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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

Registration date
26/03/2014

Overall study status
Completed

Last Edited
18/07/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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 Gaudducheau
Saint-Herblain
France
44805

Study participating centre
Institut Gustave Roussy
Dept d'oncologie - Cancer du sein
VilleJuif
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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes