

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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
03/04/2014	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
29/04/2014	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
29/05/2020	Cancer	<input type="checkbox"/> 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

Dr Suzette Delaloge

### Contact details

Institut Gustave Roussy  
114 rue Edouard Vaillant  
Villejuif  
France  
94805

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes