ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 02/22/2016

ClinicalTrials.gov ID: NCT00573157

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | 28113 |
| Brief Title: | The Efficacy and Safety of Atacicept in Combination With Mycophenolate Mofetil Used to Treat Lupus Nephritis |
| Official Title: | A Phase 2/3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Atacicept in Subjects With Lupus Nephritis in Combination With Mycophenolate Mofetil Therapy. |
| Secondary IDs: | 493G01 |

## Study Status

| | |
|---|---|
| Record Verification: | February 2016 |
| Overall Status: | Terminated |
| Study Start: | December 2007 |
| Primary Completion: | April 2009 [Actual] |
| Study Completion: | April 2009 [Actual] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | EMD Serono |
| Responsible Party: | Sponsor |
| Collaborators: | ZymoGenetics |

## Oversight

| | |
|---|---|
| FDA Regulated?: | Yes |
| Applicable Trial?: | Section 801 Clinical Trial? Yes |

| | |
|---|---|
| | Delayed Posting? No |
| IND/IDE Protocol?: | Yes |
| IND/IDE Information: | Grantor: CDER<br>IND/IDE Number: BB-IND11584<br>Serial Number: 040<br>Has Expanded Access? No |
| Review Board: | Approval Status: Approved<br>Approval Number: 20071261<br>Board Name: Western Institutional Review Board<br>Board Affiliation: Northwest Louisiana Nephrology Research<br>Phone: 1-800-562-4789<br>Email: clientservices@wirb.com |
| Data Monitoring?: | Yes |
| Plan to Share Data?: | |
| Oversight Authorities: | United States: Food and Drug Administration |

## Study Description

| | |
|---|---|
| Brief Summary: | The purpose of this study is to learn whether atacicept treatment leads to improvement in kidney function in subjects with active lupus nephritis in combination with mycophenolate mofetil (MMF) and corticosteroids. The study was sponsored by Merck Serono International; operational oversight was provided by ZymoGenetics. |
| Detailed Description: | |

## Conditions

| | |
|---|---|
| Conditions: | Lupus Nephritis |
| Keywords: | nephritis<br>atacicept |

## Study Design

| | |
|---|---|
| Study Type: | Interventional |
| Primary Purpose: | Treatment |
| Study Phase: | Phase 2/Phase 3 |
| Intervention Model: | Parallel Assignment |
| Number of Arms: | 2 |

| | |
|---|---|
| Masking: | Double Blind (Subject, Investigator) |
| Allocation: | Randomized |
| Endpoint Classification: | |
| Enrollment: | 6 [Actual] |

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: Atacicept Plus Mycophenolate mofetil Plus Corticosteroids | Drug: Atacicept<br>Atacicept will be administered at a dose of 150 milligram (mg) subcutaneously (SC) twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks.<br>Drug: Mycophenolate mofetil<br>MMF will be administered orally with a starting dose of 500 mg twice daily for 1 week, will be increased to 1000 mg twice daily for 1 week, then it will be adjusted to 1500 mg or lower twice daily as per investigator's discretion.<br>Drug: Corticosteroids<br>High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever is less will be administered for 4 Weeks and will be tapered to 7.5 to 10 mg/day up to Week 12. |
| Placebo Comparator: Placebo Plus Mycophenolate mofetil Plus Corticosteroids | Drug: Mycophenolate mofetil<br>MMF will be administered orally with a starting dose of 500 mg twice daily for 1 week, will be increased to 1000 mg twice daily for 1 week, then it will be adjusted to 1500 mg or lower twice daily as per investigator's discretion.<br>Drug: Placebo<br>Placebo will be administered at a dose of 150 mg SC twice weekly for 4 weeks followed by 150 mg SC once weekly for 48 weeks.<br>Drug: Corticosteroids<br>High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever is less will be administered for 4 Weeks and will be tapered to 7.5 to 10 mg/day up to Week 12. |

## Outcome Measures

[See Results Section.]

## Eligibility

Minimum Age: 16 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Diagnosis of systemic lupus erythematosus (SLE) satisfying at least 4 out of the 11 American College of Rheumatology (ACR) criteria (Appendix B)
- Renal biopsy performed consistent with active International Society of Nephrology/Renal Pathology Society (ISN/PRS) class III or IV lupus nephritis

Exclusion Criteria:

- Estimated glomerular filtration rate (GFR) less than or equal to (<=) 30 milliliter per minute (mL/min) per 1.73 square meter (m^2)
- Active central nervous system SLE deemed to be severe or progressive and/or associated with significant cognitive impairment
- Any treatment with MMF, azathioprine, or cyclophosphamide within the last 6 months, or known hypersensitivity to MMF or atacicept.
- Any prior treatment with abatacept, rituximab, belimumab, or other B cell modulating agents.

