# Supplementary Materials

**Supplementary Table S1.** Inclusion and exclusion criteria for Stage I of the study.

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| **Inclusion criteria** |
| 1. Adult males and females ≥20 years at the time of consent
2. Written informed consent obtained from the subject/legal representative prior to performing any protocol-related procedures, including screening evaluations
3. Diagnosis of SLE: Patients had previously met ≥4 of the 11 revised ACR criteria
4. Positive ANA at ≥1:80 serum dilution documented in the past or at screening
5. At least 1 system with a score of A or 2 systems with a score of B on the BILAG index at screening, or had a SELENA-SLEDAI score ≥6
6. Women who were surgically sterile or at least 2 years post-menopausal, or were able to practice abstinence or use an effective method of avoiding pregnancy (including oral contraceptives, intrauterine device, or sterile sexual partner) in addition to the use of condoms (male or female condoms) from screening through the end of the study
7. Men who were surgically sterile or were able to practice two effective methods of birth control from Study Day 1 through the end of the study
8. Ability to complete study period of 365 days as required by the protocol
9. Willing to forego other forms of experimental treatment during the study
10. Female whose cervix had been surgically removed or who had had the documented result of a PAP smear with no evidence of malignancy within 6 months prior to Day
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| **Exclusion criteria** |
| 1. Weight <40 kg
2. Had received prednisone >20 mg/day (or an equivalent dose of another oral corticosteroid) within 14 days before Visit 2 (Day 1)
3. Had received the following medications within 28 days before Visit 2 (Day 1):
* Systemic cyclophosphamide at any dose
* Cyclosporine at any dose
* Tacrolimus at any dose
* Thalidomide at any dose
* Mycophenolate mofetil >2 g/day
* Methotrexate >15 mg/week
* Azathioprine >2 mg/kg/day
1. Had received leflunomide >20 mg/day in the 6 months prior to Visit 2 (Day 1)
2. Had received fluctuating doses of the following within 28 days before Visit 2 (Day 1):
* Mycophenolate mofetil
* Methotrexate
* Leflunomide
* Azathioprine
* Mizoribine

Or fluctuating doses of the following within 14 days before Visit 2 (Day 1):* Oral NSAID (Nonsteroidal anti-inflammatory drug) or oral corticosteroids
1. Vaccination with live attenuated viruses within 28 days before Visit 2 (Day 1)
2. Treatment with immunoglobulin or blood products within 28 days before Visit 2 (Day 1)
3. Patients who were treated with immunoabsorption therapy and/or plasma exchange therapy within 28 days before the Visit 2 (Day 1)
4. Treatment with any investigational drug therapy within 28 days before Visit 2 (Day 1) into the study, B cell-depleting therapies within 12 months before Visit 2 (Day 1), or biologic therapies within 30 days or 5 half-lives of the biologic agent, whichever was longer, before Visit 2 (Day 1)
5. History of primary immunodeficiency
6. History of allergic reactions likely to be exacerbated by any component of the study drug or by hamster protein, or hypersensitivity to other humanized monoclonal antibodies
7. History of any disease, evidence of any current disease (other than SLE), any finding upon physical examination, or any laboratory abnormality that, in the opinion of the investigators, may compromise the safety of the subject in the study or confound the analysis of the study
8. Clinically significant cardiac disease, including: unstable angina; myocardial infarction within 6 months; congestive heart failure; arrhythmia requiring active therapy, with the exception of clinically insignificant extra systoles, or minor conduction abnormalities; and history of clinically significant abnormality on ECG
9. Either of the following conditions was met:
* Clinical significant active infection, including ongoing ,chronic infection within 28 days before Day 1 (except for Chronic nail bed fungal infections)
* Any infection requiring hospitalisation or treatment with IV anti-infectives within 28 days before Day 1
* Treatment with oral anti-infectives within 14 days before Day 1
1. Evidence of infection with hepatitis B or C virus, or HIV-1 or HIV-2, or active infection with hepatitis A, as determined by results of testing at screening. Regarding hepatitis B virus, HBsAg, HBsAb and HBcAb were measured, then 1) patient with positive for HBsAg, 2) in case of patient with positive for HBcAb but negative for HBsAg, patient with HBV DNA levels >200 copies/mL (quantified by real-time PCR)
2. A history of severe viral infection as judged by the investigators, including severe infections of either CMV or the herpes family such as disseminated herpes, herpes encephalitis, ophthalmic herpes
3. Herpes zoster ≤3 months prior to screening
4. History of active TB infection or newly positive TB skin test (defined as a reaction ≥10 mm in diameter if not on systemic immunosuppressive medication or ≥5 mm if on systemic immunosuppressive medication
5. History of latent TB infection without completion of an appropriate course of treatment
6. Subjects with mixed connective tissue disease and overlap syndromes of SLE with rheumatoid arthritis or scleroderma
7. Breastfeeding or lactating women
8. History of alcohol or drug abuse within the past 1 year
9. Presence of end-stage renal disease, or rapidly progressive glomerulonephritis
10. History of stroke, or any cerebrovascular disease requiring medication/treatment
11. Evidence of any malignant disease (except basal cell carcinoma or in situ carcinoma of the cervix treated with apparent success with curative therapy >1 year prior to entry)
12. Elective surgery planned from the time of screening through the end of the study
13. At screening (must be within 28 days before Visit 2 [Day 1]) any of the following:
* AST >2.5x upper limit of normal range
* ALT >2.5x upper limit of normal range
* Creatinine >2x upper limit of normal
* Serum K above or below the normal range
* Hemoglobin <8 g/dl
* White blood cell count <1,800/mm3
* Neutrophils <1,500/mm3
* Platelet count <50,000/mm3
* Other abnormal laboratory values in the screening panel that in the opinion of the principal investigator were judged to potentially confound analysis of study results
1. Any condition that, in the opinion of the investigator, would interfere with evaluation of the investigational product or interpretation of subject safety or study results
2. Concurrent enrolment in another clinical study
3. Employees of the clinical study site or any other individuals involved with the conduct of the study, or immediate family members of such individuals
4. Women who appeared to be pregnant at Visit 1
5. Patients who had received herbal medicine (Oral administration) within 28 days before Visit2 (Day 1)
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| ACR: revised American College of Rheumatology; ALT: alanine aminotransferase; ANA: antinuclear antibody test; AST: aspartate aminotransferase; BILAG: British Isles Lupus Assessment Group; CMV: cytomegalovirus; ECG: electrocardiogram; HBcAB: hepatitis B core antibody; HBsAg: hepatitis B virus surface antigen; HIV: human immunodeficiency virus; NSAID: nonsteroidal anti-inflammatory drug; PCR: polymerase chain reaction; SELENA-SLEDAI: Safety of Estrogens in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index; SLE: systemic lupus erythematosus; TB: tuberculosis |