The Paisley Study is a Phase 2, randomized, double-blind, placebo-controlled research study to evaluate an oral investigational drug, BMS-986165, in participants with systemic lupus erythematosus (SLE).

**RANDOMIZATION GOAL**
Approximately 360

**PARTICIPATING COUNTRIES**
- Argentina
- Brazil
- Bulgaria
- Colombia
- France
- Germany
- Hungary
- Israel
- Japan
- Korea (South)
- Mexico
- Poland
- Romania
- Russia
- Taiwan
- Ukraine
- United States

**RESEARCH STUDY FOCUS**
The objective of this research study is to evaluate the efficacy and safety of treatment with BMS-986165 in patients with SLE. The research study is also attempting to determine the dose that provides the optimal balance of efficacy and safety.

**ABOUT THE INVESTIGATIONAL DRUG**
BMS-986165 is a highly selective small molecule inhibitor of tyrosine kinase 2 (Tyk2). Several lines of evidence indicate that Tyk2 inhibition may reduce SLE disease activity. Experience in nonclinical models supports the potential benefits of treatment with BMS-986165 for SLE and other immune-mediated conditions.

**COMPARATOR TREATMENT**
Placebo

**ELIGIBILITY OVERVIEW** *
- Males and females, aged 18–75 years
- Diagnosis of moderate to severe SLE
  - Meets the Systemic Lupus International Collaborating Clinics (SLICC) classification criteria for SLE
  - Either elevated antinuclear antibodies (ANA) ≥1:80 OR positive anti-double-stranded DNA (dsDNA) (positive includes indeterminate results) OR positive anti-Smith (anti-Sm)
  - Total SLEDAI-2K score ≥6 points and clinical SLEDAI-2K score ≥4 points with joint involvement and/or rash
  - At least 1 of the following:
    - BILAG A or B grade in the mucocutaneous body system
    - Modified BILAG A or B score in the musculoskeletal body system due to active polyarthritis
    - If only 1 B and no A grade are present in the mucocutaneous body system or in the musculoskeletal body system due to arthritis, then at least 1 B grade must be present in 1 of the other body systems, for a total of 2 BILAG B body system grades
- On stable dose of background therapy with immunosuppressants/antimalarials; corticosteroid therapy is permitted but not required
- No other autoimmune diseases except for type I autoimmune diabetes mellitus, thyroid autoimmune disease, and secondary Sjögren’s syndrome
- No prior exposure to Tyk2 inhibitors, anifrolumab, rontalizumab, or ustekinumab

*For complete inclusion/exclusion criteria, see sections 5 and 6 of the study protocol.*
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**STUDY DESIGN**

Participants will be randomized into 1 of 4 treatment groups. There is a 1 in 4 chance participants will receive placebo.

- Participation will last about 56 weeks
  - Screening is up to 28 days
  - The treatment period is 48 weeks long
  - For all groups, there will be a 28-day follow-up

- Dosing is twice daily (capsules)

Subjects' background SLE medication continues on study; must be taken for ≥ 12 weeks and stable for ≥ 8 weeks before screening visit.

*Study treatment assignment is based upon twice daily dosing at the assigned dose.*

**Primary Efficacy Endpoint Analysis**

- Participants will be randomized into 1 of 4 treatment groups. There is a 1 in 4 chance participants will receive placebo.
- Participation will last about 56 weeks
  - Screening is up to 28 days
  - The treatment period is 48 weeks long
  - For all groups, there will be a 28-day follow-up
- Dosing is twice daily (capsules)