

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

Submission date 13/05/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/08/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/04/2018	Condition category Cancer	☐ 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

CL1-78454-002

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

All

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