

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/01/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

NCT03274882

Protocol serial number

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 Council 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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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Sponsor information

Organisation

Institut de Recherche Internationales Servier (IRIS)

ROR

<https://ror.org/034e7c066>

Funder(s)

Funder type

Industry

Funder Name

ADIR

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/> 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?
Results article	results	01/07/2019	02/01/2020	Yes	No
Basic results				No	No
Plain English results				No	Yes