ISRCTN14228310 https://doi.org/10.1186/ISRCTN14228310

Study of efficacy and safety of S 95005 (TAS-102) in patients with metastatic colorectal cancer who failed standard chemotherapies

Submission date 22/09/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/11/2016	**Overall study status** Completed	
Last Edited 02/01/2020	**Condition category** Cancer	

Plain English summary of protocol
Not provided at the time of registration and not expected to be provided in the future.

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT03274882

Secondary identifying numbers
CL2-95005-003

Study information

Scientific Title
Open-label multicentre confirmatory study of efficacy and safety of S 95005 (TAS-102) in patients with metastatic colorectal cancer who are refractory or intolerant to standard chemotherapies

Study objectives
To evaluate the efficacy and the safety of S 95005 in patients with metastatic colorectal cancer who are refractory or intolerant to standard chemotherapies

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Counsil at Ministry of Healthcare of Russian Federation, 09/08/2016, ref: 4017917-20-1

Study design
Multi-centre open-label single-arm study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

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
Metastatic colorectal cancer

Interventions
Single arm study where film-coated tablets of S95005 containing 15mg of trifluridine and 7.065 mg of tipiracil hydrochloride, or 20mg of trifluridine and 9.42mg of tipiracil hydrochloride, are given orally twice daily at the dose of 35 mg/m2/dose. The treatment is given until unacceptable toxicity according to the investigator, disease progression or patient withdrawal. If a patient

discontinues study treatment for reasons other than radiologic disease progression (e.g., intolerable side effects), patients will be followed for tumour response until radiologic disease progression or initiation of new anticancer therapy (whichever occurs first).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Trifluridine + tipiracil hydrochloride (S 95005/TAS-102)

Primary outcome measure
Progression free survival (PFS) rate at 2 months (percentage of patients alive without investigator-assessed radiological disease progression according to RECIST 1.1 after 2 months).

Secondary outcome measures
1. Antitumor activity (Progression-Free Survival, Overall Response Rate, Disease Control Rate) based on Investigator review of the images according to RECIST 1.1, within 28 days prior to Day 1 of Cycle 1 and every 8 weeks thereafter.
2. Safety and tolerability, at each visit, from the informed consent signature to the withdrawal visit , assessed by:
2.1. Incidence of Adverse Events
2.2. Laboratory tests: haematology, blood biochemistry and urinalysis
2.3. Physical examination and performance status (ECOG)
2.4. Vital signs: blood pressure, heart rate, body temperature, respiration rate, body weight
2.5. 12-leads ECG parameters (only at baseline and at withdrawal visit)

Overall study start date
04/07/2016

Completion date
03/12/2018

Eligibility

Key inclusion criteria
1. Male or female aged ≥18 years of age
2. Has definitive histologically or cytologically confirmed adenocarcinoma of the colon or rectum
3. Has received at least 2 prior regimens of standard chemotherapies for metastatic colorectal cancer (including fluoropyrimidines, irinotecan and oxaliplatin and, if accessible, an anti-VEGF monoclonal antibody and at least one of the anti-EGFR monoclonal antibodies for RAS wild-type patients (if RAS mutation status was evaluated)) and was refractory or intolerant to those chemotherapies
4. Has Eastern Cooperative Group (ECOG) performance status of 0 or 1
5. Has at least one measurable metastatic lesion(s)
6. Has adequate organ function
7.Women of childbearing potential must have been tested negative in a serum pregnancy test within 3 days prior to inclusion

8. Female participants of childbearing potential and male participants with partners of childbearing potential must agree to use a highly effective method of birth control during the study and for 6 months after the discontinuation of study medication

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
26

Total final enrolment
26

Key exclusion criteria
1. Pregnancy, breastfeeding
2, Has previously received S 95005 or history of allergic reaction attributed to compounds of similar composition to S 95005
3. Has certain serious illnesses or medical conditions
4. Has had certain other recent treatment e.g. major surgery, field radiation, anticancer therapy, within the specified time frames prior to inclusion
5. Has unresolved toxicity of greater than or equal to Common Terminology Criteria for Adverse Events (CTCAE) Grade 2 attributed to any prior therapies (excluding anaemia, alopecia, skin pigmentation, and platinum-induced neurotoxicity)

Date of first enrolment
23/01/2017

Date of final enrolment
23/07/2017

Locations

Countries of recruitment
Russian Federation

Study participating centre
Russian Cancer Research Center n.a. NN Blokhin (RCRC)
Moscow
Russian Federation
115478

Study participating centre
Saint Petersburg Clinical Scientific-Practical Center of Special Medical Care (Oncology Center)
Saint Petersburg
Russian Federation
197758

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Moscow
Russian Federation
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Sponsor information

Organisation
Institut de Recherche Internationales Servier (IRIS)

Sponsor details
50 rue Carnot
Suresnes
France
92284

Sponsor type
Industry

Website
https://clinicaltrials.servier.com/

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
ADIR

Results and Publications

Publication and dissemination plan
Summary results and a lay summary will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.

Intention to publish date
31/12/2019

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/ after the Marketing Authorisation has been granted.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Plain English results				No	Yes
Results article	results	01/07/2019	02/01/2020	Yes	No