

# A ten week randomised, double-blind, parallel-group, placebo-controlled phase II study to investigate the extent of symptom relief and the safety and tolerability of SMP-986 (20 mg, 40 mg, 80 mg and 120 mg) administered once daily for eight weeks to patients with overactive bladder syndrome

<b>Submission date</b> 01/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/12/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/04/2019	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

EudraCT/CTIS number

2006-003730-15

**IRAS number**

**ClinicalTrials.gov number**

NCT00409539

**Secondary identifying numbers**

D3601113

## **Study information**

**Scientific Title**

A ten week randomised, double-blind, parallel-group, placebo-controlled phase II study to investigate the extent of symptom relief and the safety and tolerability of SMP-986 (20 mg, 40 mg, 80 mg and 120 mg) administered once daily for eight weeks to patients with overactive bladder syndrome

**Study objectives**

SMP-986 demonstrates greater efficacy in reducing the symptoms of OverActive Bladder Syndrome (OABS) compared to placebo.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval has been received in the following countries on the dates provided:

1. Estonia, 11/10/2006, Tallinn Medical Research Ethics Committee (ref: 947)
2. Latvia, 07/11/2006, Ethics Committee for Clinical Research of Medicines and Pharmaceutical Products (ref: 201006-6E)
3. Lithuania, 22/11/2006, Lithuanian Bioethics Committee (N° EudraCT: 2006-003730-15)
4. Poland, 09/11/2006, The Ethics Committee at Instytut Centrum Zdrowia Matki Polki (N° EudraCT: 2006-003730-15)
5. US central IRB, 09/11/2006, Copernicus Group IRB, NC (N° EudraCT: 2006-003730-15)
6. Spain, 12/01/2007, Ethic Committee of Hospital Universitario de Canarias(N° EudraCT: 2006-003730-15)
7. Germany, 05/01/2007, Ethics Committee of the Medical Faculty, Ludwig-Maximilians-University (N° EudraCT: 2006-003730-15)
8. UK, 22/01/2007, Huntingdon Local Research Ethics (ref: 06/Q0104/119)
9. France, 08/03/2007, Paris CPP (ref: 2006/61)

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

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

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

OverActive Bladder Syndrome (OABS)

**Interventions**

Added 06/08/2008: Patient follow-up was completed on the 05/06/2008.

SMP-986 (20mg, 40mg, 80mg, 120 mg) or placebo. The treatment is delivered as tablets taken orally for a total of ten weeks.

**Intervention Type**

Drug

**Phase**

Phase II

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

SMP-986

**Primary outcome measure**

To quantify the extent of symptomatic relief provided by 20, 40, 80 and 120 mg SMP 986 (once daily [o.d.]) following eight-weeks of treatment in patients with OABS.

**Secondary outcome measures**

1. To assess the safety and tolerability of 20, 40, 80 and 120 mg SMP 986 (o.d.) following eight-weeks of treatment in patients with OABS
2. To determine the most clinically appropriate dose range for SMP-986 in terms of treatment benefit (efficacy, safety, tolerability and Quality of Life outcomes)

**Overall study start date**

01/12/2006

**Completion date**

19/06/2008

**Eligibility****Key inclusion criteria**

1. Males, or females who are not of child bearing potential. Female subjects must be either postmenopausal, surgically sterile or using a highly effective non oral form of contraception.
2. Aged 20 to 80 years (inclusive)

3. Diagnosis of OABS based on symptomatic reporting over a period of more than six months (micturition frequency, and urgency with or without incontinence) prior to screening.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Approximately 710 patients

**Key exclusion criteria**

1. Patients with an indication of any bladder outlet obstruction or polyuria
2. Patients with the following conditions, or who have undergone the following procedures, will be excluded:
  - 2.1. Stress urinary incontinence
  - 2.2. Pelvic organ prolapse (more than stage two)
  - 2.3. Genitourinary or lower bowel surgery (within 12 months prior to screening),
  - 2.4. Pathological conditions including poorly controlled diabetes, painful bladder syndrome /interstitial cystitis or history of chronic urinary tract infection
  - 2.5. Neurological conditions including multiple sclerosis, Parkinson's disease or neuropathy
3. Patients will also be excluded if they have an indwelling catheter or perform intermittent self catheterisation
4. Patients should not have a current or past medical condition contraindicating the use of antimuscarinics and must have discontinued use of the following drugs:
  - 4.1. Drugs used to treat OABS or urinary incontinence
  - 4.2. Cholinergics
  - 4.3. Anticholinergics
  - 4.4. Alpha adrenergic antagonists
  - 4.5. Opioid analgesics
  - 4.6. Compound analgesics containing an opioid
  - 4.7. Warfarin
5. Patients with a current or past malignancy (within the last five years), and patients who have ever had a tumour affecting the genitourinary tract (not including benign prostatic hyperplasia)
6. Patients will be ineligible if they have a clinically significant cardiac, neurological, hepatic, renal, respiratory, haematological or gastrointestinal disorder (including, a significant history of constipation or an active bowel disease e.g. inflammatory bowel disease) or any other illness which in the opinion of the Investigator would preclude the safe or compliant participation of a subject
7. Patients unable to complete the study diary

**Date of first enrolment**

01/12/2006

**Date of final enrolment**

19/06/2008

# Locations

## Countries of recruitment

England

Estonia

France

Germany

Latvia

Lithuania

Poland

Spain

United Kingdom

United States of America

## Study participating centre

### Clinical Department

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

## Website

<http://www.ds-pharma.co.jp/english/index.html>

**ROR**

<https://ror.org/03sh4z743>

## Funder(s)

### Funder type

Industry

### Funder Name

Dainippon Sumitomo Pharma Co., Ltd (UK)

### Alternative Name(s)

Dainippon Sumitomo Pharma Co., Ltd.

### Funding Body Type

Private sector organisation

### Funding Body Subtype

For-profit companies (industry)

### Location

Japan

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>				No	No
<a href="#">Basic results</a>				No	No