PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

A 10-week Randomised, DB, PG, PC Phase 2 Study to Investigate the Extent of Symptom Relief and the Safety and Tolerability of SMP-986 (20, 40, 80 and 120 mg) Administered Once Daily for 8 Weeks to Patients With Overactive Bladder Syndrome

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

SMP-986 is a compound being developed for the treatment of overactive bladder syndrome (OABS). This clinical study is designed to test the hypothesis that SMP-986 at doses of 20mg, 40mg, 80mg or 120mg provides greater symptom relief in OABS compared to placebo. The hypothesis will be tested by measuring the change in mean voids/24 hrs after treatment with SMP-986 compared to placebo, as well comparing the change in: the severity of urgency episodes, mean number of urgency episodes/24 hr, mean number of incontinence episodes/24 hr and the mean void volume/void between SMP-986 and placebo.

Brief Summary in Scientific Language

A multicenter study conducted in patients with OABS comprising a 2-week single blind placebo run-in period followed by an 8-week randomized, double-blind, placebo controlled treatment period with patients randomized to receive 20 mg, 40 mg, 80 mg or 120 mg SMP 986 or placebo in a 1:1:1:1:1 ratio in parallel groups on an outpatient basis with study center visits.

Do you plan to share individual participant data with other researchers?

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[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004137**
- Date of Registration in DRKS: **2012/10/17**
- Date of Registration in Partner Registry or other Primary Registry: **2006/12/08**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT00409539 (ClinicalTrials.gov)**
- Sponsor-ID: **D3601113 (Dainippon Sumitomo Pharma Europe LTd.)**

Health condition or Problem studied

- Free text: **Overactive Bladder Syndrome (OABS)**
- ICD10: **N32.8 - Other specified disorders of bladder**

Interventions/Observational Groups

- Arm 1: **Drug: Placebo**
- Arm 2: **Drug: Placebo**
- Arm 3: **Drug: SMP-986**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, investigator/therapist, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Change From Baseline to Week 8 in the Number of Voids/24 Hours; time frame: 8 Weeks

Secondary Outcome

- To Assess the Safety and Tolerability of 20, 40, 80 and 120 mg SMP 986 (o.d) Following 8-weeks of Treatment in Patients With Over Active Bladder Syndrome; time frame: 8 Weeks; Treatment emergent adverse event summary

Countries of recruitment

- US **United States**
- EE **Estonia**
- FR **France**
- DE **Germany**
- LV **Latvia**
- LT **Lithuania**
- PL **Poland**
- ES **Spain**
- UK **United Kingdom**

Locations of Recruitment

- **Gem. Praxis fur Urologie und Mannerheilkunde, Berlin**
- **Klinische Forschung Berlin, Berlin**
- **Urologische Praxis, Berlin**
- **Urologische Praxis, Berlin**
- **Urologische Praxis, Buchholz**
- <style fontName='DejaVu Sans' isBold='true'>Gem. Praxis Jacobi & Hellmis, Duisburg</style>
- **Urologische Gem. Praxis, Düsseldorf**
- **Urologische Praxis, Düsseldorf**
- **Poststr. 25, Hagenow**
- **Urologische Gem. Praxis, Hamburg**
- **Urologische Praxisgemeinschaft, Hamburg**
- **Urologische Praxis, Leipzig**
- **Universitat Heidelberg, Mannheim**
- **HauptstraBe 10, Markkleeberg**
- **Beckenboden Zentrum Munchen, Munchen**
- **Josef-Retzer-Str. 46, München**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2006/12/31**
- Target Sample Size: **551**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **20 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

Main Inclusion Criteria:

- Males, or females who are not of child-bearing potential

- Aged 20-80 years (inclusive) with a diagnosis of OABS based on symptomatic reporting

over a period of 6 months (micturition frequency, and urgency with or without incontinence) prior to screening.

Exclusion criteria

Main Exclusion Criteria:

- Patients will be excluded if there is an indication of any bladder outlet obstruction or polyuria

- Patients with the following conditions, or who have undergone the following procedures, will be excluded:

- stress urinary incontinence

- pelvic organ prolapse (stage 2)

- genitourinary or lower bowel surgery (within 12 months prior to screening),

- pathological conditions including poorly controlled diabetes, painful bladder syndrome/interstitial cystitis or history of chronic urinary tract infection

- neurological conditions including multiple sclerosis, Parkinson's disease or neuropathy)

- Patients will also be excluded if they have an indwelling catheter or perform intermittent self catheterisation

- Patients should not have a current or past medical condition contraindicating the use of antimuscarinics and must have discontinued use of the following drugs:

- drugs used to treat OABS or urinary incontinence

- cholinergics

- anticholinergics

- alpha adrenergic antagonists

- opioid analgesics

- compound analgesics containing an opioid

- warfarin

- Patients with a current or past malignancy (within the last 5 years)

- Patients who have ever had a tumour affecting the genitourinary tract (not including benign prostatic hyperplasia) will be excluded.

- 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.

- Patients will be excluded if they are unable to complete the study diary

Addresses

■ **Primary Sponsor**

Sunovion

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Royal Hallamshire Hospital
Prof C Chappel

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Public Queries**

Royal Hallamshire Hospital
Prof C Chappel

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

■ **[---]***

[---]*

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2008/07/01**

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 5
- Last processed date by ClinicalTrials.gov: 2016/01/14
Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.