

# Phase I study of S 78454 in combination with a fixed dose infusion of cisplatin in patients with advanced solid tumours

<b>Submission date</b> 04/10/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/12/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/04/2018	<b>Condition category</b> 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

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### Contact details

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## Additional identifiers

### Protocol serial number

CL1-78454-008

## Study information

### Scientific Title

Phase I dose-escalation study of oral administration of the Histone Deacetylase (HDAC) Inhibitor S 78454 given in combination with a fixed dose infusion of Cisplatin in patients with advanced solid tumours

### **Study objectives**

To establish the safety profile and the recommended Phase II dose of S 78454 in combination with a fixed dose infusion of cisplatin

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval was obtained before recruitment of the first participants

### **Primary study design**

Interventional

### **Study design**

National multicentric non-randomised open-label dose escalation Phase I study

### **Study type(s)**

Treatment

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

Advanced solid tumours

### **Interventions**

1. Capsules containing 20 mg and 100 mg of S 78454 / Oral use / Treatment duration is at the discretion of the investigator
2. Fixed dose of i.v. infusion of cisplatin at 75 mg/m<sup>2</sup> / Cisplatin administration for up to 6 cycles, S 78454 could be maintained beyond

### **Intervention Type**

Drug

### **Phase**

Phase I

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

S 78454, cisplatin

### **Primary outcome(s)**

1. DLTs and MTDs within the cycle 1 - Methods used: blood samples (biochemistry, haematology, coagulation analysis), physical examination and vital signs assessment, urinary analysis, ECG, clinical neurological examination, audiometric test
2. Safety profile of the combination at each visit

### **Key secondary outcome(s)**

1. Pharmacokinetic evaluation on cycle 1 by blood sample
2. Circulating Tumour Cells measurements every 2 cycles by blood sample
3. Tumour response evaluation every 2 cycles according to RECIST criteria

**Completion date**

05/02/2014

## Eligibility

**Key inclusion criteria**

1. Male or female patient aged > or equal to 18 years
2. Any histological confirmed diagnosis of advanced solid tumours that have relapsed or is refractory to conventional standard forms of therapy
3. Ability to swallow oral capsule(s)
4. Estimated life expectancy > 12 weeks
5. ECOG performance status < 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**

All

**Key exclusion criteria**

1. Major surgery within previous 4 weeks
2. Chemotherapy within previous 3 weeks (6 weeks for nitroso-ureas)
3. Hormonotherapy within 2 weeks (6 weeks for bicalutamide)
4. Any other prior therapy directed at the solid tumours within 3 weeks
5. Radiotherapy within previous 4 weeks (except for palliative radiotherapy at localised lesions)
6. Cumulative radiation therapy involving > 25 % of total bone marrow
7. Pregnant or breast-feeding women, women of childbearing potential or men without effective contraception
8. Peripheral Neuropathy > grade 1
9. Hearing impairment/tinnitus > grade 2
10. Prior treatment with cisplatin reaching a cumulative dose of 300 mg/m<sup>2</sup>
11. Concomitant uncontrolled infection or severe systemic disease
12. Symptomatic or progressive brain metastasis
13. Patients with pre-existing gastrointestinal disorders
14. Concurrent therapeutic anticoagulation by AVK

- 15. Patient with impaired cardiac function
- 16. Patients with pre-existing gastro-intestinal disorders
- 17. Uncontrolled diabetes mellitus

**Date of first enrolment**

05/04/2012

**Date of final enrolment**

05/02/2014

## Locations

**Countries of recruitment**

France

**Study participating centre**

Institut Paoli Calmettes

Marseille Cedex 9

France

13273

## 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?
<a href="#">Basic results</a>				No	No