A Pilot Study of CC-220 to Treat Systemic Lupus Erythematosus.

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT02185040	COMPLETED	JULY 9, 2014	MARCH 19, 2020

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to determine whether CC-220 is effective for the treatment of skin, joint and serological manifestations of systemic lupus erythematosus.

Condition or Disease: Systemic Lupus Erythematosus

Intervention/treatment: Drug: CC-220
Drug: CC-220
Drug: CC-220
Drug: CC-220
Drug: Placebo

Phase: Phase 2

DETAILED DESCRIPTION

The study consists of 2 parts. Part 1 is a randomized, double-blind, placebo controlled, ascending dose study to evaluate the safety and tolerability of CC-220 in SLE subjects. Subject participation in Part 1 consists of 3 phases:
- Pre-treatment Screening Phase: up to 28 days prior to the first dose of the investigational product (IP)
- Treatment Phase: up to 84 days
- Observation Phase: 84 day post-treatment A total of approximately 40 subjects will be randomized into 4 dose groups with a 4:1 ratio of CC-220 (0.3 mg every other day [QOD], 0.3 mg everyday [QD], 0.6 mg and 0.3 mg on alternating days, and 0.6 mg QD) or matching placebo. In each dosing arm, 8 subjects will receive active drug and 2 subjects will receive placebo. The Treatment Phase will be up to 84 days in duration for all dose groups. Subjects who discontinue IP early and all subjects who complete the 84 day treatment phase will enter into the Observational Follow-up Phase for an 84 day period. A subject will be permitted to reduce their dose one time during Part 1 of the study. Part 2 is the Active Treatment Extension Phase (ATEP) which is an extension to evaluate the long-term efficacy and safety/tolerability of CC-220 in SLE subjects who completed Part 1 of the study. Subjects who complete the Treatment Phase of Part 1 of the study will be eligible to receive CC-220 in the ATEP for up to 2 years. All subjects who participate in the ATEP will receive either 0.3 mg QD or 0.6 mg and 0.3 mg QD on alternating days. Subjects who terminate the Treatment Phase of Part 1 early will not be eligible for entry into the ATEP. Subject participation consists of two phases:
- Active Treatment Extension Phase: Up to 2 years
- Observational Follow-up Phase: One month

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 42 participants

Intervention Model : Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: A Pilot, Phase 2, Randomized, Placebo-Controlled, Double-Blind, Study To Evaluate Efficacy, Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Pharmacogenetics of CC-220 In Subjects With Systemic Lupus Erythematosus

Actual Study Start Date: September 2014

Actual Primary Completion Date: September 2018

Actual Study Completion Date: September 2018

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: CC-220 0.3mg Every Other Day (QOD) Part 1: CC-220 0.3mg capsules by mouth every other day (QOD)	Drug: CC-220 0.3 mg oral capsules once every other day with or without food

Experimental: CC-220 0.3mg Every Day (QD) Part 1: CC-220 0.3mg capsules by mouth every day (QD) ATEP: CC-220 0.3 mg capsules by mouth every day (QD)	Drug: CC-220 Subjects will receive 0.3 mg oral capsules every day with or without food
Experimental: CC-220 0.6mg/0.3mg alternating dose QD Part 1: CC-220 0.6 mg and 0.3mg capsules PO on alternating days ATEP:CC-220 0.6 mg and 0.3 mg capsules PO on alternating days	Drug: CC-220 CC-220 oral capsules 0.6 mg and 0.3 mg on alternating days with or without food
Experimental: CC-220 0.6mg QD Part 1: CC-220 0.6mg capsules by mouth QD	Drug: CC-220 CC-220 oral capsule 0.6 mg QD with or without food
Placebo Comparator: Placebo QD Part 1: Identically matching placebo capsules PO QD	Drug: Placebo Matching oral placebo daily

OUTCOME MEASURES

Primary Outcome Measures: 1. Number of Participants With Treatment Emergent Adverse Events (TEAEs) in Part 1 Treatment Phase [Time Frame: From the start of the first dose of IP until 28 days after the last dose or study discontinuation in Part 1; median treatment duration = 12.0 weeks for the placebo, 0.3 mg QOD and 0.3 mg iberdomide QD arms, 11.9 weeks for the 0.6/0.3 ALT and 0.6 cohorts.]
A TEAE was defined as any adverse event (AE) that began or worsened on or after the start of IP up to 28 days after the last dose of IP or IP discontinuation date, whichever was later. Each participant was counted once for each applicable category. An IP-related TEAE was defined as a TEAE that the investigator considered to be of suspected relationship to IP. The severity of each adverse event and serious AE (SAE) was assessed by the investigator and graded based on a scale from mild - mild symptoms to severe AEs (non-serious or serious). A serious adverse event (SAE) was any AE which: • Resulted in death • Was life-threatening • Required inpatient hospitalization or prolongation of existing hospitalization • Resulted in persistent or significant disability/incapacity • Was a congenital anomaly/birth defect • Constituted an important medical event.
2. Number of Participants With Treatment Emergent Adverse Events (TEAEs) in the Active Treatment Extension Phase [Time Frame: From the date of the first dose of IP in the ATEP until 28 days after the last dose in the ATEP or study discontinuation; median duration of IP was 95.86 weeks for the 0.3 mg iberdomide QD cohort and 60.64 weeks for the 0.6 mg/0.3 mg ALT QD cohorts.]
A TEAE was defined as any adverse event (AE) that began or worsened on or after the start of IP through 28 days after the last dose of IP or IP discontinuation date, whichever was later. Each participant was counted once for each applicable category. An IP-related TEAE was defined as a TEAE that the investigator considered to be of suspected relationship to IP. The severity of each adverse event and serious AE (SAE) was assessed by the investigator and graded based on a scale from mild - mild symptoms to severe AEs (non-serious or serious). A serious adverse event (SAE) was any AE which: • Resulted in death • Was life-threatening • Required inpatient hospitalization or prolongation of existing hospitalization • Resulted in persistent or significant disability/incapacity • Was a congenital anomaly/birth defect • Constituted an important medical event.

Secondary Outcome Measures: 1. Area Under the Plasma Concentration-Time Curve From Time 0 to the Last Measurable Concentration (AUCt) of Iberdomide [Time Frame: Pharmacokinetic (PK) blood samples were collected on Day 1 and Day 29 pre-dose (Time = 0 hours) and at 1, 2, 3, 4, between 6 and 8 hours and 24 hours after administration of IP.]
The area under the plasma concentration time curve (AUCt) was defined as area under the concentration-time curve from time zero to the last quantifiable time point, calculated by the linear trapezoidal rule when concentrations are increasing and the logarithmic trapezoidal method when concentrations are decreasing. Single and multiple-dose PK were collected in Part 1 of the study for all dose groups. Iberdomide reaches steady state within 7 days. PK collection on Day 29 was sufficient to understand PK once steady state was reached. As no dose adjustments were made in ATEP, further PK collection was not needed.
2. Maximum Observed Concentration (Cmax) Of Iberdomide [Time Frame: Pharmacokinetic blood samples were collected on Day 1 and Day 29 at pre-dose (Time = 0 hours) and at 1, 2, 3, 4, between 6 and 8 hours and 24 hours after administration of IP.]
Maximum observed plasma concentration, obtained directly from the observed concentration versus time data. Single and multiple-dose PK were collected in Part 1 of the study for all dose groups. Iberdomide reaches steady state within 7 days. PK collection on Day 29 was sufficient to understand PK once steady state was reached. As no dose adjustments were made in ATEP, further PK collection was not needed.
3. Time to Reach Maximum Concentration (Tmax) of Iberdomide [Time Frame: Pharmacokinetic blood samples were collected on Day 1 and Day 29 at pre-dose (Time = 0 hours) and at 1, 2, 3, 4, between 6 and 8 hours and 24 hours after administration of IP.]
Time to Cmax, obtained directly from the observed concentration versus time data. Single and multiple-dose PK were collected in Part 1 of the study for all dose groups. Iberdomide reaches steady state within 7 days. PK collection on Day 29 was sufficient to understand PK once steady state was reached. As no dose adjustments were made in ATEP, further PK collection was not needed.
4. Terminal Phase Half-Life (T1/2) Of Iberdomide [Time Frame: Pharmacokinetic blood samples were collected on Day 1 and Day 29 at pre-dose (Time = 0 hours) and at 1, 2, 3, 4, between 6 and 8 hours and 24 hours after administration of IP.]
Terminal phase half-life in plasma, calculated as [(ln 2)/λz]. T1/2 half was only calculated when a reliable estimate for λz could be obtained. Single and multiple-dose PK were collected in Part 1 of the study for all dose groups. Iberdomide reaches steady state within 7 days. PK collection on Day 29 was sufficient to understand PK once steady state was reached. As no dose adjustments were made in ATEP, further PK collection was not needed.
5. Percentage of Participants Who Achieved ≥4 Points Reduction From Baseline in Hybrid Safety of Estrogens in Systemic Lupus Erythematosus National Assessment SLE Disease Activity Index Score (SELENA SLEDAI) During the ATEP by Time Point [Time Frame: Baseline to Weeks 1, 4, 12, 24, 36, 48, 60, 72, 84, 96 and follow-up at Week 100 during the ATEP.]
The SELENA SLEDAI score measures SLE disease activity through assessment of 24 lupus descriptors/manifestations. Each descriptor (clinical or lab values) receives a positive score if it is present over the previous assessment period; a score of '0' indicates inactive disease while a positive score (from 1 to 8 based on the relative importance of each descriptor in the total scoring) indicates disease activity. The SELENA SLEDAI score is the sum of all 24 descriptors' scores for the assessment period. The SELENA SLEDAI score can range from '0' (no SLE disease activity) to a maximum theoretical score of 105 (maximum SLE disease activity). The higher the SELENA SLEDAI score the greater of SLE disease activity.
6. Change From Baseline in the Hybrid Systemic Lupus Erythematosus Disease Activity Index (SELENA SLEDAI) During the ATEP by Time Point [Time Frame: Baseline to Weeks 1, 4, 12, 24, 36, 48, 60, 72, 84, 96 and follow-up at Week 100 during the ATEP.]
The SELENA SLEDAI score measures SLE disease activity through assessment of 24 lupus descriptors/manifestations. Each descriptor (clinical or lab values) receives a positive score if it is present over the previous assessment period; a score of '0' indicates inactive disease while a positive score (from 1 to 8 based on the relative importance of each descriptor in the total scoring) indicates disease activity. The SELENA SLEDAI score is the sum of all 24 descriptors' scores for the assessment period. The SELENA SLEDAI score can range from '0' (no SLE disease activity) to a maximum theoretical score of 105 (maximum SLE disease activity). The higher the SELENA SLEDAI score the greater of SLE disease activity.
7. Change From Baseline in Swollen Joint Count During the ATEP by Time Point [Time Frame: Baseline to Weeks 1, 4, 12, 24, 36, 48, 60, 72, 84, 96 and follow-up at Week 100 during the ATEP.]
Joint swelling was noted as present or absent. Forty-four joints were assessed for swelling, including the sternoclavicular, acromioclavicular, shoulder, elbow, wrist, metacarpophalangeal (MCP), proximal interphalangeal (PIP), knee, ankle, and metatarsophalangeal (MTP) joints were included in this joint count.
8. Change From Baseline in Tender Joint Count During the ATEP by Time Point [Time Frame: Baseline to Weeks 1, 4, 12, 24, 36, 48, 60, 72, 84, 96 and follow-up at Week 100 during the ATEP.]
Joint tenderness was noted as present or absent. Forty-four joints were assessed for swelling, including the sternoclavicular, acromioclavicular, shoulder, elbow, wrist, metacarpophalangeal (MCP), proximal interphalangeal (PIP), knee, ankle, and metatarsophalangeal (MTP) joints were included in this joint count.

9. Percent Change From Baseline in Cutaneous Lupus Area and Severity Index (CLASI) Activity Score During the ATEP by Time Point [Time Frame: Baseline to Weeks 1, 4, 12, 24, 36, 48, 60, 72, 84, 96 and follow-up at Week 100 during the ATEP.]
The CLASI Activity Score ranges from 0 to 70. To generate the activity score erythema is scored on a scale of 0 (absent) to 3 (dark red; purple/violaceous/crusted/hemorrhagic) and scale/hypertrophy are scored on a scale of 0 (absent) to 2 (verrucous/hypertrophic). Both the erythema and scale/hypertrophy scores are assessed in 13 different anatomical locations. In addition, the presence of mucous membrane lesions is scored on a scale of 0 (absent) to 1 (lesion or ulceration), the occurrence of recent hair loss is captured (1=yes; 0=no) and nonscarring alopecia is scored on a scale of 0 (absent) to 3 (focal or patchy in more than one quadrant). To calculate the CLASI activity score, all scores for erythema, scale/hypertrophy, mucous membrane lesions and alopecia are added together. Composite scores are calculated by summing the individual component scores. The higher the score, the greater the cutaneous disease activity.
10. Change From Baseline in the Physician's Global Assessment (PGA) Score During the ATEP by Time Point [Time Frame: Baseline to Weeks 1, 4, 12, 24, 36, 48, 60, 72, 84, 96 and follow-up at Week 100 during the ATEP.]
The physician's global assessment was administered by the treating physician and was used to gauge the participants overall state of health. The instrument uses a visual analogue scale with scores between 0 and 3 to indicate worsening of disease. The scoring is as follows: 0 = none 1 = mild disease 2 = moderate disease 3 = severe disease
11. Change From Baseline in the British Isles Lupus Assessment Group (BILAG) 2004 Global Score During the ATEP by Time Point [Time Frame: Baseline to Weeks 1, 4, 12, 24, 36, 48, 60, 72, 84, 96 and follow-up at Week 100 during the ATEP.]
The BILAG-2004 index measures clinical disease activity in systemic lupus erythematosus (SLE). A single alphabetic score (A through E) is used to denote disease severity for each of the 9 domains (constitutional, mucocutaneous, neuropsychiatric, musculoskeletal, cardiorespiratory, gastrointestinal, ophthalmic, renal, and hematologic). BILAG A represents the most active disease or severe disease; BILAG B represents intermediate activity or moderate disease; BILAG C represents stable mild disease; BILAG D represents organ system previously affected but now inactive; and BILAG E represents organ system never involved. The global BILAG score is the sum of a converted numerical score (A=9, B=3, C=1, D=0, E=0) over 9 domains. The theoretical range spans from 0 (no activity) to 13 active or severe disease activity BILAG. A higher score means more severe disease activity while a lower score means lower disease activity (or no disease activity for score of zero).
12. Change From Baseline in the Pericardial/Pleuritic Pain Scale During ATEP by Time Poimt [Time Frame: Baseline to Weeks 1, 4, 12, 24, 36, 48, 60, 72, 84, 96 and follow-up at Week 100 during the ATEP.]
The pericardial/pleuritic pain scale was scored using numerical values of 1 through 10 with 1 representing 'no pain' and 10 representing 'worst possible pain'. These were self-administered by the participants and gauged the severity of their SLE pain related to pericardial and pleuritic discomfort. Any indication from participants or study assessments, aside from pain, which indicated clinically significant pericardial or pleuritic manifestations of SLE was thoroughly investigated; if clinically significant SLE related complications were found, the participants was to be discontinued from the study and entered into the Observational Follow-up Period and treated appropriately.
13. Change From Baseline in the Fatigue Visual Analog Scale (VAS) During the ATEP by Time Point [Time Frame: Baseline to Weeks 1, 4, 12, 24, 36, 48, 60, 72, 84, 96 and follow-up at Week 100 during the ATEP.]
The Fatigue VAS evaluates SLE-related fatigue using a 0 to 100 mm VAS scale. The Fatigue VAS allowed the participant to indicate the degree of SLE-related fatigue by placing an "X" representing how they feel, along a visual analog line that extends between two extremes (e.g., from not at all tired to extremely tired) over the previous week. A decrease in the fatigue VAS indicates improvement.
14. Change From Baseline in the Cutaneous Lupus Area and Severity Index (CLASI) Damage Score During the ATEP by Time Point [Time Frame: Baseline to Weeks 1, 4, 12, 24, 36, 48, 60, 72, 84, 96 and follow-up at Week 100 during the ATEP.]
The CLASI Activity Score ranges from 0 to 70. To generate the activity score erythema is scored on a scale of 0 (absent) to 3 (dark red; purple/violaceous/crusted/hemorrhagic) and scale/hypertrophy are scored on a scale of 0 (absent) to 2 (verrucous/hypertrophic). Both the erythema and scale/hypertrophy scores are assessed in 13 different anatomical locations. In addition, the presence of mucous membrane lesions is scored on a scale of 0 (absent) to 1 (lesion or ulceration), the occurrence of recent hair loss is captured (1=yes; 0=no) and nonscarring alopecia is scored on a scale of 0 (absent) to 3 (focal or patchy in more than one quadrant). To calculate the CLASI activity score, all scores for erythema, scale/hypertrophy, mucous membrane lesions and alopecia are added together. Composite scores are calculated by summing the individual component scores. The higher the score, the greater the cutaneous disease activity.
15. Change From Baseline in the Systemic Lupus International Collaborating Clinics/American College of Rheumatology Systemic Lupus Erythematosus (SLICC/ACR SLE) Damage Index Score During the ATEP by Time Point [Time Frame: Baseline to Weeks 1, 4, 12, 24, 36, 48, 60, 72, 84, 96 and follow-up at Week 100 during the ATEP.]
SLICC/ACR score or damage index is a measure of cumulative damage due to Systemic Lupus Erythematosus (SLE). Damage is defined as nonreversible change (not related to active inflammation) occurring since onset of lupus, ascertained by clinical assessment and present for at least 6 months. Damage is defined for 12 separate organ systems: ocular (range 0-2), neuropsychiatric (0-6), renal (0-3), pulmonary (0-5), cardiovascular (0-6), peripheral vascular (0-5), gastrointestinal (0-6), musculoskeletal (0-7), skin (0-3), endocrine (diabetes) (0-1), gonadal (0-1) and malignancies (0-2). A score of 0=no damage, early damage is defined as ≥1. The total maximum score is 47, and increasing score indicates increasing disease damage severity.

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
Part 1
- The subject has an established diagnosis of systemic lupus erythematosus (SLE) as defined by the 1997 Update of the 1982 ACR Revised Criteria for Classification of SLE at screening. The diagnosis is fulfilled provided that at least 4 criteria are met.
- Disease history of SLE ≥ 6 months at baseline
- Females of childbearing potential (FCBP) must:
- Have two negative pregnancy tests as verified by the study doctor prior to starting study therapy. She must agree to ongoing pregnancy testing during the course of the study, and after end of study therapy. This applies even if the subject practices true abstinence from heterosexual contact.
- Either commit to true abstinence from heterosexual contact (which must be reviewed on a monthly basis) or agree to use, and be able to comply with, effective contraception without interruption, 28 days prior to starting IP, during the study therapy (including dose interruptions), and for 28 days after discontinuation of study therapy.
- Male subjects must:
- Must practice true abstinence or agree to use a condom during sexual contact with a pregnant female or a female of childbearing potential while participating in the study, during dose interruptions and for at least 28 days following IP discontinuation, even if he has undergone a successful vasectomy.
- If the subject is using oral corticosteroids, the daily dose must be less than or equal to 10 mg of prednisone or equivalent during the study; the dose must be stable over the 4 weeks preceding screening and throughout the study.
- All subjects taking hydroxychloroquine, chloroquine and/or quinacrine during the study must have documentation of a normal ophthalmologic examination performed within 1 year of the Baseline Visit.
- For subjects not taking corticosteroids, or antimalarials, the last dose (in case of previous use) must be at least 4 weeks prior to screening.
ATEP
- Male or female 18 years of age or older
- Understand and voluntarily sign an ICD prior to the initiation of any study related assessments/procedures
- Able to adhere to the study visit schedule and other protocol requirements. Pregnancy
- Females of childbearing potential (FCBP) must:
- Have two negative pregnancy tests as verified by the study doctor prior to starting study therapy. She must agree to ongoing pregnancy testing during the course of the study, and after end of study therapy. This applies even if the subject practices true abstinence* from heterosexual contact.
- Either commit to true abstinence* from heterosexual contact (which must be reviewed on a monthly basis) or agree to use, and be able to comply with, effective contraception without interruption, 28 days prior to starting IP, during the study therapy (including dose interruptions), and for 28 days after discontinuation of study therapy.
- Male subjects must:
- Practice true abstinence or agree to use a condom during sexual contact with a pregnant female or a female of childbearing potential while participating in the study, during dose interruptions and for at least 28 days following IP discontinuation, even if he has undergone a successful vasectomy. True abstinence is acceptable when this is in line with the preferred and usual lifestyle of the subject. (Periodic abstinence [eg, calendar, ovulation, symptothermal, post-ovulation methods] and withdrawal are not acceptable methods of contraception.)
- Male subjects must agree not to donate semen or sperm during therapy and for at least 90 days following the discontinuation of IP.
- All subjects must:
- Understand that the IP could have potential teratogenic risk
- Agree to abstain from donating blood while taking IP and for 28 days following discontinuation of the IP
- Agree not to share IP with another person
- Other than the subject, FCBP and males able to father a child should not handle the IP or touch the capsules unless gloves are worn
- Be counseled about pregnancy precautions and risks of fetal exposure as described in the Pregnancy Prevention Plan. Concomitant Medications
- If the subject is using oral corticosteroids, the daily dose must be less than or equal to 10 mg of prednisone or equivalent during the study; the dose must be stable over the 4 weeks preceding randomization and throughout the study.
- All subjects taking hydroxychloroquine, chloroquine or quinacrine during the study must have documentation of a normal ophthalmologic examination performed within 1 year of the Baseline Visit.
- For subjects not taking corticosteroids the last dose (in case of previous use) must be at least 4 weeks prior to screening.
Exclusion Criteria
- The subject has been treated with intra-articular, intramuscular or IV pulse corticosteroids within 4 weeks of screening.
- The subject has received high dose oral prednisone (> 100 mg/day) within 4 weeks of screening.
- The subject has received cyclophosphamide, azathioprine or mycophenolate mofetil within 12 weeks of screening.
- The subject has participated in a clinical trial and has received an investigational product within 30 days, 5 pharmacokinetic half-lives or twice the duration of the biological effect of the investigational product (whichever is longer) prior to screening; OR participation in two or more investigational drug trials within 12 months of screening.
- Unstable lupus nephritis defined as: proteinuria > 1.0 g/24 hour /1.73 m2 OR eGFR of less than 60 mL/1.73 m2 CNS disease, including active severe CNS lupus (including seizures, psychosis, organic brain syndrome, cerebrovascular accident (CVA), cerebritis or CNS vasculitis) requiring therapeutic intervention within 6 months of screening.
- The subject has New York Heart Association (NYHA) Class III or IV congestive heart failure.
- Presence of hepatitis B surface antigen (HBsAG). Subjects may have a positive anti-hepatitis B core antibody (anti-HBc) if the anti-hepatitis B surface antibody (anti-HBs) is positive as well.
- Antibodies to hepatitis C at Screening.
- The subject has a known positive history of antibodies to human immunodeficiency virus (HIV) or HIV disease or acquired immune deficiency syndrome (AIDs).
- Has a history of an organ transplant (e.g., heart, lung, kidney, liver) or hematopoietic stem cell/marrow transplant.
- Malignancy or history of malignancy, except for:
- treated (ie, cured) basal cell or squamous cell in situ skin carcinomas;
- treated (ie, cured) cervical intraepithelial neoplasia (CIN) or carcinoma in situ of the cervix with no evidence of recurrence within 5 years of Screening
- Systemic bacterial infections requiring treatment with oral or injectable antibiotics, or significant viral or fungal infections, within 4 weeks of Screening. Any treatment for such infections must have been completed and the infection cured, at least 2 weeks prior to Screening and no new or recurrent infections prior to the Baseline visit.
- History of venous thrombosis or any thromboembolic events within 2 years of screening.
- Clinical evidence of significant unstable or uncontrolled acute or chronic disease not due to SLE (ie, cardiovascular, pulmonary, hematologic, gastrointestinal, hepatic, renal, neurological, malignancy, psychiatric or infectious disease) which in the opinion of the investigator could put the subject at undue risk or confound study results.
- Presence of active uveitis or any other clinically significant ophthalmological finding.
- History or current diagnosis of peripheral or radicular neuropathy. Any clinically significant abnormalities on ECG, which, in the opinion of the investigator would interfere with safe participation in the study.

