Open-label Phase 2 study evaluating efficacy and safety of SAR566658 treatment in patients with CA6 positive metastatic Triple Negative Breast Cancer

Published: 04-08-2016
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The goal of the trial is to investigate the safety and efficacy of SAR566658, if it is provided to CA6 protein positive metastaticTBN breastcancer patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON46882

Source
ToetsingOnline

Brief title
ACT14884

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, mamma carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis
Source(s) of monetary or material Support: Sanofi

Intervention

Keyword: breast cancer, efficacy, metastatic, phase 2

Outcome measures

Primary outcome

To select in the first part the SAR566658 dose based on Objective Response Rate

(ORR) and

safety of 2 dose levels and to demonstrate in the second part the efficacy of

the selected dose

based on ORR.

Secondary outcome

-To assess:

-Disease Control Rate (DCR), Duration Of Response (DOR), Progression-Free

Survival (PFS),

and Time To Progression (TTP);

-The impact of ocular primary prophylaxis on the incidence of keratopathies

Study description

Background summary

At the moment limited treatment options are available for triple negative metastatic breast cancer (TBN) patients. No targeted therapy is available. About 20% of all breast cancers is TBN, and the majority of these patients will receive this diagnoses before they reach the age of 40. 80% of these patients are diagnosed with an aggressive form.
SAR566658 could offer a targeted therapy for a part of these patients, in which previous treatments were not successful.

Study objective

The goal of the trial is to investigate the safety and efficacy of SAR566658, if it is provided to CA6 protein positive metastaticTBN breastcancer patients.

Study design

Open label randomized trial.

Intervention

Patients receive 90 mg/m2 SAR566658 or 120 mg/m2 SAR566658 on day 1 and 8 of each cycle.

Study burden and risks

The risks are related to the blood draws and the possible side effects of the study drug. The burden for the patient will be the frequency of the visits to the hospital.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Measurable Metastatic triple negative breast cancer (TNBC).
-Patients with CA6-positive disease.
-Patients received at least 1 prior chemotherapy regimen but no more than 3 for advanced/metastatic disease.;-Prior anticancer therapy must have contained anthracycline (eg, doxorubicin), if not contraindicated, and a taxane (eg, docetaxel, paclitaxel) in an adjuvant/neo-adjuvant or metastatic setting.

Exclusion criteria

-Eastern Cooperative Oncology Group (ECOG) performance status *2.
-Patient less than 18 years old.
-Pregnant or breast-feeding women.
-Patients with reproductive potential who do not agree to use accepted and effective method of contraception during the study treatment period and for 6 months following discontinuation of study drug.
-Wash out period of less than 3 weeks or 5 half-lives from previous antitumor chemotherapy, immunotherapy, or any investigational treatment.
-History of brain metastasis, spinal cord compression or carcinomatous meningitis, or new evidence of brain leptomeningeal disease.
-Prior treatment with eribulin as last prior therapy or prior maytansinoid treatments.
-Known intolerance to infused protein products including other monoclonal antibodies and ADCs.
-Poor bone marrow reserve and/or poor organ function.
-Symptomatic peripheral neuropathy Grade *2.
-Previous history of chronic corneal diseases or unresolved acute nonrecurrent corneal conditions.
-Patients wearing contact lenses who are not willing to stop wearing them for the duration of the study.
-Medical conditions requiring concomitant administration of strong CYP3A4 inhibitors, unless it can be discontinued at least 2 weeks before 1st administration of SAR566658.
-Contraindications to the use of ophthalmic vasoconstrictor and/or corticosteroid.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2017
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	unknown
Generic name:	unknown

Ethics review

Approved WMO

Date:	04-08-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	07-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	23-12-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-01-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-01-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-02-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-11-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-11-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-01-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-02-2018
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2016-001962-27-NL
CCMO	NL58637.068.16
Other	U1111-1182-7044