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Phase I study of S 78454 in combination with FOLFOX in patients with digestive cancer

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

Contact name
Prof Philippe Rougier

Contact details
Hôpital Européen George Pompidou
20 rue Leblanc
Paris
France
75015

Additional identifiers

Protocol serial number
CL1-78454-006

Study information

Scientific Title
Phase I dose-escalation study of S 78454 (HDACi) p.o. in combination with FOLFOX in patients with locally advanced or metastatic digestive cancer

Study objectives

To establish the safety profile and the recommended Phase II dose of S 78454 in combination with FOLFOX (folinic acid, fluorouracil, oxaliplatin).

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 dose escalation phase I study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Locally advanced or metastatic digestive cancer

Interventions
1. Capsules containing 20 mg and 100 mg of S 78454 / Oral use / Treatment duration is at the discretion of the investigator
2. Concomitant intravenous (i.v.) infusion of FOLFOX / Treatment duration is at the discretion of the investigator

No control group is involved

Intervention Type
Drug

Phase
Phase I

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

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

Key secondary outcome(s))
1. Pharmacokinetic evaluation on the cycle 1 by blood sample
2. Tumour response evaluation during the study by imagery
3. Tumour markers evaluation at each cycle by blood sample

Completion date
15/09/2014

Eligibility

Key inclusion criteria
1. Male or female patient aged > or equal to 18 years
2. Any histological confirmed measurable or evaluable metastatic colorectal cancer (mCRC) or locally advanced or metastatic gastric or pancreatic cancer with a true primary resistance to FOLFOX
3. Ability to swallow oral capsule(s)
4. Ability to receive FOLFOX regimen
5. Estimated life expectancy > 12 weeks
6. Eastern Cooperative Oncology Group (ECOG) performance status < or equal to 1
7. Body mass index (BMI) > or equal to 20
8. 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 previous 4 weeks
2. Chemotherapy (other than FOLFOX) within previous 3 weeks
3. Small molecules treatment (tyrosine kinase inhibitor) or antibodies within previous 1 week
4. Radiotherapy within previous 4 weeks (except for palliative radiotherapy at localised lesions)
5. Pregnant or breastfeeding women, women of childbearing potential or men without effective contraception
6. Prior exposure to any histone deacetylase inhibitors (HDACi)
7. Neuropathy > grade 1
8. Unresolved diarrhea > grade 1
9. Concomitant uncontrolled severe systemic disease
10. Patient with impaired cardiac function

Date of first enrolment
15/09/2011

Date of final enrolment
15/09/2014

Locations

Countries of recruitment
Belgium

France

Italy

Study participating centre
Hôpital Européen George Pompidou
Paris
France
75015

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