

# Efficacy and safety of S 38093 versus placebo in patients with mild to moderate Alzheimer's disease

<b>Submission date</b> 20/05/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/07/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/04/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration and not expected to be available in the future

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

2010-024626-37

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

## Study information

### Scientific Title

Efficacy and safety of three doses of S 38093 (2, 5 and 20 mg/day) versus placebo in patients with mild to moderate Alzheimer's disease

### Study objectives

To demonstrate efficacy of at least one dose of S 38093 as compared to placebo on primary endpoint

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

### Study design

A 24-week international, multi-centre, randomised, double-blind, placebo-controlled phase IIb study followed by a 24-week extension period

### 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

Mild to moderate Alzheimer's disease

### Interventions

1. 2, 5 or 20mg/day of S 38093 or placebo, orally, during a 24-week treatment period + 24-week treatment extension period
2. A 2-6-week selection period without study treatment will be followed by a 24-week double-blind treatment with 4-parallel groups (doses : 2, 5 and 20 mg/day of S38093 and placebo) and a 24-week optional treatment extension period (patients on placebo will be re-randomised to S 38093 2; 5 or 20mg) and a 2-week follow-up period
3. One tablet of S 38093 (2, 5 or 20mg) or placebo will be taken orally, once a day, during study participation from inclusion visit +1 until follow-up period

**Intervention Type**

Drug

**Phase**

Phase II

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

S 38093

**Primary outcome measure**

1. The Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog) 11-items 2. ADAS-Cog will be assessed at week 0, week 24, week 36 and week 48

**Secondary outcome measures**

1. Disability Assessment for Dementia (DAD)
2. DAD will be assessed at week 0, week 24 and week 48

**Overall study start date**

22/08/2011

**Completion date**

30/04/2014

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

1. Age 55-85 years
2. School education more than or equal to 4 years
3. Able to perform neuropsychological tests
4. Have adequate visual and auditory acuity with the usual corrective aids to allow neuropsychological testing
5. Have a responsible informant Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR) criteria for Dementia of the Alzheimer's type
6. National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria for probable Alzheimer's disease (AD)
7. Mini-Mental State Examination (MMSE) between 15 and 24

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

600

**Total final enrolment**

711

**Key exclusion criteria**

1. Inpatients
2. Female patients of child-bearing potential
3. Dementia due to any condition other than AD
4. History of epilepsy or solitary seizure
5. History or presence of Parkinson's disease or Parkinsonism
6. Major neurological or neurodegenerative conditions associated with significant cognitive impairment such as Multiple Sclerosis or Huntington's Disease
7. Major psychiatric conditions

**Date of first enrolment**

22/08/2011

**Date of final enrolment**

30/04/2014

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

Australia

Brazil

Bulgaria

Chile

Czech Republic

France

Germany

Hungary

Mexico

Portugal

Romania

Russian Federation

South Africa

**Study participating centre**

**CHU La Grave-Casselardit**  
Toulouse  
France  
31059

## **Sponsor information**

### **Organisation**

Institut de Recherches Internationales Servier (France)

### **Sponsor details**

50 rue Carnot  
Suresnes  
France  
92284

### **Sponsor type**

Industry

### **Website**

<http://www.servier.com/>

### **ROR**

<https://ror.org/034e7c066>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Institut de Recherches Internationales Servier (France)

## **Results and Publications**

### **Publication and dissemination plan**

Publication plan:

Summary results are published in <https://clinicaltrials.servier.com>.

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from <https://clinicaltrials.servier.com> if a Marketing Authorisation has been granted after 1st January 2014.

## IPD sharing plan summary

Available on request

## 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>			20/04/2020	No	No