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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
13/05/2013		☐ Protocol		
<b>Registration date</b> 06/08/2013	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
18/04/2018	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

Prof Jean-Charles Soria

#### Contact details

Institut de Cancérologie Gustave Roussy 39 rue Camille Desmoulins Villejuif France 94805

# Additional identifiers

#### Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

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

# Key secondary outcome(s))

- 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

# 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

#### Healthy volunteers allowed

No

#### Age group

Adult

## Lower age limit

18 years

#### Sex

ΔII

#### 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)

#### **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?
Results article	results	01/09/2013		Yes	No
Basic results				No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes