Appendices to the Clinical Trial Report of ‘Miltefosin bei AD’

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16 Appendices

16.1 Trial information

16.1.1 Protocol of the clinical trial, patients information and informed consent

The clinical trial was conducted according to the protocol; version 1.3 dated 31st August 2007 including the patient information and informed consent, from the 31st August 2007. No formal protocol amendments were made.

All 3 documents are enclosed separately.

16.1.2 Sample Case Report Form (CRF) and diary card

A sample CRF is enclosed separately with all visit pages including the screening and follow up, with the page for concomitant medication, adverse events, drug accountability and pipette control as well as the termination page.

Also a sample diary card is enclosed separately.

16.1.3 Chairmen and member of the local IEC

Ausschuss 3

Mitglied			**Stellvertreter/in**	
Funktion	**Name, Vorname**	**Erlernter/ausgeübter Beruf**	**Name, Vorname**	**Erlernter/ausgeübter Beruf**
Facharzt/-ärztin (Vorsitzende/r **Chairmen**)	**Prof. Dr. med. Stefan Müller-Lissner**	Facharzt f. Innere Medizin u. Gastro-enterologie/ Leiter einer Klinikabteilung	Prof. Dr. med. Edeltraut Garbe	Fachärztin f. Innere Medizin u. klinische Pharmakologie/ Hochschullehrerin
Facharzt/ärztin (Stellvertretende/r Vorsitzende/r)	Prof. Dr. med. Michael Dettling	Facharzt f. Psychiatrie u. Neurologie	Prof. Dr. med. Ulrich Keilholz	Facharzt für Innere Medizin, Hämatologie u. Onkologie/Oberarzt, Hochschullehrer
Pharmakologe/in	Prof. Dr. med. Heide Hörtnagl	Fachärztin f. Pharmakologie, Wiss. Mitarbeiterin	Dr. med. Frank Andersohn	Facharzt f. Klinische Pharrmakologie/ Wiss. Mitarbeiter
Volljurist/in	Dr. iur. Marc C. Baumgart	Volljurist/ Rechtsanwalt	Prof. Dr. iur. Dr. phil. Ulrich Lohmann	Volljurist/ Fachhochschullehrer
Biometriker/in	Dr. med. Peter Schlattmann	Arzt, Biometriker/ Wiss. Mitarbeiter	Dr. rer. nat. Ingeborg Küchler	Mathematikerin/i.R.
Apotheker/in	Dr. rer. nat. Wolfgang Mehnert	Pharmazeut/ Wiss. Mitarbeiter	Dr. Gertraud Thomas	Pharmazeutin/Leiterin einer Klinikapotheke
Laie/in	Ursula Küchler	Germanistin	Cornelia Biondo	Bürokauffrau/Ver-waltungsangestellte
Laie/in	Dr. phil. Katharina v. Falkenhayn	Philosophin u. Wirtschaftswissen-schaftlerin/ Referentin Dt. Bundestag	Gabriele Lucht	Ev. Theologin/ Landespfarrerin Krankenhausseelsorge

Strahlenschutz	Dr. rer. nat. Lutz Lüdemann	Physiker/Wiss. Mitarbeiter	Dr. med. Thomas Schmitz	Facharzt f. Kinderheil-kunde/ Assistenzarzt,

		Kinderheilkunde		Wiss. Mitarbeiter

16.1.4 List of investigators and other important participants in the clinical trial including curricula vitae

Prof. Dr. med. Margitta Worm is the principle investigator and sponsor of the clinical trial "Miltefosine by AD". Because, her clinical and experimental investigations focus on the immunmodulation of atopic dermatitis, she initiated a clinical trial with the lipid raft molecule - miltefosine. Other clinical priorities are allergies to aeroallergens, autoimmune diseases, food allergy, and environmental medicine. Basic experimental research is focusing on the regulation of IgE synthesis and the immunmodulation of Typ I allergic diseases.

Curricula vitae Prof. Dr. med. Margitta Worm

Date of Birth: 25th October 1964

Present Position: Head of Allergy branch, Clinical study unit**;** Department of Dermatology and Allergology, Charité – Universitätsmedizin Berlin, Germany

Medical Graduation and/or Other Professional Training:
Sept. 2007 - specialisation course for study coordination in clinical trials; KKS-Charité
Since 2004 - University Professor
2002 - Specialisation in allergy and environmental medicine
2000 - Attendant in dermatology and allergy
1998 - Specialisation in dermatology and venerology
1991 - Medical Doctor

Experience in Controlled Clinical Trials:
Since 1998 principle investigator and investigator in different studies (>40) phases II-III in allergology and dermatology, mainly specific immunotherapy with different allergens, immunmodulation of atopic dermatitis, allergic asthma and autoimmune diseases.
Experienced in audit performance; regular ICH/GCP-training

Dr. med. Hae-Hyuk Lee is sub-investigator in the clinical trial "Miltefosine by AD". His clinical interest focuses on atopic dermatitis and Typ I allergic diseases. He is experienced in conducting clinical trials since 2002.

Curricula vitae Dr. med. Hae-Hyuk Lee

Date of Birth: 3rd September 1974

Present Position Assistant Doctor**;** Department of Dermatology and Allergology, Charité – Universitätsmedizin Berlin, Germany

Medical Graduation and/or Other Professional Training:
2002 - Resident in dermatology and allergy
2002 - Doctoral thesis
2001 - Medical Graduation

Experience in Controlled Clinical Trials:
Sub-Investigator in different controlled clinical trials phases II-III since 2002, e.g. specific immuntherapy with different allergens by allergy to aeroallergens and atopic dermatitis.
Experienced in audit performance; regular ICH/GCP-training

Dr. med. Claudia Rasche is sub-investigator in the clinical trial "Miltefosine by AD". Her clinical interest also focuses on atopic dermatitis and Typ I allergic diseases as well as on autoimmune diseases. She is experienced in conducting clinical trials since 2005.

Curricula vitae Dr. med. Hae-Hyuk Lee

Date of Birth: 10th July 1977

Present Position: Assistant Doctor**,** Department of Dermatology and Allergology, Charité – Universitätsmedizin Berlin, Germany

Medical Graduation and/or Other Professional Training:
Spring 2007 - Specialisation course for clinical trials; KKS-Charité
Autumn 2006 - Basic principles for clinical trials; KKS-Charité including GCP/ICH-training
February 2005 - Resident in dermatology and allergy
December 2004 - Medical Graduation

Experience in Controlled Clinical Trials:
Sub-Investigator in different controlled clinical trials phases II-III since 2005, e.g. specific immuntherapy with different allergens by allergy to aeroallergens and atopic dermatitis, allergic asthma as well as clinical trials with autoimmune diseases.
Regular ICH/GCP-training

Sabine Dölle studied nutrition science and is specialised in allergology. Her clinical and experimental focuses are atopic dermatitis and food allergy. She is study coordinator and study assistant in the clinical trial "Miltefosine by AD".

Curricula vitae Sabine Dölle

Date of Birth: **20th October 1980**

Present Position: Scientific assistant; Department of Dermatology and Allergology, Charité – Universitätsmedizin Berlin, Germany

Medical Graduation and/or Other Professional Training:
Since 2007 - Study coordinator in IITs
Spring 2006 - Special course for study nurses at clinical Investigation center; KKS-Charité
January 2006 - Basic principles for clinical trials; KKS-Charité including GCP/ICH-training

Experience in controlled clinical trials:
Study nurse in different controlled clinical trials phases II-III since 2006, e.g. specific immuntherapy with different allergens (house dust mite and birch allergen) by atopic dermatitis; Study coordinator in IITs since 2007; Regular ICH/GCP-training

16.1.5 Signatures List of investigators and other important participants in the clinical trial including curricula vitae

PRINCIPAL INVESTIGATOR SIGNATURE

TITLE: **Explorative analysis of topical miltefosine application in adult patients with atopic dermatitis**

STUDY AUTHORS: Prof. Dr. med. M. Worm (principle investigator)
Sabine Dölle (study coordinator)

I have read this clinical trial report and confirm that to the best of my knowledge it accurately describes the conduct and results of the clinical trail.

INVESTIGATOR:_____ SIGNATURE_____

AFFILIATION:_____ _____

DATE:_____

16.1.6 Sample of labels for the trial medication

Labelling of the fixed secondary package:

Miltefosin bei AD **Code-Nr.: 001-A**
Zur klinischen Prüfung bestimmt
Miltex® 10 ml Lösung, Wirkstoff: Miltefosin 60 mg/ml oder
Hydrogalen® 30 ml Lösung, Wirkstoff: Hydrocortison 10 mg/g
Ch.-B.:230807 Verwendbar bis: 05/2009
Zum Auftragen auf die Haut
Dosierung und weitere Hinweise zur Anwendung und Entsorgung:
siehe Anleitung im Tagebuch
Nicht über +25 °C lagern EudraCT-Nr.: 2007-003471-39
Prüfpräparat unzugänglich für Kinder aufbewahren
Prof. Dr. med. Margitta Worm, Charité-Universitätsmedizin Berlin,
Charitéplatz 1, D-10117 Berlin, Tel. +49 30 450 518 105

Labelling of the KIT:

Miltefosin bei AD **KIT 001**
Zur klinischen Prüfung bestimmt
Miltex® 10 ml Lösung, Wirkstoff: Miltefosin 60 mg/ml oder
Hydrogalen® 30 ml Lösung, Wirkstoff: Hydrocortison 10 mg/g
Ch.-B.:230807 Verwendbar bis: 05/2009
Zum Auftragen auf die Haut
Dosierung und weitere Hinweise zur Anwendung und Entsorgung:
siehe Anleitung im Tagebuch
Nicht über +25 °C lagern EudraCT-Nr.: 2007-003471-39
Prüfpräparat unzugänglich für Kinder aufbewahren
Prof. Dr. med. Margitta Worm, Charité-Universitätsmedizin Berlin,
Charitéplatz 1, D-10117 Berlin, Tel. +49 30 450 518 105

16.1.7 Randomization scheme and codes (patient identification and treatment assigned)

Patient number	Assignment (Location A/B)	_	Subject number	Comment
01	A=hydrocortisone / B=miltefosine			Used as sample to show the application procedure.
02	A=hydrocortisone / B=miltefosine		S01	
03	A=miltefosine / B=hydrocortisone		S03	
04	A=miltefosine / B=hydrocortisone		S04	
05	A=hydrocortisone / B=miltefosine		S07	
06	A=hydrocortisone / B=miltefosine		S06	

07	A=miltefosine / B=hydrocortisone		S05	
08	A=miltefosine / B=hydrocortisone		S10	
09	A=hydrocortisone / B=miletfosine		S09	
10	A=miltefosine / B=hydrocortisone		S12	
11	A=hydrocortisone / B=miletfosine		S11	
12	A=miltefosine / B=hydrocortisone		S14	
13	A=miltefosine / B=hydrocortisone		S15	
14	A=hydrocortisone / B=miletfosine		S13	
15	A=miltefosine / B=hydrocortisone		S16	
16	A=hydrocortisone / B=miletfosine		S17	
17	A=hydrocortisone / B=miletfosine		S18	
18	A=miltefosine / B=hydrocortisone			Not used.
19	A=miltefosine / B=hydrocortisone			Not used.
20	A=hydrocortisone / B=miletfosine			Not used.

16.1.8 Publications based on the study

Congress-Abstract:

Clinical Efficacy of Miltefosine in Atopic Dermatitis
– a parallel controlled trial –
Sabine Dölle, Dana Hoser, Claudia Rasche, Hae-Hyuk Lee und Margitta Worm
Charité-Universitätsmedizin Berlin, Department of Dermatology and Allergology, Germany

Atopic dermatitis (AD) is a chronic inflammatory skin disease affecting approximately 2 % of the adult population. The anti-inflammatory topical treatment of AD is currently primarily performed with corticosteroids and calcineurininhibitors. However, both treatments have disadvantages like the induction of skin atrophy, limited efficacy or burning of the skin. Therefore, novel anti-inflammatory treatments are needed.
In this study we examined the impact of miltefosine a lipid raft molecule on the local inflammatory immune response in AD patients in comparison to hydrocortisone (1 %).
16 patients were recruited, in each patient 2 skin lesions with a TIS (Three Item Severity) score of 6 [5 to 7] were treated for 3 weeks. Clinical and histological parameters were analysed before and after the treatment.
The TIS score dropped in both groups significantly after treatment and remained stable at the follow up visit 4 weeks later. Analysis of skin sections revealed a significant decrease of epidermal thickness in the hydrocortisone (234.2 ±90.4 μm to 128.6 ±55.5 μm but not the miltefosine group (223.6 ±90.6 μm179.2 ±32.6 μm, NS). No local side effects were

observed.
The data indicates that miltefosine is a topically inflammatory substance not causing atrophy of the epidermis after a 3 week treatment phase. Further clinical studies are needed to explore the therapeutical role of miltefosine in AD.

Publication:
- Manuscript in preparation

16.2 Patients listing

16.2.1 Discontinued patients

Table 16.2.1: Listing of patients who gave informed consent but could not be randomised.

S.-No.	P.-No.	Age (years)	Sex	Observation excluded	Reason(s)
S02	No randomisation	28	m	Screening	Screening failure
S08	No randomisation	35	m	Visit 1	Screening failure

S.-No. = Screening number, P.-No. = Patient number, m = male

16.2.2 Intend-to-treat population

Table 16.2.2 Listing of observations excluded from the primary effect analysis (TIS score)

S.-No.	P.-No.	Age (years)	Sex	Observation excluded	Reason(s)
S01	002	38	f	Follow Up 2	FU2 was not performed.
S03	003	41	m	Visit 1	Visit 1 was not performed because screening included visit 1.
				Follow Up 2	FU2 was not performed.
S04	006	42	f	Visit 1	Visit 1 was not performed because screening included visit 1.
S07	005	28	f	Visit 1	Visit 1 was not performed because screening included visit 1.
				Follow Up 2	FU2 was not performed.
S09	009	58	f	Screening, Follow Up 1	TIS score was not assessable.
S10	008	28	m	Visit 1	Visit 1 was not performed because screening included visit 1.
S12	010	25	m	Visit 1	Visit 1 was not performed because screening included visit 1.
S13	014	25	f	Screening	TIS score was not assessable.
S14	012	38	m	Visit 1	Visit 1 was not performed because screening included visit 1.
S15	013	23	m	Visit 1	Visit 1 was not performed because screening included visit 1.
S16	015	24	m	Visit 1	Visit 1 was not performed because screening included visit 1.
S17	016	28	m	Visit 1	Visit 1 was not performed because screening included visit 1.
				Follow Up 2	FU2 was not performed.
S18	017	18	m	Visit 1	Visit 1 was not performed because screening included visit 1.

S.-No. = Screening number, P.-No. = Patient number, m = male, f = female, FU = Follow Up

Table 16.2.3 Listing of patients and observations excluded from the exploratory effect analysis

Skin physiology

S.-No.	P.-No.	Age (years)	Sex	Observation and measurement excluded	Reason(s)
S06	006	45	f	Visit 2,3 Corneometry	Sensor was defect.
S05	007	39	m	Visit 1,2 Corneometry	Sensor was defect.
S09	009	58	f	Visit 1, Corneometry	Sensor was defect.
S10	008	28	m	Visit 1, Corneometry Visit 4, pH-metry	Sensor was defect. pH-meter was broken.
S11	011	28	m	Visit 3,4 pH-metry	pH-meter was broken.
S12	010	25	m	Visit 4, pH-metry	pH-meter was broken.
S13	014	25	f	Visit 1,2,3 pH-metry	pH-meter was broken.
S14	012	38	m	Visit 1, Sebumetry Visit 1,2 pH-metry	Sebum cassette did not function. pH-meter was broken.
S15	013	23	m	Visit 1,2,3 pH-metry	pH-meter was broken.
S16	015	24	m	Visit 1,2,3 pH-metry	pH-meter was broken.
S17	016	28	m	Visit 1,2,3 pH-metry	pH-meter was broken.
S18	017	18	m	Visit 1,2,3, pH-metry	pH-meter was broken.

S.-No. = Screening number, P.-No. = Patient number, m = male, f = female, M = male, F = female

Thermography

S.-No.	P.-No.	Age (years)	Sex	Observation excluded	Reason(s)
S01	002	38	f	Visit 2 and 4	Not done, because of organisational reasons
S04	004	42	f	Visit 1 (M), 2, 3 and 4 Visit 1 (H)	Values could not used for statistical analysis, because of unclear outlines and not distinguishable lesion. Thermographic picture could not analysed.
S06	006	45	f	Visit 3 (M) Visit 4	Thermographic picture could not analysed. Not done, because of organisational reasons
S09	009	58	f	Visit 2	Not done, because of organisational reasons
S11	011	28	m	Visit 3	Not done, because of organisational reasons
S12	010	25	m	Visit 2, 3	Not done, because of organisational reasons
S13	014	25	f	Visit 2 (H)	Thermographic picture could not analysed.

S.-No. = Screening number, P.-No. = Patient number, m = male, f = female,
M = Miltefosine, H = Hydrocortisone

16.2.3 Per-Protocol population

Table 16.2.4 Listing of patients excluded from the immunhistological analysis

S.-No.	P.-No.	Age (years)	Sex	Observation excluded	Reason(s)
S07	005	28	f	Visit 1 and 4	Refused biopsies at visit 4.
S14	012	38	m	Visit 1 and 4	Completely refused biopsies.
S16	015	24	m	Visit 1 and 4	Completely refused biopsies.
S17	016	28	m	Visit 1 and 4	Completely refused biopsies.

S.-No. = Screening number, P.-No. = Patient number, m = male, f = female

16.2.4 Protocol deviations

Table 16.2.5: Protocol deviations of the patients

S.-No.	P.-No.	Protocol Deviation		
		1	2	3
S01	002	The termination visit was performed on FU1 instead of V4.	The FU2 was not performed because of private organisational reasons.	
S03	003	The termination visit was performed on FU1 instead of V4.	The FU2 was not performed because of private organisational reasons.	
S04	004	The termination visit was performed on FU2 instead of V4.		
S07	005	The termination visit was performed on FU1 instead of V4.	The FU2 was not performed because of private organisational reasons.	2nd biopsies (V4) were not taken.
S06	006	The termination visit was performed on FU2 instead of V4.		
S05	007	The termination visit was performed on FU2 instead of V4.		
S10	008	The termination visit was performed on FU2 instead of V4.		
S09	009	The termination visit was performed on FU2 instead of V4.		
S12	010	The termination visit was performed on FU2 instead of V4.		
S11	011	The termination visit was performed on FU2 instead of V4.		
S14	012	The termination visit was performed on FU2 instead of V4.		Biopsies were not taken.
S15	013	The termination visit was performed on FU2 instead of V4.		
S13	014	The termination visit was performed on FU2 instead of V4.		
S16	015	The termination visit was performed on FU2 instead of V4.		Biopsies were not taken.
S17	016	The termination visit was performed on FU1 instead of V4.	The FU2 was not performed because of private organisational reasons.	Biopsies were not taken.
S18	017	The termination visit was performed on FU2 instead of V4.		

S.-No. = Screening number, P.-No. = Patient number, V = visit, FU = Follow Up

16.2.5 Individual primary effect criteria

Table 16.2.6 Individual patient data listings of TIS score

S.-No.	P.-No.	Visit	TIS score							
			Hydrocortisone				Miltefosine			
			Ery	E/P	Ex	TIS total	Ery	E/P	Ex	TIS total
S01	002	screening	2	2	2	6	2	2	2	6
		1	2	2	2	6	2	2	2	6
		2	1	2	1	4	1	2	1	4
		3	1	1	1	3	1	2	1	4
		4	1	1	1	3	2	1	2	5
		FU1	0	0	0	0	0	1	0	1
		FU2	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
S03	003	screening	3	2	1	5	2	1	2	5
		1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
		2	1	1	1	3	1	1	1	3
		3	1	1	1	3	2	1	1	4
		4	0	0	0	0	1	2	1	4
		FU1	1	0	0	1	1	0	0	1
		FU2	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
S04	004	screening	2	1	2	5	2	1	2	5
		1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
		2	1	1	1	3	1	1	1	3
		3	1	1	1	3	2	1	1	4
		4	1	1	0	2	2	1	0	3
		FU1	1	1	0	2	1	1	0	2
		FU2	2	2	0	4	1	1	0	2
S07	005	screening	2	2	2	6	2	2	2	6
		1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
		2	1	1	1	3	1	1	1	3
		3	1	1	1	3	1	1	1	3
		4	0	0	0	0	0	0	0	0
		FU1	1	0	0	1	0	0	0	0
		FU2	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
S06	006	screening	2	2	2	6	2	2	2	6
		1	2	3	2	7	2	3	2	7
		2	2	1	0	3	2	2	1	5
		3	2	1	0	3	2	2	1	5
		4	2	1	0	3	2	2	1	5
		FU1	2	1	0	3	2	1	0	3
		FU2	2	3	1	6	2	3	1	6
S05	007	screening	2	2	2	6	2	2	2	6
		1	2	2	2	6	2	2	2	6
		2	1	1	0	2	2	2	1	5
		3	1	1	1	3	2	2	1	5
		4	0	1	0	1	1	1	0	2
		FU1	1	1	1	3	0	1	0	1
		FU2	1	1	1	3	2	2	1	5
S10	008	screening	2	2	1	5	2	2	1	5
		1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

		2	1	1	1	3	2	2	1	5
		3	0	1	0	1	1	1	1	3
		4	1	1	1	3	0	0	0	0
		FU1	0	0	0	0	1	0	0	1
		FU2	1	1	0	2	1	0	0	1
S09	009	screening	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
		1	2	2	1	5	2	2	1	5
		2	1	1	1	3	2	2	2	6
		3	1	1	1	3	2	2	2	6
		4	0	1	0	1	2	1	1	4
		FU1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
		FU2	2	1	0	3	2	1	0	3
S12	010	screening	2	2	2	6	2	2	2	6
		1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
		2	2	1	1	4	2	2	1	5
		3	1	1	0	2	2	1	1	4
		4	1	0	0	1	1	1	1	3
		FU1	2	1	2	5	1	0	0	1
		FU2	1	0	0	1	1	1	0	2
S11	011	screening	2	2	1	5	2	2	1	5
		1	1	2	2	5	1	2	2	5
		2	1	1	1	3	2	1	1	4
		3	0	0	0	0	1	1	1	3
		4	0	0	0	0	1	1	1	3
		FU1	1	1	0	2	1	1	0	2
		FU2	1	0	0	1	1	1	0	2
S14	012	screening	2	2	1	5	2	2	1	5
		1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
		2	2	1	0	3	1	1	1	3
		3	1	2	0	3	2	1	0	3
		4	1	1	1	3	2	1	1	4
		FU1	2	1	2	5	2	1	0	3
		FU2	2	1	2	5	2	1	1	4
S15	013	screening	2	2	2	6	2	2	2	6
		1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
		2	2	2	2	6	2	2	2	6
		3	1	2	2	5	1	2	1	4
		4	1	2	1	4	1	2	1	4
		FU1	1	1	0	2	1	1	0	2
		FU2	1	1	1	3	1	1	1	3
S13	014	screening	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
		1	2	2	1	5	2	2	1	5
		2	1	1	1	3	1	1	1	3
		3	1	2	0	3	1	2	0	3
		4	0	0	0	0	1	2	1	4
		FU1	1	0	0	1	1	1	0	2
		FU2	0	1	1	2	1	1	1	3
S16	015	screening	3	2	2	7	3	2	2	7
		1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
		2	1	2	1	4	1	1	1	3
		3	1	2	1	4	1	1	0	2

		4	1	1	1	3	1	0	1	2
		FU1	1	2	0	3	1	1	0	2
		FU2	1	0	1	2	1	0	1	2
S17	016	screening	2	2	2	6	2	2	2	6
		1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
		2	1	0	0	1	1	1	0	2
		3	0	0	0	0	1	1	0	2
		4	0	0	0	0	1	1	0	2
		FU1	1	1	0	2	1	1	0	2
		FU2	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
S18	017	screening	2	2	2	6	2	2	2	6
		1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
		2	2	1	2	5	2	2	2	6
		3	2	1	0	3	2	2	1	5
		4	1	1	0	2	2	2	1	5
		FU1	2	2	2	6	2	2	1	5
		FU2	1	1	1	3	1	1	1	3

S.-No. = Screening number, P.-No. = Patient number, FU = Follow up, Ery = Erytheme, E/P = Oedema/papulation, Ex = Excoriation, n.a. = not applicable, n.d. = not done

16.2.6 Individual exploratory effect criteria

16.2.6.1 Listing of objective SCORAD by patients

Table 16.2.7 Individual patient data listings of objective SCORAD

S.-No.	P.-No.	Objective SCORAD							
		Screening	Visit 1	Visit 2	Visit 3	Visit 4	Follow-up 1	Follow-up 2	ΔSCORAD
S01	002	40.6	41.1	29.8	26.0	26.0	26.3	n.d.	15.1
S03	003	32.1	n.a.	24.9	24.9	18.7	22.0	n.d.	13.4
S04	004	44.6	n.a.	27.8	31.3	31.1	34.9	28.0	13.5
S07	005	39.7	n.a.	32.3	29.0	32.9	25.0	n.d.	6.8
S06	006	39.9	43.6	44.1	43.6	38.0	38.2	60.9	5.6
S05	007	47.6	44.1	46.1	40.4	35.9	34.9	34.4	8.2
S10	008	30.3	n.a.	37.7	22.4	23.3	23.3	23.1	7.0
S09	009	30.0	33.9	50.2	33.5	32.9	29.6	37.5	1.0
S12	010	25.3	n.a.	25.1	25.2	25.4	21.6	18.0	-0.1
S11	011	36.0	33.4	29.0	25.8	21.8	23.0	23.2	11.6
S14	012	37.0	n.a.	38.6	51.0	49.0	51.0	56.9	-12.0
S15	013	50.6	n.a.	50.6	43.5	43.5	48.5	45.0	7.1
S13	014	36.5	36.7	28.9	20.2	26.3	27.0	21.9	10.4
S16	015	59.8	n.a.	29.0	26.9	19.9	25.6	22.2.	39.9
S17	016	48.1	n.a.	40.4	26.2	26.8	22.6	n.d.	21.3
S18	017	40.5	n.a.	32.7	19.9	18.6	36.2	25.7	21.9

S.-No. = Screening number, P.-No. = Patient number, FU = Follow up, n.a. = not applicable, n.d. = not done

16.2.6.2 Listing of immunhistological parameters by patient

Table 16.2.8 Epidermal thickness

S.-No.	P.-No.	observation	Epidermal thickness	
			Hydrocortisone	Miltefosine
S01	002	visit 1	148.16	122.69
		visit 4	99.92	168.45
S03	003	visit 1	133.37	311.73
		visit 4	133.68	137.92
S04	004	visit 1	320.06	296.15
		visit 4	122.04	214.79
S06	006	visit 1	197.04	151.46
		visit 4	103.72	209.45
S05	007	visit 1	214.26	223.60
		visit 4	63.36	134.71
S18	017	visit 1	362.29	356.74
		visit 4	191.83	177.58
S09	009	visit 1	179.12	128.37
		visit 4	86.43	153.49
S12	010	visit 1	155.91	133.21
		visit 4	119.59	138.11
S11	011	visit 1	359.07	257.16
		visit 4	108.12	191.15
S15	013	visit 1	150.25	151.34
		visit 4	258.83	205.08
S13	014	visit 1	234.00	187.88
		visit 4	78.21	228.14
S18	017	visit 1	356.74	362.29
		visit 4	177.58	191.83

S.-No. = Screening number, P.-No. = Patient number

Table 16.2.9 $CD4^+$ T-cells

S.-No.	P.-No.	observation	Counted $CD4^+$ T-cells	
			Hydrocortisone	Miltefosine
S01	002	visit 1	64	70
		visit 4	98	71
S03	003	visit 1	133	157
		visit 4	121	82
S04	004	visit 1	192	282
		visit 4	110	254
S06	006	visit 1	188	140
		visit 4	77	190
S05	007	visit 1	46	137
		visit 4	48	112
S10	008	visit 1	130	108
		visit 4	51	64
S09	009	visit 1	133	59
		visit 4	67	119
S12	010	visit 1	55	115

		visit 4	163	62
S11	011	visit 1	179	110
		visit 4	66	131
S15	013	visit 1	119	97
		visit 4	113	104
S13	014	visit 1	228	176
		visit 4	94	95
S18	017	visit 1	96	225
		visit 4	58	98

S.-No. = Screening number, P.-No. = Patient number

Table 16.2.10 CD8* T-cells

S.-No.	P.-No.	observation	Counted $CD8^+$ T-cells	
			Hydrocortisone	Miltefosine
S01	002	visit 1	3	5
		visit 4	4	2
S03	003	visit 1	8	14
		visit 4	11	5
S04	004	visit 1	50	411
		visit 4	23	22
S06	006	visit 1	16	16
		visit 4	13	23
S05	007	visit 1	6	6
		visit 4	7	21
S10	008	visit 1	7	n.a.
		visit 4	8	n.a.
S09	009	visit 1	6	2
		visit 4	1	3
S12	010	visit 1	4	6
		visit 4	22	8
S11	011	visit 1	5	7
		visit 4	3	9
S15	013	visit 1	9	4
		visit 4	9	4
S13	014	visit 1	17	10
		visit 4	1	7
S18	017	visit 1	1	10
		visit 4	12	2

S.-No. = Screening number, P.-No. = Patient number, n.a. = not analysable

Table 16.2.11 Mast cells

S.-No.	P.-No.	observation	Counted mast cells	
			Hydrocortisone	Miltefosine
S01	002	visit 1	3	5
		visit 4	7	3
S03	003	visit 1	3	5
		visit 4	7	2
S04	004	visit 1	9	31

		visit 4	16	5
S06	006	visit 1	4	8
		visit 4	5	2
S05	007	visit 1	4	8
		visit 4	10	7
S10	008	visit 1	5	3
		visit 4	1	2
S09	009	visit 1	3	1
		visit 4	2	1
S12	010	visit 1	2	0
		visit 4	2	3
S11	011	visit 1	2	4
		visit 4	5	9
S15	013	visit 1	9	7
		visit 4	2	4
S13	014	visit 1	3	1
		visit 4	0	3
S18	017	visit 1	1	2
		visit 4	7	5

S.-No. = Screening number, P.-No. = Patient number

16.2.6.3 Listing of skin physiological parameters by patient

Table 16.2.12 Individual patient data listings of skin physiological parameters

S.-No.	P.-No.	visit	Skin physiological parameters							
			Hydrocortisone				Miltefosine			
			TEWL	SEBUM	CORNEUM	pH	TEWL	SEBUM	CORNEUM	pH
S01	002	1	49.60	0	27.23	5.35	26.40	1.00	24.63	5.42
		2	17.70	35.10	51.74	5.15	51.40	214.00	16.26	5.71
		3	70.70	0	20.62	5.32	45.50	0	24.82	5.27
		4	27.50	0	20.59	6.14	22.80	3.00	26.55	5.67
S03	003	1(=screening)	22.40	18.00	6.6	5.24	36.60	19.32	3.00	5.13
		2	14.40	150.00	20.13	5.11	30.20	130.00	16.47	4.69
		3	26.30	1.00	49.04	4.51	24.50	4.00	8.42	4.62
		4	11.10	173.00	n.d.	4.68	21.80	258.00	n.d.	5.28
S04	004	1(=screening)	59.60	109.00	37.5	5.96	52.80	280.00	21.28	5.87
		2	59.70	256.00	20.70	5.69	62.30	232.00	16.16	5.73
		3	55.20	0	13.62	5.89	60.80	0	9.76	5.80
		4	33.40	253.00	n.d.	5.63	41.80	109.00	n.d.	5.67
S07	005	1(=screening)	40.40	0	14.88	5.44	21.60	0	7.58	5.57
		1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
		2	13.80	0	19.62	6.01	14.70	9.00	7.82	5.84
		3	26.40	1.00	25.22	5.66	27.60	1.00	12.88	5.37
		4	9.50	182.00	n.d.	5.74	16.80	270.00	n.d.	6.08
S06	006	1	57.00	0	8.84	5.66	41.20	0	17.06	5.60
		2	28.80	216.00	n.d.	5.70	78.90	77.00	n.d.	6.27
		3	29.30	58.00	n.d.	5.67	36.20	85.00	n.d.	5.69
		4	12.10	66.00	28.30	5.18	31.70	40.00	9.62	5.21
S05	007	1	45.10	171.00	n.d.	4.58	45.60	237.00	n.d.	4.51

		2	15.70	237.00	n.d.	4.65	53.70	47.00	n.d.	5.22
		3	22.10	299.00	23.76	4.53	33.00	305.00	4.66	4.96
		4	15.80	19.00	47.40	4.71	24.50	267.00	12.30	4.97
S10	008	1(=screening)	36.60	199.00	n.d.	6.02	34.20	149.00	n.d.	5.91
		2	18.60	268.00	25.31	5.92	20.40	263.00	15.14	5.83
		3	14.10	279.00	25.80	5.59	21.80	273.00	16.32	5.34
		4	9.70	346.00	36.28	n.d.	27.20	299.00	16.10	n.d.
S09	009	1	27.40	19.50	n.d.	5.07	30.10	329.00	n.d.	5.00
		2	17.90	246.00	34.28	5.36	23.50	286.00	10.94	5.29
		3	15.90	306.00	41.78	5.00	22.20	336.00	10.26	5.23
		4	12.20	98.00	52.5	4.55	21.10	421.00	12.60	5.42
S12	010	1(=screening)	40.90	293.00	23.28	6.25	61.70	298.00	63.82	6.86
		2	29.20	308.00	16.20	5.64	43.60	152.00	14.04	5.51
		3	24.10	348.00	17.82	5.27	50.60	34.10	22.78	5.74
		4	42.80	85.00	29.70	n.d.	28.90	19.00	19.32	n.d.
S11	011	1	16.60	263.00	8.16	4.94	12.10	265.00	7.00	5.07
		2	15.30	298.00	5.48	5.36	13.20	294.00	9.42	5.37
		3	13.70	265.00	31.26	n.d.	19.80	268.00	11.96	n.d.
		4	10.20	282.00	24.52	n.d.	18.40	282.00	8.56	n.d.
S14	012	1(=screening)	28.70	n.d.	10.3	n.d.	47.20	n.d.	15.60	n.d.
		2	34.60	284.00	15.86	n.d.	52.30	287.00	14.22	n.d.
		3	19.10	277.00	7.88	n.d.	34.50	281.00	20.84	n.d.
		4	16.50	47.00	14.56	5.92	65.60	33.80	9.38	6.08
S15	013	1(=screening)	28.00	4.00	12.62	n.d.	24.80	69.00	5.90	n.d.
		2	29.80	275.00	7.76	n.d.	30.30	272.00	3.60	n.d.
		3	31.60	329.00	9.58	n.d.	24.40	169.00	5.70	n.d.
		4	37.00	182.00	8.74	5.40	26.00	239.00	8.32	5.48
S13	014	1	28.70	n.d.	10.03	n.d.	47.20	n.d.	15.60	n.d.
		2	31.90	263.00	30.26	n.d.	22.20	381.00	9.34	n.d.
		3	32.20	330.00	14.14	n.d.	46.10	343.00	4.30	n.d.
		4	29.30	329.00	46.30	4.97	39.10	329.00	7.48	5.57
S16	015	1(=screening)	54.80	313.00	15	n.d.	33.30	299.00	19.06	n.d.
		2	37.70	307.00	35.26	n.d.	22.20	297.00	22.34	n.d.
		3	15.20	258.00	21.32	n.d.	13.80	240.00	22.46	n.d.
		4	22.40	320.00	19.98	5.37	13.70	325.00	14.38	5.62
S17	016	1(=screening)	34.10	83.00	17.48	n.d.	43.70	268.00	14.64	n.d.
		2	30.70	456.00	27.98	n.d.	49.00	433.00	15.10	n.d.
		3	51.90	316.00	33.42	n.d.	53.90	289.00	8.68	n.d.
		4	19.40	32.00	14.06	5.31	41.80	305.00	10.18	5.29
S18	017	1(=screening)	65.00	284.00	4.98	n.d.	60.10	261.00	4.92	n.d.
		2	76.50	170.00	19.52	n.d.	64.60	254.00	6.18	n.d.
		3	44.80	272.00	19.02	n.d.	74.10	232.00	10.76	n.d.
		4	14.30	88.00	39.44	6.22	64.30	17.00	9.08	6.60

S.-No. = Screening number, P.-No. = Patient number, n.d. = not done

16.2.6.4 Listing of thermographic parameters by patient

Table 16.2.13 Individual patient data listings of maximum temperature

S.-No.	P.-No.	visit	Maximum Temperature of the lesion (°C)	
			Hydrocortisone	Miltefosine
S01	002	1	37.9	35.3
		2	n.d.	n.d.
		3	34.2	34.5
		4	n.d.	n.d.
S03	003	1	31.1	31.4
		2	33.9	36.1
		3	33.4	33.1
		4	33.5	33.5
S04	004	1	n.a.	35.7 n.u.
		2	35.5 n.u.	35.0 n.u.
		3	35.2 n.u.	35.3 n.u.
		4	35.7 n.u.	35.4 n.u.
S07	005	1	35.7	35.2
		2	35.6	35.7
		3	35.6	35.3
		4	35.1	32.8
S06	006	1	32.4	32.3
		2	31.3	32.7
		3	31.9	n.a.
		4	n.d.	n.d.
S05	007	1	36.4	36.0
		2	35.7	35.3
		3	36.0	36.2
		4	34.7	35.7
S10	008	1	33.3	33.8
		2	34.9	35.3
		3	34.9	34.3
		4	35.5	34.9
S09	009	1	41.9	39.3
		2	n.d.	n.d.
		3	35.7	35.1
		4	34.0	35.4
S12	010	1	35.0	34.8
		2	n.d.	n.d.
		3	n.d.	n.d.
		4	31.9	32.1
S11	011	1	34.7	33.9
		2	34.5	33.2
		3	n.d.	n.d.
		4	34.7	34.5
S14	012	1	33.9	37.1
		2	34.9	36.6
		3	33.3	35.7
		4	33.9	35.2
S15	013	1	36.6	35.5

		2	36.2	36.5
		3	36.2	35.5
		4	35.3	34.8
S13	014	1	36.4	35.8
		2	n.a.	34.3
		3	35.6	35.2
		4	34.2	34.2
S16	015	1	34.8	35.8
		2	33.0	32.9
		3	33.4	33.0
		4	34.0	33.1
S17	016	1	34.6	36.5
		2	34.2	35.8
		3	34.1	35.2
		4	33.5	34.8
S18	017	1	36.7	36.7
		2	36.3	37.1
		3	35.9	37.2
		4	35.1	35.2

n.a. = not analysable, n.d. = not done, n.u. = not usable

16.3 Individual patient data listings

Table 16.3.1: Individual patient date listing of general adverse events

S.-no.	P.-no.	AE-no.	Diagnosis	start date	end date	severity	intensity	drug relation	treatment	Other treatment	outcome
S04	004	1	bruise and swelling of the eye (right)	25.09.2007	04.10.2007	no	moderate	non	unchanged	Diclofenac	recovered
		2	knee swelling	02.10.2007	04.10.2007	no	moderate	non	unchanged	Diclofenac	recovered
		3	Headache	07.10.2007	07.10.2007	no	mild	possible	unchanged	ASS	recovered
		4	Blepharitis	10.10.2007	14.10.2007	no	moderate	non	unchanged	Gentamycin	recovered
		5	Cold	19.10.2007	26.10.2007	no	mild	non	unchanged	Paracetamol	recovered
		6	Headache	26.09.2007	26.09.2007	no	mild	possible	unchanged	Aerius	recovered
		7	Headache	30.09.2007	30.09.2007	no	mild	possible	unchanged	Aerius	recovered
S07	005	1	exacerbation of AD	08.10.2007	19.10.2007	no	moderate	possible	unchanged	No	stabilised
		2	jammed nerve in the back	31.10.2007	ongoing	no	severe	non	unchanged	analgetic, Tramal	ongoing
S06	006	1	exacerbation of AD	26.09.2007	15.10.2007	no	moderate	non	unchanged	Ecural	stabilised
		2	sore throat	02.11.2007	03.11.2007	no	mild	non	unchanged	Tonsigrel	recovered
		3	Headache	17.10.2007	17.10.2007	no	mild	possible	unchanged	No	recovered
		4	Headache	19.10.2007	19.10.2007	no	mild	possible	unchanged	No	recovered
S05	007	1	exacerbation of AD	20.10.2007	31.10.2007	no	moderate	possible	unchanged	Bethamethason 0,1%, Tricloron 1,0%, DAL Basiscreme ad 100	stabilised
S09	009	1	inflammation of biopsy left arm	28.10.2007	09.11.2007	no	moderate	non	unchanged	Linola Sep	recovered
		2	Pruritus	25.10.2007	25.10.2007	no	mild	non	unchanged	Lorano	recovered
		3	Pruritus	30.10.2007	30.10.2007	no	mild	possible	unchanged	Lorano	recovered
		4	Pruritus	02.11.2007	02.11.2007	no	moderate	possible	unchanged	Lorano	recovered
		5	Pruritus	13.11.2007	13.11.2007	no	moderate	possible	unchanged	Lorano	recovered
		6	Pruritus	15.11.2007	15.11.2007	no	moderate	possible	unchanged	Lorano	recovered
S12	010	1	exacerbation of AD	16.11.2007	06.12.2007	no	moderate	possible	unchanged	Dermatop	stabilised
S11	011	1	abdominal influenza	29.12.2007	02.01.2008	no	mild	non	unchanged	No	recovered
S14	012	1	mycosis	22.11.2007	06.12.2007	no	moderate	non	unchanged	Sempera 7 100 mg	ongoing
		2	mycosis	23.12.2007	29.12.2007	no	moderate	non	unchanged	Sempera 7 100 mg	ongoing
		3	sore throat	24.12.2007	10.01.2008	no	mild	non	unchanged	No	recovered
		4	common cold	24.12.2007	02.01.2008	no	moderate	non	unchanged	ASS 500	recovered

		5	pruritus	14.12.2007	18.12.2008	no	moderate	possible	unchanged	Ebartel	stabilised
S13	014	1	common cold	01.12.2007	08.12.2007	no	moderate	non	unchanged	Paracetamol 500 Olynth 0,1%	recovered
		2	headache	06.12.2007	07.12.2007	no	mild	possible	unchanged	ASS 500	recovered
S16	015	1	headache	29.11.2007	29.11.2007	no	mild	possible	unchanged	ASS	recovered
		2	headache	16.12.2007	16.12.2007	no	mild	non	unchanged	ASS	recovered
S17	016	1	common cold	02.10.2007	08.12.2007	no	mild	non	unchanged	No	recovered

S.-No. = Screening number, P.-No. = Patient number, AE-No. = general AE number

Table 16.3.2: Individual patient date listing of local skin-related adverse events

S.-no.	P.-no.	AE-no.	Diagnosis	start date	end date	severity	intensity	drug relation	treatment	Other treatment	outcome
S01	002	1	burning at H-treated lesions	16.09.2007	16.09.2007	no	mild	certain	unchanged	no	recovered
		2	burning at both lesions	17.09.2007	17.09.2007	no	mild	certain	unchanged	no	recovered
		3	burning at both lesions	20.09.2007	20.09.2007	no	mild	certain	unchanged	no	recovered
		4	burning at both lesions	23.09.2007	23.09.2007	no	mild	certain	unchanged	no	recovered
S03	003	1	tingling at both lesions	05.10.2007	05.10.2007	no	mild	certain	unchanged	no	recovered
		2	tingling at both lesions	09.10.2007	09.10.2007	no	mild	certain	unchanged	no	recovered
		3	burning at M-treated lesion	17.10.2007	17.10.2007	no	mild	certain	unchanged	no	recovered
S06	006	1	pruritus at M-treated lesion	18.10.2007	18.10.2007	no	mild	certain	unchanged	no	recovered
		2	pruritus at M-treated lesion	20.10.2007	20.10.2007	no	mild	certain	unchanged	no	recovered
		3	pruritus at M-treated lesion	25.10.2007	25.10.2007	no	mild	certain	unchanged	no	recovered
S05	007	1	tingling at both lesions	18.10.2007	22.10.2007	no	mild	certain	unchanged	no	recovered
		2	tingling at M-treated lesions	24.10.2007	30.10.2007	no	mild	certain	unchanged	no	recovered
		3	dry skin at M-treated lesions	24.10.2007	30.10.2007	no	mild	certain	unchanged	no	recovered
S09	009	1	dry skin at M-treated lesions	24.10.2007	09.11.2007	no	moderate	certain	unchanged	no	recovered
		2	dry skin at H-treated lesions	24.10.2007	24.10.2007	no	moderate	certain	unchanged	no	recovered
S11	011	1	tingling at both lesions	07.11.2007	07.11.2007	no	mild	certain	unchanged	no	recovered
		2	tingling at both lesions	07.11.2007	07.11.2007	no	mild	certain	unchanged	no	recovered
S15	013	1	pruritus at both lesion	25.11.2007	25.11.2007	no	mild	certain	unchanged	no	recovered
		2	pruritus at both lesion	28.11.2007	29.11.2007	no	mild	certain	unchanged	no	recovered

		3	pruritus at both lesion	01.12.2007	03.12.2007	no	mild	certain	unchanged	no	recovered
		4	pruritus at both lesion	06.12.2007	06.12.2007	no	mild	certain	unchanged	no	recovered
S17	016	1	Tingling at M-treated lesion	29.11.2007	01.10.2007	no	mild	certain	unchanged	no	recovered
S04	004	1	burning at M-treated lesions	29.09.2007	30.09.2007	no	mild	certain	unchanged	no	recovered
		2	burning at M-treated lesions	04.10.2007	10.10.2007	no	mild	certain	unchanged	no	recovered
		3	burning at M-treated lesions	13.10.2007	13.10.2007	no	mild	certain	unchanged	no	recovered
		4	burning at M-treated lesions	16.10.2007	16.10.2007	no	mild	certain	unchanged	no	recovered
S18	017	1	pruritus at both lesion	01.11.2007	04.11.2007	no	mild	certain	unchanged	no	recovered
		2	burning at H-treated lesion	08.12.2007	08.12.2007	no	mild	certain	unchanged	no	recovered
		3	dry skin at M-treated lesion	13.12.2007	14.12.2007	no	mild	certain	unchanged	no	recovered
		4	pruritus at both lesion	15.12.2007	15.12.2007	no	mild	certain	unchanged	no	recovered
		5	pruritus at both lesion	17.12.2007	17.12.2007	no	mild	certain	unchanged	no	recovered

S.-No. = Screening number, P.-No. = Patient number, AE-No. = skin related AE number

Table 16.3.3: Individual patient date listing of laboratory values

Screening

S.-no.	P.-no.	sodium (mmol/l)	potassium (mmol/l)	calcium (mmol/l)	creatinine (mg/ dl)	ALT (U/l)	AP (U/l)	GGT (U/l)	Leucocytes (/nl)	erythrocytes (/pl)	haemoglobin (g/dl)	haematocrit (l/l)	MCH (pg)	MCHC (g/dl)	MCV (fl)	RDW (%)	thrombocytes (/nl)	MPV (fl)	neutrophiles (/nl)	lymphocytes (/nl)	monocytes (/nl)	eosinophiles (/nl)	basophiles (/nl)
S01	002	138	3.7	2.28	0.74	10	64	14	8.83	4.46	13.0	0.38	29.1	34.0	86	13.9	254	10	5.60	2.43	0.50	0.28	0.02
S03	003	141	4.0	2.22	0.93	23	64	32	3.84	4.92	14.9	0.44	30.3	34.3	88	13.2	265	11	1.90	1.47	0.26	0.20	0.01
S04	004	141	3.9	2.48	1.00	39	50	35	6.52	4.92	14.8	0.44	30.1	33.9	89	13.4	355	10	3.63	1.54	0.59	0.73	0.03
S07	005	138	4.2	2.30	0.71	13	47	19	7.59	4.64	13.2	0.39	28.4	33.8	84	15.4	376	9	3.90	2.89	0.45	0.33	0.02
S06	006	141	4.1	2.17	0.68	17	53	14	6.69	4.43	13.0	0.38	29.3	33.8	87	12.2	212	12	3.21	1.89	0.66	0.89	0.04
S05	007	142	4.0	2.32	0.83	23	52	15	7.86	4.70	14.5	0.43	30.9	33.8	91	12.6	302	11	5.21	1.08	0.66	0.87	0.04
S10	008	139	3.9	2.37	0.93	11	72	22	7.65	4.63	14.2	0.42	30.7	34.0	90	14.6	228	11	5.07	1.62	0.60	0.28	0.08
S09	009	139	4.2	2.24	1.05	33	60	55	6.36	4.09	14.3	0.41	35.0	35.1	100	12.7	194	10	3.55	1.60	0.76	0.42	0.03
S12	010	139	3.2	2.28	0.84	16	50	13	8.31	5.00	14.5	0.42	29.0	34.6	84	12.9	231	9	4.79	2.54	0.51	0.46	0.01
S11	011	140	3.7	n.d.	0.75	18	61	16	5.67	5.48	15.6	0.46	28.5	34.0	84	13.8	270	10	3.29	1.42	0.26	0.68	0.02
S14	012	139	3.8	2.44	0.96	30	83	35	5.82	4.91	14.7	0.43	29.9	34.2	88	13.7	275	11	3.14	1.37	0.46	0.81	0.04
S15	013	136	4.2	2.35	0.86	9	79	12	6.14	4.77	14.2	0.42	29.8	34.2	87	12.5	284	10	3.98	1.16	0.38	0.57	0.05
S13	014	136	4.0	2.44	0.87	20	50	11	5.76	4.50	13.4	0.39	29.8	34.5	86	12.8	280	10	3.31	1.79	0.43	0.21	0.02
S16	015	n.d.	3.8	n.d.	n.d.	25	72	12	8.05	5.28	15.2	0.44	28.8	34.3	84	12.5	221	11	Performed microscopically				
S17	016	141	3.9	2.31	0.93	56	76	42	8.11	5.28	16.2	0.48	30.7	33.8	91	13.4	314	10	4.84	1.75	0.77	0.72	0.03
S18	017	143	4.8	2.33	1.08	16	101	11	5.44	5.50	15.8	0.47	28.7	33.3	86	12.8	215	11	3.32	1.56	0.40	0.14	0.02

S.-No. = Screening number, P.-No. = Patient number, ALT - Alanine Aminotransferase, AP - Alkaline Phophatase, GGT - Gamma Glutamyltransferase,
MCH - Mean Corpuscular Haemoglobin, MCHC - Mean Cellular Haemoglobin Concentration, MCV - Mean Cellular Volume, RDW - Red Cell Distribution Width, MPV - Mean Platelet Volume;
Values out of range are marked;
Values performed microscopically were as followed: eosinophiles = 4%, stick neutrophiles = 1%, segmented neutrophiles = 58%, lymphocytes = 33%, monocytes = 3%

Visit 4

S.-no.	P.-no.	sodium (mmol/l)	potassium (mmol/l)	calcium (mmol/l)	creatinine (mg/ dl)	ALT (U/l)	AP (U/l)	GGT (U/l)	Leucocytes (/nl)	erythrocytes (/pl)	haemoglobin (g/dl)	haematocrit (l/l)	MCH (pg)	MCHC (g/dl)	MCV (fl)	RDW (%)	thrombocytes (/nl)	MPV (fl)	neutrophiles (/nl)	lymphocytes (/nl)	monocytes (/nl)	eosinophiles (/nl)	basophiles (/nl)
S01	002	139	3.8	2.31	0.72	12	58	12	7.96	4.51	13.1	0.38	29.0	34.0	85	14.0	275	11	5.05	2.22	0.44	0.23	0.02
S03	003	140	4.1	2.23	0.93	26	65	28	5.22	4.94	15.1	0.44	30.6	34.3	89	13.2	272	11	3.03	1.63	0.32	0.23	0.01
S04	004	138	4.1	2.35	0.78	25	48	28	6.37	4.92	14.8	0.44	30.1	33.9	89	13.0	347	10	4.29	1.21	0.53	0.33	0.01
S07	005	141	4.1	2.38	0.77	17	51	19	9.52	4.35	12.6	0.38	29.0	33.2	87	15.0	389	10	5.34	3.35	0.51	0.30	0.02
S06	006	141	3.9	2.14	0.65	18	57	12	6.68	4.51	13.1	0.39	29.0	33.4	87	12.2	181	12	4.02	1.46	0.53	0.63	0.04
S05	007	139	4.2	2.34	0.90	24	50	12	9.22	4.80	14.7	0.44	30.6	33.3	92	12.4	308	11	6.33	1.04	0.90	0.90	0.05
S10	008	142	4.1	2.37	0.86	12	60	20	12.25	4.50	13.7	0.41	30.4	33.4	91	14.4	218	11	9.60	1.66	0.71	0.23	0.05
S09	009	141	4.2	2.17	0.88	59	50	42	5.32	3.91	13.7	0.39	35.0	34.8	101	12.6	169	11	2.29	1.69	0.72	0.59	0.03
S12	010	138	4.0	2.21	0.75	n.d.	n.d.	n.d.	6.43	4.86	14.2	0.41	29.2	34.7	84	13.0	241	9	3.50	2.06	0.49	0.36	0.02
S11	011	141	3.5	2.33	0.83	32	61	13	4.32	5.41	15.5	0.45	28.7	34.3	84	13.7	268	10	2.55	1.12	0.30	0.33	0.02
S14	012	138	4.3	2.33	0.91	26	83	33	6.60	4.80	14.4	0.43	30.0	33.8	89	13.6	272	11	4.03	1.18	0.56	0.78	0.02
S15	013	140	4.2	2.34	0.93	11	73	15	7.77	4.75	14.1	0.42	29.7	33.5	89	12.5	305	10	4.82	1.56	0.54	0.78	0.07
S13	014	136	3.6	2.50	0.85	20	48	13	5.92	4.51	13.3	0.39	29.5	34.4	86	12.6	301	10	3.13	2.00	0.44	0.31	0.04
S16	015	136	4.1	2.35	0.80	17	59	12	8.75	5.58	15.8	0.47	28.3	33.6	84	12.5	222	11	5.40	2.55	0.66	0.13	0.01
S17	016	138	4.0	2.32	0.87	38	78	37	6.86	5.21	16.1	0.48	30.9	33.9	91	13.3	327	10	4.33	1.42	0.62	0.46	0.03
S18	017	137	4.2	2.43	0.98	12	111	12	6.82	5.70	16.5	0.49	28.9	33.4	87	12.4	207	11	4.50	1.64	0.51	0.14	0.03

S.-No. = Screening number, P.-No. = Patient number, ALT - Alanine Aminotransferase, AP - Alkaline Phophatase, GGT - Gamma Glutamyltransferase,
MCH - Mean Corpuscular Haemoglobin, MCHC - Mean Cellular Haemoglobin Concentration, MCV - Mean Cellular Volume, RDW - Red Cell Distribution Width, MPV - Mean Platelet Volume;
Values out of range are marked;

Table 16.3.4: Individual patient date listing of vital signs

S.-No.	P.-No.	Observation	Pulse	Blood Pressure	
			Beat	Systolic	Diastolic
S01	002	Screening	80	130	70
		Visit 1	80	115	80
		Visit 2	72	120	80
		Visit 3	76	110	80
		Visit 4	72	120	80
		Follow Up 1	72	110	80
		Follow Up 2	n.d.	n.d.	n.d.
S03	003	Screening	52	110	80
		Visit 1	n.a.	n.a.	n.a.
		Visit 2	64	120	80
		Visit 3	64	120	70
		Visit 4	48	115	80
		Follow Up 1	72	120	80
		Follow Up 2	n.d.	n.d.	n.d.
S04	004	Screening	80	120	70
		Visit 1	n.a.	n.a.	n.a.
		Visit 2	72	130	70
		Visit 3	76	120	80
		Visit 4	80	140	100
		Follow Up 1	80	140	100
		Follow Up 2	80	130	80
S05	007	Screening	n.d.	n.d.	n.d.
		Visit 1	76	145	100
		Visit 2	60	140	90
		Visit 3	64	160	110
		Visit 4	72	150	100
		Follow Up 1	86	160	110
		Follow Up 2	76	160	110
S06	006	Screening	76	130	90
		Visit 1	72	130	100
		Visit 2	80	130	95
		Visit 3	72	125	85
		Visit 4	80	125	80
		Follow Up 1	68	130	80
		Follow Up 2	72	145	80
S07	005	Screening	96	110	70
		Visit 1	n.a.	n.a.	n.a.
		Visit 2	92	110	80
		Visit 3	92	120	80
		Visit 4	80	115	80
		Follow Up 1	96	100	60
		Follow Up 2	n.d.	n.d.	n.d.
S09	009	Screening	80	115	80
		Visit 1	n.d.	n.d.	n.d.
		Visit 2	80	110	90
		Visit 3	60	140	90
		Visit 4	60	110	80

		Follow Up 1	80	130	90
		Follow Up 2	68	130	90
S10	008	Screening	68	125	90
		Visit 1	n.a.	n.a.	n.a.
		Visit 2	76	110	70
		Visit 3	80	100	70
		Visit 4	68	110	80
		Follow Up 1	64	110	70
		Follow Up 2	68	110	80
S11	011	Screening	60	110	70
		Visit 1	68	120	80
		Visit 2	n.d.	n.d.	n.d.
		Visit 3	n.d.	n.d.	n.d.
		Visit 4	72	110	70
		Follow Up 1	52	100	70
		Follow Up 2	68	110	70
S12	010	Screening	72	120	70
		Visit 1	n.a.	n.a.	n.a.
		Visit 2	60	105	75
		Visit 3	n.d.	n.d.	n.d.
		Visit 4	64	120	85
		Follow Up 1	76	155	80
		Follow Up 2	80	110	70
S13	014	Screening	84	120	80
		Visit 1	72	120	80
		Visit 2	80	110	80
		Visit 3	88	100	70
		Visit 4	56	110	80
		Follow Up 1	68	110	80
		Follow Up 2	80	110	80
S14	012	Screening	80	120	80
		Visit 1	n.a.	n.a.	n.a.
		Visit 2	80	120	90
		Visit 3	76	100	80
		Visit 4	76	110	70
		Follow Up 1	76	120	80
		Follow Up 2	80	130	80
S15	013	Screening	64	120	80
		Visit 1	n.a.	n.a.	n.a.
		Visit 2	80	110	70
		Visit 3	88	120	70
		Visit 4	56	120	80
		Follow Up 1	80	110	60
		Follow Up 2	80	130	70
S16	015	Screening	76	130	90
		Visit 1	n.a.	n.a.	n.a.
		Visit 2	68	120	80
		Visit 3	68	120	80
		Visit 4	80	120	80
		Follow Up 1	88	140	90
		Follow Up 2	80	130	90

S17	016	Screening	n.d.	n.d.	n.d.
		Visit 1	n.a.	n.a.	n.a.
		Visit 2	84	130	100
		Visit 3	84	150	100
		Visit 4	84	130	90
		Follow Up 1	80	130	80
		Follow Up 2	n.d.	n.d.	n.d.
S18	017	Screening	84	130	90
		Visit 1	n.a.	n.a.	n.a.
		Visit 2	84	140	100
		Visit 3	80	130	80
		Visit 4	68	130	90
		Follow Up 1	84	140	90
		Follow Up 2	84	150	90

S.-No. = Screening number, P.-No. = Patient number,
n.d. = not done, n.a. = not applicable

Table 16.3.5: Individual patient date listing of physical examination;

A standard physical examination were done at every visit included the following inspections: hair and skin; lymph nodes; eyes; nose, ears and throat; chest; respiratory; heart; abdomen; urogenital; pelvis; rectal, musculoskeletal, neurological; assessed as normal (n), abnormal (a) or were not done (n.d.).

The inspection of the urogenital and rectal tract was never done. The inspection of the hair and skin was abnormal for all patients at all visits because of the investigated disease, atopic dermatitis. Therefore, the abnormality of skin are not listed in the following table.

S.-No.	P.-No.	Observation	Complete Physical Examination	Comments, Abnormalities
S01	002	S, V1, V2, V3, V4 and FU1 FU2	Yes n.d.	FU2 was not performed.
S03	003	S, V2, V3, V4 and FU1 V1 FU2	Yes n.a. n.d.	Screening included visit 1. FU2 was not performed.
S04	004	S, V2, V3, V4, FU1 and FU2 V1	Yes n.a.	Screening included visit 1.
S05	007	S, V1, V2, V3, V4, FU1 and FU2	Yes	
S06	006	S, V1, V2, V3, V4, FU1 and FU2	Yes	
S07	005	S, V2, V3, V4 and FU1 V1 FU2	Yes n.d. n.d.	Screening included visit 1. FU2 was not performed.
S09	009	S, V1, V2, V3, V4, FU1 and FU2	Yes, heart abnormal	Heart abnormal, because of underlying disease (hypertension).
S10	008	S, V2, V3, V4, FU1 and FU2 V1	Yes n.a.	Screening included visit 1.

S11	011	S, V1, V2, V3, V4, FU1 and FU2	Yes	
S12	010	S, V2, V3, V4, FU1 and FU2 V1	Yes n.a.	 Screening included visit 1.
S13	014	S, V2, V3, V4, FU1 and FU2 V1	Yes n.a.	 Screening included visit 1.
S14	012	S, V2, V3, V4, FU1 and FU2 V1	Yes n.a.	 Screening included visit 1.
S15	013	S, V2, V3, V4, FU1 and FU2 V1	Yes n.a.	 Screening included visit 1.
S16	015	S, V2, V3, V4, FU1 and FU2 V1	Y n.a.	 Screening included visit 1.
S17	016	S, V2, V3, V4 and FU1 V1 FU2	Yes, musculo-skeletal abnormal n.a. n.d.	Musculoskeletal abnormal, because of prolaps. Screening included visit 1. FU2 was not performed.
S18	017	S, V2, V3, V4, FU1 and FU2 V1	Yes n.a.	 Screening included visit 1.

S.-No. = Screening number, P.-No. = Patient number, V = Visit, FU = Follow Up,
n.d. = not done, n.a. = not applicable

Table 16.3.6: Individual patient date listing concomitant medication

S.-No.	P.-No.	M.-No.	Medication	Indication	Route	Daily dosis	Start date	End date	Ongoing?
S04	004	01	Diclofenac	bruise and swelling right eye	i.m.	OD	28.09.2007	29.09.2007	n
		02	Diclofenac	bruise and swelling right eye	i.m.	OD	01.10.2007	01.10.2007	n
		03	Aerius	pruritus	PO	PRN	NK.NK.2002		y
		04	Aerius	pruritus	PO	5 mg	26.09.2007	26.09.2007	n
		05	Aerius	pruritus	PO	5 mg	30.09.2007	30.09.2007	n
		06	Dermatop	atopic dermatitis	TO	PRN	NK.NK.2000		y
		07	Urea 5%	atopic dermatitis	TO	PRN	NK.NK.2000		y
		08	Aspirin	headache (AE3)	PO	OD, 100 mg	07.10.2007	07.10.2007	n
		09	Gentamycin 0,3%	Blepuritis	TO	n.a.	10.10.2007	14.10.2007	n
		10	Diclofenac	knee swelling	i.m.	OD	02.10.2007	04.10.2007	n
S07	005	01	Cefixdura	common cold	PO	400 mg	24.09.2007	03.10.2007	n
		02	NK	contraception	PO	NK	NK.NK.1994		y
		03	Betaglen	atopic dermatitis	TO	PRN	NK.NK.2005	12.09.2007	n
		04	Advantan	atopic dermatitis	TO	PRN	NK.NK.2005	12.09.2007	n
		05	Promethazin	pruritus	PO	PRN	NK.NK.2006	10.09.2007	n
		06	analgestic active agent NK	jammed nerve (AE2)	NK	NK	01.11.2007	02.11.2007	n
		07	Tramal 200	jammed nerve (AE2)	PO	200 mg	01.11.2007		y
		08	analgestic active agent NK	jammed nerve (AE2)	NK	NK	04.11.2007	04.11.2007	n
		09	Betaglen	atopic dermatitis	TO	PRN	26.09.2007		y
		10	Advantan	atopic dermatitis	TO	PRN	26.09.2007		y
S06	006	01	Oxis 6mg	asthma	i.h.	TD, 12 mg	NK.NK.1990		y
		02	Pulmicort	asthma	i.h.	TD, 1 mg	NK.NK.1990		y
		03	Cetirizin	allergic rhinitis, pruritus	PO	PRN	NK.NK.1978	10.10.07	n
		04	Ecural	atopic dermatitis	TO	PRN	NK.NK.2001		y
		05	Tonsiprect	sore throat	PO	n.a.	07.11.2007	07.11.2007	n
S05	007	01	Advantan	atopic dermatitis	TO	PRN	NK.NK.2006	25.10.2007	n
		02	Elidel	atopic dermatitis	TO	PRN	NK.NK:2006	25.10.2007	n
		03	Urea 5%	atopic dermatitis	TO	PRN	NK.NK :2006		y
		04	Sultanol	asthma	i.h.	PRN	NK.NK.2001		y

		05	Dermoxin	atopic dermatitis	TO	TD, n.a.	26.10.2007		y
		06	Bethamethason 0,1%, Tricloron 1,0%, DAL Basiscreme ad 100	atopic dermatitis	TO	TD, n.a.	26.10.2007		y
S10	008	01	Elidel	atopic dermatitis	TO	PRN	NK.NK.2006	17.09.2007	n
		02	Dermatop	atopic dermatitis	TO	PRN	NK.NK.2006	17.09.2007	n
		03	Elidel	atopic dermatitis	TO	PRN	25.10.2007		y
		04	Dermatop	atopic dermatitis	TO	PRN	25.10.2007		
S09	009	01	Atacand 16 mg	hypertension	PO	8 mg	NK.07.2003		y
		02	Allopurinol - ratiopharm 300	hyperuricemia	PO	150 mg	NK.NK.1997		y
		03	Gynohadin	hormone replacement	PO	OD, 2 mg	NK.08.2006		y
		04	Reslex		PO	OD	NK.NK.2003		y
		05	Symbicort Turbohaler 160mg/4,5 dosis	asthma	i.h.	OD, 160 µg	NK.NK.2003		y
		06	Singulair 10 mg	asthma	i.h.	10 mg	NK.10.2006	04.11.2007	n
		07	Lorano acut	pruritus	PO	PRN	NK.07.2007	20.10.2007	n
		08	Tavegil	allergic rhinitis, pruritus	PO	PRN	Nk.NK.2007		y
		09	Eucerin ph 5	atopic dermatitis	TO	OD	NK.NK.1987		y
		10	Bepanthen	atopic dermatitis	TO	OD	NK.NK.2002		y
		11	Advantan Milch 0,1%	atopic dermatitis	TO	PRN	NK.07.2007	10.10.2007	n
		12	Betamethasonvalerat 0,15 in Eucerin cum aqua	atopic dermatitis	TO	PRN	NK.NK.1997		n
		13	Lorano	pruritus	PO	10 mg	25.10.2007	25.10.2007	n
		14	Lorano	pruritus	PO	10 mg	30.10.2007	30.10.2007	n
		15	Lorano	pruritus	PO	10 mg	02.11.2007	02.11.2007	n
		16	Linola Sep	inflammation of biopsy (AE1)	TO	OD, n.a.	28.10.2007	08.11.2007	n
		17	Lorano	pruritus	PO	10 mg	13.11.2007	13.11.2007	n
		18	Lorano	pruritus	PO	10 mg	15.11.2007	15.11.2007	n
		19	Voltaren (Tbl.)	pain in joints	PO	PRN	NK		y
		21	Sic-ophtal	dry eyes	OPH	PRN	NK		y
S12	010	01	Ibuprofen	shoulder pain	PO	PRN	19.10.2007	02.11.2007	n
		02	Dermatop	atopic dermatitis	TO	PRN	23.11.2007		y
S11	011	01	Viasi	asthma	i.h.	TD, n.a.	10.10.2007		y

		02	Advantan	atopic dermatitis	TO	PRN	NK.09.2007		y
		03	Dermatop	atopic dermatitis	TO	PRN	NK.NK.2003		y
S14	012	01	Dermoxin	atopic dermatitis	TO	PRN	NK.NK.2002		y
		02	Advantan	atopic dermatitis	TO	PRN	NK.NK.2000		y
		03	Elidel	atopic dermatitis	TO	PRN	NK.NK.2003		y
		04	Sempera 7	myeosis (AE1)	PO	200 mg	30.11.2007	06.12.2007	n
		05	AeroBec 100	asthma	i.h.	100 mg	19.12.2007		y
		06	Berodual	asthma	i.h.	PRN	19.12.2007		y
		07	Sempera 7	myeosis (AE1)	PO	200 mg	23.12.2007	29.12.2007	n
		08	Ebastel	pruritus	PO	20 mg	16.12.2007	16.12.2007	n
S15	013	01	Dermatop	atopic dermatitis	TO	PRN	NK.NK.2005		y
S13	014	01	Protopic	atopic dermatitis	TO	n.a.	NK.10.2007		y
		02	Prednisolon Augensalbe	atopic dermatitis	OP	n.a.	NK.10.2007		y
		03	Paracetamol 500	common cold (AE1)	PO	PRN	01.12.2007	06.12.2007	n
		04	Olynth 0,1%	common cold (AE1)	i.h.	PRN	03.12.2007	08.12.2007	n
		05	Aspirin plus C	common cold (AE1)	PO	PRN	05.12.2007	07.12.2007	n
		06	ASS	headache (AE2)	PO	500 mg	06.12.2007	07.12.2007	n
S16	015	01	Advantan	atopic dermatitis	TO	PRN	NK.NK.2000	17.11.2007	n
		02	Ecural	atopic dermatitis	TO	PRN	28.11.2007		y
		03	Aspirin	headache (AE1)	PO	100 mg	29.11.2007	29.11.2007	n
		04	Aspirin	headache (AE2)	PO	100 mg	16.12.2007	16.12.2007	n
S17	016	01	Triamcindonacetonid 0,1 Leutrichtol 3,0 Ungr. Emulsif aquar Ungt. Alcohol. Lah. Aquar	atopic dermatitis	TO	PRN	NK.NK.2004		y
		Comment: The patient used cortisone since 2004. He stopped application 14 days before screening. After definition of lesion A and B the patient continued cortisone treatment on other skin areas. He kept an appropriate distance of one finger length around each lesions.							
S18	017	01	Advantan	atopic dermatitis	TO	PRN	NK.07.2007		y
		02	Elidel	atopic dermatitis	TO	PRN	NK.07.2007	NK.08.2007	n
		03	Eucerin 10%	atopic dermatitis	TO	PRN	NK.11/2006		y
		04	Elidel	atopic dermatitis	TO	PRN	01.12.2007		y

S.-No. = Screening number, P.-No. = Patient number, i.m. = intramuscular, PO = per oral, TO = topic, NK = not known, i.h. = inhalative, OPH = ophtalemic, OD = one daily, PRN = as needed, n.a. = not applicable, TD = twice daily, y = yes, n = no

Table 16.3.7: Individual patient date listing demographic information and adherence to inclusion and exclusion criteria

S.-No.	P.-No.	Age (years)	Height (cm)	Weight (kg)	Sex	Ethnic group	Adherence to inclusion and exclusion criteria
S01	002	38	155	57	f	Caucasian	Yes
S03	003	41	186	110	m	Caucasian	Yes
S04	004	42	179	76	m	Caucasian	Yes
S07	005	28	162	62	f	Caucasian	Yes
S06	006	45	159	73	f	Caucasian	Yes
S05	007	39	169	65	m	Caucasian	Yes
S10	008	28	182	65	m	Caucasian	Yes
S09	009	58	167	74	f	Caucasian	Yes; The inclusion criteria no. 5 was confirmed at visit 1.
S12	010	25	188	78	m	Caucasian	Yes
S11	011	28	178	69	m	Caucasian	Yes
S14	012	38	160	57	m	Caucasian	Yes
S15	013	23	174	69	m	Asian	Yes
S13	014	25	168	60	f	Caucasian	Yes; The inclusion criteria no. 5 was confirmed at visit 1.
S16	015	24	176	77	m	Caucasian	Yes
S17	016	28	178	78	m	Caucasian	Yes
S18	017	18	193	94	m	Caucasian	Yes
S02	n.a.	28	171	73	m	Caucasian	No; The inclusion criteria no. 5 was not fulfilled and the exclusion criteria no. 9 was met.
S08	n.a.	35	182	102	m	Caucasian	No; The inclusion criterion no. 5 was not any more fulfilled at visit 1.

S.-No. = Screening number, P.-No. = Patient number, m = male, f = female, n.a. = not applicable