

# Phase Ib dose allocation study of oral administration of lucitanib given in combination with fulvestrant in patients with metastatic breast cancer

<b>Submission date</b> 12/02/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/07/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

Prof Mario Campone

### Contact details

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44805

## Additional identifiers

### Protocol serial number

CL1-80881-002

## Study information

Scientific Title

Phase Ib dose allocation study of oral administration of lucitanib given in combination with fulvestrant in patients with oestrogen receptor-positive and FGFR1-amplified or non-amplified metastatic breast cancer

### **Study objectives**

To establish the safety profile and the recommended Phase II dose of lucitanib in combination with fulvestrant

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval was obtained before recruitment of the first participants

### **Study design**

Multicentric open non-comparative phase Ib study

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

FGFR1-amplified or non-amplified estrogen receptor positive metastatic breast cancer

### **Interventions**

1. Capsules containing 5, 10 or 15 mg of lucitanib taken orally on a daily basis, treatment duration at the investigator's discretion
2. Concomitant intramuscular injection of fulvestrant 500 mg on a monthly basis

The study is composed of two successive parts: the dose allocation (Continual Reassessment Method) and the dose expansion part.

For the dose allocation cohorts, a minimum of three patients will be enrolled at the initial dose level of 10 mg once per day in combination with fulvestrant. Patients will be included by groups of three. A minimum of nine patients will be included at the Maximal Tolerated Dose. Intra-patient dose-escalation will be considered in the patient's best interest.

For the dose expansion part, two cohorts of 14 patients will be treated with the lucitanib Recommended Dose defined in the dose allocation part of this study in combination with fulvestrant given on a monthly basis.

In both parts, each patient will receive the combination of lucitanib with fulvestrant until unacceptable toxicity according to the investigator, disease progression or patient withdrawal. The maximum number of cycles is at the discretion of the investigator.

### **Intervention Type**

Drug

### **Phase**

Phase I

**Drug/device/biological/vaccine name(s)**

Lucitanib, fulvestrant

**Primary outcome(s)**

1. Maximum tolerated dose (MTD) and dose-limiting toxicities (DLTs) of lucitanib in combination with fulvestrant, at the end of dose allocation cycles
2. Safety profile of lucitanib in combination with fulvestrant at each visit

**Key secondary outcome(s)**

1. Clinical benefit rate (CBR), progression-free survival (PFS) and duration of response over the study
2. Pharmacokinetic and pharmacodynamic profile of lucitanib in combination with fulvestrant at each cycle

**Completion date**

06/03/2017

## **Eligibility**

**Key inclusion criteria**

1. Menopausal women aged 18 years old or over
2. Histologically confirmed breast adenocarcinoma
3. Relapsing during or after treatment with fulvestrant
4. Tumour progression at study entry demonstrated by radiological assessment
5. Adequate haematological, hepatic and renal functions

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Key exclusion criteria**

1. Previously treated with more than three chemotherapy regimen in the metastatic/advanced setting
2. Previous treatment with bevacizumab within 3 months before the first day of lucitanib administration
3. Active central nervous system metastases, cerebral oedema, and/or progressive growth
4. Patients with impaired cardiac function

5. Serum potassium level below lower limit of normal
6. Uncontrolled hypothyroidism
7. Pregnant or breastfeeding women
8. Patient with any other concomitant severe and/or uncontrolled medical condition that would, in the investigators' opinion, contraindicate patient participation in the clinical study

**Date of first enrolment**

04/04/2014

**Date of final enrolment**

25/10/2015

## **Locations**

**Countries of recruitment**

France

**Study participating centre**

**Institut de Cancérologie de l'Ouest René Gauducheau**

Saint-Herblain

France

44805

**Study participating centre**

**Institut Gustave Roussy**

Dept d'oncologie - Cancer du sein

Villejuif

France

94805

**Study participating centre**

**Centre Léon BERARD**

Service d'oncolgie

Lyon

France

69008

**Study participating centre**

**Centre Jean Perrin**

Clermont Ferrand

France

63011

# Sponsor information

## Organisation

Institut de Recherches Internationales Servier (France)

## ROR

<https://ror.org/034e7c066>

# Funder(s)

## Funder type

Industry

## Funder Name

Institut de Recherches Internationales Servier (France)

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from [www.clinicaltrials.servier.com](http://www.clinicaltrials.servier.com) after the Marketing Authorisation has been granted.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		18/07/2022	18/07/2022	Yes	No
<a href="#">Basic results</a>				No	No