

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
Registration date 02/08/2013	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

CL1-49076-001

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

Primary study design

Interventional

Study design

International 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

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

