

# Phase I dose-escalation study of S 78454 in patients with solid tumour

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| <b>Submission date</b><br>13/05/2013   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>06/08/2013 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>18/04/2018       | <b>Condition category</b><br>Cancer               | <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

Prof Jean-Charles Soria

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CL1-78454-002

## Study information

Scientific Title

Phase I dose-escalation study of oral administration of Pan-Histone Deacetylase (HDAC) Inhibitor S 78454 in patients with solid tumour

**Study objectives**

To establish the safety profile, the optimal administration schedule and the recommended Phase II dose of S 78454 in patients with solid tumour.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Ethics committee Ile de France II (06/11/2009)

**Study design**

Monocentric non-randomised non-comparative open Phase I study

**Primary study design**

Interventional

**Secondary study design**

Non randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Solid tumours

**Interventions**

Capsules containing 20 mg and 100 mg / oral use / treatment duration is at the discretion of the investigator.

**Intervention Type**

Drug

**Phase**

Phase I

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

Pan-Histone Deacetylase (HDAC) Inhibitor S 78454

**Primary outcome measure**

1. Maximum tolerated dose (MTD)
2. Dose limiting toxicity (DLT) of S 78454. This is evaluated at the end of cycle 1.

### **Secondary outcome measures**

1. Safety profile at each visit
2. Pharmacokinetics (PK) and pharmacodynamics (PD) parameters: PK parameters are evaluated in cycle 1, and PD parameters during cycle 1, cycle 2 and cycle 3
3. Tumour response at baseline and every 2 cycles

### **Overall study start date**

22/02/2010

### **Completion date**

07/05/2012

## **Eligibility**

### **Key inclusion criteria**

1. Male or female patient aged > or equal to 18
2. Solid tumour with measurable or evaluable disease, that has relapsed or is refractory to conventional standard forms of therapy
3. Ability to swallow oral capsule(s) without difficulty
4. Estimated life expectancy > 12 weeks
5. Eastern Cooperative Oncology Group (ECOG) performance status less or equal to 1
6. Adequate haematological, renal and hepatic functions

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

Up to 60 patients

### **Key exclusion criteria**

1. Allogenic bone marrow transplant
2. Major surgery within previous 4 weeks
3. Chemotherapy within previous 3 weeks (6 weeks in case of nitrosoureas)
4. Radiotherapy within previous 4 weeks (except for palliative radiotherapy at localised lesions)
5. Immunotherapy or hormonotherapy within previous 2 weeks, except stable luteinizing hormone-releasing hormone (LHRH) agonist therapy for prostate cancer, stable oral glucocorticoid and mineralocorticoid replacement for adrenal insufficiency, stable mitotane for

adrenal carcinoma, or oral contraceptives

6. Concurrent therapeutic anticoagulation by anti-vitamin K (AVK)

7. Patients treated by valproic acid

8. Any other previous (in the last 3 years) or concurrent cancer, other than resected non-melanoma skin cancer or cancer in situ of the uterine cervix

9. Risk factors for, or use of drugs known to prolong QTc interval and that may be associated with Torsades de Pointes

**Date of first enrolment**

22/02/2010

**Date of final enrolment**

07/05/2012

## **Locations**

**Countries of recruitment**

France

**Study participating centre**

Institut de Cancérologie Gustave Roussy

Villejuif

France

94805

## **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="#">Results article</a> | results | 01/09/2013   |            | Yes            | No              |