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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	[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/12/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
70

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)

Sponsor details
999 East Arques Avenue
Sunnyvale
United States of America
94085

Sponsor type
Industry

Website
www.pharmacyclics.com

ROR
https://ror.org/03hm8w204

Funder(s)

Funder type
Industry

Funder Name
Pharmacyclics LLC (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration