ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 01/26/2014

ClinicalTrials.gov ID: NCT00739882

Study Identification

Unique Protocol ID:	27808
Brief Title:	TRUST Study: Raptiva ® in Hand & Foot Psoriasis
Official Title:	A Phase IV Multicentre, Randomised, Double-blind, Placebo Controlled, Trial to Evaluate the Safety and Efficacy of Raptiva ® in the Treatment of Subjects With Moderate to Severe Plaque Psoriasis Involving Hands and/or Feet, With or Without Pustules.
Secondary IDs:	

Study Status

Record Verification:	January 2014
Overall Status:	Terminated
Study Start:	April 2008
Primary Completion:	June 2009 [Actual]
Study Completion:	June 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Merck KGaA
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No

Review Board:	Approval Status: Approved Approval Number: 2870 Board Name: Ethik-Kommission der Ärztekammer Hamburg Board Affiliation: Independent Phone: + 040/ 22 802 - 596 Email: post@aekhh.de
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Austria: Federal Office for Safety in Health Care Belgium: Federal Agency for Medicinal Products and Health Products France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Paul-Ehrlich-Institut Greece: National Organization of Medicines Italy: The Italian Medicines Agency Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Spain: Ethics Committee Turkey: Ministry of Health United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study Description

Brief Summary:	To evaluate the safety and efficacy of Raptiva ® compared with placebo to control chronic moderate to severe plaque psoriasis involving the hands and/or feet scoring Physician's Global Assessment (PGA - H&F) greater-than or equal to 3 in subjects not suitable for other systemic therapies including cyclosporine, methotrexate, and Psoralen-Ultraviolet Light A (PUVA).
Detailed Description:	

Conditions

Conditions:	Chronic Plaque Psoriasis
Keywords:	Efalizumab, Chronic plaque psoriasis moderate to severe involving hands feet

Study Design

Study Type:	Interventional

Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	76 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Efalizumab	Drug: Efalizumab - anti CD11a recombinant human monoclonal antibody Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week. The treatment period will be 24 weeks divided into two phases: 1) double-blind for 12 weeks, and 2) open-label for 12 additional weeks, in which all subjects from the placebo group and those subjects from the Raptiva ® group with ≥ 50% of improvement will be allocated to extended treatment with Raptiva ® for 12 additional weeks while non-responders to Raptiva ® (improvement ≤ 50%) will be followed in an observational manner for 12 additional weeks without treatment.
Placebo Comparator: Placebo	Drug: Placebo Placebo will be administered at Study Day (SD) 1, Week (W) 1, W 4, W 8 and W 12. Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week for 12 weeks (double-blind phase)

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

1. Subject with chronic (disease history of at least 6 months from diagnosis) moderate to severe plaque psoriasis involving the hands and/or feet (PGA - H&F ratings of 3 or 4) at screening, who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including cyclosporin, methotrexate and PUVA. Subjects will be outpatients.
2. Stable disease at study entry (i.e. no exacerbation of psoriasis during the screening period).
3. At least 18 years old.
4. For women of childbearing potential, use of an acceptable method of contraception to prevent pregnancy and agreement to continue to practice an acceptable method of contraception for the duration of their participation in the study. For men, during the participation, it is mandatory to practice birth control, as there are not existing data on the effect of Raptiva ® on spermatogenesis.
5. Discontinuation of any systemic psoriasis treatment at study entry. No washout period is required for these traditional systemic psoriasis agents prior to starting study treatment.
6. Discontinuation of all biological agents at least 3 months prior to first study injection.
7. Discontinuation of any investigational drug or treatment at least 3 months prior to SD 1 or as per washout requirements from previous protocol.
8. Willingness and ability to comply with the protocol requirements for the duration of the study.
9. Written informed consent, given prior to any study-related procedure not part of normal medical care, with the understanding that the subject may withdraw his/her consent at any time without prejudice to future medical care.

Exclusion Criteria:

1. Hypersensitivity to efalizumab or to any of the excipients
2. Current use of any prohibited therapy (systemic or topical treatments for psoriasis, immunosuppressive drugs, any other experimental drug, etc)
3. Previous or current exposure to Raptiva®
4. History of or ongoing alcohol or drug abuse
5. History of or an ongoing opportunistic infection (e.g. systemic fungal infection, parasites) or any other serious infection. This includes diagnoses that required more than 2 weeks of therapy, such as endocarditis and osteomyelitis, that have been treated in the past 6 months. In addition, if the subject is currently receiving antibiotics, antivirals, or antifungals for an infection or for suppression or prophylaxis for any diagnosis, the subject will be excluded.
6. Seropositivity for hepatitis B antigen, hepatitis C antibody, or human immunodeficiency virus (HIV). Subjects will undergo testing during screening, and any subjects who are seropositive for hepatitis B antigen, hepatitis C antibody, or HIV will be excluded.
7. History of active or latent tuberculosis within one year prior to screening (to be determined by assessment according to national and/or local recommendation).
8. Presence or history of malignancy, including lymphoproliferative disorders.
9. Pregnancy or breast-feeding
10. History of hepatic cirrhosis, regardless of cause or severity
11. History of thrombocytopenia, haemolytic anaemia, clinically significant anaemia, a white blood cell count <4,000 cells/µL or >14,000 cells/µL, a haematocrit (HCT) <30% or a haemoglobin (Hgb) level <11 g/dL, a platelet count <150,000 cells/µL
12. Hepatic enzyme levels ≥3 times the upper limit of normal or serum creatinine level ≥2 times the upper limit of normal

13. Vaccination with a live or live-attenuated virus or live or live-attenuated bacteria vaccine within the 14 days prior to the first dose of Raptiva®
14. Any medical condition that, in the judgment of the Investigator, would jeopardise the subject's safety following exposure to investigational medicinal product (Raptiva® or placebo equivalent) or would significantly interfere with the Subject's ability to comply with the provisions of this protocol.
15. Other specific forms of psoriasis like guttate, erythrodermic or pustular psoriasis as sole or predominant for of psoriasis.
16. Immunodeficiencies.

Contacts/Locations

Study Officials: Nicole Selenko-Gebauer, MD
Study Director
Merck Serono S.A. - Geneva, an affiliate of Merck KGaA, Darmstadt, Germany

Locations: Austria
University of Vienna Medical School
Vienna, Austria

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	First subject’s first visit: 08 April 2008, last subject’s last visit: 15 June 2009. Seventy six subjects entered the study, 46 completed the double-blind period and 31 of these then entered the open-label period. The remaining 15 entered an observational follow-up.
Pre-Assignment Details	During the screening period, approximately 200 subjects were to be screened for trial eligibility within 14 days before Day 1. A total of 100 subjects had been screened at the time the trial was terminated, of whom 76 subjects were enrolled in the trial.

Reporting Groups

	Description
Efalizumab	Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week. The treatment period will be 24 weeks divided into two phases: 1) double-blind for 12 weeks, and 2) open-label for 12 additional weeks, in which all subjects from the placebo group and those subjects from the Raptiva ® group with ≥ 50% of improvement will be allocated to extended treatment with Raptiva ® for 12 additional weeks while non-responders to Raptiva ® (improvement ≤ 50%) will be followed in an observational manner for 12 additional weeks without treatment.
Placebo	Placebo will be administered at Study Day (SD) 1, Week (W) 1, W 4, W 8 and W 12. Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week for 12 weeks (double-blind phase)

Double-blind Period

	Efalizumab	Placebo
Started	51	25
Completed	32	14
Not Completed	19	11
Adverse Event	1	2
Protocol Violation	1	0
Lack of Efficacy	1	1
Not specified	16	8

Open-label Period

	Efalizumab	Placebo
Started	17	14
Completed	7	9
Not Completed	10	5
Adverse Event	1	0
Other	9	5

Baseline Characteristics

Reporting Groups

	Description
Efalizumab	Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week. The treatment period will be 24 weeks divided into two phases: 1) double-blind for 12 weeks, and 2) open-label for 12 additional weeks, in which all subjects from the placebo group and those subjects from the Raptiva ® group with ≥ 50% of improvement will be allocated to extended treatment with Raptiva ® for 12 additional weeks while non-responders to Raptiva ® (improvement ≤ 50%) will be followed in an observational manner for 12 additional weeks without treatment.
Placebo	Placebo will be administered at Study Day (SD) 1, Week (W) 1, W 4, W 8 and W 12. Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week for 12 weeks (double-blind phase)

Baseline Measures

	Efalizumab	Placebo	Total
Number of Participants	51	25	76
Age, Customized [units: participants]			
18-40 years	16	4	20
41-64 years	29	17	46
>64 years	6	4	10
Age, Continuous [units: years] Mean (Standard Deviation)	49.0 (13.3)	51.7 (12.9)	49.9 (13.1)
Gender, Male/Female [units: participants]			
Female	21	10	31
Male	30	15	45
Region of Enrollment [units: participants]			
Austria	7	4	11
Belgium	4	0	4
France	8	5	13
Germany	14	4	18

	Efalizumab	Placebo	Total
Italy	2	2	4
Netherlands	0	2	2
Spain	7	4	11
Turkey	9	4	13

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Proportion Of Participants Achieving A Physician's Global Assessment - Hand & Foot (PGA - H&F) Rating Of Clear, Almost Clear Or Mild At Week 12
Measure Description	The proportion of subjects achieving a PGA – H&F rating of clear, almost clear, or mild at Week 12: Clear - No signs of plaque psoriasis on the hands and/or feet; Almost Clear - Just perceptible erythema and just perceptible scaling on the hands and/or feet; Mild - Light pink erythema with minimal scaling and with or without pustules on the hands and/or feet
Time Frame	12 weeks
Safety Issue?	No

Analysis Population Description

Due to the termination of the trial, analysis of efficacy-related endpoints was not performed

Reporting Groups

	Description
Efalizumab	Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week. The treatment period will be 24 weeks divided into two phases: 1) double-blind for 12 weeks, and 2) open-label for 12 additional weeks, in which all subjects from the placebo group and those subjects from the Raptiva ® group with ≥ 50% of improvement will be allocated to extended treatment with Raptiva ® for 12 additional weeks while non-responders to Raptiva ® (improvement ≤ 50%) will be followed in an observational manner for 12 additional weeks without treatment.
Placebo	Placebo will be administered at Study Day (SD) 1, Week (W) 1, W 4, W 8 and W 12. Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week for 12 weeks (double-blind phase)

Measured Values

	Efalizumab	Placebo
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

2. Secondary Outcome Measure:

Measure Title	Proportion Of Participants Achieving A Physician's Global Assessment - Hand & Foot (PGA - H&F) Rating Of Clear, Or Almost Clear At Week 12
Measure Description	The proportion of participants achieving a PGA – H&F rating of clear, or almost clear, at Week 12: Clear - No signs of plaque psoriasis on the hands and/or feet; Almost Clear - Just perceptible erythema and just perceptible scaling on the hands and/or feet
Time Frame	12 weeks
Safety Issue?	No

Analysis Population Description

Due to the termination of the trial, analysis of efficacy-related endpoints was not performed

Reporting Groups

	Description
Efalizumab	Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week. The treatment period will be 24 weeks divided into two phases: 1) double-blind for 12 weeks, and 2) open-label for 12 additional weeks, in which all subjects from the placebo group and those subjects from the Raptiva ® group with ≥ 50% of improvement will be allocated to extended treatment with Raptiva ® for 12 additional weeks while non-responders to Raptiva ® (improvement ≤ 50%) will be followed in an observational manner for 12 additional weeks without treatment.
Placebo	Placebo will be administered at Study Day (SD) 1, Week (W) 1, W 4, W 8 and W 12. Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week for 12 weeks (double-blind phase)

Measured Values

	Efalizumab	Placebo
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

3. Secondary Outcome Measure:

Measure Title	Proportion Of Participants Achieving A Physician's Global Assessment - Hand & Foot (PGA - H&F) Rating Of Clear, Almost Clear Or Mild At Week 24

Measure Description	The proportion of participants achieving a PGA - H&F rating of clear, almost clear, or mild at Week 24: Clear - No signs of plaque psoriasis on the hands and/or feet; Almost Clear - Just perceptible erythema and just perceptible scaling on the hands and/or feet; Mild - Light pink erythema with minimal scaling and with or without pustules on the hands and/or feet
Time Frame	24 weeks
Safety Issue?	No

Analysis Population Description

Due to the termination of the trial, analysis of efficacy-related endpoints was not performed

Reporting Groups

	Description
Efalizumab	Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week. The treatment period will be 24 weeks divided into two phases: 1) double-blind for 12 weeks, and 2) open-label for 12 additional weeks, in which all subjects from the placebo group and those subjects from the Raptiva ® group with ≥ 50% of improvement will be allocated to extended treatment with Raptiva ® for 12 additional weeks while non-responders to Raptiva ® (improvement ≤ 50%) will be followed in an observational manner for 12 additional weeks without treatment.
Placebo	Placebo will be administered at Study Day (SD) 1, Week (W) 1, W 4, W 8 and W 12. Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week for 12 weeks (double-blind phase)

Measured Values

	Efalizumab	Placebo
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

4. Secondary Outcome Measure:

Measure Title	Proportion of Participants From the Initial Placebo Group Achieving a PGA - H&F of Rating of Clear, Almost Clear, or Mild From Week 12 to Week 24.
Measure Description	The proportion of participants achieving a PGA – H&F rating of clear, or almost clear, at Week 24: Clear - No signs of plaque psoriasis on the hands and/or feet; Almost Clear - Just perceptible erythema and just perceptible scaling on the hands and/or feet; Mild - Light pink erythema with minimal scaling and with or without pustules on the hands and/or feet
Time Frame	24 weeks

Safety Issue?	No

Analysis Population Description

Due to the termination of the trial, analysis of efficacy-related endpoints was not performed

Reporting Groups

	Description
Efalizumab	Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week. The treatment period will be 24 weeks divided into two phases: 1) double-blind for 12 weeks, and 2) open-label for 12 additional weeks, in which all subjects from the placebo group and those subjects from the Raptiva ® group with ≥ 50% of improvement will be allocated to extended treatment with Raptiva ® for 12 additional weeks while non-responders to Raptiva ® (improvement ≤ 50%) will be followed in an observational manner for 12 additional weeks without treatment.
Placebo	Placebo will be administered at Study Day (SD) 1, Week (W) 1, W 4, W 8 and W 12. Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week for 12 weeks (double-blind phase)

Measured Values

	Efalizumab	Placebo
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

5. Secondary Outcome Measure:

Measure Title	Proportion Of Participants Achieving A Physician's Global Assessment (PGA) Rating of Good, Excellent, Or Cleared At Week 12
Measure Description	The proportion of participants achieving a PGA rating of good, excellent, or cleared at Week 12. Cleared = 100% improvement; Excellent = 75-99% improvement; Good = 50-74% improvement
Time Frame	12 weeks
Safety Issue?	No

Analysis Population Description

Due to the termination of the trial, analysis of efficacy-related endpoints was not performed

Reporting Groups

	Description
Efalizumab	Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week. The treatment period will be 24 weeks divided into two phases: 1) double-blind for 12 weeks, and 2) open-label for 12 additional weeks, in which all subjects from the placebo group and those subjects from the Raptiva ® group with ≥ 50% of improvement will be allocated to extended treatment with Raptiva ® for 12 additional weeks while non-responders to Raptiva ® (improvement ≤ 50%) will be followed in an observational manner for 12 additional weeks without treatment.
Placebo	Placebo will be administered at Study Day (SD) 1, Week (W) 1, W 4, W 8 and W 12. Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week for 12 weeks (double-blind phase)

Measured Values

	Efalizumab	Placebo
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

6. Secondary Outcome Measure:

Measure Title	Proportion Of Participants Achieving A Physician's Global Assessment (PGA) Rating of Excellent, Or Cleared At Week 12
Measure Description	The proportion of participants achieving a PGA rating of excellent, or cleared at Week 12. Cleared = 100% improvement; Excellent = 75-99% improvement
Time Frame	12 weeks
Safety Issue?	No

Analysis Population Description

Due to the termination of the trial, analysis of efficacy-related endpoints was not performed

Reporting Groups

	Description
Efalizumab	Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week. The treatment period will be 24 weeks divided into two phases: 1) double-blind for 12 weeks, and 2) open-label for 12 additional weeks, in which all subjects from the placebo group and those subjects from the Raptiva ® group with ≥ 50% of improvement will be allocated to extended treatment with Raptiva ® for 12 additional weeks while non-responders to Raptiva ® (improvement ≤ 50%) will be followed in an observational manner for 12 additional weeks without treatment.

	Description
Placebo	Placebo will be administered at Study Day (SD) 1, Week (W) 1, W 4, W 8 and W 12. Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1.0 mg/kg/week for 12 weeks (double-blind phase)

Measured Values

	Efalizumab	Placebo
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

Time Frame	Adverse events occurring during the 12-week double-blind period and the 12-week open-label period are reported
Additional Description	Treatment-emergent adverse events are reported. 'Other Adverse Events' table shows the number of participants experiencing any adverse event and the listing shows all adverse events occurring above the reporting threshold during the double-blind period and open-label period.

Reporting Groups

	Description
Efalizumab - Double-blind Period	
Placebo - Double-blind Period	
Efalizumab - Open-label Period	
Placebo - Open-label Period	

Serious Adverse Events

	Efalizumab - Double-blind Period	Placebo - Double-blind Period	Efalizumab - Open-label Period	Placebo - Open-label Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/51 (1.96%)	1/25 (4%)	0/17 (0%)	2/14 (14.29%)
Infections and infestations				
Meningitis aseptic [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	0/14 (0%)

	Efalizumab - Double-blind Period	Placebo - Double-blind Period	Efalizumab - Open-label Period	Placebo - Open-label Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Musculoskeletal and connective tissue disorders				
Back pain [A] †	0/51 (0%)	0/25 (0%)	0/17 (0%)	1/14 (7.14%)
Skin and subcutaneous tissue disorders				
Psoriasis [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Surgical and medical procedures				
Tendon operation [A] †	0/51 (0%)	0/25 (0%)	0/17 (0%)	1/14 (7.14%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Efalizumab - Double-blind Period	Placebo - Double-blind Period	Efalizumab - Open-label Period	Placebo - Open-label Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	35/51 (68.63%)	13/25 (52%)	8/17 (47.06%)	7/14 (50%)
Blood and lymphatic system disorders				
Iron deficiency anaemia [A] †	0/51 (0%)	0/25 (0%)	0/17 (0%)	1/14 (7.14%)
Leukocytosis [A] †	6/51 (11.76%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Lymphocytosis [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Ear and labyrinth disorders				
Vertigo [A] †	1/51 (1.96%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Eye disorders				
Conjunctival hyperaemia [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Conjunctivitis [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Eye pain [A] †	0/51 (0%)	0/25 (0%)	0/17 (0%)	1/14 (7.14%)

	Efalizumab - Double-blind Period	Placebo - Double-blind Period	Efalizumab - Open-label Period	Placebo - Open-label Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Eye swelling [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Eyelid oedema [A] †	0/51 (0%)	0/25 (0%)	1/17 (5.88%)	0/14 (0%)
Ocular hyperaemia [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Gastrointestinal disorders				
Abdominal pain [A] †	0/51 (0%)	2/25 (8%)	0/17 (0%)	0/14 (0%)
Cheilitis [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Colitis ulcerative [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Constipation [A] †	0/51 (0%)	0/25 (0%)	1/17 (5.88%)	0/14 (0%)
Diarrhoea [A] †	1/51 (1.96%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Dyspepsia [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Gastrointestinal disorder [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Nausea [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Oral mucosa erosion [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Stomatitis [A] †	0/51 (0%)	0/25 (0%)	1/17 (5.88%)	0/14 (0%)
General disorders				
Asthenia [A] †	2/51 (3.92%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Chest pain [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Chills [A] †	2/51 (3.92%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Fatigue [A] †	5/51 (9.8%)	0/25 (0%)	0/17 (0%)	2/14 (14.29%)
Influenza like illness [A] †	5/51 (9.8%)	1/25 (4%)	1/17 (5.88%)	1/14 (7.14%)
Non-cardiac chest pain [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Oedema peripheral [A] †	1/51 (1.96%)	2/25 (8%)	0/17 (0%)	0/14 (0%)

	Efalizumab - Double-blind Period	Placebo - Double-blind Period	Efalizumab - Open-label Period	Placebo - Open-label Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Pain [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Pyrexia [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Infections and infestations				
Acute tonsillitis [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Bronchitis [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Cellulitis [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Gastroenteritis [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	1/14 (7.14%)
Gastrointestinal infection [A] †	2/51 (3.92%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Impetigo [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Influenza [A] †	2/51 (3.92%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Meningitis aseptic [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Nasopharyngitis [A] †	2/51 (3.92%)	3/25 (12%)	0/17 (0%)	2/14 (14.29%)
Rhinitis [A] †	3/51 (5.88%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Tonsillitis [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Upper respiratory tract infection [A] †	2/51 (3.92%)	0/25 (0%)	1/17 (5.88%)	0/14 (0%)
Urinary tract infection [A] †	2/51 (3.92%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Injury, poisoning and procedural complications				
Joint sprain [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Investigations				
Alanine aminotransferase increased [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Aspartate aminotransferase increased [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Blood glucose increased [A] †	0/51 (0%)	0/25 (0%)	0/17 (0%)	1/14 (7.14%)

	Efalizumab - Double-blind Period	Placebo - Double-blind Period	Efalizumab - Open-label Period	Placebo - Open-label Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Gamma-glutamyltransferase increased [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Transaminases increased [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Metabolism and nutrition disorders				
Cachexia [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] †	2/51 (3.92%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Back pain [A] †	0/51 (0%)	0/25 (0%)	0/17 (0%)	1/14 (7.14%)
Bone pain [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Myalgia [A] †	1/51 (1.96%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Neck pain [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	1/14 (7.14%)
Nervous system disorders				
Carotid arteriosclerosis [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Headache [A] †	10/51 (19.61%)	1/25 (4%)	1/17 (5.88%)	2/14 (14.29%)
Paraesthesia [A] †	1/51 (1.96%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Sciatica [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Psychiatric disorders				
Anxiety [A] †	0/51 (0%)	2/25 (8%)	0/17 (0%)	0/14 (0%)
Depression [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Insomnia [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Renal and urinary disorders				
Dysuria [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Reproductive system and breast disorders				

	Efalizumab - Double-blind Period	Placebo - Double-blind Period	Efalizumab - Open-label Period	Placebo - Open-label Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Endometrial hyperplasia [A] †	0/51 (0%)	0/25 (0%)	0/17 (0%)	1/14 (7.14%)
Sinus congestion [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Vaginal haemorrhage [A] †	0/51 (0%)	0/25 (0%)	0/17 (0%)	1/14 (7.14%)
Respiratory, thoracic and mediastinal disorders				
Chronic obstructive pulmonary disease [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Cough [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Epistaxis [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Lung disorder [A] †	0/51 (0%)	0/25 (0%)	1/17 (5.88%)	0/14 (0%)
Pharyngolaryngeal pain [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Skin and subcutaneous tissue disorders				
Dermatitis [A] †	2/51 (3.92%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Dermatitis contact [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Dry skin [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Eczema [A] †	2/51 (3.92%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Erythema [A] †	0/51 (0%)	0/25 (0%)	1/17 (5.88%)	0/14 (0%)
Generalised erythema [A] †	0/51 (0%)	0/25 (0%)	1/17 (5.88%)	0/14 (0%)
Hyperhidrosis [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	0/14 (0%)
Pruritus [A] †	0/51 (0%)	3/25 (12%)	0/17 (0%)	0/14 (0%)
Psoriasis [A] †	2/51 (3.92%)	1/25 (4%)	1/17 (5.88%)	1/14 (7.14%)
Rash papular [A] †	2/51 (3.92%)	0/25 (0%)	0/17 (0%)	0/14 (0%)
Urticaria [A] †	0/51 (0%)	0/25 (0%)	1/17 (5.88%)	0/14 (0%)
Surgical and medical procedures				

	Efalizumab - Double-blind Period	Placebo - Double-blind Period	Efalizumab - Open-label Period	Placebo - Open-label Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Tendon operation [A] †	0/51 (0%)	1/25 (4%)	0/17 (0%)	1/14 (7.14%)
Vascular disorders				
Hypertension [A] †	1/51 (1.96%)	0/25 (0%)	0/17 (0%)	0/14 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.1)

Limitations and Caveats

Following the recommendation of the European Medicines Agency (EMEA) to suspend the marketing authorization of Raptiva® and the subsequent premature termination of this trial analysis of efficacy-related endpoints was not performed

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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