## Contacts/Locations

Study Officials: Medical Responsible
Study Director
EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany

Locations: United States, Louisiana
Northwest Louisiana Nephrology Research
Shreveport, Louisiana, United States, 71101

United States, New York
Seligman Center for Advanced Therapeutics
New York, New York, United States, 10003

The Feinstein Institute for Medical Research
Manhasset, New York, United States, 11030

United States, Ohio
Rheumatology Clinical Research Unit, Division of Rheumatology University Hospitals Case Medical Center

Beachwood, Ohio, United States, 44122

United States, South Carolina
1711 St. Julian Place
Columbia, South Carolina, United States, 29204

United States, Ohio
Southwest Rheumatology and Research Group, LLC
Middleburg Heights, Ohio, United States, 44130

United States, South Carolina
ACME Research, LLC
Orangeburg, South Carolina, United States, 29118

Czech Republic
Institute of Rheumatology
Prague, 128 50, Czech Republic

United States, Ohio
University of Cincinnati College of Medicine
Cincinnati, Ohio, United States, 45267

The Ohio State University Medical Center
Columbus, Ohio, United States, 43210

United States, North Carolina
Wake Forest University Health Sciences
Winston-Salem, North Carolina, United States, 27109

United States, Louisiana
Tulane University Hospital and Clinic Department of Internal Medicine
New Orleans,, Louisiana, United States

United States, Michigan
Wayne State University Lupus Database Departments of Internal Medicine and Obstetrics & Gynecology Division of Rheumatology Wayne State University School of Medicine
Detroit, Michigan, United States

Singapore
Singapore General Hospital
Singapore, Singapore

Changi General Hospital
Singapore, Singapore

Malaysia

Hospital University Kebangsaan Malaysia
Kuala Lumpur, Malaysia

Hospital Sultanah Bahiyah
Kedah, Malaysia

University of Malaya Medical Centre
Kuala Lumpur, Malaysia

Hospital Pulau Pinang
Pulau Pinang, Malaysia

Taiwan
Kaohsiung Veterans General Hospital
Kaohsiung, Taiwan

## References

Citations:

Links:

Study Data/Documents:

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# Study Results

## Participant Flow

Reporting Groups

| | Description |
|---|---|
| Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Atacicept was administered subcutaneously (SC) at a loading dose of 150 milligram (mg) twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose corticosteroids (CS) of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |

| | Description |
|---|---|
| Placebo Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo was administered SC at a loading dose of 150 mg twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |

Overall Study

| | Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo Plus Mycophenolate Mofetil Plus Corticosteroids |
|---|---|---|
| Started | 4 | 2 |
| Completed | 0 | 0 |
| Not Completed | 4 | 2 |
| Adverse Event | 3 | 1 |
| Unspecified | 1 | 1 |

## Baseline Characteristics

Analysis Population Description

Baseline analysis population included all the participants randomized in the trial.

Reporting Groups

| | Description |
|---|---|
| Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Atacicept was administered SC at a loading dose of 150 mg twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |
| Placebo Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo was administered SC at a loading dose of 150 mg twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |

Baseline Measures

| | Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo Plus Mycophenolate Mofetil Plus Corticosteroids | Total |
|---|---|---|---|
| Number of Participants | 4 | 2 | 6 |
| Age, Continuous<br>[units: years]<br>Mean (Standard Deviation) | 36.8 (11.3) | 36.0 (25.5) | 36.5 (14.4) |
| Gender, Male/Female<br>[units: participants] | | | |
| Female | 3 | 1 | 4 |
| Male | 1 | 1 | 2 |

## Outcome Measures

1. Primary Outcome Measure:

| | |
|---|---|
| Measure Title | Percentage of Participants With Confirmed Complete Renal Response (CRR), Partial Response, and Non-response |
| Measure Description | Complete renal response (CRR): from baseline, a return to within 10% of normal for renal function (assessed by calculated glomerular filtration rate [GFR]), improvement in proteinuria (urine protein/creatinine ratio <0.5) & resolution of hematuria. Partial response (PR): from baseline, a <= 10% worsening in renal function ( by calculated GFR); 50% improvement in proteinuria (assessed by urine protein/creatinine ratio) & resolution of hematuria, Non-response (NR): Neither criteria for CR or PR was met. Subjects were also deemed NR if they had treatment failure, regardless of CR or PR status. Subjects cannot be treatment failures. A response of CRR was confirmed if the Week 52 value is CRRand if the Week 48 value is CRR and at least 4 weeks apart from Week 52 /if the Week 48 value was missing/ less than 4 weeks from Week 52, then the Week 56 response must be CRR - if the Week 52 value was missing, then Week 48 and Week 56 must be CRR. |
| Time Frame | At Week 52 |
| Safety Issue? | No |

Analysis Population Description

Due to early termination of the study caused by unanticipated safety issues, the outcome measure was not assessed.

