# Descartes-08 for Children, Adolescents, and Young Adults With Autoimmune Disorders

Status: RECRUITING

## Eligibility Criteria

Sex: ALL
Age: 12 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- At least age 12
- definitive diagnosis of childhood-onset systemic lupus erythematous, juvenile Myasthenie gravis, juvenile dermatomyositis and AAV
- Signs and symptoms of moderate disease
- History of systemic treatment
- Parent/Guardian/Patient must be able to give written informed consent

Exclusion Criteria:

- Major chronic illness that is not well managed at the time of study entry and in the opinion of the investigator may increase the risk to the patient;
- Abnormal PT/INR or PTT increased > 1.5-fold or patient is on anticoagulation therapy (except in cases of elevated PTT with documented lupus anticoagulant; or in patients who have been on stable doses of anticoagulation therapy for more than 6 months of VTE diagnosis; or in patients on stable doses of anticoagulation therapy for at least 8 weeks of atrial fibrillation diagnosis; these conditions will not be exclusionary unless, in the investigator's opinion, they make participation in the study unsafe);
- ANC < 1000 cells/microliter ;
- Hemoglobin < 8.0 g/dL ;
- Platelets < 50,000/mm3 (NOTE: platelet transfusions are permissible);
- ALT and/or AST with GGT ≥ 3× upper limit of normal
- Creatine Clearance less than 30mL/min /1.73 m2;
- History of primary immunodeficiency, organ, or allogeneic bone marrow transplant;
- Patients must be seronegative for hepatitis B surface antigen;
- Patients must be seronegative for hepatitis C antibody. If hepatitis C antibody test is positive, then patients must be tested for the presence of viremia by RT-PCR and must be HCV RNA negative;
- History of positive HIV or positive HIV at screening;
- Active tuberculosis or positive QuantiFERON test at screening;
- Any other laboratory abnormality that, in the opinion of the investigator, may jeopardize the subject's ability to participate in the study; 23. Any active significant cardiac or pulmonary disease not related to the primary indication as determined by principal investigator and medical monitor Note: Patients with asthma and COPD controlled with inhaled medications are allowed; 24. Any arterial or venous thromboembolic events in the past 3 months; 25. History of malignancy that required treatment in the past 3 years except for successfully-treated squamous cell and/or basal cell carcinoma of the skin and/or breast or colon cancer that is surgically removed and did not require adjuvant chemotherapy or radiotherapy; 26. Treatment with any investigational agent within 4 weeks of screening or 5 half-lives of the investigational drug (whichever is longer); 27. Receipt of a live vaccination within 4 weeks prior to baseline (Day 1) or intent to receive live vaccination during the study (Note: mRNA-based vaccines such as those against SARS-CoV-2 are not considered live; likewise, the Janssen Covid-19 vaccine is not live); 28. History of significant recurrent infections or any active infection that may interfere with the patient's participation in the opinion of the investigator; 29. Any known psychiatric illness that may interfere with the patient's participation in the study in the opinion of the investigator.

## Conditions & Interventions

Interventions:
DRUG: Descartes-08
Conditions:
Childhood-onset Systemic Lupus Erythematous, ANCA-Associated Vasculitis (AAV), Juvenile Myasthenia Gravis, Juvenile Dermatomyositis

## More Information

Description:
Safety, tolerability and efficacy of Descarte-08 in children, adolescents and young adults with childhood-onset systemic lupus erythematosus, ANCA-associated vasculitis, juvenile myasthenia gravis, and juvenile dermatomyositis

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