ISRCTN38378163 https://doi.org/10.1186/ISRCTN38378163

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

Registration date
24/04/2008

Overall study status
Completed

Last Edited
20/04/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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).

Primary study design
Interventional

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

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