

# SM101 In systemic lupus erythematosus patients with or without a history of lupus nephritis

<b>Submission date</b> 30/06/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 25/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 14/12/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

In autoimmune diseases such as systemic lupus erythematosus (SLE), the immune system has lost the ability to discriminate between body-own ('self') and foreign proteins. In consequence, antibodies are generated to attack 'self'-proteins and form immune complexes which continuously activate the immune system through binding to specific immune cells in the body. As a result, the activated immune system can lead to severe organ damage, including the kidney. This study investigates a new treatment for preventing and/ or ameliorating SLE in patients with or without a history of lupus nephritis ((prolonged inflammation of kidneys). Previous investigations in SLE animal studies suggest that the drug SM101 competes with the immune complex binding and has the potential to prevent organ damage caused by the activated immune system. The aim of this study is to investigate the safety and efficacy of SM101 in the treatment of SLE patients with or without a history of lupus nephritis and a SELENA-SLEDAI score of  $\geq 6$ .

### Who can participate?

SLE patients with or without a history of lupus nephritis and a SELENA-SLEDAI score of  $\geq 6$ .

### What does the study involve?

The study includes 10 visits for non-pharmacokinetic (PK) patients and 13 visits for PK patients. There is a 3 weeks screening period, a 4 weeks treatment and a 5 months follow-up period.

### What are the possible benefits and risks of participating?

Previous studies suggest that SM101 appears to be generally well tolerated and safe. However, some patients may experience some adverse reactions which have not been reported so far. The side effects may be a minor inconvenience or could be severe. Patients will be watched closely for any side effects, and the drug will be stopped if serious side effects develop.

### Where is the study run from?

Thirty clinical trial sites for the SMILE study are located in Australia, Belgium, Czech Republic, France, Germany, Italy, Netherlands, Poland, Spain and UK.

When is the study starting and how long is it expected to run for?  
The first enrolment of patients is planned for August 2011 with a recruitment period of 14 months until October 2012.

Who is funding the study?  
SuppreMol GmbH (Germany)

Who is the main contact?  
Sascha Tillmanns, Medical Director, SuppreMol GmbH  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Sascha Tillmanns

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
SM101-201-sle-10

## Study information

**Scientific Title**  
Phase IIa, 2:2:1 randomised, double-blind, placebo-controlled, parallel group, multi-centre clinical trial to investigate the safety, efficacy and pharmacokinetics of recombinant human soluble Fc-gamma receptor IIb (SM101) for intravenous application in the treatment of systemic lupus erythematosus (SLE) patients with or without a history of lupus nephritis

**Acronym**  
SMILE

**Study objectives**

The human soluble Fcγ receptor SM101 competes with the binding of systemic lupus erythematosus (SLE)-specific immune complexes to effector cells and therefore interrupts the immunological cascade leading to inflammation and organ damage.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approval pending as of 30/06/2011

**Study design**

Phase IIa 2:2:1 randomised double-blind placebo-controlled parallel group multi-centre proof-of-concept clinical trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Systemic lupus erythematosus patients with or without a history of lupus nephritis

**Interventions**

Three treatment arms, two interventions groups and a placebo in parallel fashion:

1. Intervention group 1: 6 mg/kg/week SM101 for 4 weeks
2. Intervention group 2: 12 mg/kg/week SM101 for 4 weeks
3. Placebo

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

SM101

**Primary outcome measure**

Incidence of adverse events (AEs) during the study period according to Common Terminology Criteria for Adverse Events (CTCAE)

### **Secondary outcome measures**

1. Physical examination (screening)
2. Vital signs (screening, treatment, follow-up)
3. Body temperature (screening, treatment, follow-up)
4. Body weight (screening, treatment)
5. Electrocardiogram (ECG) (screening, treatment, follow-up)
6. Safety laboratory assessments (screening, treatment, follow-up)
7. Anti-drug antibody (ADA) (treatment, follow-up)
8. AE recording (continuously)
9. Overall and renal disease score assessments, proteinuria, urine sediment, glomerular filtration rate (GFR), biological markers, anti-double-stranded DNA (dsDNA), anti-C1q, C3, C4, urinary neutrophil gelatinase-associated lipocalin (uNGAL) (continuously)
10. Use of rescue medication (all during screening, treatment, follow-up)

### **Overall study start date**

01/08/2011

### **Completion date**

01/07/2013

## **Eligibility**

### **Key inclusion criteria**

1. Patient has provided written informed consent prior to any study-related procedure
2. Male or female adult patients aged 18 years or older
3. Diagnosis of SLE meeting at least four revised main classification criteria of the American College of Rheumatology (ACR) with or without a history of glomerulonephritis
4. Clinically active patients with a SLE Disease Activity Index (SELENA-SLEDAI) score of  $\geq 6$
5. Patients with a current serological active status (anti-dsDNA or C3)
6. Concurrent maintenance immunosuppressant SLE treatment (if any) with prednisone alone or in combination with either azathioprine or mycophenolate mofetil
7. Adequate liver function

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

50 patients

**Key exclusion criteria**

1. Patient is intended to receive immunosuppressive SLE treatment other than listed in the inclusion criteria
2. Patients with proteinuria > 3.5 g/day at baseline or glomerular filtration rate (GFR) < 60 mL/min/1.73 m<sup>2</sup>
3. Patients with active SLE neurological disorders
4. Patients with an acute British Isles Lupus Assessment Group (BILAG) score defined as ≥ 1 BILAG A score or ≥ 2 BILAG B scores
5. History of class VI glomerulonephritis
6. Patients with non-lupus related renal disease such as microthrombotic disease associated with antiphospholipid syndrome
7. Patients with other acute infections
8. Patient received any B cell depleting therapy

**Date of first enrolment**

01/08/2011

**Date of final enrolment**

01/10/2012

**Locations****Countries of recruitment**

Australia

Belgium

Czech Republic

France

Germany

Italy

Poland

Spain

United Kingdom

**Study participating centre**

**SuppreMol GmbH**

Martinsried/Munich

Germany

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# Sponsor information

## Organisation

SuppreMol GmbH (Germany)

## Sponsor details

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## Sponsor type

Industry

## ROR

<https://ror.org/05jgtkc28>

# Funder(s)

## Funder type

Industry

## Funder Name

SuppreMol GmbH (Germany)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration