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

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|---|---|---|
| **Submission date**<br>03/04/2014 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>29/04/2014 | **Overall study status**<br>Completed | |
| **Last Edited**<br>29/05/2020 | **Condition category**<br>Cancer | |

**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**
CL1-78454-011

## 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

## Study type(s)
Treatment

## 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(s)
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)

## Key secondary outcome(s)
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

## 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Female

### 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)

**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