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Phase I study of S 78454 with tamoxifen 20 mg in patients with breast cancer

Submission date 03/04/2014	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 29/04/2014	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 29/05/2020	**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
CL1-78454-011

Study information

Scientific Title

Phase I dose-escalation study of oral administration of S 78454 given with tamoxifen 20 mg in the treatment of patients with advanced breast cancer

Study objectives
To establish the safety profile and the recommended Phase II dose of S 78454 in combination with a fixed dose of tamoxifen 20 mg.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
International multicentric non-randomised open dose-escalation Phase I 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Advanced breast cancer

Interventions
Capsules containing 20 mg and 100 mg of S 78454 / oral use / 120 mg b.i.d to 160 mg b.i.d (dose de-escalation up to 80 mg b.i.d can be performed), and
Fixed dose of tamoxifen 20 mg per day / oral use

Treatment duration is at the discretion of the investigator

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
S 78454, tamoxifen

Primary outcome measure
1. Dose limiting toxicities and maximum tolerated doses at the end of cycle 2. Methods used: blood samples, physical examination, vital signs assessment, ECG
2. Safety profile of the combination at each visit (adverse events, laboratory tests, physical examination, ECOG, vital signs, ECG)

Secondary outcome measures
1. Pharmacokinetic evaluation within cycle 2 by blood samples
2. Pharmacodynamic assessment every cycle by blood samples
3. Tumour response evaluation every two cycles according to RECIST criteria

Overall study start date
30/08/2012

Completion date
28/01/2015

Eligibility

Key inclusion criteria
1. Female patients aged 18 years or over
2. Ability to swallow oral capsule(s)
3. Estimated life expectancy > 12 weeks
4. ECOG performance status less than or equal to 1
5. Adequate haematological and hepatic functions
6. Histologically confirmed primary adenocarcinoma of the breast
7. Patients whose tumor has significant expression of Estrogen Receptor
8. Absence of Human Epidermal Growth Factor Receptor-2 overexpression or amplification

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
40 patients

Key exclusion criteria
1. Major surgery within previous 4 weeks
2. Any previous chemotherapy within 3 weeks (6 weeks in case of nitroso-ureas) before starting the study drug
3. Any radiotherapy within previous 4 weeks (except for palliative radiotherapy at localised lesions)

4. Any other prior therapy directed at breast cancer within previous 3 weeks, including biologic /targeted therapy or immunologic agents
5. Hormonotherapy within 2 weeks, except stable oral glucocorticoid and mineralocorticoid replacement for adrenal insufficiency, topical corticosteroids (e.g. cream, spray)
6. Concomitant uncontrolled infection or systemic disease
7. Known endometrial hyperplasia, or endometrial cancer
8. Patients with prior thromboembolic events or at high risk of such events
9. Rapidly progressive visceral, central nervous system, or liver metastases or significant symptomatic lymphangitic pulmonary metastases
10. Patients with pre-existing gastrointestinal disorders (including significant malabsorption syndrome, significant chronic digestive or gastrointestinal inflammatory syndrome, gastroduodenal disorders at risk for bleeding) that might interfere with proper absorption of the oral drugs
11. Patients with impaired cardiac function

Date of first enrolment
30/08/2012

Date of final enrolment
07/07/2014

Locations

Countries of recruitment
France

Italy

Spain

Study participating centre
Institut Gustave Roussy
Villejuif
France
94805

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