ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 01/20/2014

ClinicalTrials.gov ID: NCT00697593

Study Identification

Unique Protocol ID:	27809
Brief Title:	ChangE From Any Systemic psoriasiS therapY to Raptiva (EASY)
Official Title:	A Phase IV Open Label Study in Moderate to Severe Chronic Plaque Psoriasis Subjects Transitioning From Previous Systemic Antipsoriasis Therapies (Methotrexate, Cyclosporine, Retinoids or Psoralen-Ultraviolet Light A (PUVA), Narrow-Band Ultraviolet Light B (NBUVB) to Raptiva 1mg/kg/ Week Therapy.
Secondary IDs:	

Study Status

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

Sponsor/Collaborators

Sponsor:	Merck KGaA
Responsible Party:	
Collaborators:	

Oversight

FDA Regulated?:	No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 07-09-002 Board Name: Canadian SHIELD Ethics Review Board Board Affiliation: No Affiliation Phone: 905-681-8661 Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Canada: Health Canada

Study Description

Brief Summary:	To assess the safety of transitioning subjects to Raptiva therapy from standard oral systemic or phototherapy by overlapping with Raptiva whilst tapering the initial systemic therapy or phototherapy dose.
Detailed Description:	

Conditions

Conditions:	Chronic Plaque Psoriasis
Keywords:	Efalizumab Chronic Plaque Psoriasis Transition from systemic therapies on to Efalizumab

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label
Allocation:	N/A
Endpoint Classification:	Safety Study

Enrollment: 70 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Efalizumab	Drug: Efalizumab - anti CD11a recombinant human monoclonal antibody (mAb) Each subject will receive an initial conditioning dose of 0.7 mg/kg/week and then will continue treatment at a dose of 1mg/kg/week for up to 12 weeks.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

1. Are at least 18 years old.
2. Have plaque psoriasis with an sPGA score of at least moderate or severe at time of initiation of previous systemic treatment.
3. Are transitioning from methotrexate, cyclosporine, retinoids, PUVA or NBUVB and initiating treatment with Raptiva according to the decision of the investigator and in accordance with the indication and the recommendations of the Raptiva Investigator Brochure, i.e. to which they have failed to respond, have a contraindication to or are intolerant of other systemic therapies.
4. Agree to participate in the study, and to disclose any medical events to the investigator. The subject must be willing and able to comply with the protocol requirements for the duration of the study.
5. Have given written informed consent with the understanding that consent may be withdrawn at any time without prejudice to future medical care.
6. Women of childbearing potential must use appropriate contraception during treatment and up to the last study visit (safety follow-up visit). For men, it is also mandatory to practice contraception during participation in the trial, as there are no existing data on the effect of Raptiva on spermatogenesis.
7. Discontinuation of any investigational drug or treatment 3 months prior to study start or as per washout requirements from previous protocol.

No primary vaccinations (e.g., tetanus, booster, influenza vaccine) for at least 14 days prior to first dose of study drug.For the purposes of this trial, women of childbearing potential is defined as: "All female subjects after puberty unless they are post-menopausal for at least two years, are surgically sterile or are sexually inactive."

Exclusion Criteria:

1. Any contra-indication to Raptiva, according to the Investigator Brochure, or as follows:
    - Hypersensitivity to Raptiva or to any of the excipients.
    - Subjects with history of malignancies.
    - History of active tuberculosis (TB) or currently undergoing treatment for TB. Purified Protein Derivative (PPD) testing or chest X-ray is required for high-risk subjects. Subjects with a positive PPD (not due to BCG vaccination) or chest X-ray will be excluded.
    - Subjects with specific forms of psoriasis like guttate, erythrodermic or pustular psoriasis as sole or predominant form of psoriasis.
    - Subjects with immunodeficiencies.
2. Simultaneous participation in another clinical trial.
3. Subjects experiencing a psoriasis exacerbation during screening period.
4. Subjects who have previously been on Raptiva treatment who withdrew due to lack of efficacy or an adverse event. If withdrawal was due to another non-drug reason (vaccination, or infection) then the subject can be included in this study.
5. History of hepatitis B, hepatitis C or human immunodeficiency virus (HIV).
6. History of thrombocytopenia, haemolytic anaemia or clinically significant anaemia.
7. Hepatic enzyme levels =/>3 times the upper limit of normal or serum creatinine level =/>2 times the upper limit of normal.
8. Pregnant or breast-feeding.
9. Any medical condition (prior or existing) that, in the judgment of the investigator or sponsor, could jeopardize the subject's safety following exposure to study drug.

Contacts/Locations

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

Locations: Canada, Ontario
Probity Medical Research
City Waterloo, Ontario, Canada, N2J 1C4

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Date of first subject first visit: 22 January 2008 Date of last subject last visit: 21 April 2009 Subjects were enrolled at 13 study centers in 2 countries, including 10 study centers in Canada and 3 study centers in the Netherlands.
Pre-Assignment Details	Subjects were to be screened for study eligibility within 14 days before Day 1

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Overall Study

	Efalizumab
Started	70
Completed	51
Not Completed	19
Adverse Event	3
Protocol Violation	1
Lack of Efficacy	3
Suspension of the study by sponsor	12

Baseline Characteristics

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Baseline Measures

	Efalizumab
Number of Participants	70
Age, Continuous [units: years] Mean (Standard Deviation)	46.9 (14.7)
Age, Customized [units: participants]	
18 - 40 years	26
41 to 64 years	36
>64 years	8
Gender, Male/Female [units: participants]	
Female	25
Male	45
Region of Enrollment [units: participants]	
Canada	60
Netherlands	10
static Physician's Global Assessment (sPGA) [1] [units: participants]	
Clear	0
Minimal	4
Mild	6
Moderate	38
Severe	21
Very Severe	1
Biochemistry - C-Reactive Protein (CRP) [2] [units: participants]	
Participants with <3 mg/L	36

	Efalizumab
Participants with 3 mg/ L-6mg/L	19
Participants with >6 mg/L	15
Biochemistry - Alanine Transaminase (ALT) [units: IU/L] Mean (Standard Deviation)	27.8 (12.2)
Biochemistry - Alkaline Phosphatase [units: IU/L] Mean (Standard Deviation)	76.6 (19.0)
Biochemistry - Aspartate Transaminase (AST) [units: IU/L] Mean (Standard Deviation)	23.0 (7.8)
Biochemistry - Creatinine [units: µmol/L] Mean (Standard Deviation)	82.9 (18.9)
Biochemistry - Glutamyl Transferase [units: IU/L] Mean (Standard Deviation)	25.9 (15.3)
Biochemistry - Potassium [units: mmol/L] Mean (Standard Deviation)	4.19 (0.36)
Biochemistry - Values: Sodium [units: mmol/L] Mean (Standard Deviation)	139.5 (1.9)
Biochemistry - Total Bilirubin [units: µmol/L] Mean (Standard Deviation)	8.0 (4.7)
Biochemistry - Urea [units: mmol/L] Mean (Standard Deviation)	5.677 (1.633)
Hematology - Hematocrit [units: packed cell volume] Mean (Standard Deviation)	0.430 (0.040)
Hematology - Hemoglobin [units: g/L] Mean (Standard Deviation)	145.0 (13.7)

	Efalizumab
Hematology - Red Blood Cell Count [units: x10^12/L] Mean (Standard Deviation)	4.69 (0.52)
Hematology - White Blood Cell Count [units: x10^9/L] Mean (Standard Deviation)	7.11 (1.95)
Hematology - Basophils [units: x10^9/L] Mean (Standard Deviation)	0.032 (0.033)
Hematology - Eosinophils [units: x10^9/L] Mean (Standard Deviation)	0.177 (0.135)
Hematology - Lymphocytes [units: x10^9/L] Mean (Standard Deviation)	1.911 (0.670)
Hematology - Monocytes [units: x10^9/L] Mean (Standard Deviation)	0.462 (0.188)
Hematology - Neutrophils [units: x10^9/L] Mean (Standard Deviation)	4.533 (1.582)
Hematology - Platelet Count [units: x10^9/L] Mean (Standard Deviation)	256.0 (54.7)
Urinalysis - Glucose [3] [units: participants]	
Negative	66
Present	4
Urinalysis - Ketones [4] [units: participants]	
Negative	67
Present	3
Urinalysis - Values - Nitrite [5] [units: participants]	
Negative	69

	Efalizumab
Positive	1
Urinalysis - Leukocytes Esterase [6] [units: participants]	
Negative	60
Present	10
Urinalysis - Values - Protein [units: participants]	
Negative	59
Present	11
Urinalysis - Blood [7] [units: participants]	
Negative	66
Present	4
Urinalysis - pH [units: pH units] Mean (Standard Deviation)	5.84 (0.49)

[1] Numbers of participants with sPGA ratings of clear; minimal; mild; moderate; severe; or very severe

[2] Numbers of participants with CRP values <3 mg/L, 3-6 mg/L, and >6 mg/L

[3] Number of participants with or without glucose detected in urine

[4] Number of participants with or without ketones detected in urine

[5] Number of participants with or without nitrite detected in urine

[6] Number of participants with or without leukocytes esterase detected in urine

[7] Number of participants with or without blood detected in urine

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Hematology - Hematocrit
Measure Description	Blood samples were taken for clinical laboratory testing

Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 4 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	66
Hematology - Hematocrit [units: packed cell volume] Mean (Standard Deviation)	0.434 (0.039)

2. Primary Outcome Measure:

Measure Title	Hematology - Hemoglobin
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Hematology - Hemoglobin [units: g/L] Mean (Standard Deviation)	144.8 (13.0)

3. Primary Outcome Measure:

Measure Title	Hematology - Red Blood Cell Count
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Hematology - Red Blood Cell Count [units: x10^12/L] Mean (Standard Deviation)	4.78 (0.52)

4. Primary Outcome Measure:

Measure Title	Hematology - White Blood Cell Count
Measure Description	Blood samples were taken for clinical laboratory testing

Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Hematology - White Blood Cell Count [units: x10^9/L] Mean (Standard Deviation)	10.06 (2.69)

5. Primary Outcome Measure:

Measure Title	Hematology - Neutrophils
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Hematology - Neutrophils [units: x10^9/L] Mean (Standard Deviation)	5.047 (1.976)

6. Primary Outcome Measure:

Measure Title	Hematology - Eosinophils
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Hematology - Eosinophils [units: x10^9/L] Mean (Standard Deviation)	0.206 (0.130)

7. Primary Outcome Measure:

Measure Title	Hematology - Basophils
Measure Description	Blood samples were taken for clinical laboratory testing

Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Hematology - Basophils [units: x10^9/L] Mean (Standard Deviation)	0.050 (0.038)

8. Primary Outcome Measure:

Measure Title	Hematology - Monocytes
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Hematology - Monocytes [units: x10^9/L] Mean (Standard Deviation)	0.526 (0.205)

9. Primary Outcome Measure:

Measure Title	Hematology - Lymphocytes
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Hematology - Lymphocytes [units: x10^9/L] Mean (Standard Deviation)	4.209 (1.220)

10. Primary Outcome Measure:

Measure Title	Hematology - Platelet Count
Measure Description	Blood samples were taken for clinical laboratory testing

Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 4 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	66
Hematology - Platelet Count [units: x10^9/L] Mean (Standard Deviation)	255.5 (64.8)

11. Primary Outcome Measure:

Measure Title	Biochemistry - Sodium
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 1 participant missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	69
Biochemistry - Sodium [units: mmol/L] Mean (Standard Deviation)	139.0 (2.1)

12. Primary Outcome Measure:

Measure Title	Biochemistry - Potassium
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 1 participant missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	69
Biochemistry - Potassium [units: mmol/L] Mean (Standard Deviation)	4.23 (0.41)

13. Primary Outcome Measure:

Measure Title	Biochemistry - Creatinine
Measure Description	Blood samples were taken for clinical laboratory testing

Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 1 participant missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	69
Biochemistry - Creatinine [units: µmol/L] Mean (Standard Deviation)	83.1 (20.1)

14. Primary Outcome Measure:

Measure Title	Biochemistry - Total Bilirubin
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 1 participant missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	69
Biochemistry - Total Bilirubin [units: µmol/L] Mean (Standard Deviation)	7.2 (3.7)

15. Primary Outcome Measure:

Measure Title	Biochemistry - Aspartate Transaminase (AST)
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 2 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	68
Biochemistry - Aspartate Transaminase (AST) [units: IU/L] Mean (Standard Deviation)	22.2 (9.6)

16. Primary Outcome Measure:

Measure Title	Biochemistry - Alanine Transaminase (ALT)
Measure Description	Blood samples were taken for clinical laboratory testing

Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 1 participant missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	69
Biochemistry - Alanine Transaminase (ALT) [units: IU/L] Mean (Standard Deviation)	28.7 (19.3)

17. Primary Outcome Measure:

Measure Title	Biochemistry - Alkaline Phosphatase
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 1 participant missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	69
Biochemistry - Alkaline Phosphatase [units: IU/L] Mean (Standard Deviation)	80.2 (21.1)

18. Primary Outcome Measure:

Measure Title	Biochemistry - Glutamyl Transferase
Measure Description	Blood samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 1 participant missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	69
Biochemistry - Glutamyl Transferase [units: IU/L] Mean (Standard Deviation)	28.6 (20.1)

19. Primary Outcome Measure:

Measure Title	Biochemistry - Urea
Measure Description	Blood samples were taken for clinical laboratory testing

Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 1 participant missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	69
Biochemistry - Urea [units: mmol/L] Mean (Standard Deviation)	5.283 (1.628)

20. Primary Outcome Measure:

Measure Title	Biochemistry - C-Reactive Protein (CRP)
Measure Description	Blood samples were taken for clinical laboratory testing of the numbers of participants with CRP values <3 mg/L, 3-6 mg/L, and >6 mg/L
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 1 participant with missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	69
Biochemistry - C-Reactive Protein (CRP) [units: participants]	
participants with <3 mg/L	28
participants with 3-6 mg/L	22
participants with >6 mg/L	19

21. Primary Outcome Measure:

Measure Title	Urinalysis - pH
Measure Description	Urine samples were taken for clinical laboratory testing
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Urinalysis - pH [units: pH units] Mean (Standard Deviation)	5.75 (0.47)

22. Primary Outcome Measure:

Measure Title	Urinalysis - Protein
Measure Description	Urine samples were taken for clinical laboratory testing of the number of participants with or without protein in urine
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Urinalysis - Protein [units: participants]	
Negative	54
Present	13

23. Primary Outcome Measure:

Measure Title	Urinalysis - Ketones
Measure Description	Urine samples were taken for clinical laboratory testing of the number of participants with or without ketones in urine
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Urinalysis - Ketones [units: participants]	
Negative	58
Present	9

24. Primary Outcome Measure:

Measure Title	Urinalysis - Glucose
Measure Description	Urine samples were taken for clinical laboratory testing of the number of participants with or without glucose in urine
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants with missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Urinalysis - Glucose [units: participants]	

	Efalizumab
Negative	64
Present	3

25. Primary Outcome Measure:

Measure Title	Urinalysis - Blood
Measure Description	Urine samples were taken for clinical laboratory testing of the number of participants with or without blood in urine
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants with missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Urinalysis - Blood [units: participants]	
Negative	58
Present	9

26. Primary Outcome Measure:

Measure Title	Urinalysis - Nitrite
Measure Description	Urine samples were taken for clinical laboratory testing of the number of participants with or without nitrite in urine

Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants with missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Urinalysis - Nitrite [units: participants]	
Negative	65
Positive	2

27. Primary Outcome Measure:

Measure Title	Urinalysis - Leukocytes Esterase
Measure Description	Urine samples were taken for clinical laboratory testing of the number of participants with or without leukocytes esterase in urine
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Analysis Population Description

Safety Population - 3 participants with missing values

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	67
Urinalysis - Leukocytes Esterase [units: participants]	
Negative	60
Present	7

28. Primary Outcome Measure:

Measure Title	Adverse Events, Serious Adverse Events, and Laboratory Data (Haematology and Biochemistry) and Urinalysis
Measure Description	Information on adverse events are displayed in the adverse events section. Information laboratory data and urinalysis findings are displayed individually above
Time Frame	Week 12 / Early Termination
Safety Issue?	Yes

Outcome Measure Data Not Reported

29. Secondary Outcome Measure:

Measure Title	Static Physician's Global Assessment (sPGA)
Measure Description	Number of subjects who achieve an Static Physician’s Global Assessment (sPGA) rating of clear; minimal; mild; moderate; severe; or very severe at Week 12 (Day 85).
Time Frame	12 Weeks/Early Termination
Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Measured Values

	Efalizumab
Number of Participants Analyzed	69
Static Physician's Global Assessment (sPGA) [units: participants]	
Clear	3
Minimal	19
Mild	20
Moderate	21
Severe	6
Very Severe	0

Reported Adverse Events

Time Frame	12 Weeks
Additional Description	'Other Adverse Events' table shows the number of participants experiencing any adverse event and the listing shows all treatment emergent adverse events occuring above the threshold value in the Safety Population

Reporting Groups

	Description
Efalizumab	Each subject received an initial conditioning dose of efalizumab of 0.7 mg/kg/week and then was to continue treatment at a dose of 1 mg/kg/week for up to 12 weeks. Efalizumab was administered by subcutaneous injection

Serious Adverse Events

	Efalizumab
	Affected/At Risk (%)
Total	0/70 (0%)