Reporting Groups

| | Description |
|---|---|
| Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Atacicept was administered SC at a loading dose of 150 mg twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |
| Placebo Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo was administered SC at a loading dose of 150 mg twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |

Measured Values

| | Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo Plus Mycophenolate Mofetil Plus Corticosteroids |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

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

2. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Percentage of Participants With Normalization of Renal Function |
| Measure Description | |
| Time Frame | At Week 52 |
| Safety Issue? | No |

Analysis Population Description

Due to early termination of the study caused by unanticipated safety issues, the outcome measure was not assessed.

Reporting Groups

| | Description |
|---|---|
| Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Atacicept was administered SC at a loading dose of 150 mg twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |
| Placebo Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo was administered SC at a loading dose of 150 mg twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |

Measured Values

| | Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo Plus Mycophenolate Mofetil Plus Corticosteroids |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

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

3. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Participants With New Lupus Flares |
| Measure Description | |
| Time Frame | At Week 52 |
| Safety Issue? | No |

Analysis Population Description

Due to early termination of the study caused by unanticipated safety issues, the outcome measure was not assessed.

Reporting Groups

| | Description |
|---|---|
| Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Atacicept was administered SC at a loading dose of 150 mg twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |
| Placebo Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo was administered SC at a loading dose of 150 mg twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |

Measured Values

| | Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo Plus Mycophenolate Mofetil Plus Corticosteroids |
|---|---|---|
| Number of Participants Analyzed | 0 | 0 |

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

## Reported Adverse Events

| | |
|---|---|
| Time Frame | From the first dose of trial medication to 24-Week follow-up after last dose of trial medication. |
| Additional Description | A Serious adverse event (SAE) was an AE that resulted in any of the following outcomes: death; life threatening; persistent/significant disability/incapacity; initial or prolonged inpatient hospitalization; congenital anomaly/birth defect. |

Reporting Groups

| | Description |
|---|---|
| Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Atacicept was administered SC at a loading dose of 150 mg twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |

| | Description |
|---|---|
| Placebo Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo was administered SC at a loading dose of 150 mg twice weekly for 4 weeks followed by maintenance dose of 150 mg SC once weekly for 48 weeks. MMF was administered orally with a starting dose of 500 mg twice daily for 1 week, increased to 1000 mg twice daily for 1 week, then adjusted to 1500 mg or lower twice daily as per investigator's discretion. High dose CS of 0.8 mg per kilogram per day or maximum of 60 mg per day prednisone or prednisone equivalent, whichever was less was administered for 4 Weeks and tapered to 7.5 to 10 mg/day up to Week 12. |

Serious Adverse Events

| | Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo Plus Mycophenolate Mofetil Plus Corticosteroids |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 3/4 (75%) | 0/2 (0%) |
| Blood and lymphatic system disorders | | |
| Anaemia [A] * | 1/4 (25%) | 0/2 (0%) |
| Infections and infestations | | |
| Empyema [A] * | 1/4 (25%) | 0/2 (0%) |
| Pneumonia [A] * | 1/4 (25%) | 0/2 (0%) |
| Pneumonia legionella [A] * | 1/4 (25%) | 0/2 (0%) |
| Sepsis [A] * | 1/4 (25%) | 0/2 (0%) |
| Nervous system disorders | | |
| Syncope [A] * | 1/4 (25%) | 0/2 (0%) |
| Renal and urinary disorders | | |
| Renal failure acute [A] * | 1/4 (25%) | 0/2 (0%) |
| Respiratory, thoracic and mediastinal disorders | | |
| Pneumothorax [B] * | 1/4 (25%) | 0/2 (0%) |
| Pulmonary embolism [A] * | 1/4 (25%) | 0/2 (0%) |
| Vascular disorders | | |
| Hypertensive crisis [A] * | 1/4 (25%) | 0/2 (0%) |

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA Version 12.0
B Term from vocabulary, MedDRA Version 11.1

