4.10	2.81
	MIN	34.20	37.40
	MAX	49.10	45.60
	N	33	7
Haemoglobin (g/dl)	MEAN	14.57	14.40
	MEDIAN	15.10	14.30
	STD	1.63	1.06

TABLE 30. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT (ITT, PP Population)
10:22 Monday, July 27, 2020

Variables		ITT	PP
Haemoglobin (g/dl)	MIN	11.40	12.60
	MAX	17.10	15.90
Lymphocytes (10 ⁹)	N	33	7
	MEAN	3.05	2.04
	MEDIAN	2.08	1.60
	STD	5.43	0.75
	MIN	1.10	1.20
	MAX	33.10	3.00
Monocytes (10 ⁹)	N	33	7
	MEAN	0.55	0.57
	MEDIAN	0.56	0.60
	STD	0.17	0.18
	MIN	0.18	0.30
	MAX	1.00	0.80
Neutrophils (10 ⁹)	N	33	7
	MEAN	4.98	9.51
	MEDIAN	3.40	3.40
	STD	7.24	15.56
	MIN	2.00	2.40
	MAX	44.70	44.70
Platelets (10 ³ /ul)	N	33	7
	MEAN	235.21	218.00
	MEDIAN	230.00	233.00
	STD	44.08	41.98
	MIN	153.00	153.00
	MAX	345.00	255.00
Potassium (mEq/l)	N	33	7
	MEAN	4.35	4.49
	MEDIAN	4.30	4.30
	STD	0.28	0.30
	MIN	3.80	4.20
	MAX	5.00	4.90

TABLE 30. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT (ITT, PP Population)
10:22 Monday, July 27, 2020

Variables		ITT	PP
RBC (10 ³ /ul)	N	33	7
	MEAN	5.07	4.68
	MEDIAN	5.13	4.54
	STD	0.52	0.38
	MIN	3.82	4.30
	MAX	5.95	5.40
Sodium (mEq/l)	N	33	7
	MEAN	140.24	139.57
	MEDIAN	140.00	139.00
	STD	2.45	2.76
	MIN	136.00	136.00
	MAX	144.00	144.00
Total bilirubin (mg/dl)	N	33	7
	MEAN	0.58	0.53
	MEDIAN	0.50	0.50
	STD	0.37	0.24
	MIN	0.21	0.30
	MAX	1.92	0.80
Urea (mmol/L)	N	33	7
	MEAN	30.45	23.43
	MEDIAN	33.00	28.00
	STD	12.19	17.20
	MIN	0.00	0.00
	MAX	47.00	41.00
WBC (10 ³ /ul)	N	33	7
	MEAN	6.71	6.53
	MEDIAN	6.50	5.35
	STD	1.77	2.15
	MIN	4.04	4.55
	MAX	10.36	10.36

TABLE 31. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS (ITT, PP Population)
10:22 Monday, July 27, 2020

		Worsening?	ITT	PP
SBP (mmHg)	No	Frequency	34	7
		%	100.00	100.00
	Yes	Frequency	.	.
		%	.	.
DBP (mmHg)	No	Frequency	34	7
		%	100.00	100.00
	Yes	Frequency	.	.
		%	.	.
Pulse (beats/min)	No	Frequency	34	7
		%	100.00	100.00
	Yes	Frequency	.	.
		%	.	.
FEV1 (l)	Yes	Frequency	.	.
		%	.	.
FEV1 predicted(%)	Yes	Frequency	.	.
		%	.	.
FVC (l)	Yes	Frequency	.	.
		%	.	.
FVC predicted(%)	Yes	Frequency	.	.
		%	.	.
PEF (l/s)	No	Frequency	36	.
		%	105.88	.
	Yes	Frequency	.	.
		%	.	.
PEF predicted(%)	No	Frequency	35	.
		%	102.94	.
	Yes	Frequency	1	.
		%	2.94	.
	Frequency	.	.	

TABLE 31. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS (ITT, PP Population)
10:22 Monday, July 27, 2020

	Worsening?		ITT	PP
PEF predicted(%)	Yes	%	.	.
ALT (UI/l)	No	Frequency %	34 100.00	7 100.00
AST (UI/l)	No	Frequency %	34 100.00	7 100.00
	Yes	Frequency %
Albumin (g/dl)	No	Frequency %	34 100.00	7 100.00
	Yes	Frequency %
Basophils (10 ⁹)	No	Frequency %	32 94.12	6 85.71
	Yes	Frequency %	2 5.88	1 14.29
Calcium Total Protein (mg/dl)	No	Frequency %	34 100.00	7 100.00
Chloride (mmol/L)	No	Frequency %	34 100.00	7 100.00
Creatinine (mg/dl)	No	Frequency %	33 97.06	6 85.71
	Yes	Frequency	1	1
		%	2.94	14.29
		Frequency %
Eosinophils (10 ⁹)	No	Frequency %	34 100.00	7 100.00
GGT (UI/l)	No	Frequency	33	7

TABLE 31. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS (ITT, PP Population)
10:22 Monday, July 27, 2020

	Worsening?		ITT	PP
GGT (UI/l)	No	%	97.06	100.00
	Yes	Frequency	1	.
		%	2.94	.
		Frequency	.	.
	%	.	.	
Haematocrit (%)	No	Frequency	34	7
		%	100.00	100.00
Haemoglobin (g/dl)	No	Frequency	34	7
		%	100.00	100.00
Lymphocytes (10 ⁹)	No	Frequency	33	7
		%	97.06	100.00
	Yes	Frequency	1	.
		%	2.94	.
Monocytes (10 ⁹)	No	Frequency	34	7
		%	100.00	100.00
	Yes	Frequency	.	.
		%	.	.
Neutrophils (10 ⁹)	No	Frequency	32	6
		%	94.12	85.71
	Yes	Frequency	2	1
		%	5.88	14.29
Platelets (10 ³ /ul)	No	Frequency	34	7
		%	100.00	100.00
	Yes	Frequency	.	.
		%	.	.
Potassium (mEq/l)	No	Frequency	34	7
		%	100.00	100.00
	Yes	Frequency	.	.
		%	.	.
RBC (10 ³ /ul)	No	Frequency	34	7

TABLE 31. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS (ITT, PP Population)
10:22 Monday, July 27, 2020

	Worsening?		ITT	PP
RBC (10 ³ /ul)	No	%	100.00	100.00
	Yes	Frequency	.	.
		%	.	.
Sodium (mEq/l)	No	Frequency	34	7
		%	100.00	100.00
	Yes	Frequency	.	.
		%	.	.
Total bilirubin (UI/l)	No	Frequency	31	7
		%	91.18	100.00
	Yes	Frequency	3	.
		%	8.82	.
Urea (mmol/L)	No	Frequency	34	7
		%	100.00	100.00
	Yes	Frequency	.	.
		%	.	.
WBC (10 ³ /ul)	No	Frequency	34	7
		%	100.00	100.00

TABLE 32. FREQUENCY OF PATIENTS WHO USED RESCUE MEDICATION (ITT, PP Population)
 10:22 Monday, July 27, 2020

Rescue medication taken?		ITT	PP
No	Frequency	22	3
	%	64.71	42.86
Yes	Frequency	12	4
	%	35.29	57.14

TABLE 33. FREQUENCY OF USE OF RESCUE MEDICATION DURING TREATMENT PHASE (ITT, PP Population)
10:22 Monday, July 27, 2020

Number of Dose of Rescue Medication		ITT	PP
1	Frequency %	8 23.53	2 28.57
2	Frequency %	3 8.82	2 28.57
18	Frequency %	1 2.94	. .

TABLE 34. PROPORTION OF PATIENTS WHO REACHED MAXIMUM IMP DOSE (ITT, PP Population)
 10:22 Monday, July 27, 2020

Maximum IMP dose reached?		ITT	PP
No	Frequency	1	.
	%	2.94	.
Yes	Frequency	33	7
	%	97.06	100.00

TABLE 35. FREQUENCY OF MAXIMUM IMP DOSE (ITT, PP Population)
 10:22 Monday, July 27, 2020

Dose		ITT	PP
2000	Frequency	.	.
	%	.	.
5000	Frequency	.	.
	%	.	.
10000	Frequency	.	.
	%	.	.
15000	Frequency	.	.
	%	.	.
25000	Frequency	1	.
	%	3.03	.
50000	Frequency	32	7
	%	96.97	100.00

LISTING 1. SUBJECT DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Population
Chiaravalle Centrale	1010001	Screened, Safety, ITT
	0171010002	Screened, Safety, ITT
	0171010003	Screened, Safety, ITT
	0171010004	Screened, Safety, ITT
	0171010005	Screened, Safety, ITT
	0171010006	Screened, Safety, ITT
	0171010007	Screened, Safety, ITT
	0171010008	Screened
	0171010009	Screened
	0171010010	Screened, Safety, ITT
	0171010011	Screened, Safety, ITT
	0171010012	Screened, Safety, ITT
	0171010013	Screened, Safety, ITT
	0171010014	Screened, Safety, ITT
	0171010015	Screened
	0171010016	Screened, Safety, ITT
	0171010017	Screened, Safety, ITT
	0171010018	Screened, Safety, ITT
	0171010019	Screened, Safety, ITT
	0171010020	Screened, Safety, ITT
	0171010021	Screened
	0171010022	Screened
	0171010023	Screened, Safety, ITT
	0171010024	Screened, Safety, ITT
	0171010025	Screened, Safety, ITT
TROPEA	0181030001	Screened, Safety, ITT, PP
	0181030002	Screened, Safety, ITT, PP
	0181030003	Screened, Safety, ITT, PP
	0181030004	Screened, Safety, ITT
	0181030005	Screened, Safety, ITT
	0181030006	Screened, Safety, ITT
	0181030007	Screened, Safety, ITT, PP
	0181030008	Screened, Safety, ITT
	0181030009	Screened, Safety, ITT, PP
	0181030010	Screened, Safety, ITT

CONFIDENTIAL

LISTING 1. SUBJECT DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Population
TROPEA	0181030011	Screened, Safety, ITT, PP
	0181030012	Screened, Safety, ITT, PP
	0181030013	Screened, Safety, ITT, PP
	0181030014	Screened, Safety, ITT

LISTING 2. DISCONTINUED PATIENTS DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Has the patient completed the study?	Date of withdrawal	Cause of end of study	If Other, specify	If adverse events, specify AE n°	Population
Chiaravalle Centrale	1010001	Yes	Screened, Safety, ITT
	0171010002	Yes	Screened, Safety, ITT
	0171010003	Yes	Screened, Safety, ITT
	0171010004	Yes	Screened, Safety, ITT
	0171010005	Yes	Screened, Safety, ITT
	0171010006	Yes	Screened, Safety, ITT
	0171010007	Yes	Screened, Safety, ITT
	0171010008	No	29MAR2019	Withdrawal of consent	.	.	Screened
	0171010009	No	29MAR2019	Investigator's decision	.	.	Screened
	0171010010	Yes	Screened, Safety, ITT
	0171010011	Yes	Screened, Safety, ITT
	0171010012	Yes	Screened, Safety, ITT
	0171010013	Yes	Screened, Safety, ITT
	0171010014	Yes	Screened, Safety, ITT
	0171010015	No	29MAR2019	Investigator's decision	.	.	Screened
	0171010016	Yes	Screened, Safety, ITT

LISTING 2. DISCONTINUED PATIENTS DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Has the patient completed the study?	Date of withdrawal	Cause of end of study	If Other, specify	If adverse events, specify AE n°	Population
Chiaravalle Centrale	0171010017	Yes	Screened, Safety, ITT
	0171010018	Yes	Screened, Safety, ITT
	0171010019	Yes	Screened, Safety, ITT
	0171010020	Yes	Screened, Safety, ITT
	0171010021	No	29MAR2019	Withdrawal of consent	.	.	Screened
	0171010022	No	29MAR2019	Withdrawal of consent	.	.	Screened
	0171010023	Yes	Screened, Safety, ITT
	0171010024	Yes	Screened, Safety, ITT
	0171010025	Yes	Screened, Safety, ITT
TROPEA	0181030001	Yes	Screened, Safety, ITT, PP
	0181030002	Yes	Screened, Safety, ITT, PP
	0181030003	No	15APR2019	Other	motivi di lavoro, non riesce a presentarsi alle visite di controllo	.	Screened, Safety, ITT, PP
	0181030004	Yes	Screened, Safety, ITT
	0181030005	Yes	Screened, Safety, ITT

LISTING 2. DISCONTINUED PATIENTS DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Has the patient completed the study?	Date of withdrawal	Cause of end of study	If Other, specify	If adverse events, specify AE n°	Population
TROPEA	0181030006	Yes	Screened, Safety, ITT
	0181030007	Yes	Screened, Safety, ITT, PP
	0181030008	Yes	Screened, Safety, ITT
	0181030009	Yes	Screened, Safety, ITT, PP
	0181030010	Yes	Screened, Safety, ITT
	0181030011	Yes	Screened, Safety, ITT, PP
	0181030012	Yes	Screened, Safety, ITT, PP
	0181030013	Yes	Screened, Safety, ITT, PP
	0181030014	Yes	Screened, Safety, ITT

LISTING 3. DISCONTINUED TREATMENT DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Did the patient discontinued the drug?	If Yes, specify for how many days the drug has been discontinued	Population
Chiaravalle Centrale	1010001	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
	0171010002	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
	0171010003	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
	0171010004	V3 - 2nd Treatment Visit	.	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	.	Screened, Safety, ITT
	0171010005	V3 - 2nd Treatment Visit	.	.	Screened, Safety, ITT

LISTING 3. DISCONTINUED TREATMENT DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Did the patient discontinued the drug?	If Yes, specify for how many days the drug has been discontinued	Population
Chiaravalle Centrale	0171010005	V4 - 3rd Treatment Visit	.	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	.	Screened, Safety, ITT
	0171010006	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
	0171010007	V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
	0171010008	V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	.	Screened
		V4 - 3rd Treatment Visit	.	.	Screened
	0171010009	V5 - 4th Treatment Visit	.	.	Screened
		V6 - End of study/Early termination Visit	.	.	Screened
		V3 - 2nd Treatment Visit	.	.	Screened
V4 - 3rd Treatment Visit		.	.	Screened	
0171010010	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT	

LISTING 3. DISCONTINUED TREATMENT DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Did the patient discontinued the drug?	If Yes, specify for how many days the drug has been discontinued	Population
Chiaravalle Centrale	0171010010	V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
	0171010011	V3 - 2nd Treatment Visit	.	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	Screened, Safety, ITT
	0171010012	V6 - End of study/Early termination Visit	.	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	.	Screened, Safety, ITT
	0171010013	V5 - 4th Treatment Visit	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	.	Screened, Safety, ITT
	0171010014	V4 - 3rd Treatment Visit	.	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	Screened, Safety, ITT
V6 - End of study/Early termination Visit		.	.	Screened, Safety, ITT	
0171010014	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT	
	V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT	

LISTING 3. DISCONTINUED TREATMENT DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Did the patient discontinued the drug?	If Yes, specify for how many days the drug has been discontinued	Population
Chiaravalle Centrale	0171010014	V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
	0171010015	V3 - 2nd Treatment Visit	.	.	Screened
		V4 - 3rd Treatment Visit	.	.	Screened
		V5 - 4th Treatment Visit	.	.	Screened
		V6 - End of study/Early termination Visit	.	.	Screened
	0171010016	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
	0171010017	V3 - 2nd Treatment Visit	.	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	.	Screened, Safety, ITT
	0171010018	V3 - 2nd Treatment Visit	.	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	.	Screened, Safety, ITT
	0171010019	V3 - 2nd Treatment Visit	.	.	Screened, Safety, ITT

LISTING 3. DISCONTINUED TREATMENT DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Did the patient discontinued the drug?	If Yes, specify for how many days the drug has been discontinued	Population
Chiaravalle Centrale	0171010019	V4 - 3rd Treatment Visit	.	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
	0171010020	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
	0171010021	V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	.	Screened
		V4 - 3rd Treatment Visit	.	.	Screened
		V5 - 4th Treatment Visit	.	.	Screened
	0171010022	V6 - End of study/Early termination Visit	.	.	Screened
		V3 - 2nd Treatment Visit	.	.	Screened
		V4 - 3rd Treatment Visit	.	.	Screened
		V5 - 4th Treatment Visit	.	.	Screened
	0171010023	V6 - End of study/Early termination Visit	.	.	Screened
		V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
	0171010024	V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT

LISTING 3. DISCONTINUED TREATMENT DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Did the patient discontinued the drug?	If Yes, specify for how many days the drug has been discontinued	Population
Chiaravalle Centrale	0171010024	V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
	0171010025	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
TROPEA	0181030001	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	.	.	Screened, Safety, ITT, PP
	0181030002	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	.	.	Screened, Safety, ITT, PP
	0181030003	V3 - 2nd Treatment Visit	.	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	.	Screened, Safety, ITT, PP

LISTING 3. DISCONTINUED TREATMENT DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Did the patient discontinued the drug?	If Yes, specify for how many days the drug has been discontinued	Population	
TROPEA	0181030003	V5 - 4th Treatment Visit	.	.	Screened, Safety, ITT, PP	
		V6 - End of study/Early termination Visit	.	.	Screened, Safety, ITT, PP	
	0181030004	V3 - 2nd Treatment Visit	.	.	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT	
	0181030005	V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT	
		V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT	
	0181030006	V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT	
		V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	Yes	4	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT	
	0181030007	V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT	
		V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT, PP	
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT, PP	
			V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT, PP

LISTING 3. DISCONTINUED TREATMENT DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Did the patient discontinued the drug?	If Yes, specify for how many days the drug has been discontinued	Population
TROPEA	0181030007	V6 - End of study/Early termination Visit	.	.	Screened, Safety, ITT, PP
	0181030008	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
	0181030009	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	.	.	Screened, Safety, ITT, PP
	0181030010	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT
	0181030011	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	.	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT, PP

LISTING 3. DISCONTINUED TREATMENT DISPOSITION
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Did the patient discontinued the drug?	If Yes, specify for how many days the drug has been discontinued	Population
TROPEA	0181030012	V3 - 2nd Treatment Visit	Yes	3	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit Unscheduled Visit	.	.	Screened, Safety, ITT, PP
	0181030013	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	.	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT, PP
	0181030014	V3 - 2nd Treatment Visit	No	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	No	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	No	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	No	.	Screened, Safety, ITT

LISTING 4. MINOR PROTOCOL DEVIATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Dispensing/administering of IMP	Treatment compliance at home	Inclusion and exclusion criteria	Visit schedule	Withdrawal criteria	Examination's execution	Other	Population
Chiaravalle Centrale	1010001	5	1	.	3	.	.	.	Screened, Safety, ITT
	0171010002	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010003	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010004	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010005	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010006	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010007	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010008	Screened
	0171010009	Screened
	0171010010	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010011	3	.	.	3	.	.	.	Screened, Safety, ITT

LISTING 4. MINOR PROTOCOL DEVIATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Dispensing/adm inister ing of IMP	Treatme nt complia nce at home	Inclusi on and exclusi on criteri a	Visit schedul e	Withdra wal criteri a	Examina tion's executi on	Other	Population
Chiaravalle Centrale	0171010012	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010013	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010014	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010015	Screened
	0171010016	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010017	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010018	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010019	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010020	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010021	Screened
	0171010022	Screened
	0171010023	3	.	.	3	.	.	.	Screened, Safety, ITT

LISTING 4. MINOR PROTOCOL DEVIATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Dispensing/administering of IMP	Treatment compliance at home	Inclusion and exclusion criteria	Visit schedule	Withdrawal criteria	Examination's execution	Other	Population
Chiaravalle Centrale	0171010024	3	.	.	3	.	.	.	Screened, Safety, ITT
	0171010025	3	.	.	3	.	.	.	Screened, Safety, ITT
TROPEA	0181030001	.	.	.	2	.	.	.	Screened, Safety, ITT, PP
	0181030002	.	.	.	1	.	.	.	Screened, Safety, ITT, PP
	0181030003	Screened, Safety, ITT, PP
	0181030004	.	.	.	3	.	.	.	Screened, Safety, ITT
	0181030005	.	.	.	3	.	.	.	Screened, Safety, ITT
	0181030006	.	.	.	3	.	.	.	Screened, Safety, ITT
	0181030007	Screened, Safety, ITT, PP
	0181030008	Screened, Safety, ITT
	0181030009	Screened, Safety, ITT, PP

LISTING 4. MINOR PROTOCOL DEVIATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Dispensing/adm inister ing of IMP	Treatme nt complia nce at home	Inclusi on and exclusi on criteri a	Visit schedul e	Withdra wal criteri a	Examina tion's executi on	Other	Population
TROPEA	0181030010	.	.	.	4	.	.	.	Screened, Safety, ITT
	0181030011	Screened, Safety, ITT, PP
	0181030012	.	.	.	3	.	.	.	Screened, Safety, ITT, PP
	0181030013	.	.	.	2	.	.	.	Screened, Safety, ITT, PP
	0181030014	Screened, Safety, ITT

LISTING 5. MAJOR PROTOCOL DEVIATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Patients of Chiaravalle Centrale	More than 10 days over the expected visit	Use of not allowed drugs and procedures	Treatment permanently discontinued	No dose of the study treatment taken	Population
Chiaravalle Centrale	1010001	x	Screened, Safety, ITT
	0171010002	x	Screened, Safety, ITT
	0171010003	x	.	x	.	.	Screened, Safety, ITT
	0171010004	x	Screened, Safety, ITT
	0171010005	x	Screened, Safety, ITT
	0171010006	x	Screened, Safety, ITT
	0171010007	x	Screened, Safety, ITT
	0171010008	x	Screened
	0171010009	x	Screened
	0171010010	x	Screened, Safety, ITT
	0171010011	x	Screened, Safety, ITT
	0171010012	x	Screened, Safety, ITT

LISTING 5. MAJOR PROTOCOL DEVIATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Patients of Chiaravalle Centrale	More than 10 days over the expected visit	Use of not allowed drugs and procedures	Treatment permanently discontinued	No dose of the study treatment taken	Population
Chiaravalle Centrale	0171010013	x	Screened, Safety, ITT
	0171010014	x	Screened, Safety, ITT
	0171010015	x	Screened
	0171010016	x	Screened, Safety, ITT
	0171010017	x	Screened, Safety, ITT
	0171010018	x	Screened, Safety, ITT
	0171010019	x	Screened, Safety, ITT
	0171010020	x	Screened, Safety, ITT
	0171010021	x	Screened
	0171010022	x	Screened
	0171010023	x	Screened, Safety, ITT
	0171010024	x	Screened, Safety, ITT

LISTING 5. MAJOR PROTOCOL DEVIATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Patients of Chiaravalle Centrale	More than 10 days over the expected visit	Use of not allowed drugs and procedures	Treatment permanently discontinued	No dose of the study treatment taken	Population
Chiaravalle Centrale	0171010025	x	Screened, Safety, ITT
TROPEA	0181030001	Screened, Safety, ITT, PP
	0181030002	Screened, Safety, ITT, PP
	0181030003	Screened, Safety, ITT, PP
	0181030004	.	.	x	.	.	Screened, Safety, ITT
	0181030005	.	.	x	.	.	Screened, Safety, ITT
	0181030006	.	.	x	.	.	Screened, Safety, ITT
	0181030007	Screened, Safety, ITT, PP
	0181030008	.	.	x	.	.	Screened, Safety, ITT
	0181030009	Screened, Safety, ITT, PP
	0181030010	.	x	.	.	.	Screened, Safety, ITT

LISTING 5. MAJOR PROTOCOL DEVIATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Patients of Chiaravalle Centrale	More than 10 days over the expected visit	Use of not allowed drugs and procedures	Treatment permanently discontinued	No dose of the study treatment taken	Population
TROPEA	0181030011	Screened, Safety, ITT, PP
	0181030012	Screened, Safety, ITT, PP
	0181030013	Screened, Safety, ITT, PP
	0181030014	.	.	x	.	.	Screened, Safety, ITT

LISTING 6. DEMOGRAPHIC CHARACTERISTICS
10:22 Monday, July 27, 2020

Center	Patient No.	Year of birth	Age (year)	Gender	Ethnic	Weight (kg)	Height (cm)	Population
Chiaravalle Centrale	1010001	1971	48	Female	Caucasian	70	151	Screened, Safety, ITT
	0171010002	1985	34	Female	Caucasian	60	157	Screened, Safety, ITT
	0171010003	1991	28	Female	Caucasian	109	157	Screened, Safety, ITT
	0171010004	1995	24	Male	Caucasian	72	165	Screened, Safety, ITT
	0171010005	1997	22	Male	Caucasian	68	179	Screened, Safety, ITT
	0171010006	1966	53	Female	Caucasian	94	106	Screened, Safety, ITT
	0171010007	1967	52	Male	Caucasian	90	172	Screened, Safety, ITT
	0171010008	1991	28	Female	Caucasian	57	164	Screened
	0171010009	1979	40	Male	Caucasian	82	175	Screened
	0171010010	1986	33	Male	Caucasian	83	175	Screened, Safety, ITT
	0171010011	1997	22	Female	Caucasian	49	152	Screened, Safety, ITT
	0171010012	1990	29	Female	Caucasian	64	160	Screened, Safety, ITT
	0171010013	1998	21	Male	Caucasian	65	170	Screened, Safety, ITT
	0171010014	1993	26	Male	Caucasian	72	170	Screened, Safety, ITT
	0171010015	1998	21	Male	Caucasian	90	175	Screened
	0171010016	1980	39	Male	Caucasian	75	170	Screened, Safety, ITT
	0171010017	1981	38	Female	Caucasian	79	151	Screened, Safety, ITT
	0171010018	1980	39	Male	Caucasian	78	175	Screened, Safety, ITT
	0171010019	1959	60	Male	Caucasian	109	170	Screened, Safety, ITT

LISTING 6. DEMOGRAPHIC CHARACTERISTICS
10:22 Monday, July 27, 2020

Center	Patient No.	Year of birth	Age (year)	Gender	Ethnic	Weight (kg)	Height (cm)	Population
Chiaravalle Centrale	0171010020	1996	23	Male	Caucasian	55	174	Screened, Safety, ITT
	0171010021	1986	33	Male	Caucasian	58	175	Screened
	0171010022	1985	34	Female	Caucasian	43	152	Screened
	0171010023	1984	35	Male	Caucasian	96	182	Screened, Safety, ITT
	0171010024	1959	60	Male	Caucasian	80	167	Screened, Safety, ITT
	0171010025	1991	28	Male	Caucasian	86	181	Screened, Safety, ITT
TROPEA	0181030001	1999	20	Male	Caucasian	70	175	Screened, Safety, ITT, PP
	0181030002	1989	30	Female	Caucasian	63	175	Screened, Safety, ITT, PP
	0181030003	1991	28	Male	Caucasian	70	170	Screened, Safety, ITT, PP
	0181030004	1984	35	Female	Caucasian	58	165	Screened, Safety, ITT
	0181030005	1998	21	Male	Caucasian	72	178	Screened, Safety, ITT
	0181030006	1998	21	Female	Caucasian	66	165	Screened, Safety, ITT
	0181030007	1993	26	Female	Caucasian	58	165	Screened, Safety, ITT, PP
	0181030008	1992	27	Female	Caucasian	66	165	Screened, Safety, ITT
	0181030009	1993	26	Male	Caucasian	70	175	Screened, Safety, ITT, PP
	0181030010	1992	27	Male	Caucasian	66	170	Screened, Safety, ITT
	0181030011	1990	29	Female	Caucasian	55	164	Screened, Safety, ITT, PP
	0181030012	1990	29	Female	Caucasian	52	162	Screened, Safety, ITT, PP

CONFIDENTIAL

Statistical Analysis Report
Study Code: DE_LODRO_GR19

LISTING 6. DEMOGRAPHIC CHARACTERISTICS
10:22 Monday, July 27, 2020

Center	Patient No.	Year of birth	Age (year)	Gender	Ethnic	Weight (kg)	Height (cm)	Population
TROPEA	0181030013	1967	52	Male	Caucasian	69	174	Screened, Safety, ITT, PP
	0181030014	2000	19	Male	Caucasian	98	185	Screened, Safety, ITT

LISTING 7. ARIA RESULTS
10:22 Monday, July 27, 2020

Center	Patient No.	Are the rhinitis symptoms troublesome ?	Do the rhinitis symptoms cause impairment of the patient's daily activities, in sports, at work or at leisure?	Do the rhinitis symptoms cause impairment at school?	Do the rhinitis symptoms disturb the patient's sleep?	Frequency and duration of occurrence of rhinitis	Previous anaphylaxis episodes?	Population
Chiaravalle Centrale	1010001	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010002	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010003	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010004	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010005	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010006	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010007	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010008	Yes	Yes	Yes	Yes	Persistent	No	Screened
	0171010009	Yes	Yes	Yes	Yes	Persistent	No	Screened
	0171010010	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010011	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010012	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010013	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010014	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT

LISTING 7. ARIA RESULTS
10:22 Monday, July 27, 2020

Center	Patient No.	Are the rhinitis symptoms troublesome ?	Do the rhinitis symptoms cause impairment of the patient's daily activities, in sports, at leisure?	Do the rhinitis symptoms cause impairment at work or at school?	Do the rhinitis symptoms disturb the patient's sleep?	Frequency and duration of occurrence of rhinitis	Previous anaphylaxis episodes?	Population
Chiaravalle Centrale	0171010015	No	No	No	No	Intermittent	No	Screened
	0171010016	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010017	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010018	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010019	No	No	No	No	Intermittent	No	Screened, Safety, ITT
	0171010020	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010021	Yes	Yes	Yes	Yes	Persistent	No	Screened
	0171010022	Yes	Yes	Yes	Yes	Persistent	No	Screened
	0171010023	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0171010024	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
0171010025	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT	
TROPEA	0181030001	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT, PP
	0181030002	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT, PP
	0181030003	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT, PP

LISTING 7. ARIA RESULTS
10:22 Monday, July 27, 2020

Center	Patient No.	Are the rhinitis symptoms troublesome ?	Do the rhinitis symptoms cause impairment of the patient's daily activities, in sports, at leisure?	Do the rhinitis symptoms cause impairment at work or at school?	Do the rhinitis symptoms disturb the patient's sleep?	Frequency and duration of occurrence of rhinitis	Previous anaphylaxis episodes?	Population
TROPEA	0181030004	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0181030005	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0181030006	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0181030007	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT, PP
	0181030008	Yes	Yes	No	Yes	Persistent	No	Screened, Safety, ITT
	0181030009	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT, PP
	0181030010	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT
	0181030011	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT, PP
	0181030012	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT, PP
	0181030013	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT, PP
	0181030014	Yes	Yes	Yes	Yes	Persistent	No	Screened, Safety, ITT

LISTING 8. ASTHMA DIAGNOSIS. GINA 2018 RESULTS
10:22 Monday, July 27, 2020

Center	Patient No.	Has the patient asthma?	Daytime asthma symptoms more than twice a week?	Daytime asthma symptoms more than twice a week?	Reliever needed for symptoms more than twice/week?	Any activity limitation due to asthma?	Current control status	Population
Chiaravalle Centrale	1010001	No	Screened, Safety, ITT
	0171010002	Yes	No	No	No	No	Well controlled	Screened, Safety, ITT
	0171010003	Yes	No	No	No	No	Well controlled	Screened, Safety, ITT
	0171010004	No	Screened, Safety, ITT
	0171010005	No	Screened, Safety, ITT
	0171010006	No	Screened, Safety, ITT
	0171010007	No	Screened, Safety, ITT
	0171010008	No	Screened
	0171010009	No	Screened
	0171010010	Yes	No	No	No	No	Well controlled	Screened, Safety, ITT
	0171010011	No	Screened, Safety, ITT
	0171010012	No	Screened, Safety, ITT
	0171010013	No	Screened, Safety, ITT
	0171010014	No	Screened, Safety, ITT
	0171010015	Yes	No	No	No	No	Well controlled	Screened
	0171010016	No	Screened, Safety, ITT
	0171010017	No	Screened, Safety, ITT

LISTING 8. ASTHMA DIAGNOSIS. GINA 2018 RESULTS
10:22 Monday, July 27, 2020

Center	Patient No.	Has the patient asthma?	Daytime asthma symptoms more than twice a week?	Daytime asthma symptoms more than twice a week?	Reliever needed for symptoms more than twice/week?	Any activity limitation due to asthma?	Current control status	Population
Chiaravalle Centrale	0171010018	Yes	No	No	No	No	Well controlled	Screened, Safety, ITT
	0171010019	No	Screened, Safety, ITT
	0171010020	No	Screened, Safety, ITT
	0171010021	No	Screened
	0171010022	Yes	No	No	No	No	Well controlled	Screened
	0171010023	No	Screened, Safety, ITT
	0171010024	No	Screened, Safety, ITT
	0171010025	No	Screened, Safety, ITT
TROPEA	0181030001	No	Screened, Safety, ITT, PP
	0181030002	No	Screened, Safety, ITT, PP
	0181030003	No	Screened, Safety, ITT, PP
	0181030004	No	Screened, Safety, ITT
	0181030005	No	Screened, Safety, ITT
	0181030006	No	Screened, Safety, ITT
	0181030007	No	Screened, Safety, ITT, PP
	0181030008	No	Screened, Safety, ITT

LISTING 8. ASTHMA DIAGNOSIS. GINA 2018 RESULTS
10:22 Monday, July 27, 2020

Center	Patient No.	Has the patient asthma?	Daytime asthma symptoms more than twice a week?	Daytime asthma symptoms more than twice a week?	Reliever needed for symptoms more than twice/week?	Any activity limitation due to asthma?	Current control status	Population
TROPEA	0181030009	No	Screened, Safety, ITT, PP
	0181030010	No	Screened, Safety, ITT
	0181030011	No	Screened, Safety, ITT, PP
	0181030012	No	Screened, Safety, ITT, PP
	0181030013	No	Screened, Safety, ITT, PP
	0181030014	Yes	No	No	No	No	Well controlled	Screened, Safety, ITT

LISTING 9. MEDICAL HYSTORY
10:22 Monday, July 27, 2020

Center	Patient No.	Organs/Organ Systems	Description of the disease	PT	PT Code	Start Date	End Date	Ongoing	Population
Chiaravalle Centrale	1010001	Screened, Safety, ITT
	0171010002	Screened, Safety, ITT
	0171010003	Respiratory	OSA	Sleep apnoea syndrome	10040979	01/04/2017	.	Yes	Screened, Safety, ITT
	0171010004	Screened, Safety, ITT
	0171010005	Screened, Safety, ITT
	0171010006	Screened, Safety, ITT
	0171010007	Metabolic	Diabetes	Diabetes mellitus	10012601	01/01/2018	.	Yes	Screened, Safety, ITT
	0171010007	Cardiovascular	Hypertension	Hypertension	10020772	01/10/2016	.	Yes	Screened, Safety, ITT
	0171010008	Screened
	0171010009	Screened
	0171010010	Screened, Safety, ITT
	0171010011	Screened, Safety, ITT
	0171010012	Screened, Safety, ITT
	0171010013	Screened, Safety, ITT
	0171010014	Screened, Safety, ITT
	0171010015	Screened
	0171010016	Screened, Safety, ITT
0171010017	Screened, Safety, ITT	

LISTING 9. MEDICAL HYSTORY
10:22 Monday, July 27, 2020

Center	Patient No.	Organs/Organ Systems	Description of the disease	PT	PT Code	Start Date	End Date	Ongoing	Population
Chiaravalle Centrale	0171010018	Screened, Safety, ITT
	0171010019	Cardiovascular	Hypertension	Hyperten sion	10020772	01/01/2014	.	Yes	Screened, Safety, ITT
	0171010020	Screened, Safety, ITT
	0171010021	Screened
	0171010022	Screened
	0171010023	Screened, Safety, ITT
	0171010024	Screened, Safety, ITT
	0171010025	Screened, Safety, ITT
TROPEA	0181030001	Screened, Safety, ITT, PP
	0181030002	Screened, Safety, ITT, PP
	0181030003	Screened, Safety, ITT, PP
	0181030004	Screened, Safety, ITT
	0181030005	Screened, Safety, ITT
	0181030006	Screened, Safety, ITT
	0181030007	Screened, Safety, ITT, PP
	0181030008	Screened, Safety, ITT
	0181030009	Screened, Safety, ITT, PP
	0181030010	Screened, Safety, ITT

LISTING 9. MEDICAL HYSTORY
10:22 Monday, July 27, 2020

Center	Patient No.	Organs/Organ Systems	Description of the disease	PT	PT Code	Start Date	End Date	Ongoing	Population
TROPEA	0181030011	Screened, Safety, ITT, PP
	0181030012	Screened, Safety, ITT, PP
	0181030013	Screened, Safety, ITT, PP
	0181030014	Screened, Safety, ITT

LISTING 10. PREVIOUS MEDICATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Active Compound /Name of Drug	ATC Code	Indication	Relation ship	Specify n° AE or MH	Daily dose	Unit	Route	Start Date	End Date
Chiaravalle Centrale	1010001
	0171010002
	0171010003	flutifor mo 125/5	R03AK11	asthma	No	.	2	puff	Inhalatory	25/03/2019	.
	0171010004
	0171010005
	0171010006
	0171010007	Metformina	A10BA02	Diabetes	Yes	2	500	mg	Oral	01/01/2018	.
	0171010007	Tripliam	C09BX01	Hypertension	Yes	1	10	mg	Oral	01/10/2016	.
	0171010008
	0171010009
	0171010010
	0171010011
	0171010012
	0171010013
	0171010014
	0171010015
0171010016	

LISTING 10. PREVIOUS MEDICATIONS
 10:22 Monday, July 27, 2020

Center	Patient No.	Ongoing	Population
Chiaravalle Centrale	1010001	.	Screened, Safety, ITT
	0171010002	.	Screened, Safety, ITT
	0171010003	Yes	Screened, Safety, ITT
	0171010004	.	Screened, Safety, ITT
	0171010005	.	Screened, Safety, ITT
	0171010006	.	Screened, Safety, ITT
	0171010007	Yes	Screened, Safety, ITT
	0171010007	Yes	Screened, Safety, ITT
	0171010008	.	Screened
	0171010009	.	Screened
	0171010010	.	Screened, Safety, ITT
	0171010011	.	Screened, Safety, ITT
	0171010012	.	Screened, Safety, ITT
	0171010013	.	Screened, Safety, ITT
	0171010014	.	Screened, Safety, ITT
	0171010015	.	Screened
0171010016	.	Screened, Safety, ITT	

LISTING 10. PREVIOUS MEDICATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Active Compound /Name of Drug	ATC Code	Indication	Relation ship	Specify n° AE or MH	Daily dose	Unit	Route	Start Date	End Date
Chiaravalle Centrale	0171010017
	0171010018
	0171010019	Amlodipi na	C08CA01	Hypertensio n	Yes	1	5	mg	Oral	01/01/2014	.
	0171010019	Perindop ril	C09AA04	Hypertensio n	Yes	1	5	mg	Oral	01/01/2014	.
	0171010020
	0171010021
	0171010022
	0171010023
	0171010024
0171010025	
TROPEA	0181030001
	0181030002
	0181030003
	0181030004
	0181030005
	0181030006
	0181030007

LISTING 10. PREVIOUS MEDICATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Ongoing	Population
Chiaravalle Centrale	0171010017	.	Screened, Safety, ITT
	0171010018	.	Screened, Safety, ITT
	0171010019	Yes	Screened, Safety, ITT
	0171010019	Yes	Screened, Safety, ITT
	0171010020	.	Screened, Safety, ITT
	0171010021	.	Screened
	0171010022	.	Screened
	0171010023	.	Screened, Safety, ITT
	0171010024	.	Screened, Safety, ITT
	0171010025	.	Screened, Safety, ITT
TROPEA	0181030001	.	Screened, Safety, ITT, PP
	0181030002	.	Screened, Safety, ITT, PP
	0181030003	.	Screened, Safety, ITT, PP
	0181030004	.	Screened, Safety, ITT
	0181030005	.	Screened, Safety, ITT
	0181030006	.	Screened, Safety, ITT
	0181030007	.	Screened, Safety, ITT, PP

LISTING 10. PREVIOUS MEDICATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Active Compound /Name of Drug	ATC Code	Indication	Relation ship	Specify n° AE or MH	Daily dose	Unit	Route	Start Date	End Date
TROPEA	0181030008	bilastin a	R06AX29	allergic rhinitis	No	.	20	1	Sublingual	15/03/2019	29/03/2019
	0181030009
	0181030010
	0181030011
	0181030012
	0181030013
	0181030014

LISTING 10. PREVIOUS MEDICATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Ongoing	Population
TROPEA	0181030008	No	Screened, Safety, ITT
	0181030009	.	Screened, Safety, ITT, PP
	0181030010	.	Screened, Safety, ITT
	0181030011	.	Screened, Safety, ITT, PP
	0181030012	.	Screened, Safety, ITT, PP
	0181030013	.	Screened, Safety, ITT, PP
	0181030014	.	Screened, Safety, ITT

LISTING 11. CONCOMITANT MEDICATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Active Compound /Name of Drug	ATC Code	Indication	Relation ship	Specify n° AE or MH	Daily dose	Unit	Route	Start Date	End Date
Chiaravalle Centrale	1010001
	0171010002
	0171010003
	0171010004
	0171010005
	0171010006
	0171010007
	0171010008
	0171010009
	0171010010	fluspiral 125 mcg	R03BA05	asthma	Not related	2		puff	Inhalatory	25/03/2019	.
	0171010010	montelukast	R03DC03	asthma	Not related	10		mg	Oral	30/03/2019	.
	0171010011
	0171010012
	0171010013
	0171010014
0171010015	

LISTING 11. CONCOMITANT MEDICATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Ongoing	Population
Chiaravalle Centrale	1010001	.	Screened, Safety, ITT
	0171010002	.	Screened, Safety, ITT
	0171010003	.	Screened, Safety, ITT
	0171010004	.	Screened, Safety, ITT
	0171010005	.	Screened, Safety, ITT
	0171010006	.	Screened, Safety, ITT
	0171010007	.	Screened, Safety, ITT
	0171010008	.	Screened
	0171010009	.	Screened
	0171010010	Yes	Screened, Safety, ITT
	0171010010	Yes	Screened, Safety, ITT
	0171010011	.	Screened, Safety, ITT
	0171010012	.	Screened, Safety, ITT
	0171010013	.	Screened, Safety, ITT
	0171010014	.	Screened, Safety, ITT
0171010015	.	Screened	

LISTING 11. CONCOMITANT MEDICATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Active Compound /Name of Drug	ATC Code	Indication	Relation ship	Specify n° AE or MH	Daily dose	Unit	Route	Start Date	End Date
Chiaravalle Centrale	0171010016
	0171010017
	0171010018
	0171010019
	0171010020
	0171010021
	0171010022
	0171010023
	0171010024
TROPEA	0181030001
	0181030002
	0181030003
	0181030004
	0181030004	rupatadi na	R06AX28	allergic rhinitis	Not related		10	1	Oral	08/04/2019	19/05/2019
	0181030005
	0181030005
						

LISTING 11. CONCOMITANT MEDICATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Ongoing	Population
Chiaravalle Centrale	0171010016	.	Screened, Safety, ITT
	0171010017	.	Screened, Safety, ITT
	0171010018	.	Screened, Safety, ITT
	0171010019	.	Screened, Safety, ITT
	0171010020	.	Screened, Safety, ITT
	0171010021	.	Screened
	0171010022	.	Screened
	0171010023	.	Screened, Safety, ITT
	0171010024	.	Screened, Safety, ITT
	0171010025	.	Screened, Safety, ITT
TROPEA	0181030001	.	Screened, Safety, ITT, PP
	0181030002	.	Screened, Safety, ITT, PP
	0181030003	.	Screened, Safety, ITT, PP
	0181030004	.	Screened, Safety, ITT
	0181030004	No	Screened, Safety, ITT
	0181030005	.	Screened, Safety, ITT
	0181030005	.	Screened, Safety, ITT

LISTING 11. CONCOMITANT MEDICATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Active Compound /Name of Drug	ATC Code	Indication	Relation ship	Specify n° AE or MH	Daily dose	Unit	Route	Start Date	End Date
TROPEA	0181030005
	0181030005	bilastin a	R06AX29	allergic rhinitis	Not related	.	20	1	Oral	10/05/2019	11/05/2019
	0181030005	bilastin a	R06AX29	allergic rhinitis	Not related	.	20	1	Oral	20/05/2019	22/05/2019
	0181030006
	0181030006	ebastina	R06AX22	allergic rhinitis	Not related	.	10	1	Oral	05/05/2019	05/05/2019
	0181030007
	0181030008	bilastin a	R06AX29	allergic rhinitis	Not related	.	1	20 mg	Oral	20/04/2019	20/04/2019
	0181030009
	0181030009
	0181030010
	0181030011
	0181030011
	0181030012
	0181030013
	0181030014	mometasone	R01AD09	allergic rhinitis	Not related	.	2	50 mcg	Intranasal	22/04/2019	23/04/2019

LISTING 11. CONCOMITANT MEDICATIONS
10:22 Monday, July 27, 2020

Center	Patient No.	Ongoing	Population
TROPEA	0181030005	.	Screened, Safety, ITT
	0181030005	No	Screened, Safety, ITT
	0181030005	No	Screened, Safety, ITT
	0181030006	.	Screened, Safety, ITT
	0181030006	No	Screened, Safety, ITT
	0181030007	.	Screened, Safety, ITT, PP
	0181030008	No	Screened, Safety, ITT
	0181030009	.	Screened, Safety, ITT, PP
	0181030009	.	Screened, Safety, ITT, PP
	0181030010	.	Screened, Safety, ITT
	0181030011	.	Screened, Safety, ITT, PP
	0181030011	.	Screened, Safety, ITT, PP
	0181030012	.	Screened, Safety, ITT, PP
	0181030013	.	Screened, Safety, ITT, PP
	0181030014	No	Screened, Safety, ITT

LISTING 12. ADVERSE EVENTS
10:22 Monday, July 27, 2020

Center	Patient No.	Location	Type	During which period	Administ ration*	Resolved within 60 minutes*	Description	SOC	SOC Code	PT	PT Code
Chiaravalle Centrale	1010001
	0171010002
	0171010003	At site	Solicited Systemic AEs	V2	2nd administration	Yes	Sleepiness and tingling
	0171010003	At home	Unsolicited AEs	After V2	.	.	sleepiness	Psychiatric disorders	10037175	Somnolence	10041349
	0171010004
	0171010005
	0171010006	At home	Unsolicited AEs	After V3	.	.	Pomfisolabro superio re	Skin and subcutaneous tissue disorders	10040785	Lip swelling	10024570

Notes:
*Only for on at site AE

LISTING 12. ADVERSE EVENTS
10:22 Monday, July 27, 2020

Center	Patient No.	Intensity/Severity	SAE	Start Date	Ongoing	End Date	Actions Taken	Other actions taken	Outcome	Causality	Population
Chiaravalle Centrale	1010001	Screened, Safety, ITT
	0171010002	Screened, Safety, ITT
	0171010003	Grade I	No	29/03/2019	.	.	No change	None	Resolved	Possibly related	Screened, Safety, ITT
	0171010003	Mild	No	30/03/2019	No	09/05/2019	No change	None	Resolved	Possibly related	Screened, Safety, ITT
	0171010004	Screened, Safety, ITT
	0171010005	Screened, Safety, ITT
	0171010006	Mild (1)	No	02/04/2019	No	03/04/2019	No change	None	Resolved	Possibly related	Screened, Safety, ITT

Notes:
*Only for on at site AE

LISTING 12. ADVERSE EVENTS
10:22 Monday, July 27, 2020

Center	Patient No.	Location	Type	During which period	Administ ration*	Resolved within 60 minutes*	Description	SOC	SOC Code	PT	PT Code
Chiaravalle Centrale	0171010006	At home	Unsolici ted AEs	After V2	.	.	cough	Respirat ory, thoracic and mediasti nal disorder s	10038738	Cough	10011224
	0171010007	At home	Unsolici ted AEs	After V2	.	.	Arrossam ento congiutn ivale	Eye disorder s	10015919	Conjunct ival hyperaem ia	10051625
	0171010008
	0171010009
	0171010010
	0171010011
	0171010012
	0171010013

Notes:
*Only for on at site AE

LISTING 12. ADVERSE EVENTS
10:22 Monday, July 27, 2020

Center	Patient No.	Intensity/Severity	SAE	Start Date	Ongoing	End Date	Actions Taken	Other actions taken	Outcome	Causality	Population
Chiaravalle Centrale	0171010006	Mild (1)	No	30/03/2019	No	31/03/2019	No change	None	Resolved	Unknown	Screened, Safety, ITT
	0171010007	Mild	No	30/03/2019	No	31/03/2019	No change	None	Resolved	Possibly related	Screened, Safety, ITT
	0171010008	Screened
	0171010009	Screened
	0171010010	Screened, Safety, ITT
	0171010011	Screened, Safety, ITT
	0171010012	Screened, Safety, ITT
	0171010013	Screened, Safety, ITT

Notes:
*Only for on at site AE

LISTING 12. ADVERSE EVENTS
10:22 Monday, July 27, 2020

Center	Patient No.	Location	Type	During which period	Administ ration*	Resolved within 60 minutes*	Description	SOC	SOC Code	PT	PT Code
Chiaravalle Centrale	0171010014	At home	Unsolicited AEs	After V2	.	.	salve di starnuti	Respiratory, thoracic and mediastinal disorders	10038738	Sneezing	10041232
	0171010015
	0171010016	At home	Unsolicited AEs	After V4	.	.	Starnuti	Respiratory, thoracic and mediastinal disorders	10038738	Sneezing	10041232
	0171010017
	0171010018	At home	Unsolicited AEs	After V3	.	.	Ostruzione nasale	Respiratory, thoracic and mediastinal disorders	10038738	Nasal obstruction	10028748
	0171010019

Notes:
*Only for on at site AE

LISTING 12. ADVERSE EVENTS
10:22 Monday, July 27, 2020

Center	Patient No.	Intensity/Severity	SAE	Start Date	Ongoing	End Date	Actions Taken	Other actions taken	Outcome	Causality	Population
Chiaravalle Centrale	0171010014	Mild (1)	No	30/03/2019	No	31/03/2019	No change	None	Resolved	Possibly related	Screened, Safety, ITT
	0171010015	Screened
	0171010016	Mild	No	06/04/2019	No	08/04/2019	No change	Medication	Resolved	Possibly related	Screened, Safety, ITT
	0171010017	Screened, Safety, ITT
	0171010018	Mild	No	02/04/2019	No	03/04/2019	No change	None	Resolved	Possibly related	Screened, Safety, ITT
	0171010019	Screened, Safety, ITT

Notes:
*Only for on at site AE

LISTING 12. ADVERSE EVENTS
10:22 Monday, July 27, 2020

Center	Patient No.	Location	Type	During which period	Administ ration*	Resolved within 60 minutes*	Description	SOC	SOC Code	PT	PT Code
Chiaravalle Centrale	0171010020	At site	Solicited Local AEs	V2	2nd administ ration	Yes	Itching of lips
	0171010020	At home	Unsolicited AEs	After V2	.	.	Itching of oral mucose	Gastrointestinal disorders	10017947	Oral pruritus	10052894
	0171010021
	0171010022
	0171010023
	0171010024	At site	Solicited Systemic AEs	V2	1st administ ration	Yes	Vertigine
TROPEA	0181030001	At site	Solicited Local AEs	V5	1st administ ration	Yes	Itching of oral mucosa
	0181030002
	0181030003
	0181030004
	0181030005

Notes:
*Only for on at site AE

LISTING 12. ADVERSE EVENTS
10:22 Monday, July 27, 2020

Center	Patient No.	Intensity/Severity	SAE	Start Date	Ongoing	End Date	Actions Taken	Other actions taken	Outcome	Causality	Population
Chiaravalle Centrale	0171010020	Mild (1)	No	29/03/2019	.	.	No change	None	Resolved	Related	Screened, Safety, ITT
	0171010020	Mild	No	30/03/2019	No	01/04/2019	No change	None	Resolved	Related	Screened, Safety, ITT
	0171010021	Screened
	0171010022	Screened
	0171010023	Screened, Safety, ITT
0171010024	Grade I	No	29/03/2019	.	.	No change	None	Resolved	Unrelated	Screened, Safety, ITT	
TROPEA	0181030001	Mild (1)	No	24/04/2019	.	.	No change	None	Resolved	Related	Screened, Safety, ITT, PP
	0181030002	Screened, Safety, ITT, PP
	0181030003	Screened, Safety, ITT, PP
	0181030004	Screened, Safety, ITT
	0181030005	Screened, Safety, ITT

Notes:
*Only for on at site AE

LISTING 12. ADVERSE EVENTS
10:22 Monday, July 27, 2020

Center	Patient No.	Location	Type	During which period	Administ ration*	Resolved within 60 minutes*	Description	SOC	SOC Code	PT	PT Code
TROPEA	0181030006
	0181030007
	0181030008
	0181030009	At site	Solicited Local AEs	V5	1st administration	Yes	Itching of oral mucosa
	0181030010
	0181030011	At site	Solicited Local AEs	V4	1st administration	Yes	Mouth ulcer
	0181030012	At home	Unknown	After V2	.	.	dolore addominale
	0181030013
	0181030014

Notes:
*Only for on at site AE

LISTING 12. ADVERSE EVENTS
10:22 Monday, July 27, 2020

Center	Patient No.	Intensity/Severity	SAE	Start Date	Ongoing	End Date	Actions Taken	Other actions taken	Outcome	Causality	Population
TROPEA	0181030006	Screened, Safety, ITT
	0181030007	Screened, Safety, ITT, PP
	0181030008	Screened, Safety, ITT
	0181030009	Mild (1)	No	07/05/2019	.	.	No change	None	Resolved	Possibly related	Screened, Safety, ITT, PP
	0181030010	Screened, Safety, ITT
	0181030011	Mild (1)	No	26/04/2019	.	.	No change	None	Resolved	Related	Screened, Safety, ITT, PP
	0181030012	Mild	No	20/04/2019	No	23/04/2019	Temporarily discontinued	None	Resolved	Unknown	Screened, Safety, ITT, PP
	0181030013	Screened, Safety, ITT, PP
	0181030014	Screened, Safety, ITT

Notes:
*Only for on at site AE

LISTING 13. SOLICITED AEs (WHATEVER THE TYPE)
10:22 Monday, July 27, 2020

Center	Patient No.	Solicited AE	Type	Population
Chiaravalle Centrale	1010001	No	.	Screened, Safety, ITT
	0171010002	No	.	Screened, Safety, ITT
	0171010003	Yes	Solicited Systemic AEs	Screened, Safety, ITT
	0171010004	No	.	Screened, Safety, ITT
	0171010005	No	.	Screened, Safety, ITT
	0171010006	No	.	Screened, Safety, ITT
	0171010006	No	.	Screened, Safety, ITT
	0171010007	No	.	Screened, Safety, ITT
	0171010008	No	.	Screened
	0171010009	No	.	Screened
	0171010010	No	.	Screened, Safety, ITT
	0171010011	No	.	Screened, Safety, ITT
	0171010012	No	.	Screened, Safety, ITT
	0171010013	No	.	Screened, Safety, ITT
	0171010014	No	.	Screened, Safety, ITT
	0171010015	No	.	Screened
	0171010016	No	.	Screened, Safety, ITT
	0171010017	No	.	Screened, Safety, ITT
0171010018	No	.	Screened, Safety, ITT	

LISTING 13. SOLICITED AEs (WHATEVER THE TYPE)
10:22 Monday, July 27, 2020

Center	Patient No.	Solicited AE	Type	Population
Chiaravalle Centrale	0171010019	No	.	Screened, Safety, ITT
	0171010020	Yes	Solicited Local AEs	Screened, Safety, ITT
	0171010021	No	.	Screened
	0171010022	No	.	Screened
	0171010023	No	.	Screened, Safety, ITT
	0171010024	Yes	Solicited Systemic AEs	Screened, Safety, ITT
TROPEA	0181030001	Yes	Solicited Local AEs	Screened, Safety, ITT, PP
	0181030002	No	.	Screened, Safety, ITT, PP
	0181030003	No	.	Screened, Safety, ITT, PP
	0181030004	No	.	Screened, Safety, ITT
	0181030005	No	.	Screened, Safety, ITT
	0181030006	No	.	Screened, Safety, ITT
	0181030007	No	.	Screened, Safety, ITT, PP
	0181030008	No	.	Screened, Safety, ITT
	0181030009	Yes	Solicited Local AEs	Screened, Safety, ITT, PP
	0181030010	No	.	Screened, Safety, ITT
	0181030011	Yes	Solicited Local AEs	Screened, Safety, ITT, PP
	0181030012	No	.	Screened, Safety, ITT, PP
	0181030013	No	.	Screened, Safety, ITT, PP

CONFIDENTIAL

LISTING 13. SOLICITED AEs (WHATEVER THE TYPE)
10:22 Monday, July 27, 2020

Center	Patient No.	Solicited AE	Type	Population
TROPEA	0181030014	No	.	Screened, Safety, ITT

LISTING 14. LOCAL REACTIONS AT THE ADMINISTRATION SITE
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administ ration	IMP dose administered	Volume of solution	System	Specific ation	Intensity/ Severity	Population
Chiaravalle Centrale	1010001	Screened, Safety, ITT
	0171010002	Screened, Safety, ITT
	0171010003	Screened, Safety, ITT
	0171010004	Screened, Safety, ITT
	0171010005	Screened, Safety, ITT
	0171010006	Screened, Safety, ITT
	0171010007	Screened, Safety, ITT
	0171010008	Screened
	0171010009	Screened
	0171010010	Screened, Safety, ITT
	0171010011	Screened, Safety, ITT
	0171010012	Screened, Safety, ITT
	0171010013	Screened, Safety, ITT
	0171010014	Screened, Safety, ITT
	0171010015	Screened
	0171010016	Screened, Safety, ITT
	0171010017	Screened, Safety, ITT
	0171010018	Screened, Safety, ITT
	0171010019	Screened, Safety, ITT

LISTING 14. LOCAL REACTIONS AT THE ADMINISTRATION SITE
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administ ration	IMP dose administered	Volume of solution	System	Specific ation	Intensity/ Severity	Population
Chiaravalle Centrale	0171010020	V2	2nd administ ration	5000	20000	Orophary ngeal	Itching of lips	Mild (1)	Screened, Safety, ITT
	0171010021	Screened
	0171010022	Screened
	0171010023	Screened, Safety, ITT
	0171010024	Screened, Safety, ITT
	0171010025	Screened, Safety, ITT
TROPEA	0181030001	V5	1st administ ration	50000	100000	Orophary ngeal	Itching of oral mucosa	Mild (1)	Screened, Safety, ITT, PP
	0181030002	Screened, Safety, ITT, PP
	0181030003	Screened, Safety, ITT, PP
	0181030004	Screened, Safety, ITT
	0181030005	Screened, Safety, ITT
	0181030006	Screened, Safety, ITT
	0181030007	Screened, Safety, ITT, PP
	0181030008	Screened, Safety, ITT
	0181030009	V5	1st administ ration	50000	100000	Orophary ngeal	Itching of oral mucosa	Mild (1)	Screened, Safety, ITT, PP
	0181030010	Screened, Safety, ITT

LISTING 14. LOCAL REACTIONS AT THE ADMINISTRATION SITE
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administ ration	IMP dose administered	Volume of solution	System	Specific ation	Intensity/ Severity	Population
TROPEA	0181030011	V4	1st administ ration	25000	100000	Orophary ngeal	Mouth ulcer	Mild (1)	Screened, Safety, ITT, PP
	0181030012	Screened, Safety, ITT, PP
	0181030013	Screened, Safety, ITT, PP
	0181030014	Screened, Safety, ITT

LISTING 15. SYSTEMIC REACTIONS
10:22 Monday, July 27, 2020

Center	Patient No.	During which period?	Administered dose	Volume of solution	Specification	Intensity/Severity	Population
Chiaravalle Centrale	1010001	Screened, Safety, ITT
	0171010002	Screened, Safety, ITT
	0171010003	V2	5000	20000	Sleepiness and tingling	Grade I	Screened, Safety, ITT
	0171010004	Screened, Safety, ITT
	0171010005	Screened, Safety, ITT
	0171010006	Screened, Safety, ITT
	0171010007	Screened, Safety, ITT
	0171010008	Screened
	0171010009	Screened
	0171010010	Screened, Safety, ITT
	0171010011	Screened, Safety, ITT
	0171010012	Screened, Safety, ITT
	0171010013	Screened, Safety, ITT
	0171010014	Screened, Safety, ITT
	0171010015	Screened
	0171010016	Screened, Safety, ITT
	0171010017	Screened, Safety, ITT
	0171010018	Screened, Safety, ITT
	0171010019	Screened, Safety, ITT

LISTING 15. SYSTEMIC REACTIONS
10:22 Monday, July 27, 2020

Center	Patient No.	During which period?	Administered dose	Volume of solution	Specification	Intensity/Severity	Population
Chiaravalle Centrale	0171010020	Screened, Safety, ITT
	0171010021	Screened
	0171010022	Screened
	0171010023	Screened, Safety, ITT
	0171010024	V2	2000	20000	Vertigine	Grade I	Screened, Safety, ITT
	0171010025	Screened, Safety, ITT
TROPEA	0181030001	Screened, Safety, ITT, PP
	0181030002	Screened, Safety, ITT, PP
	0181030003	Screened, Safety, ITT, PP
	0181030004	Screened, Safety, ITT
	0181030005	Screened, Safety, ITT
	0181030006	Screened, Safety, ITT
	0181030007	Screened, Safety, ITT, PP
	0181030008	Screened, Safety, ITT
	0181030009	Screened, Safety, ITT, PP
	0181030010	Screened, Safety, ITT
	0181030011	Screened, Safety, ITT, PP
	0181030012	Screened, Safety, ITT, PP

CONFIDENTIAL

Statistical Analysis Report
Study Code: DE_LODRO_GR19

LISTING 15. SYSTEMIC REACTIONS
10:22 Monday, July 27, 2020

Center	Patient No.	During which period?	Administered dose	Volume of solution	Specification	Intensity/Severity	Population
TROPEA	0181030013	Screened, Safety, ITT, PP
	0181030014	Screened, Safety, ITT

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
Chiaravalle Centrale	1010001	Screening	110	60	70	Screened, Safety, ITT
		V2 - 1st Treatment Visit	105	60	70	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	110	70	80	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	120	60	74	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	100	60	68	Screened, Safety, ITT
	0171010002	Screening	100	60	95	Screened, Safety, ITT
		V2 - 1st Treatment Visit	110	70	68	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	120	70	68	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	120	60	68	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	110	60	68	Screened, Safety, ITT
	0171010003	Screening	120	70	84	Screened, Safety, ITT
		V2 - 1st Treatment Visit	120	60	78	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	120	80	80	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	120	60	74	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
Chiaravalle Centrale	0171010003	V6 - End of study/Early termination Visit	120	70	68	Screened, Safety, ITT
	0171010004	Screening	110	70	60	Screened, Safety, ITT
		V2 - 1st Treatment Visit	110	70	60	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	110	70	80	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	120	60	74	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	120	60	68	Screened, Safety, ITT
	0171010005	Screening	100	60	72	Screened, Safety, ITT
		V2 - 1st Treatment Visit	120	70	78	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	100	70	96	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	110	60	78	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	110	60	78	Screened, Safety, ITT
	0171010006	Screening	115	80	84	Screened, Safety, ITT
		V2 - 1st Treatment Visit	130	80	82	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	110	70	72	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	110	60	82	Screened, Safety, ITT

CONFIDENTIAL

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
Chiaravalle Centrale	0171010006	V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	140	80	68	Screened, Safety, ITT
	0171010007	Screening	120	70	72	Screened, Safety, ITT
		V2 - 1st Treatment Visit	130	70	72	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	140	80	80	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	130	80	80	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	120	87	84	Screened, Safety, ITT
	0171010008	Screening	120	80	60	Screened
		V2 - 1st Treatment Visit	.	.	.	Screened
		V3 - 2nd Treatment Visit	.	.	.	Screened
		V4 - 3rd Treatment Visit	.	.	.	Screened
		V5 - 4th Treatment Visit	.	.	.	Screened
		V6 - End of study/Early termination Visit	.	.	.	Screened
	0171010009	Screening	120	80	56	Screened
		V2 - 1st Treatment Visit	.	.	.	Screened
		V3 - 2nd Treatment Visit	.	.	.	Screened
		V4 - 3rd Treatment Visit	.	.	.	Screened
		V5 - 4th Treatment Visit	.	.	.	Screened
		V6 - End of study/Early termination Visit	.	.	.	Screened
	0171010010	Screening	120	70	66	Screened, Safety, ITT

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
Chiaravalle Centrale	0171010010	V2 - 1st Treatment Visit	130	80	80	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	125	80	70	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	130	70	78	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	115	60	68	Screened, Safety, ITT
		Screening	110	60	88	Screened, Safety, ITT
	0171010011	V2 - 1st Treatment Visit	110	60	70	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	100	60	68	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	110	60	70	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	110	60	68	Screened, Safety, ITT
		Screening	110	70	76	Screened, Safety, ITT
	0171010012	V2 - 1st Treatment Visit	120	60	78	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	110	60	80	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	120	60	68	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	110	60	68	Screened, Safety, ITT
		Screening	110	70	76	Screened, Safety, ITT

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
Chiaravalle Centrale	0171010013	Screening	100	70	62	Screened, Safety, ITT
		V2 - 1st Treatment Visit	110	60	72	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	110	70	78	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	110	70	78	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	120	60	68	Screened, Safety, ITT
	0171010014	Screening	90	60	78	Screened, Safety, ITT
		V2 - 1st Treatment Visit	130	70	80	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	100	60	68	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	120	60	74	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	130	80	68	Screened, Safety, ITT
	0171010015	Screening	110	70	68	Screened
		V2 - 1st Treatment Visit	.	.	.	Screened
		V3 - 2nd Treatment Visit	.	.	.	Screened
		V4 - 3rd Treatment Visit	.	.	.	Screened
		V5 - 4th Treatment Visit	.	.	.	Screened
		V6 - End of study/Early termination Visit	.	.	.	Screened
	0171010016	Screening	120	80	68	Screened, Safety, ITT

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
Chiaravalle Centrale	0171010016	V2 - 1st Treatment Visit	130	80	78	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	130	80	80	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	120	70	76	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	130	80	68	Screened, Safety, ITT
		0171010017	Screening	100	60	60
	V2 - 1st Treatment Visit	120	70	80	Screened, Safety, ITT	
	V3 - 2nd Treatment Visit	110	70	72	Screened, Safety, ITT	
	V4 - 3rd Treatment Visit	120	70	78	Screened, Safety, ITT	
	V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT	
	V6 - End of study/Early termination Visit	120	80	74	Screened, Safety, ITT	
	0171010018	Screening	110	60	60	Screened, Safety, ITT
	V2 - 1st Treatment Visit	115	60	72	Screened, Safety, ITT	
	V3 - 2nd Treatment Visit	130	80	76	Screened, Safety, ITT	
	V4 - 3rd Treatment Visit	120	70	72	Screened, Safety, ITT	
	V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT	
	V6 - End of study/Early termination Visit	120	70	72	Screened, Safety, ITT	

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
Chiaravalle Centrale	0171010019	Screening	130	80	78	Screened, Safety, ITT
		V2 - 1st Treatment Visit	130	70	82	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	140	80	76	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	130	80	82	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	140	70	78	Screened, Safety, ITT
	0171010020	Screening	100	60	76	Screened, Safety, ITT
		V2 - 1st Treatment Visit	120	60	76	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	110	70	74	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	120	70	72	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	115	60	72	Screened, Safety, ITT
	0171010021	Screening	100	60	60	Screened
		V2 - 1st Treatment Visit	.	.	.	Screened
		V3 - 2nd Treatment Visit	.	.	.	Screened
		V4 - 3rd Treatment Visit	.	.	.	Screened
		V5 - 4th Treatment Visit	.	.	.	Screened
		V6 - End of study/Early termination Visit	.	.	.	Screened
	0171010022	Screening	110	70	72	Screened
		V2 - 1st Treatment Visit	.	.	.	Screened
		V3 - 2nd Treatment Visit	.	.	.	Screened

CONFIDENTIAL

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
Chiaravalle Centrale	0171010022	V4 - 3rd Treatment Visit	.	.	.	Screened
		V5 - 4th Treatment Visit	.	.	.	Screened
		V6 - End of study/Early termination Visit	.	.	.	Screened
	0171010023	Screening	120	80	72	Screened, Safety, ITT
		V2 - 1st Treatment Visit	130	80	78	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	130	80	76	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	130	80	68	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	130	80	76	Screened, Safety, ITT
	0171010024	Screening	110	70	68	Screened, Safety, ITT
		V2 - 1st Treatment Visit	130	80	70	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	125	80	72	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	130	70	78	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	130	70	68	Screened, Safety, ITT
	0171010025	Screening	120	80	72	Screened, Safety, ITT
		V2 - 1st Treatment Visit	120	70	74	Screened, Safety, ITT

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
Chiaravalle Centrale	0171010025	V3 - 2nd Treatment Visit	110	70	72	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	110	60	70	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	130	70	74	Screened, Safety, ITT
TROPEA	0181030001	Screening	ND	ND	ND	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	ND	ND	ND	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	115	75	72	Screened, Safety, ITT, PP
	0181030002	Screening	125	70	72	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	ND	ND	ND	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	ND	ND	ND	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	125	80	68	Screened, Safety, ITT, PP
0181030003	Screening	.	.	.	Screened, Safety, ITT, PP	

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
TROPEA	0181030003	V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	.	.	.	Screened, Safety, ITT, PP
		Screening	.	.	.	Screened, Safety, ITT
	0181030004	V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	.	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	110	60	70	Screened, Safety, ITT
		Screening	.	.	.	Screened, Safety, ITT
	0181030005	V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	.	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	125	70	68	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	120	80	70	Screened, Safety, ITT
		Screening	.	.	.	Screened, Safety, ITT

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
TROPEA	0181030006	Screening	.	.	.	Screened, Safety, ITT
		V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	110	60	74	Screened, Safety, ITT
		V5 - 4th Treatment Visit	115	70	78	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	130	80	70	Screened, Safety, ITT
	0181030007	Screening	.	.	.	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	110	60	74	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	100	65	66	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	120	70	68	Screened, Safety, ITT, PP
	0181030008	Screening	.	.	.	Screened, Safety, ITT
		V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	.	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	.	.	Screened, Safety, ITT

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
TROPEA	0181030008	V6 - End of study/Early termination Visit	120	70	74	Screened, Safety, ITT
	0181030009	Screening	120	70	68	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	120	80	70	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	120	70	74	Screened, Safety, ITT, PP
	0181030010	Screening	.	.	.	Screened, Safety, ITT
		V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	120	70	74	Screened, Safety, ITT
		V5 - 4th Treatment Visit	115	70	78	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	115	65	66	Screened, Safety, ITT
	0181030011	Screening	.	.	.	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	.	.	Screened, Safety, ITT, PP

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
TROPEA	0181030011	V5 - 4th Treatment Visit	120	70	70	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	115	65	72	Screened, Safety, ITT, PP
	0181030012	Screening	110	70	74	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	120	70	68	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	125	70	78	Screened, Safety, ITT, PP
		Unscheduled Visit	120	70	66	Screened, Safety, ITT, PP
	0181030013	Screening	.	.	.	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	.	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	140	85	76	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	140	80	76	Screened, Safety, ITT, PP
	0181030014	Screening	.	.	.	Screened, Safety, ITT
		V2 - 1st Treatment Visit	.	.	.	Screened, Safety, ITT

CONFIDENTIAL

LISTING 16. VITAL SIGNS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	SBP (mmHg)	DBP (mmHg)	Pulse (beats/min)	Population
TROPEA	0181030014	V3 - 2nd Treatment Visit	.	.	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	.	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	115	70	73	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	125	70	76	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
Chiaravalle Centrale	1010001	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
Chiaravalle Centrale	1010001	V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT
	0171010002	Screening	Asthma Test	Yes	3.86	141	4.81	152	7.05	109	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	Yes	6.60	103	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	6.60	103	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	Yes	6.60	103	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	6.60	103	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	6.60	103	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	Yes	6.60	103	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	6.60	103	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	Yes	6.60	103	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
Chiaravalle Centrale	0171010002	V5 - 4th Treatment Visit	Asthma Test After 1st Administration	Yes	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Asthma Test	Yes	6.60	103	Screened, Safety, ITT
	0171010003	Screening	Asthma Test	Yes	3.09	105	3.72	111	4.92	73	Screened, Safety, ITT
	V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	Yes	5.80	86	Screened, Safety, ITT	
	V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	4.20	62	Screened, Safety, ITT	
	V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	Yes	5.00	74	Screened, Safety, ITT	
	V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	5.00	74	Screened, Safety, ITT	
	V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	5.00	74	Screened, Safety, ITT	
	V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	Yes	5.00	74	Screened, Safety, ITT	
	V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	3.30	49	Screened, Safety, ITT	
	V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	Yes	4.20	62	Screened, Safety, ITT	

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010003	V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	Yes	Screened, Safety, ITT	
		V6 - End of study/Early termination Visit	Asthma Test	Yes	5.80	87	Screened, Safety, ITT	
	0171010004	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010004	V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT	
	0171010005	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010005	V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT
		0171010006	Screening	Asthma Test	No	Screened, Safety, ITT
	0171010006	V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010006	V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT	
	0171010007	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population		
Chiaravalle Centrale	0171010007	V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT		
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT		
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT		
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT		
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT		
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT		
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT	
		0171010008	Screening	Asthma Test	No	Screened
			V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened
			V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened
			V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population		
Chiaravalle Centrale	0171010008	V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened		
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened		
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened		
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened		
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened		
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened		
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened		
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened	
		0171010009	Screening V2 - 1st Treatment Visit	Asthma Test	No	Screened
			V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened
			V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population		
Chiaravalle Centrale	0171010009	V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened		
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened		
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened		
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened		
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened		
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened		
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened		
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened		
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened	
			0171010010	Screening	Asthma Test	Yes	4.65	113	5.29	108	9.76	103	Screened, Safety, ITT
				V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	Yes	5.00	52	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010010	V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	6.70	70	Screened, Safety, ITT	
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	Yes	5.00	52	Screened, Safety, ITT	
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	6.70	70	Screened, Safety, ITT	
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	5.00	52	Screened, Safety, ITT	
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	Yes	5.00	52	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	6.60	70	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	Yes	5.00	52	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	Yes	Screened, Safety, ITT	
		V6 - End of study/Early termination Visit	Asthma Test	Yes	5.00	52	Screened, Safety, ITT	
			0171010011	Screening	Asthma Test	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010011	V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT	
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT	
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT	
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
Chiaravalle Centrale	0171010012	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
Chiaravalle Centrale	0171010012	V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT
	0171010013	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010013	V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT	
	0171010014	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
Chiaravalle Centrale	0171010014	V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT
	0171010015	Screening	Asthma Test	Yes	4.47	100	5.67	109	8.13	81	Screened
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	Screened
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	Yes	Screened
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	Screened
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	Yes	Screened
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010015	V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	Yes	Screened	
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened	
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	Yes	Screened	
		V6 - End of study/Early termination Visit	Asthma Test	Yes	Screened	
	0171010016	Screening	Asthma Test		No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration		No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration		No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration		No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration		No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration		No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration		No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010016	V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT
		0171010017	Screening	Asthma Test	No	Screened, Safety, ITT
	0171010017	V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010017	V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT	
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT
	0171010018	Screening	Asthma Test		Yes	3.74	95	4.30	91	10.20	110	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	Yes	8.30	90	90	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	8.30	90	90	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	Yes	8.30	90	90	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	6.60	73	73	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population		
Chiaravalle Centrale	0171010018	V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	6.60	72	Screened, Safety, ITT		
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	Yes	6.60	72	Screened, Safety, ITT		
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	8.30	90	Screened, Safety, ITT		
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	Yes	6.60	72	Screened, Safety, ITT		
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened, Safety, ITT		
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	Yes	Screened, Safety, ITT		
		V6 - End of study/Early termination Visit	Asthma Test	Yes	7.50	81	Screened, Safety, ITT		
		0171010019	Screening	Asthma Test	No	Screened, Safety, ITT
			V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
			V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
	V2 - 1st Treatment Visit		Asthma Test After 2nd Administration	No	Screened, Safety, ITT	

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population		
Chiaravalle Centrale	0171010019	V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT		
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT		
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT		
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT		
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT		
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT		
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT		
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT	
		0171010020	Screening	Asthma Test	No	Screened, Safety, ITT
			V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
			V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population		
Chiaravalle Centrale	0171010020	V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT		
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT		
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT		
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT		
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT		
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT		
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT		
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT		
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT	
			0171010021	Screening	Asthma Test	No	Screened
				V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population		
Chiaravalle Centrale	0171010021	V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened		
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened		
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened		
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened		
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened		
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened		
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened		
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened		
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened		
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened	
			0171010022	Screening	Asthma Test	Yes	2.72	106	3.49	118	4.47	72	Screened

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010022	V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened	
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	Screened	
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	Yes	Screened	
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened	
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	Yes	Screened	
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	Yes	Screened	
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened	
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	Yes	Screened	
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	Yes	Screened	
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	Yes	Screened	
		V6 - End of study/Early termination Visit	Asthma Test	Yes	Screened

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
Chiaravalle Centrale	0171010023	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
Chiaravalle Centrale	0171010023	V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT
	0171010024	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population	
Chiaravalle Centrale	0171010024	V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT	
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT	
	0171010025	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
Chiaravalle Centrale	0171010025	V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT
TROPEA	0181030001	Screening	Asthma Test	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030001	V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT, PP
	0181030002	Screening	Asthma Test	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030002	V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT, PP
	0181030003	Screening	Asthma Test	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030003	V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT, PP
	0181030004	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030004	V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT
	0181030005	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population		
TROPEA	0181030005	V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT		
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT		
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT		
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT		
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT		
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT		
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT		
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT	
		0181030006	Screening	Asthma Test	No	Screened, Safety, ITT
			V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
			V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030006	V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT
	0181030007	Screening	Asthma Test	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030007	V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT, PP
	0181030008	Screening	Asthma Test	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030008	V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030009	Screening	Asthma Test	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030009	V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT, PP
	0181030010	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030010	V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT
	0181030011	Screening	Asthma Test	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030011	V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT, PP
	0181030012	Screening	Asthma Test	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030012	V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT, PP
		Unscheduled Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		Unscheduled Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
	0181030013	Screening	Asthma Test	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030013	V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT, PP
	0181030014	Screening	Asthma Test	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V2 - 1st Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT

LISTING 17. PULMONARY FUNCTION IN ASTHMATIC PATIENTS ONLY
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Administration	Asthmatic Patient	FEV1 (l)	FEV1 predicted (%)	FVC (l)	FVC predicted (%)	PEF (l/s)	PEF predicted (%)	Population
TROPEA	0181030014	V3 - 2nd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test Prior to 2nd Administration	No	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	Asthma Test After 2nd Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test Prior to 1st Administration	No	Screened, Safety, ITT
		V5 - 4th Treatment Visit	Asthma Test After 1st Administration	No	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Asthma Test	No	Screened, Safety, ITT

LISTING 18. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Exam performed	Date of sampling	Haemoglobin (g/dl)	Haematocrit (%)	RBC (10 ³ /ul)	WBC (10 ³ /ul)	Neutrophils (10 ⁹)	Lymphocytes (10 ⁹)	Monocytes (10 ⁹)	Eosinophils (10 ⁹)	Basophils (10 ⁹)	Platelets (10 ³ /ul)	Creatinine (mg/dl)	Urea (mmol/L)
Chiaravalle Centrale	1010001	Yes	25/03/2019	14	40.9	4.7	6.17	2.8	2.71	0.4	0.22	0.04	250	0.59	22
	0171010002	Yes	25/03/2019	14.4	42.7	4.89	4.88	1.93	2.4	0.4	0.11	0.04	241	0.93	37
	0171010003	Yes	25/03/2019	13.2	41	4.77	10.48	6.09	3.27	0.61	0.47	0.04	339	0.53	24
	0171010004	Yes	25/03/2019	17.5	50.3	5.72	8.58	4.45	2.61	0.89	0.55	0.08	289	0.78	21
	0171010005	Yes	25/03/2019	16.5	49	5.35	8.57	4.1	2.92	1.02	0.43	0.1	240	0.87	37
	0171010006	Yes	25/03/2019	11.7	38.1	6.22	5.7	2.61	2.6	0.37	0.06	0.06	261	0.75	29
	0171010007	Yes	25/03/2019	15.9	47.4	5.59	8.94	4.79	2.95	0.77	0.36	0.07	378	0.79	42
	0171010008	Yes	25/03/2019	13.6	37.2	4.86	9.12	6.37	1.95	0.63	0.1	0.07	314	0.58	14
	0171010009	Yes	25/03/2019	14.7	43.2	4.81	4.82	3.24	1.19	0.3	0.06	0.03	182	0.93	41
	0171010010	Yes	25/03/2019	15.6	44.3	5.46	3.88	2.18	1.3	0.29	0.09	0.02	125	0.69	33

LISTING 18. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Sodium (mEq/l)	Potassium (mEq/l)	Chloride (mol/L)	Calcium Total Protein (mg/dl)	Albumin (g/dl)	AST (U/l)	ALT (U/l)	GGT (U/l)	Total bilirubin (mg/dl)	Grass pollen specific IgE (U/l)	Population
Chiaravalle Centrale	1010001											Screened, Safety, ITT
	0171010002	140	4	98	9.54	4.6	16	14	14	0.43	2.11	Screened, Safety, ITT
	0171010003	141	4.6	102	9.18	4.6	29	26	8	1.35	25.2	Screened, Safety, ITT
	0171010004	141	5	101	9.07	4.1	13	10	11	0.44	23.8	Screened, Safety, ITT
	0171010005	142	4.6	100	9.88	5	19	21	14	0.69	5.28	Screened, Safety, ITT
	0171010006	144	4.2	101	9.9	5	18	21	27	0.14	18.5	Screened, Safety, ITT
	0171010007	141	4.6	102	9.19	4.7	23	33	19	0.41	8.48	Screened, Safety, ITT
	0171010008	142	4	95	9.7	4.7	25	44	42	0.81	9.96	Screened
	0171010009	138	5.1	101	9.17	4.4	22	24	16	0.35	16.6	Screened
	0171010010	145	4.4	106	8.73	4.7	39	73	45	0.71	100	Screened, Safety, ITT
	141	4.4	101	8.87	4.6	12	12	25	1.06	28.3		

LISTING 18. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Exam performed	Date of sampling	Haemoglobin (g/dl)	Haematocrit (%)	RBC (10 ³ /ul)	WBC (10 ³ /ul)	Neutrophils (10 ⁹)	Lymphocytes (10 ⁹)	Monocytes (10 ⁹)	Eosinophils (10 ⁹)	Basophils (10 ⁹)	Platelets (10 ³ /ul)	Creatinine (mg/dl)	Urea (mmol/L)
Chiaravalle Centrale	0171010011	Yes	25/03/2019												
	0171010012	Yes	25/03/2019	12.2	37.6	4.71	10.44	5.1	3.96	1.19	0.1	0.09	382	0.62	28
	0171010013	Yes	25/03/2019	11.3	33.2	3.68	6.58	3.76	1.77	0.5	0.47	0.08	200	0.64	37
	0171010014	Yes	25/03/2019	15.3	45	5.29	8.21	5.02	2.03	0.69	0.43	0.04	194	0.82	39
	0171010015	Yes	25/03/2019	15.5	44.1	5.32	7.08	4.35	2.07	0.52	0.12	0.02	208	0.67	45
	0171010016	Yes	25/03/2019	16.6	48.1	5.87	6.79	3.75	2.27	0.45	0.27	0.05	203	0.79	26
	0171010017	Yes	25/03/2019	16.3	47.4	5.5	8.56	4.73	2.62	0.6	0.53	0.08	217	0.96	49
	0171010018	Yes	26/03/2019	12.6	39.4	5.34	9.43	5.3	3.49	0.43	0.14	0.07	275	0.65	25
	0171010019	Yes	26/03/2019	15.5	44	5.11	6.96	2.89	3.09	0.54	0.38	0.06	238	0.98	41
	0171010020	Yes	26/03/2019	15.1	44.5	5.17	8.7	5.54	2.32	0.6	0.2	0.04	227	0.82	35
				16.4	47.5	5.74	8.04	2.52	4.6	0.74	0.13	0.05	259	0.89	27

LISTING 18. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Sodium (mEq/l)	Potassium (mEq/l)	Chloride (mol/L)	Calcium Total Protein (mg/dl)	Albumin (g/dl)	AST (U I/l)	ALT (U I/l)	GGT (U I/l)	Total bilirubin (mg/dl)	Grass pollen specific IgE (U I/l)	Population
Chiaravalle Centrale	0171010011											Screened, Safety, ITT
	0171010012	139	3.7	98	9.2	4.4	11	9	7	0.13	1.12	Screened, Safety, ITT
	0171010013	141	4.2	103	8.87	4.1	26	9	10	0.27	100	Screened, Safety, ITT
	0171010014	141	4.6	101	9.4	5	17	14	19	0.54	47	Screened, Safety, ITT
	0171010015	141	5	102	9.6	4.8	23	16	7	0.33	74.8	Screened
	0171010016	143	4.3	100	9.49	5	66	52	20	0.78	12.6	Screened, Safety, ITT
	0171010017	141	4.2	100	9.08	4.3	32	40	26	0.45	1.38	Screened, Safety, ITT
	0171010018	141	4.2	101	9.11	4.5	19	21	18	0.42	54.7	Screened, Safety, ITT
	0171010019	141	4.8	100	9.82	5	23	28	10	0.41	2.27	Screened, Safety, ITT
	0171010020	142	5.1	102	9.35	4.7	16	15	17	0.62	2.66	Screened, Safety, ITT
		142	4.2	101	9.39	4.8	18	32	22	0.52	100	Screened, Safety, ITT

LISTING 18. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Exam performed	Date of sampling	Haemoglobin (g/dl)	Haematocrit (%)	RBC (10 ³ /ul)	WBC (10 ³ /ul)	Neutrophils (10 ⁹)	Lymphocytes (10 ⁹)	Monocytes (10 ⁹)	Eosinophils (10 ⁹)	Basophils (10 ⁹)	Platelets (10 ³ /ul)	Creatinine (mg/dl)	Urea (mmol/L)
Chiaravalle Centrale	0171010021	Yes	26/03/2019												
	0171010022	Yes	26/03/2019	15.5	46.4	5.25	5.73	3.05	1.65	0.56	0.39	0.08	226	0.8	27
	0171010023	Yes	26/03/2019	13	41	4.74	6.43	3.47	1.73	0.77	0.42	0.04	258	0.61	27
	0171010024	Yes	26/03/2019	16.8	48.7	5.83	5.04	2.55	1.77	0.55	0.14	0.03	205	0.86	42
	0171010025	Yes	26/03/2019	15	43.8	5.31	7.17	4.62	1.72	0.58	0.18	0.07	301	0.91	40
TROPEA	0181030001	Yes	05/04/2019	15.1	46.3	6.04	4.91	2.5	1.85	0.48	0.06	0.02	297	1.02	32
	0181030002	Yes	29/03/2019	16	45.9	5.48	7.82	3.5	3.1	0.8	0.3	0.1	232	1	42
	0181030003	Yes	04/04/2019	12.8	36.1	4.17	7.69	4.8	2.2	0.4	0.2	0.1	186	0.7	26
	0181030004	Yes	03/04/2019	17.2	47.7	5.48	6.15	2.91	2.63	0.4	0.19	0.02	183	0.8	25
	0181030005	Yes	02/04/2019	12.9	38	4.61	6.78	3.8	1.7	0.6	0.5	0.1	168	0.6	27
				16.2	43.3	5.24	6.53	2.9	2.9	0.4	0.2	0.1	292	0.7	32

LISTING 18. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Sodium (mEq/l)	Potassium (mEq/l)	Chloride (mol/L)	Calcium Total Protein (mg/dl)	Albumin (g/dl)	AST (U/l)	ALT (U/l)	GGT (U/l)	Total bilirubin (mg/dl)	Grass pollen specific IgE (U/l)	Population
Chiaravalle Centrale	0171010021											Screened
	0171010022	142	4.2	102	9.11	4.6	16	13	16	0.27	42.4	Screened
	0171010023	140	4.8	101	9.14	4.4	12	10	8	0.37	26.2	Screened, Safety, ITT
	0171010024	141	5.1	101	8.97	4.7	30	36	16	0.5	5.26	Screened, Safety, ITT
	0171010025	143	3.8	98	9.52	4.6	15	28	13	0.49	41.6	Screened, Safety, ITT
TROPEA	0181030001	140	5.6	99	9.86	5	26	34	14	0.76	100	Screened, Safety, ITT, PP
	0181030002	143	4.4	103	9.9	5	17	21	11	0.9	2.36	Screened, Safety, ITT, PP
	0181030003	140	4.2	104	9.2	4.2	11	8	3	0.3	2.87	Screened, Safety, ITT, PP
	0181030004	142	3.7	103	9.1	4.5	14	19	8	0.5	12.4	Screened, Safety, ITT
	0181030005	142	4	106	9.3	4.6	18	14	6	0.3	2.05	Screened, Safety, ITT
		142	4.6	105	9.5	4.8	12	11	8	0.5	45.8	Screened, Safety, ITT

LISTING 18. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Exam performed	Date of sampling	Haemoglobin (g/dl)	Haematocrit (%)	RBC (10 ³ /ul)	WBC (10 ³ /ul)	Neutrophils (10 ⁹)	Lymphocytes (10 ⁹)	Monocytes (10 ⁹)	Eosinophils (10 ⁹)	Basophils (10 ⁹)	Platelets (10 ³ /ul)	Creatinine (mg/dl)	Urea (mmol/L)
TROPEA	0181030006	Yes	10/04/2019												
	0181030007	Yes	08/04/2019	12	35.4	5.04	12.16	7.9	2.5	1.1	0.5	0.1	263	0.5	54
	0181030008	Yes	02/04/2019	13.8	37.7	4.53	4.86	2.7	1.6	0.3	0.1	0.1	171	0.8	28
	0181030009	Yes	05/04/2019	14.1	38.4	4.79	8.46	6.1	1.6	0.5	0.2	0.1	200	0.7	34
	0181030010	Yes	10/04/2019	16.5	45.6	5.3	6.6	3.8	1.9	0.6	0.3	0.1	256	0.9	34
	0181030011	Yes	05/04/2019	14.4	40.6	4.63	6.49	3.5	2.4	0.4	0.1	0.1	252	0.8	36
	0181030012	Yes	05/04/2019	14.5	42.1	4.73	6.2	4.7	1	0.4	0.1	0	243	0.7	19
	0181030013	Yes	10/04/2019	15	43	4.93	7.67	4.3	2.5	0.6	0.2	0.1	233	0.6	24
	0181030014	Yes	02/04/2019	14.4	39.8	4.35	5.23	2.7	1.7	0.7	0.1	0.1	163	0.9	29
				14.4	39.5	4.35	5.23	2.7	1.7	0.7	0.1	1.2	163	0.9	29

LISTING 18. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT SCREENING VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Sodium (mEq/l)	Potassium (mEq/l)	Chloride (mmol/L)	Calcium Total Protein (mg/dl)	Albumin (g/dl)	AST (U/l)	ALT (U/l)	GGT (U/l)	Total bilirubin (mg/dl)	Grass pollen specific IgE (U/l)	Population
TROPEA	0181030006											Screened, Safety, ITT
		138	4.6	103	9.2	4.2	15	16	8	0.4	3.06	
	0181030007											Screened, Safety, ITT, PP
		136	4.5	101	9.5	4.5	12	10	7	0.5	3.01	
	0181030008											Screened, Safety, ITT
		140	4.4	105	9.3	4.7	12	13	10	0.6	3.06	
	0181030009											Screened, Safety, ITT, PP
		141	4.5	103	9.5	4.8	21	31	22	0.5	2.65	
	0181030010											Screened, Safety, ITT
		140	4.2	103	9.3	4.7	19	11	13	0.5	3.05	
	0181030011											Screened, Safety, ITT, PP
		138	4.1	103	9.3	4.5	28	32	14	0.5	21.5	
	0181030012											Screened, Safety, ITT, PP
		139	4.9	104	9.2	4.2	18	26	54	0.6	3.03	
	0181030013											Screened, Safety, ITT, PP
		141	4.8	103	9.4	5.1	55	38	57	0.3	2.46	
	0181030014											Screened, Safety, ITT
		141	4.8	103	9.4	5.1	24	35	57	0.3	2.28	

LISTING 19. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Exam performed	Date of sampling	Haemoglobin (g/dl)	Haematocrit (%)	RBC (10 ³ /ul)	WBC (10 ³ /ul)	Neutrophils (10 ⁹)	Lymphocytes (10 ⁹)	Monocytes (10 ⁹)	Eosinophils (10 ⁹)	Basophils (10 ⁹)	Platelets (10 ³ /ul)	Creatinine (mg/dl)	Urea (mmol/L)
Chiaravalle Centrale	1010001	Yes	14/05/2019												
	0171010002	Yes	14/05/2019	13.6	39.9	4.55	6.13	3.15	2.36	0.38	0.19	0.05	285	0.62	33
	0171010003	Yes	14/05/2019	15.2	44	5.13	5.6	3.22	1.78	0.47	0.09	0.04	276	1.17	29
	0171010004	Yes	15/05/2019	12.6	38.1	4.59	9.1	5.2	2.63	0.72	0.49	0.06	296	0.54	22
	0171010005	Yes	17/05/2019	17.1	49.1	5.57	6.57	3.23	2.17	0.57	0.53	0.07	277	0.79	24
	0171010006	Yes	13/05/2019	15.8	45.8	5.22	6.97	4.46	1.64	0.71	0.12	0.04	280	1.3	0
	0171010007	Yes	13/05/2019	11.4	36.6	5.95	6.99	3.71	2.7	0.47	0.06	0.05	259	0.72	31
	0171010008	No	.	16	47.9	5.7	10.01	5.26	3.42	0.74	0.48	0.11	345	0.82	39
	0171010009	No
	0171010010	Yes	14/05/2019
	0171010011	Yes	13/05/2019	16.4	46.3	5.72	4.43	2.78	1.1	0.36	0.16	0.03	171	0.74	33
				11.8	35.9	4.54	4.64	2.77	1.44	0.32	0.08	0.03	256	0.62	22

LISTING 19. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Sodium (mEq/l)	Potassium (mEq/l)	Chloride (mmol/L)	Calcium Total Protein (mg/dl)	Albumin (g/dl)	AST (U/l)	ALT (U/l)	GGT (U/l)	Total bilirubin (mg/dl)	Population	
Chiaravalle Centrale	1010001										Screened, Safety, ITT	
	0171010002	139	4.4	101	9.54	4.6	14	13	15	0.45	Screened, Safety, ITT	
	0171010003	142	4.2	104	9.67	4.7	28	28	8	1.92	Screened, Safety, ITT	
	0171010004	139	4.7	101	9.34	4.1	12	11	8	0.3	Screened, Safety, ITT	
	0171010005	142	4.5	102	8.87	4.7	19	23	13	0.43	Screened, Safety, ITT	
	0171010006	140	4	96	9.52	4.9	30	18	24	0.48	Screened, Safety, ITT	
	0171010007	139	4.4	104	8.94	4.3	24	14	20	0.41	Screened, Safety, ITT	
	0171010008	141	4.1	98	9.39	4.4	26	44	42	1.04	Screened	
	0171010009	Screened
	0171010010	Screened, Safety, ITT
	0171010011	142	4.2	102	9.58	4.9	11	11	20	0.78	Screened, Safety, ITT	
		139	4.2	101	8.79	4.1	13	8	4	0.21		

LISTING 19. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Exam perfo rmed	Date of sampling	Haemo globi n (g/d l)	Haema tocri t (%)	RBC (1 0^3/u l)	WBC (1 0^3/u l)	Neutr ophil s (10^ 9)	Lymph ocyte s (10^ 9)	Monoc ytes (10^9)	Eosin ophil s (10^ 9)	Basop hils(10^9)	Plate lets(10^3/ ul)	Creat inine (mg/d l)	Urea (mmol/ L)
Chiaravalle Centrale	0171010012	Yes	13/05/2019												
	0171010013	Yes	15/05/2019	11.7	34.2	3.82	6.37	3.48	1.74	0.56	0.51	0.06	213	0.68	37
	0171010014	Yes	13/05/2019	15.3	45	5.21	7.96	4.94	2	0.59	0.39	0.04	203	0.8	26
	0171010015	No	.	15.1	43.5	5.29	5.79	3.3	1.74	0.29	0.43	0.03	212	0.75	39
	0171010016	Yes	14/05/2019
	0171010017	Yes	15/05/2019	16.9	47.6	5.61	7.96	4.42	2.39	0.6	0.48	0.07	214	0.98	45
	0171010018	Yes	14/05/2019	13.5	41.9	5.7	9.57	6.82	1.75	0.77	0.14	0.09	244	0.67	16
	0171010019	Yes	15/05/2019	15.1	43.4	5.04	5.91	2.61	2.3	0.41	0.52	0.07	215	1.01	43
	0171010020	Yes	14/05/2019	15.1	45.2	5.24	6.31	3.66	2.08	0.18	0.18	0.04	221	0.9	39
	0171010021	No	.	16.4	47	5.68	8.9	4.17	3.65	0.71	0.3	0.07	227	0.83	28
	0171010022	No

LISTING 19. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Sodium (mEq/l)	Potassium (mEq/l)	Chloride (mmol/L)	Calcium Total Protein (mg/dl)	Albumin (g/dl)	AST (U/l)	ALT (U/l)	GGT (U/l)	Total bilirubin (mg/dl)	Population	
Chiaravalle Centrale	0171010012										Screened, Safety, ITT	
		142	3.8	105	8.86	4.1	27	11	9	0.27	Screened, Safety, ITT	
	0171010013										Screened, Safety, ITT	
		144	4.1	102	8.97	4.7	18	17	20	0.26	Screened, Safety, ITT	
	0171010014										Screened, Safety, ITT	
		143	4.4	103	9.07	4.6	28	34	10	0.29	Screened	
	0171010015										Screened	
		Screened, Safety, ITT
	0171010016										Screened, Safety, ITT	
		139	4.2	100	9.35	4.6	18	25	28	0.68	Screened, Safety, ITT	
	0171010017										Screened, Safety, ITT	
		138	4.5	98	8.96	4.6	23	25	18	0.61	Screened, Safety, ITT	
	0171010018										Screened, Safety, ITT	
		141	4.4	101	9.86	4.9	17	18	10	0.23	Screened, Safety, ITT	
0171010019										Screened, Safety, ITT		
	143	4.8	104	9.3	4.4	16	19	18	0.47	Screened, Safety, ITT		
0171010020										Screened, Safety, ITT		
	142	4	103	9.52	4.8	17	27	18	0.55	Screened		
0171010021										Screened		
	Screened	
0171010022										Screened		
	Screened	

LISTING 19. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Exam perfo rmed	Date of sampling	Haemo globi n(g/d l)	Haema tocrit (%)	RBC(1 0^3/u l)	WBC(1 0^3/u l)	Neutr ophil s(10^ 9)	Lymph ocyte s(10^ 9)	Monoc ytes(10^9)	Eosin ophil s(10^ 9)	Basop hils(10^9)	Plate lets(10^3/ ul)	Creat inine (mg/d l)	Urea (mmol/ L)
Chiaravalle Centrale	0171010023	Yes	15/05/2019												
	0171010024	Yes	15/05/2019	16.6	46.8	5.62	4.04	2.09	1.32	0.42	0.17	0.04	214	0.94	34
	0171010025	Yes	14/05/2019	15.4	44.6	5.35	7.04	4.62	1.6	0.52	0.22	0.08	294	0.9	47
TROPEA	0181030001	Yes	05/09/2019	14.3	43.6	5.7	4.51	2.3	1.45	0.58	0.16	0.02	226	1.01	33
	0181030002	Yes	10/06/2019	15.9	45.6	5.4	7.84	3.4	3	0.8	0.4	0.1	230	1	41
	0181030003	No	.	12.6	37.4	4.3	10.36	6.1	3	0.7	0.3	0.1	255	0.9	28
	0181030004	Yes	20/06/2019
	0181030005	Yes	05/09/2019	12.3	36.8	4.46	4.77	2	33.1	0.5	0.6	0.1	157	0.7	32
	0181030006	Yes	27/06/2019	16.3	43.4	5.21	6.52	2.9	2.9	0.5	0.2	0.1	291	0.7	34
	0181030007	Yes	13/06/2019	11.8	35	4.91	6.42	2.9	2.4	0.6	0.5	0.1	189	0.7	45
	0181030008	Yes	28/05/2019	15.1	38.1	4.54	4.75	2.4	1.6	0.3	0.3	2.5	153	0.8	35
				14	39.4	4.94	10.03	7.1	1.3	1	0.2	4.1	195	0.7	36

LISTING 19. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Sodium (mEq/l)	Potassium (mEq/l)	Chloride (mmol/L)	Calcium Total Protein (mg/dl)	Albumin (g/dl)	AST (U/l)	ALT (U/l)	GGT (U/l)	Total bilirubin (mg/dl)	Population
Chiaravalle Centrale	0171010023										Screened, Safety, ITT
	0171010024	141	5	103	8.42	4.5	22	31	14	0.57	Screened, Safety, ITT
	0171010025	144	4.3	102	9.42	4.5	15	27	15	0.38	Screened, Safety, ITT
TROPEA	0181030001	140	4.2	102	9.8	4.7	23	27	13	0.69	Screened, Safety, ITT, PP
	0181030002	144	4.8	101	9.7	5.1	18	22	12	0.8	Screened, Safety, ITT, PP
	0181030003	137	4.3	102	9.4	4.1	15	11	3	0.3	Screened, Safety, ITT, PP
	0181030004	Screened, Safety, ITT
	0181030005	136	4.1	101	8.8	4	14	9	5	0.4	Screened, Safety, ITT
	0181030006	143	4.5	103	9.6	4.8	11	12	9	0.5	Screened, Safety, ITT
	0181030007	136	4.5	103	9.3	4.3	16	17	9	0.5	Screened, Safety, ITT, PP
	0181030008	140	4.3	106	9.4	4.7	16	17	7	0.3	Screened, Safety, ITT
		138	4.3	104	9.1	4.8	13	15	11	0.7	

LISTING 19. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Exam performed	Date of sampling	Haemoglobin (g/dl)	Haematocrit (%)	RBC (10 ³ /ul)	WBC (10 ³ /ul)	Neutrophils (10 ⁹)	Lymphocytes (10 ⁹)	Monocytes (10 ⁹)	Eosinophils (10 ⁹)	Basophils (10 ⁹)	Platelets (10 ³ /ul)	Creatinine (mg/dl)	Urea (mmol/L)
TROPEA	0181030009	Yes	19/06/2019												
	0181030010	Yes	05/09/2019	14.3	41.5	4.8	4.55	44.7	1.2	0.7	0.5	0.1	255	1	38
	0181030011	Yes	24/06/2019	14.5	40.7	4.64	6.5	3.5	2.4	0.5	0.2	0.1	254	0.8	38
	0181030012	Yes	05/09/2019	13.7	39.1	4.49	5.35	3	1.5	0.4	0.4	0.1	236	0.8	22
	0181030013	Yes	05/09/2019	14.9	42	4.9	7.6	4.2	2.4	0.5	0.2	0.1	233	0.5	0
	0181030014	Yes	24/06/2019	14.3	39.7	4.36	5.26	2.8	1.6	0.6	0.1	0.2	164	0.9	0
				15.9	44.5	5.03	6.66	3.1	3.1	0.6	0.2	0.1	222	0.9	36

LISTING 19. HEMATOLOGY & BLOOD CHEMISTRY MEASUREMENTS AT LAST VISIT
10:22 Monday, July 27, 2020

Center	Patient No.	Sodium (mEq/l)	Potassium (mEq/l)	Chloride (mmol/L)	Calcium Total Protein (mg/dl)	Albumin (g/dl)	AST (U/l)	ALT (U/l)	GGT (U/l)	Total bilirubin (mg/dl)	Population
TROPEA	0181030009										Screened, Safety, ITT, PP
	0181030010	139	4.2	100	9.3	4.7	27	40	20	0.3	Screened, Safety, ITT
	0181030011	142	4.3	102	9.5	4.7	19	14	21	0.6	Screened, Safety, ITT, PP
	0181030012	136	4.2	102	9.1	4.4	28	37	11	0.5	Screened, Safety, ITT, PP
	0181030013	139	4.7	102	9.1	4.3	19	25	28	0.7	Screened, Safety, ITT, PP
	0181030014	142	4.9	102	9.5	5	54	38	56	0.8	Screened, Safety, ITT
		136	4	98	9.4	4.4	18	27	37	1.6	

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	1010001	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010002	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Total bilirubin	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	0171010003	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
			PEF predicted	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010004	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	0171010005	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010006	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	0171010007	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010008	V2 - 1st Treatment Visit	.	Screened
		V3 - 2nd Treatment Visit	.	Screened
		V4 - 3rd Treatment Visit	.	Screened
		V5 - 4th Treatment Visit	.	Screened
		V6 - End of study/Early termination Visit	.	Screened
		Unscheduled Visit	.	Screened
	0171010009	V2 - 1st Treatment Visit	.	Screened
		V3 - 2nd Treatment Visit	.	Screened
		V4 - 3rd Treatment Visit	.	Screened

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	0171010009	V5 - 4th Treatment Visit	.	Screened
		V6 - End of study/Early termination Visit	.	Screened
		Unscheduled Visit	.	Screened
	0171010010	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010011	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
V5 - 4th Treatment Visit		.	Screened, Safety, ITT	

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	0171010011	V6 - End of study/Early termination Visit	GGT	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010012	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010013	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	0171010013	V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010014	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010015	V2 - 1st Treatment Visit	.	Screened
		V3 - 2nd Treatment Visit	.	Screened
		V4 - 3rd Treatment Visit	.	Screened
		V5 - 4th Treatment Visit	.	Screened
		V6 - End of study/Early termination Visit	.	Screened
		Unscheduled Visit	.	Screened

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	0171010016	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010017	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	0171010018	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Total bilirubin	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010019	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	0171010020	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010021	V2 - 1st Treatment Visit	.	Screened
		V3 - 2nd Treatment Visit	.	Screened
		V4 - 3rd Treatment Visit	.	Screened
		V5 - 4th Treatment Visit	.	Screened
		V6 - End of study/Early termination Visit	.	Screened
		Unscheduled Visit	.	Screened
	0171010022	V2 - 1st Treatment Visit	.	Screened
		V3 - 2nd Treatment Visit	.	Screened
		V4 - 3rd Treatment Visit	.	Screened

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	0171010022	V5 - 4th Treatment Visit	.	Screened
		V6 - End of study/Early termination Visit	.	Screened
		Unscheduled Visit	.	Screened
	0171010023	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010024	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
Chiaravalle Centrale	0171010024	V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0171010025	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
TROPEA	0181030001	V2 - 1st Treatment Visit	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT, PP

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
TROPEA	0181030001	V6 - End of study/Early termination Visit	.	Screened, Safety, ITT, PP
		Unscheduled Visit	.	Screened, Safety, ITT, PP
	0181030002	V2 - 1st Treatment Visit	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT, PP
		Unscheduled Visit	.	Screened, Safety, ITT, PP
	0181030003	V2 - 1st Treatment Visit	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT, PP

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
TROPEA	0181030003	V6 - End of study/Early termination Visit	.	Screened, Safety, ITT, PP
		Unscheduled Visit	.	Screened, Safety, ITT, PP
	0181030004	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Lymphocytes, Neutrophils	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0181030005	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
TROPEA	0181030005	V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0181030006	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0181030007	V2 - 1st Treatment Visit	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT, PP

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
TROPEA	0181030007	V6 - End of study/Early termination Visit	Basophils	Screened, Safety, ITT, PP
		Unscheduled Visit	.	Screened, Safety, ITT, PP
	0181030008	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Basophils	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0181030009	V2 - 1st Treatment Visit	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT, PP

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
TROPEA	0181030009	V6 - End of study/Early termination Visit	Neutrophils	Screened, Safety, ITT, PP
		Unscheduled Visit	.	Screened, Safety, ITT, PP
	0181030010	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	.	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT
	0181030011	V2 - 1st Treatment Visit	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT, PP

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
TROPEA	0181030011	V6 - End of study/Early termination Visit	.	Screened, Safety, ITT, PP
		Unscheduled Visit	.	Screened, Safety, ITT, PP
	0181030012	V2 - 1st Treatment Visit	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT, PP
		V6 - End of study/Early termination Visit	Creatinine	Screened, Safety, ITT, PP
		Unscheduled Visit	.	Screened, Safety, ITT, PP
	0181030013	V2 - 1st Treatment Visit	.	Screened, Safety, ITT, PP
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT, PP
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT, PP
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT, PP

LISTING 20. WORSENING IN VITAL SIGNS, PULMONARY FUNCTION FOR ASTHMATIC PATIENTS AND LABORATORY TESTS
10:22 Monday, July 27, 2020

Center	Patient No.	Visit	Worsening	Population
TROPEA	0181030013	V6 - End of study/Early termination Visit	.	Screened, Safety, ITT, PP
		Unscheduled Visit	.	Screened, Safety, ITT, PP
	0181030014	V2 - 1st Treatment Visit	.	Screened, Safety, ITT
		V3 - 2nd Treatment Visit	.	Screened, Safety, ITT
		V4 - 3rd Treatment Visit	.	Screened, Safety, ITT
		V5 - 4th Treatment Visit	.	Screened, Safety, ITT
		V6 - End of study/Early termination Visit	Total bilirubin	Screened, Safety, ITT
		Unscheduled Visit	.	Screened, Safety, ITT

LISTING 21. PATIENTS WHO USED RESCUE MEDICATION
10:22 Monday, July 27, 2020

Center	Patient No.	Related to visit	Rescue Medication	Start date	End date	Ongoing	How many times per day	Total Dose Taken	IMP Discontinued	How many days	Population
Chiaravalle Centrale	1010001	Screened, Safety, ITT
	0171010002	Screened, Safety, ITT
	0171010003	Screened, Safety, ITT
	0171010004	Screened, Safety, ITT
	0171010005	Screened, Safety, ITT
	0171010006	V5	Desloratadine	07/05/2019	07/05/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	03/05/2019	03/05/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	07/04/2019	07/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V4	Desloratadine	04/04/2019	04/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	10/04/2019	10/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V4	Desloratadine	02/04/2019	02/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	23/04/2019	23/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V2	Desloratadine	31/03/2019	31/03/2019	No	1	5 mg	No	.	Screened, Safety, ITT
	V5	Desloratadine	09/05/2019	09/05/2019	No	1	5 mg	No	.	Screened, Safety, ITT	

LISTING 21. PATIENTS WHO USED RESCUE MEDICATION
10:22 Monday, July 27, 2020

Center	Patient No.	Related to visit	Rescue Medication	Start date	End date	Ongoing	How many times per day	Total Dose Taken	IMP Discontinued	How many days	Population
Chiaravalle Centrale	0171010006	V5	Desloratadine	05/05/2019	05/05/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	01/05/2019	01/05/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	29/04/2019	29/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	27/04/2019	27/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	25/04/2019	25/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	18/04/2019	19/04/2019	No	1	10 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	21/04/2019	21/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	16/04/2019	16/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V5	Desloratadine	13/04/2019	13/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
			0171010007	V2	Desloratadine	30/03/2019	31/03/2019	No	1	10 mg	No
	0171010008	Screened	
	0171010009	Screened	
	0171010010	Screened, Safety, ITT	
	0171010011	Screened, Safety, ITT	
	0171010012	Screened, Safety, ITT	

LISTING 21. PATIENTS WHO USED RESCUE MEDICATION
10:22 Monday, July 27, 2020

Center	Patient No.	Related to visit	Rescue Medication	Start date	End date	Ongoing	How many times per day	Total Dose Taken	IMP Discontinued	How many days	Population
Chiaravalle Centrale	0171010013	Screened, Safety, ITT
	0171010014	Screened, Safety, ITT
	0171010015	Screened
	0171010016	V5	Desloratadine	06/04/2019	06/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
	0171010017	Screened, Safety, ITT
	0171010018	V3	Desloratadine	02/04/2019	02/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
	0171010019	Screened, Safety, ITT
	0171010020	V3	Desloratadine	02/04/2019	02/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT
	0171010021	Screened
	0171010022	Screened
	0171010023	Screened, Safety, ITT
	0171010024	Screened, Safety, ITT

LISTING 21. PATIENTS WHO USED RESCUE MEDICATION
10:22 Monday, July 27, 2020

Center	Patient No.	Related to visit	Rescue Medication	Start date	End date	Ongoing	How many times per day	Total Dose Taken	IMP Discontinued	How many days	Population
Chiaravalle Centrale	0171010025	Screened, Safety, ITT
TROPEA	0181030001	Screened, Safety, ITT, PP
	0181030002	Screened, Safety, ITT, PP
	0181030003	V3	Desloratadine	27/04/2019	27/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT, PP
	0181030004	Screened, Safety, ITT
	0181030005	V4	Desloratadine	02/05/2019	02/05/2019	No	1	5 mg	No	.	Screened, Safety, ITT
		V3	Desloratadine	28/04/2019	30/04/2019	No	1	15 mg	No	.	Screened, Safety, ITT
	0181030006	V3	Desloratadine	03/05/2019	05/05/2019	No	1	15 mg	No	.	Screened, Safety, ITT
	0181030007	Screened, Safety, ITT, PP
	0181030008	Screened, Safety, ITT
	0181030009	V2	Desloratadine	21/04/2019	21/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT, PP
		V2	Desloratadine	17/04/2019	17/04/2019	No	1	5 mg	No	.	Screened, Safety, ITT, PP

LISTING 21. PATIENTS WHO USED RESCUE MEDICATION
10:22 Monday, July 27, 2020

Center	Patient No.	Related to visit	Rescue Medication	Start date	End date	Ongoing	How many times per day	Total Dose Taken	IMP Discontinued	How many days	Population
TROPEA	0181030010	Screened, Safety, ITT
	0181030011	V4	Desloratadine	26/04/2019	27/04/2019	No	1	10 mg	No	.	Screened, Safety, ITT, PP
		V4	Desloratadine	28/04/2019	02/05/2019	No	1	25 mg	No	.	Screened, Safety, ITT, PP
	0181030012	V2	Desloratadine	20/04/2019	22/04/2019	No	1	15 mg	No	.	Screened, Safety, ITT, PP
	0181030013	V2	Desloratadine	24/04/2019	25/04/2019	No	1	10 mg	No	.	Screened, Safety, ITT, PP
	0181030014	Screened, Safety, ITT

LISTING 22. PATIENTS WHO REACHED MAXIMUM DOSE OF IMP
10:22 Monday, July 27, 2020

Center	Patient No.	Maximum dose	Population
Chiaravalle Centrale	1010001	25000	Screened, Safety, ITT
	0171010002	50000	Screened, Safety, ITT
	0171010003	50000	Screened, Safety, ITT
	0171010004	50000	Screened, Safety, ITT
	0171010005	50000	Screened, Safety, ITT
	0171010006	50000	Screened, Safety, ITT
	0171010007	50000	Screened, Safety, ITT
	0171010008	.	Screened
	0171010009	.	Screened
	0171010010	50000	Screened, Safety, ITT
	0171010011	50000	Screened, Safety, ITT
	0171010012	50000	Screened, Safety, ITT
	0171010013	50000	Screened, Safety, ITT

CONFIDENTIAL

LISTING 22. PATIENTS WHO REACHED MAXIMUM DOSE OF IMP
10:22 Monday, July 27, 2020

Center	Patient No.	Maximum dose	Population	
Chiaravalle Centrale	0171010014	50000	Screened, Safety, ITT	
	0171010015	.	Screened	
	0171010016	50000	Screened, Safety, ITT	
	0171010017	50000	Screened, Safety, ITT	
	0171010018	50000	Screened, Safety, ITT	
	0171010019	50000	Screened, Safety, ITT	
	0171010020	50000	Screened, Safety, ITT	
	0171010021	.	Screened	
	0171010022	.	Screened	
	0171010023	50000	Screened, Safety, ITT	
	0171010024	50000	Screened, Safety, ITT	
	0171010025	50000	Screened, Safety, ITT	
	TROPEA	0181030001	50000	Screened, Safety, ITT, PP

CONFIDENTIAL

LISTING 22. PATIENTS WHO REACHED MAXIMUM DOSE OF IMP
10:22 Monday, July 27, 2020

Center	Patient No.	Maximum dose	Population
TROPEA	0181030002	50000	Screened, Safety, ITT, PP
	0181030003	.	Screened, Safety, ITT, PP
	0181030004	50000	Screened, Safety, ITT
	0181030005	50000	Screened, Safety, ITT
	0181030006	50000	Screened, Safety, ITT
	0181030007	50000	Screened, Safety, ITT, PP
	0181030008	50000	Screened, Safety, ITT
	0181030009	50000	Screened, Safety, ITT, PP
	0181030010	50000	Screened, Safety, ITT
	0181030011	50000	Screened, Safety, ITT, PP
	0181030012	50000	Screened, Safety, ITT, PP
	0181030013	50000	Screened, Safety, ITT, PP

CONFIDENTIAL

LISTING 22. PATIENTS WHO REACHED MAXIMUM DOSE OF IMP
10:22 Monday, July 27, 2020

Center	Patient No.	Maximum dose	Population
TROPEA	0181030014	50000	Screened, Safety, ITT
