

# A Study to Evaluate the Safety and Activity of SAR448501/DR-0201 in Patients With Autoimmune Rheumatic Diseases

NCT06647069

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| Status     | RECRUITING      |
| Phase      | Phase 1         |
| Sponsor    | Sanofi          |
| Enrollment | 62 participants |

## Plain Language Summary

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This study is testing DR-0201, a new experimental drug, in patients with active autoimmune diseases including lupus (SLE or cutaneous lupus), primary Sjögren's syndrome, inflammatory muscle diseases (polymyositis/dermatomyositis), or early diffuse systemic sclerosis (a connective tissue disease affecting the skin and organs).

**\*\*You may be eligible if...\*\***

- You are between 18 and 75 years old
- You have been diagnosed with one of the following: lupus (SLE or CLE), primary Sjögren's syndrome, polymyositis/dermatomyositis, or diffuse systemic sclerosis diagnosed within the past 3 years
- Your disease is active but stable, and your doctor does not expect your treatment to need changing for the next 3–4 months
- You are willing to undergo tissue biopsies (skin, salivary gland, or muscle depending on your condition)
- You are using effective contraception if of childbearing potential

**\*\*You may NOT be eligible if...\*\***

- Your disease is not one of the specific diagnoses listed
- You have lupus or cutaneous lupus with skin scores below the required threshold
- You are not willing to undergo biopsies
- You are pregnant or breastfeeding

Talk to your doctor to see if this trial is right for you.

## Key Eligibility Criteria

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### Inclusion (15)

- Diagnosis of SLE and/or RA. American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) classification criteria should be used.
- Contraception during the study intervention period and for at least 140 days after the last administration of study intervention: Male participants must agree to refrain from donating or cryopreserving sperm, and either be abstinent or use contraception/barrier. Female participants must use of a highly effective contraceptive measure for all females of childbearing potential. Females of childbearing potential need to have a negative serum pregnancy test within 7 days prior to the first dose.
- Specific to Systemic Lupus Erythematosus (SLE):
- Systemic Lupus Erythematosus Disease Activity Index-2000 (SLEDAI-2K) score e8 at screening with at least 4 points from clinical features at screening.
- At least 1 British Isles Lupus Assessment (BILAG) A score or 1 BILAG B score at screening
- ... and 10 more (see full listing online)

### Exclusion (23)

- Severe manifestation of the selected autoimmune rheumatic diseases under study that could impact participant safety, or is likely to require interventions that will affect investigational drug PD.
- <https://clinicaltrials.gov/study/NCT06647069>

- Receipt of super-high potency (eg, clobetasol propionate, betamethasone dipropionate) or high potency (eg, fluocinonide, methylprednisolone aceponate) topical corticosteroids within 28 days prior to screening, had dose changes in other topical corticosteroids within 14 days prior to Day 1, or had dose changes in nonsteroidal topical immunosuppressants within 28 days prior to Day 1.
  - Received dose changes of mycophenolate mofetil, methotrexate, leflunomide, calcineurin inhibitors, JAK inhibitors, or azathioprine within 28 days prior to Day 1.
  - Receipt of any of the following medications within 6 months of Day 1: cyclophosphamide, leflunomide  $\geq 20$  mg/day, abatacept.
  - Receipt of any mAb or experimental immunomodulator within 28 days or 5 published half-lives prior to Day 1, whichever is longer.
- ... and 18 more (see full listing online)

## Locations (8 total)

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Investigational Site Number : 001-203, Brisbane, Queensland, Australia

Investigational Site Number : 001-201, Melbourne, Victoria, Australia

Investigational Site Number : 001-402, Mostar, Bosnia and Herzegovina

... and 5 more locations