

Efficacy and safety of two doses of S 90098 (1 and 2 mg/day), sublingual formulation for 8 weeks in out-patients with major depressive disorder: An 8-week randomised, double-blind, fixed dose, international, multicentre, placebo-controlled study with parallel groups, followed by an extension double-blind treatment period for 16 weeks

Submission date 27/03/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/04/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/04/2020	Condition category Mental and Behavioural Disorders	<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 and not expected to be available in the future

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2007-003312-65

Protocol serial number

CL2-90098-005

Study information

Scientific Title

Efficacy and safety of two doses of S 90098 (1 and 2 mg/day), sublingual formulation for 8 weeks in out-patients with major depressive disorder: An 8-week randomised, double-blind, fixed dose, international, multicentre, placebo-controlled study with parallel groups, followed by an extension double-blind treatment period for 16 weeks

Study objectives

To assess the antidepressant efficacy of S 90098 in outpatients suffering from major depressive disorder (MDD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

First ethics committee approval in France on 25/01/2008 (ref: 87-07, CPP Ile de France VI).

Study design

Randomised, double-blind, parallel group, placebo-controlled, multicentre, phase II study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Major depressive disorder

Interventions

Eight-week randomised treatment period with agomelatine orodispersible 1 or 2 mg/day versus placebo followed by an extension double-blind period for 16 weeks.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

S 90098

Primary outcome(s)

Hamilton Rating Scale for Depression (HAM-D), assessed from baseline to week 24

Key secondary outcome(s)

1. Safety
2. Sleep (Leeds Sleep Evaluation Questionnaire [LSEQ])
3. Long term efficacy
4. Pharmacokinetic

Outcome measures will be assessed from baseline to week 24.

Completion date

30/04/2009

Eligibility

Key inclusion criteria

1. Between 18 (or minimum legal age) and 70 years of age
2. Out-patients of both genders
3. Fulfilling Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria for major depressive disorder (MDD)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Total final enrolment

264

Key exclusion criteria

1. Women of childbearing potential without effective contraception
2. Patients meeting DSM-IV-TR current diagnosis of psychiatric disorder other than MDD

3. Any clinically relevant abnormality detected during the physical examination, electrocardiogram (ECG) or laboratory tests likely to interfere with the study conduct or evaluations

Date of first enrolment

25/02/2008

Date of final enrolment

30/04/2009

Locations

Countries of recruitment

Czech Republic

Estonia

Finland

France

Lithuania

Study participating centre

Centre Hospitalier de Sainte Anne CMME

PARIS cedex 14

France

75674

Sponsor information

Organisation

Institut de Recherches Internationales Servier (France)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Institut de Recherches Internationales Servier (France)

Results and Publications

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?
Basic results				No	No
Basic results			20/04/2020	No	No