CONTACTS AND LOCATIONS

Contacts

Locations

United States, Alabama	University of Alabama at Birmingham	Birmingham
United States, Arizona	Arizona Arthritis and Rheumatology Research, PLLC	Paradise Valley
United States, Arizona	University of Arizona Clinical and Translational Science Research Center	Tucson
United States, California	UCSD Center for Innovative Therapy	La Jolla
United States, California	Dermatology Research Associates	Los Angeles
United States, California	East Bay Rheumatology Medical Group Inc.	San Leandro
United States, California	Clinical Science Institute	Santa Monica
United States, California	Los Angeles Biomedical Research Institute at Harbor - UCLA	Torrance
United States, California	Inland Rheumatology Clinical Trials	Upland
United States, Florida	Vipul Joshi, MD, PA, dba Bay Area Arthritis and Osteoporosis	Brandon
United States, Georgia	Emory University School of Medicine	Atlanta
United States, Georgia	Advanced Medical Research	Atlanta
United States, Georgia	Arthritis Research and Treatment Center	Stockbridge
United States, Illinois	Northwestern Medical Group; Department of Dermatology	Chicago
United States, Illinois	Northshore University Health System	Skokie
United States, Illinois	Southern Illinois University School of Medicine	Springfield
United States, Louisiana	Tulane University Health Sciences Center	New Orleans
United States, New York	Northwell Health / Division of Rheumatology	Lake Success
United States, New York	Feinstein Institute For Medical Research	Manhasset
United States, New York	NYU Langone Medical Center	New York
United States, New York	Columbia Presbyterian Medical Center	New York
United States, New York	Univ of Rochester Medical Center	Rochester
United States, North Carolina	DJL Clinical Research	Charlotte
United States, Ohio	MetroHealth Medical Systems	Cleveland
United States, Ohio	Ohio State University Medical Center	Columbus
United States, Ohio	University of Toledo Medical Center	Toledo
United States, Oklahoma	Oklahoma Medical Research Foundation	Oklahoma City
United States, Pennsylvania	Altoona Center for Clinical Research	Duncansville
United States, Pennsylvania	University of Pennsylvania Health Systems	Philadelphia
United States, Pennsylvania	UMPC Lupus Center of Excellence	Pittsburgh
United States, South Carolina	Low Country Rheumatology PA	Charleston
United States, Texas	Austin Regional Clinic	Austin
United States, Texas	University of Texas Health Science Center at Houston	Houston
United States, Virginia	Virginia Clinical Research, Inc.	Norfolk
United States, Washington	Seattle Arthritis Clinic	Seattle

Sponsors and Collaborators

Celgene

Investigator

Study Director : Shimon Korish, M.D. Celgene

MORE INFORMATION

Responsible Party : Celgene

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