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# Phase I dose-escalation study of S 49076 in patients with advanced solid tumours

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 11/06/2013 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 02/08/2013 | Completed | [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

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## Additional identifiers

**Protocol serial number**
CL1-49076-001

## Study information

**Scientific Title**
Phase I dose-escalation study of oral administration of MET Tyrosine Kinase Inhibitor S 49076 in patients with advanced solid tumours

**Study objectives**

To establish the safety profile and the recommended dose of S 49076 with the selected treatment schedule.

### Ethics approval required
Old ethics approval format

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

### Study design
International multicentric non-randomised open-label dose escalation Phase I study

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Advanced solid tumours

### Interventions
Capsules containing 7.5 mg and 30 mg of S 49076 administered orally. Treatment duration is at the discretion of the investigator

### Intervention Type
Drug

### Phase
Phase I

### Drug/device/biological/vaccine name(s)
S 49076

### Primary outcome(s)
1. Dose limiting toxicity (DLT) and maximum tolerated dose (MTD) at the end of the cycle 1, measured by AE
2. Safety profile at each visit, measured by AE monitoring

### Key secondary outcome(s))
1. Pharmacokinetic evaluation within cycles 1 and 2: blood samples
2. Pharmacodynamic evaluation at each cycle: blood samples
3. Tumour response evaluation every two cycles: imagery

### Completion date
15/09/2014

## Eligibility

### Key inclusion criteria
1. Male or female patient aged 18 years or older
2. Advanced solid tumour that has relapsed or is refractory to standard therapy or for which no effective standard therapy is available
3. Ability to swallow oral capsule(s)
4. Estimated life expectancy of more than 12 weeks
5. ECOG performance status less than 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 4 weeks prior to the first day of the study drug administration
2. Chemotherapy within 3 weeks prior to the first day of the study drug administration (6 weeks in the case of treatment with nitroso-ureas)
3. Any other prior therapy involving an agent directed to the solid tumours within five times of the half-life of said agent but not less than 3 weeks prior to the first day of study drug administration
4. Hormonal therapy directed to the solid tumours within 2 weeks prior to the first day of study drug administration (6 weeks in the case of treatment with bicalutamide), except in the case of LHRH agonist therapy for prostate cancer which is permitted.
5. Radiotherapy within 4 weeks prior to the first day of the study drug administration (within 1 week in the case of palliative radiotherapy at localised lesions)
6. Cumulative radiation therapy involving more than 25% of the total bone marrow
7. Concomitant uncontrolled infection or severe systemic disease (at the discretion of the investigator)
8. Known organ dysfunction which would either compromise the patient's safety or interfere with the evaluation of the study drug safety
9. Patients with impaired cardiac function

### Date of first enrolment
13/02/2012

### Date of final enrolment
15/09/2014

## Locations

### Countries of recruitment
France

Spain

### 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 | 01/08/2017 | | Yes | No |

| | | |
|---|---|---|
| Basic results | No | No |