A phase II study of orally administered BEZ235 monotherapy in patients with metastatic or unresectable malignant PEComa

Published: 31-10-2012
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Efficacy of BEZ235 on objective response rate according to RECIST 1.1

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON37195

Source
ToetsingOnline

Brief title
BEZ235 in PEComa

Condition

- Soft tissue neoplasms malignant and unspecified

Synonym
Perivascular epithelioid cell tumors (PEComa); soft tissue tumor

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma A.G.

Intervention

Keyword: BEZ235, mTOR inhibitor, PEComa

Outcome measures

Primary outcome

Objective response according to RECIST 1.1.

Secondary outcome

Progression free survival

Duration of response

Time to response

Time to progression

Overall survival

Safety and tolerability of BEZ235

Study description

Background summary

This study investigates whether BEZ235 will slow the growth of PEComa tumors. Also, the study will explore the side effect of BEZ235. BEZ235 is an PI3K- and mTOR inhibitor possibly slowing the growth of tumor cells.

Study objective

Efficacy of BEZ235 on objective response rate according to RECIST 1.1

Study design

Multicenter, prospective, non-randomized, open-label, single arm phase II study in two phases.

Intervention

BEZ235 medication

Study burden and risks

The visit frequency is not much higher than normal clinical practise except for the first 8 months. Blood draw is larger than normal but not excessive.

Contacts

Public
Novartis

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NL
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Histologically confirmed diagnosis of malgnant PEComa (included epithelioid angiomyolipoma (AML) in adult patients
Unresectable/advanced and/ or metastatic and documented progressive measurable disease

Treated with 1 or 2 prior lines of treatment

Exclusion criteria

Disease exclusions: Lymphangioleiomyomatosis (LAM) exclusively
Active uncontrolled or symptomatic CNS metastases, concurent malignancy or malignancy in last three years.
Concurrent severe and/or uncontrolled medical condition (for details see protocol)

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	3
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BEZ235
Generic name:	BEZ235

Ethics review

Approved WMO

Date:	31-10-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	02-04-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-001884-39-NL
CCMO	NL42047.058.12