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

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|---|---|---|
| **Submission date**<br>13/05/2013 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>06/08/2013 | **Overall study status**<br>Completed | |
| **Last Edited**<br>18/04/2018 | **Condition category**<br>Cancer | |

**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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## 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? |
|---|---|---|---|---|---|
| Basic results | | | | No | No |
| Results article | results | 01/09/2013 | | Yes | No |