

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

Submission date 12/02/2014	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 26/03/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/07/2022	Condition category Cancer	☐ 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

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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

Primary study design

Interventional

Study design

Multicentric open non-comparative phase Ib study

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 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?
Results article		18/07/2022	18/07/2022	Yes	No
Basic results				No	No