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

| | Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo Plus Mycophenolate Mofetil Plus Corticosteroids |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 4/4 (100%) | 1/2 (50%) |
| Blood and lymphatic system disorders | | |
| Anaemia [A] * | 1/4 (25%) | 0/2 (0%) |
| Haemolytic anaemia [A] * | 1/4 (25%) | 0/2 (0%) |
| Thrombotic microangiopathy [A] * | 1/4 (25%) | 0/2 (0%) |
| Cardiac disorders | | |
| Atrial fibrillation [A] * | 1/4 (25%) | 0/2 (0%) |
| Palpitations [A] * | 0/4 (0%) | 1/2 (50%) |
| Tachycardia [A] * | 1/4 (25%) | 1/2 (50%) |
| Eye disorders | | |
| Dry eye [A] * | 1/4 (25%) | 0/2 (0%) |
| Gastrointestinal disorders | | |
| Abdominal pain [A] * | 0/4 (0%) | 1/2 (50%) |
| Diarrhoea [A] * | 1/4 (25%) | 0/2 (0%) |
| Nausea [A] * | 1/4 (25%) | 1/2 (50%) |
| Rectal haemorrhage [A] * | 1/4 (25%) | 0/2 (0%) |
| Vomiting [A] * | 1/4 (25%) | 0/2 (0%) |
| General disorders | | |
| Injection site erythema [A] * | 1/4 (25%) | 0/2 (0%) |

| | Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo Plus Mycophenolate Mofetil Plus Corticosteroids |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Injection site haematoma [A] * | 0/4 (0%) | 1/2 (50%) |
| Injection site pain [A] * | 1/4 (25%) | 0/2 (0%) |
| Oedema [A] * | 1/4 (25%) | 0/2 (0%) |
| Oedema peripheral [A] * | 1/4 (25%) | 0/2 (0%) |
| Pyrexia [A] * | 1/4 (25%) | 0/2 (0%) |
| Immune system disorders | | |
| Hypogammaglobulinaemia [A] * | 2/4 (50%) | 0/2 (0%) |
| Infections and infestations | | |
| Influenza [A] * | 1/4 (25%) | 0/2 (0%) |
| Injury, poisoning and procedural complications | | |
| Contusion [A] * | 1/4 (25%) | 0/2 (0%) |
| Renal haematoma [A] * | 1/4 (25%) | 0/2 (0%) |
| Wrist fracture [A] * | 1/4 (25%) | 0/2 (0%) |
| Investigations | | |
| Blood immunoglobulin G decreased [A] * | 1/4 (25%) | 0/2 (0%) |
| Metabolism and nutrition disorders | | |
| Anorexia [A] * | 1/4 (25%) | 0/2 (0%) |
| Hypoalbuminaemia [A] * | 1/4 (25%) | 0/2 (0%) |
| Hypokalaemia [A] * | 2/4 (50%) | 0/2 (0%) |
| Hypophosphataemia [A] * | 1/4 (25%) | 0/2 (0%) |
| Type 2 diabetes mellitus [A] * | 1/4 (25%) | 0/2 (0%) |
| Musculoskeletal and connective tissue disorders | | |

| | Atacicept Plus Mycophenolate Mofetil Plus Corticosteroids | Placebo Plus Mycophenolate Mofetil Plus Corticosteroids |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Arthralgia [A] * | 0/4 (0%) | 1/2 (50%) |
| Pain in extremity [A] * | 1/4 (25%) | 0/2 (0%) |
| Nervous system disorders | | |
| Dysgeusia [A] * | 0/4 (0%) | 1/2 (50%) |
| Tremor [A] * | 1/4 (25%) | 0/2 (0%) |
| Psychiatric disorders | | |
| Insomnia [A] * | 1/4 (25%) | 0/2 (0%) |
| Mood altered [A] * | 1/4 (25%) | 0/2 (0%) |
| Renal and urinary disorders | | |
| Dysuria [A] * | 1/4 (25%) | 0/2 (0%) |
| Renal failure acute [A] * | 1/4 (25%) | 0/2 (0%) |
| Respiratory, thoracic and mediastinal disorders | | |
| Cough [A] * | 1/4 (25%) | 0/2 (0%) |
| Epistaxis [A] * | 1/4 (25%) | 0/2 (0%) |
| Oropharyngeal pain [A] * | 1/4 (25%) | 0/2 (0%) |
| Skin and subcutaneous tissue disorders | | |
| Acne [A] * | 1/4 (25%) | 0/2 (0%) |
| Leukocytoclastic vasculitis [A] * | 0/4 (0%) | 1/2 (50%) |
| Rash [A] * | 0/4 (0%) | 1/2 (50%) |
| Vascular disorders | | |
| Hypertension [A] * | 1/4 (25%) | 0/2 (0%) |

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA Version 12.0

## Limitations and Caveats

The study was terminated due to unanticipated safety issues.

## 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.

Prior to publishing results, Institution and Principal Investigator (PI) must first provide Sponsor with a copy of proposed publication for review at least 30 days prior to submission. If Institution and PI do not agree to modification, they shall so notify Sponsor and postpone submission for additional 60 days to allow Sponsor to seek legal remedies or file patent applications. There is a need for coordinated approach to any publication of results from sites for any multi-site study.

Results Point of Contact:

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