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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	[X] Prospectively registered [_] Protocol
Registration date 26/03/2014	**Overall study status** Completed	[_] Statistical analysis plan [X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/02/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
46

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)

Sponsor details
50 rue Carnot
Suresnes
France
92284

Sponsor type
Industry

Website
http://www.servier.com/

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan
Summary results will be published on www.clinicaltrials.servier.com within 12 months after the end of the study

Intention to publish date

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