

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/04/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/05/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<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

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Contact details

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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