Other Adverse Events

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

	Efalizumab
	Affected/At Risk (%)
Total	50/70 (71.43%)
Blood and lymphatic system disorders	
Leukopenia [A] †	1/70 (1.43%)
Ear and labyrinth disorders	
Ear pain [A] †	1/70 (1.43%)
Eye disorders	
Conjunctivitis [A] †	1/70 (1.43%)
Gastrointestinal disorders	
Abdominal pain lower [A] †	1/70 (1.43%)
Abdominal pain upper [A] †	2/70 (2.86%)
Diarrhoea [A] †	1/70 (1.43%)
Nausea [A] †	1/70 (1.43%)
Vomiting [A] †	1/70 (1.43%)
General disorders	
Chills [A] †	1/70 (1.43%)
Fatigue [A] †	3/70 (4.29%)
Influenza like illness [A] †	5/70 (7.14%)
Infections and infestations	

	Efalizumab
	Affected/At Risk (%)
Candidiasis [A] †	1/70 (1.43%)
Folliculitis [A] †	2/70 (2.86%)
Furuncle [A] †	1/70 (1.43%)
Gastroenteritis [A] †	1/70 (1.43%)
Influenza [A] †	4/70 (5.71%)
Lower respiratory tract infection [A] †	1/70 (1.43%)
Nasopharyngitis [A] †	5/70 (7.14%)
Oral herpes [A] †	1/70 (1.43%)
Otitis media [A] †	1/70 (1.43%)
Pharyngitis [A] †	2/70 (2.86%)
Sinusitis [A] †	1/70 (1.43%)
Sweat gland infection [A] †	1/70 (1.43%)
Upper respiratory tract infection [A] †	8/70 (11.43%)
Urinary tract infection [A] †	2/70 (2.86%)
Viral upper respiratory tract infection [A] †	1/70 (1.43%)
Injury, poisoning and procedural complications	
Muscle strain [A] †	1/70 (1.43%)
Investigations	
Gamma-glutamyltransferase increased [A] †	1/70 (1.43%)
Heart rate increased [A] †	1/70 (1.43%)
Metabolism and nutrition disorders	
Gout [A] †	1/70 (1.43%)

	Efalizumab
	Affected/At Risk (%)
Hypercholesterolaemia [A] †	1/70 (1.43%)
Musculoskeletal and connective tissue disorders	
Arthralgia [A] †	4/70 (5.71%)
Arthritis [A] †	1/70 (1.43%)
Back pain [A] †	3/70 (4.29%)
Muscle spasms [A] †	2/70 (2.86%)
Musculoskeletal discomfort [A] †	1/70 (1.43%)
Musculoskeletal pain [A] †	2/70 (2.86%)
Myalgia [A] †	1/70 (1.43%)
Psoriatic arthropathy [A] †	1/70 (1.43%)
Tendonitis [A] †	2/70 (2.86%)
Nervous system disorders	
Dizziness [A] †	3/70 (4.29%)
Epilepsy [A] †	1/70 (1.43%)
Headache [A] †	10/70 (14.29%)
Sciatica [A] †	1/70 (1.43%)
Respiratory, thoracic and mediastinal disorders	
Cough [A] †	3/70 (4.29%)
Dry throat [A] †	1/70 (1.43%)
Dysphonia [A] †	1/70 (1.43%)
Pharyngolaryngeal pain [A] †	1/70 (1.43%)
Pharyngolaryngeal pain [A] †	1/70 (1.43%)

	Efalizumab
	Affected/At Risk (%)
Rhinitis allergic [A] †	1/70 (1.43%)
Rhinorrhoea [A] †	2/70 (2.86%)
Rhonchi [A] †	1/70 (1.43%)
Sinus congestion [A] †	1/70 (1.43%)
Skin and subcutaneous tissue disorders	
Dermal cyst [A] †	3/70 (4.29%)
Dermatitis allergic [A] †	1/70 (1.43%)
Erythema nodosum [A] †	1/70 (1.43%)
Pruritus [A] †	3/70 (4.29%)
Pruritus generalised [A] †	1/70 (1.43%)
Psoriasis [A] †	4/70 (5.71%)
Rash [A] †	1/70 (1.43%)
Vascular disorders	
Flushing [A] †	1/70 (1.43%)
Hot flush [A] †	1/70 (1.43%)
Orthostatic hypotension [A] †	1/70 (1.43%)
Vascular occlusion [A] †	1/70 (1.43%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.0)

Limitations and Caveats

[Not specified]

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.

Results Point of Contact:

Name/Official Title: Merck KGaA Communication Center
Organization: Merck Serono S.A., a division of Merck KGaA
Phone: +49-6151-72-5200
Email: service@merckgroup.com