

## A Phase III, Randomized, Double-blind, Parallel-group, Placebo-controlled Study to evaluate the Pharmacokinetics, Pharmacodynamics, Efficacy, and Safety of IV anifrolumab in Pediatric Participants 5 to < 18 Years of Age with Moderate to Severe Active Systemic Lupus Erythematosus While on Background Standard of Care Therapy

**Status:** Recruiting

### Eligibility Criteria

**Sex:** Male or Female

**Age Group:** Up to 18 years old

This study is NOT accepting healthy volunteers

#### Inclusion Criteria:

- 5 years to less than 18 years old - weight at least 15 kg (33 pounds) - diagnosis of Systemic Lupus Erythematosus (SLE) - being treated with prednisone, or antimalarial drugs - no active or chronic TB or contact with someone who has TB - females and males must be willing to use birth control during the study - see link to [clinicaltrials.gov](https://clinicaltrials.gov) for complete inclusion & exclusion criteria

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#### Exclusion Criteria:

- history of suicidal ideation within the past 6 months; or any suicidal behavior within the past 12 months - history of multiple infections requiring hospitalization and IV antibiotics over the past year - history of cancer - history of severe COVID-19 infection - prior treatment with anifrolumab

### Conditions & Interventions

#### Conditions:

Arthritis & Rheumatic Diseases, Immune Diseases, Rare Diseases

#### Keywords:

Diagnosis of SLE, Lupus, Systemic Lupus Erythematosus

### More Information

**Description:** Systemic lupus erythematosus (SLE) is a chronic autoimmune disease that can affect various organs of the body, especially the skin, joints, blood, kidneys and central nervous system. "Chronic" means that it can last for a long time. "Autoimmune" means that there is a disorder of the immune system, which, instead of protecting the body from bacteria and viruses, attacks the one's own tissues. We are doing this study to see if the investigational medication called anifrolumab may have an effect in treating pediatric SLE, to see how well it is tolerated or how safe it is, to measure levels of anifrolumab in the blood and learn more about the disease and associated health problems.

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**Phase:** PHASE3

**IRB**

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