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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

Registration date
16/09/2013

Overall study status
Completed

Last Edited
17/12/2015

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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

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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

Study design
Multicentric non-randomised open dose escalation Phase I study

Primary study design
Interventional

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes