# LUX-Breast 1; An open label, randomised phase III trial of BIBW 2992 and vinorelbine versus trastuzumab and vinorelbine in patients with metastatic HER2-overexpressing breast cancer failing one prior trastuzumab treatment

Published: 21-04-2010 Last updated: 02-05-2024

To investigate the efficacy and safety of BIBW 2992 in combination with vinorelbine iv chemotherapy as treatment in patients with HER2-overexpressing, metastatic breastcancer, who failed one prior trastuzumab treatment.

**Ethical review** Approved WMO

**Status** Recruitment stopped

**Health condition type** Breast neoplasms malignant and unspecified (incl nipple)

**Study type** Interventional

# **Summary**

### ID

NL-OMON34674

#### **Source**

**ToetsingOnline** 

#### **Brief title**

LUX-Breast 1

## **Condition**

• Breast neoplasms malignant and unspecified (incl nipple)

#### **Synonym**

Breast cancer, mammacarcinoma

## Research involving

Human

# **Sponsors and support**

**Primary sponsor:** Boehringer Ingelheim

Source(s) of monetary or material Support: Boehringer Ingelheim

## Intervention

Keyword: breastcancer, EGFR/HER2 inhibitor, trastuzumab, vinorelbine

## **Outcome measures**

## **Primary outcome**

The primary endpoint of this study is progression free survival, defined as the time from the date of randomisation to the date of disease progression, or to the date of death if a patient died earlier.

## **Secondary outcome**

Secundary endpoints:

- overall survival:
- best RECIST assesment;
- safety;
- tumour shrinkage;
- maintenance of bodyweight;
- ECOG performance status;
- incidence of brain metastases;
- health related quality of life;
- pharmokinetics of BIBW 2992.

# **Study description**

## **Background summary**

An open label, randomised phase 3 trial of BIBW 2992 and vinorelbine versus trastuzumab and vinorelbine in patients with metastatic HER2-overexpressing breast cancer failing one prior trastuzumab treatment.

## Study objective

To investigate the efficacy and safety of BIBW 2992 in combination with vinorelbine iv chemotherapy as treatment in patients with HER2-overexpressing, metastatic breastcancer, who failed one prior trastuzumab treatment.

## Study design

Open-label, randomised phase 3 study, 2;1 randomisation

#### Intervention

One group receives oral BIBW once daily and intravenously vinorelbine. The other group receives weekly intravenous trastuzumab and weekly intravenuosly vinorelbine.

## Study burden and risks

Considering the estimated mean of 9 months (described at question E2) the

burden is:

physical examination: 11x HRQOL questionnaire 11x

ECG: 5x

LVEF echo or MUGA: 4x bloodwithdrawal: 39x CT or MRI scan: 6x

Administration of studymedication per infusion: 9x

# **Contacts**

#### **Public**

Boehringer Ingelheim

Comeniusstraat 6

1817 MS ALKMAAR

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

- female patients, older than 18;
- Histologically confirmed diagnosis of HER2 overexpression breast cancer;
- Stage 4 metastatic disease;
- Progressed on one prior trastuzumab treatment, but not received and failed on more than 1 trastuzumab based treatment;
- Patient must have received anthracycline and/or taxane based chemotherapy for adjavant treatment or first line treatment;
- Must have (archived) tumour tissue sample available for central re-assessment of HER2 status and prove HER2 positive;
- Must have at least one measurable lesion according to the RECIST criteria;
- Must have an ECOG score of 0 or 1:
- Must have a life expectancy of at least 6 months.

# **Exclusion criteria**

- Prior treatment with EGFR/HER2 targeted small molecules or antibodies other than trastuzumab:
- Prior treatment with vinorelbine;
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- Known pre-existing interstitial lung disease;
- Radiotherapy, chemotherapy, hormone therapy, immunotherapy or surgery (other than biopsy) within 4 weeks prior to randomisation;
- Active brain metastases;
- Any other current malignancy or malignancy diagnosed within the last 5 years;
- Significant or recent acute gastro-intestinal disorders;
- History or presence of clinically relevant cardiovascular abnormalities;
- Cardiac left ventricular function with less than 50%.

# Study design

# **Design**

Study phase: 3

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Treatment

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-11-2010

Enrollment: 15

Type: Actual

# Medical products/devices used

Product type: Medicine

Brand name: Herceptin

Generic name: Trastuzumab

Registration: Yes - NL intended use

Product type: Medicine

Brand name: Navelbine

Generic name: Vinorelbine

Registration: Yes - NL intended use

# **Ethics review**

Approved WMO

Date: 21-04-2010

Application type: First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 17-05-2010

Application type: First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 17-06-2010

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 21-10-2010

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 19-04-2011

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 21-10-2011

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 12-03-2012

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 11-05-2012

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 20-08-2012

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 20-12-2012

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 10-06-2013

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 01-11-2013

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date: 29-08-2014

Application type: Amendment

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

# **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 EUCTR2009-015476-98-NL CCMO NL31076.096.10