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

Submission date 11/06/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/08/2013	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures
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

Overall study start date
13/02/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110

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)

Sponsor details
50 rue Carnot
Suresnes
France
92284

Sponsor type
Industry

Website

http://www.servier.com/

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan
Publication plan:
Summary results are published in https://clinicaltrials.servier.com.

Intention to publish date

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
Results article	results	01/08/2017		Yes	No