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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

Submission date
01/12/2006

Registration date
19/12/2006

Last Edited
15/04/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-003730-15

ClinicalTrials.gov (NCT)
NCT00409539

Protocol serial number
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 (Nº EudraCT: 2006-003730-15)
4. Poland, 09/11/2006, The Ethics Committee at Instytut Centrum Zdrowia Matki Polki (Nº EudraCT: 2006-003730-15)
5. US central IRB, 09/11/2006, Copernicus Group IRB, NC (Nº EudraCT: 2006-003730-15)
6. Spain, 12/01/2007, Ethic Committee of Hospital Universitario de Canarias(Nº EudraCT: 2006-003730-15)
7. Germany, 05/01/2007, Ethics Committee of the Medical Faculty, Ludwig-Maximilians-University (Nº 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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Estonia

France

Germany

Latvia

Lithuania

Poland

Spain

United States of America

Study participating centre
Clinical Department
London
United Kingdom
SW1E 6QT

Sponsor information

Organisation
Dainippon Sumitomo Pharma Europe Ltd (UK)

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

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?
Basic results				No	No
Basic results				No	No