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Phase I study of oral administration of S 78454 in association with doxorubicin in patients with solid tumour

Submission date 02/09/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/09/2013	**Overall study status** Completed	
Last Edited 18/04/2018	**Condition category** 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

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Additional identifiers

Protocol serial number
CL1-78454-005

Study information

Scientific Title
Phase I dose-escalation study of oral administration of S 78454 given with a fixed dose infusion of doxorubicin administered weekly 3 out of 4 weeks in patients with solid tumour

Study objectives
To establish the safety profile and the recommended Phase II dose of S 78454 in combination with a fixed dose infusion of doxorubicin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Multicentric non-randomised open dose escalation Phase I study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Solid tumours

Interventions
1. Capsules containing 20 mg and 100 mg of S 78454 / Oral use / Treatment duration is 6 cycles
2. Fixed dose infusion of 25 mg/m² of doxorubicin, weekly 3 out of 4 weeks / Treatment duration is 6 cycles

No control group is involved

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
S 78454, doxorubicin

Primary outcome(s)
1. Dose-limiting toxicities (DLTs) and maximum tolerated doses (MTDs) at each visit - Methods used: blood samples, physical examination, electrocardiogram (ECG)
2. Safety profile of the combination at each visit

Key secondary outcome(s))
1. Tumour response at baseline evaluation every 2 cycles using the Response Evaluation Criteria In Solid Tumors (RECIST) guideline
2. Pharmacokinetic parameters during cycle 1 and 2 by blood samples
3. Pharmacodynamic parameters during cycle1 by blood samples and tumour biopsies

Completion date

15/11/2013

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Major surgery within previous 4 weeks
2. Chemotherapy within previous 3 weeks (6 weeks in case of nitrosoureas)
3. Radiotherapy within previous 4 weeks (except for palliative radiotherapy at localised lesions)
4. Immunotherapy or hormonotherapy within previous 2 weeks, except stable oral glucocorticoid and mineralocorticoid replacement for adrenal insufficiency, or oral contraceptives or hormonal replacement therapy
5. Risk factors for, or use of drugs known to prolong QTc interval and that may be associated with Torsades de Pointes
6. Patients treated by valproic acid within previous 5 days
7. Phenytoin (and by extension fosphenytoin) within previous 3 weeks

Date of first enrolment
15/11/2010

Date of final enrolment
15/11/2013

Locations

Countries of recruitment
Belgium

France

Study participating centre
Clinical Research Unit and Pharmacology Lab EA 3035
Toulouse
France
31052

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?
Basic results				No	No