# Assessment of safety, pharmacokinetics and efficacy in a combination treatment with SMP-114

Submission date 15/02/2006	<b>Recruitment status</b> Stopped	[X] Prospectively registered [_] Protocol
<b>Registration date</b> 23/02/2006	<b>Overall study status</b> Stopped	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 10/09/2019	<b>Condition category</b> Musculoskeletal Diseases	<ul> <li>Individual participant data</li> <li>Record updated in last year</li> </ul>

### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

#### **Type(s)** Scientific

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#### **Contact details**

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# Additional identifiers

EudraCT/CTIS number

#### **IRAS number**

ClinicalTrials.gov number NCT00296257

**Secondary identifying numbers** D2450174

# Study information

#### Scientific Title

A phase II, multicentre, randomised, double-blind, placebo-controlled study evaluating the efficacy, safety and pharmacokinetics of two doses of a candidate disease modifying antirheumatic drug (DMARD) (SMP-114, 120 mg and 240 mg once daily) administered in combination with ongoing methotrexate treatment in patients with active rheumatoid arthritis

Acronym ASPECTS

**Study objectives** SMP-114 in combination with methotrexate is more efficacious than methotrexate alone.

**Ethics approval required** Old ethics approval format

Ethics approval(s) Local medical ethics committee (UK) , 29/01/2006, ref: 05/Q0501/170

**Study design** Randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Not specified

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 Rheumatoid arthritis (RA) Interventions SMP-114 (120 mg and 240 mg) in combination with methotrexate compared to r

SMP-114 (120 mg and 240 mg) in combination with methotrexate compared to methotrexate alone.

Intervention Type Drug

#### Phase

Phase II

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

SMP-114, methotrexate

#### Primary outcome measure

The efficacy of SMP-114 (120 mg and 240 mg) versus placebo in terms of the percentage of patients meeting the ACR criteria for 20% improvement in RA (ACR20) at week 24.

#### Secondary outcome measures

1. The efficacy of SMP-114 (120 mg and 240 mg) versus placebo after 24 weeks in terms of:

- 1.1. ACR50
- 1.2. ACR70
- 1.3. Disease Activity Score-28 (DAS28)
- 1.4. European League Against Rheumatism (EULAR) response
- 2. The efficacy of SMP-114 versus placebo in terms of change in:
- 2.1. Core variables
- 2.2. Time to response
- 2.3. Quality of life
- 2.4. Radiological measurements of joint damage
- 2.5. Assessment of safety and tolerability
- 2.6. Pharmacokinetics (PK) measurements

#### **Overall study start date**

28/02/2006

#### **Completion date**

21/07/2008

# Eligibility

#### Key inclusion criteria

1. Male or female patients aged at least 18, with rheumatoid arthritis (RA) for a minimum of six months

2. Has been receiving methotrexate treatment (stable for eight weeks)

3. Has active disease classified as American College of Rheumatology (ACR) functional class of I, ll or III

Participant type(s)

Patient

Age group

Adult

Lower age limit 18 Years

# Sex

Both

#### Target number of participants

Approximately 300 patients in total - 100 patients per arm

#### Key exclusion criteria

1. Has previously discontinued DMARD therapy due to hepatic intolerance

2. Has received any DMARD in addition to methotrexate during the four weeks prior to randomisation

3. Is receiving more than two DMARDs in addition to methotrexate at the time of screening 4. Is receiving or has received gold, leflunomide or biological agents including tumour necrosis factor (TNF) or Interleukin 1 (IL-1) inhibitors within the eight weeks prior to randomisation 5. Has previously failed two or more DMARDS

#### Date of first enrolment

28/02/2006

Date of final enrolment 13/07/2007

## Locations

#### **Countries of recruitment** Czech Republic

England

Germany

Hungary

Netherlands

Poland

United Kingdom

**Study participating centre Dainippon Sumitomo Pharma Europe Ltd (UK)** London United Kingdom SW1E 6QT

# Sponsor information

#### **Organisation** Dainippon Sumitomo Pharma Europe Ltd (UK)

Sponsor details

Southside 97-105 Victoria Street London United Kingdom SW1E 6QT

**Sponsor type** Industry

ROR https://ror.org/03sh4z743

## Funder(s)

Funder type Industry

**Funder Name** Dainippon Sumitomo Pharma Europe Ltd (UK)

## **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