

Phase I study of S 78454 given with a fixed dose infusion of pegylated liposomal doxorubicin in the treatment of primary epithelial ovarian, fallopian tube or primary peritoneal carcinoma

Submission date 08/07/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/09/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 17/12/2015	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

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 Ignace Vergote

Contact details

University Hospital Leuven (K.U.Leuven)
Gynaecological Oncology Herestraat 49
Leuven
Belgium
3000

Additional identifiers

Protocol serial number

CL1-78454-003

Study information

Scientific Title

Phase I study of oral administration of S 78454 given with a fixed dose infusion of pegylated liposomal doxorubicin in the treatment of primary platinum-resistant and partially platinum-sensitive, epithelial ovarian, fallopian tube or primary peritoneal carcinoma

Study objectives

To establish the safety profile and the recommended Phase II dose of S 78454 in combination with a fixed dose infusion of pegylated liposomal doxorubicin.

On 13/11/2014 the anticipated end date was changed from 01/12/2014 to 30/12/2015.

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

Multicentric non-randomised open dose escalation Phase I study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Primary epithelial ovarian, fallopian tube or primary peritoneal carcinoma

Interventions

1. Capsules containing 20 mg and 100 mg of S 78454 administered orally. Treatment duration is at the discretion of the investigator.
2. Fixed dose infusion of 40 mg/m² of pegylated liposomal doxorubicin

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

S 78454

Primary outcome(s)

1. Dose limiting toxicity (DLT) at each visit of cycle 1 and maximum tolerated dose (MTD) measured by Adverse Events monitoring
2. Safety profile at each visit measured by Adverse events monitoring

Key secondary outcome(s)

1. Tumour response evaluation every 2 cycles by imaging and every cycle by blood test
2. Pharmacokinetic and pharmacodynamic parameters during cycle1 measured using blood samples

Completion date

30/12/2015

Eligibility

Key inclusion criteria

1. Female patient aged 18 years or above
2. Histologically confirmed diagnosis of advanced relapsed epithelial ovarian carcinoma, fallopian tube carcinoma or primary peritoneal carcinoma, with measurable and evaluable disease
3. Platinum resistant and partially platinum sensitive tumour
4. Ability to swallow oral capsule(s) without difficulty
5. Estimated life expectancy of more than 12 weeks
6. Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to 2
7. Adequate haematological, renal and hepatic functions

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Pregnant or breast-feeding women, women for whom fertility function has been preserved without effective contraception
2. Major surgery within previous 4 weeks
3. Chemotherapy within previous 3 weeks (6 weeks in case of nitrosoureas)
4. Radiotherapy within previous 4 weeks (except for palliative radiotherapy at localised lesions)
5. Immunotherapy or hormonotherapy within previous 2 weeks, except stable oral glucocorticoid and mineralocorticoid replacement for adrenal insufficiency, stable mitotane for adrenal carcinoma or oral contraceptives or hormonal replacement therapy
6. Risk factors for, or use of drugs known to prolong QTc interval and that may be associated with Torsades de Pointes
7. Patients treated by valproic acid within previous 5 days before

Date of first enrolment

01/12/2010

Date of final enrolment

30/12/2015

Locations

Countries of recruitment

Belgium

France

Italy

Study participating centre

University Hospital Leuven (K.U.Leuven)

Leuven

Belgium

3000

Sponsor information

Organisation

Pharmacyclics LLC (USA)

ROR

<https://ror.org/03hm8w204>

Funder(s)

Funder type

Industry

Funder Name

Pharmacyclics LLC (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration