Trial record **1 of 1** for: INGE-B
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Efficacy/Quality of Live Study of Postmenop. Women With Advanced Breast Cancer, Treated With Letrozol and Palbociclib (INGE-B)

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified September 2016 by *iOMEDICO AG*

Sponsor:
iOMEDICO AG

Collaborator:
Pfizer

Information provided by (Responsible Party):
iOMEDICO AG

ClinicalTrials.gov Identifier:
NCT02894398

First received: August 25, 2016
Last updated: September 5, 2016
Last verified: September 2016
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

The purpose of this study is to evaluate the efficacy and quality of live in postmenopausal women with advanced breast cancer (locally advance inoperable or metastatic adenocarcinoma of the breast), HR+ / HER2-, who are treated with letrozol as baseline therapy in combination with palbociclib (PD0332991)

Condition	Intervention	Phase
Breast Cancer Hormone Receptor Positive Tumor Human Epidermal Growth Factor 2 Negative Carcinoma of Breast	Drug: Palbociclib Drug: Letrozole	Phase 2

Study Type: Interventional
Study Design: Endpoint Classification: Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: An Open-label, Multi-center, sINGlE Arm Clinical Study to Evaluate Treatment Efficacy/QoL in Postmenopausal Women With HR+, HER2-, Loco-regionally Recurrent or Metastatic Breast Cancer Receiving Palbociclib in Addition to Letrozole (**INGE-B**)

Resource links provided by NLM:

Genetics Home Reference related topics: breast cancer

MedlinePlus related topics: Breast Cancer Cancer

Drug Information available for: Letrozole Palbociclib

U.S. FDA Resources

Further study details as provided by iOMEDICO AG:

Primary Outcome Measures:

- Clinical Benefit Response (CBR) [Time Frame: 24 weeks after first administration of Palbociclib + Letrozol] [Designated as safety issue: No]

  CBR is defined as complete response (CR), partial response (PR), or stable disease (SD) according to RECIST 1.1.

Secondary Outcome Measures:

- Number of participants with Adverse Events as assessed by CTCAE V4.0 [Time Frame: From Date of Signed informed consent until PD, assessed up to 60 months.] [Designated as safety issue: Yes]

  Adverse Events as characterized by type, frequency, severity (as graded by National Cancer Institute [NCI] Common Terminology Criteria for Adverse Events [CTCAE] v.4.03), and seriousness

- Clinical Benefit Response (CBR) [Time Frame: Later than 24 weeks and at 48 weeks after first administration of Palbociclib + Letrozol] [Designated as safety issue: No]

  CBR is defined as complete response (CR), partial response (PR), or stable disease (SD) according to RECIST 1.1.

- Progression-free Survival rate [Time Frame: At 48 weeks (all patients) and 2 years (first-line patients only) after first administration of Palbociclib + Letrozol] [Designated as safety issue: No]
- Overall Survival rate [Time Frame: At 48 weeks after first administration of Palbociclib + Letrozol and yearly until EOS, assessed up to 60 months.] [Designated as safety issue: No]
- Time on treatment [Time Frame: From day of first treatment until permanent discontinuation (EOT), assessed up to 60 months.] [Designated as safety issue: No]
- Dosage [Time Frame: From day of first treatment until EOT, assessed up to 60 months.] [Designated as safety issue: No]
  - starting dose (mg)
  - adjusted doses (mg)

- Adminstration schedule [Time Frame: From day of first treatment until EOT, assessed up to 60 months.] [Designated as safety issue: No]

  - dates of administration

- Health-related quality of life (QoL) [Time Frame: From date of signed informed consent until disease progression or start of next anti-cancer therapy: every 12 weeks, assessed up to 60 months.] [Designated as safety issue: No]

  Health-related QoL will be assessed with the FACT-B (Functional Assessment of Cancer Therapy-Breast) questionnaire

- Health-related fatigue [Time Frame: From date of signed informed consent until disease progression or start of next anti-cancer therapy: every 12 weeks, assessed up to 60 months.] [Designated as safety issue: No]

  Fatigue will be assessed with the BFI (Brief Fatigue Inventory) questionnaire

- Health-related anxiety and depression [Time Frame: From date of signed informed consent until disease progression or start of next anti-cancer therapy: every 12 weeks, assessed up to 60 months.] [Designated as safety issue: No]

  Depression and anxiety will be assessed with the HADS-D (Hospital Anxiety and Depression Scale) questionnaire

- Physician's assessment of patient's overall health status and change in health status compared to previous visit [Time Frame: From Screening until disease progression or start of next anti-cancer therapy, assessed up to 60 months.] [Designated as safety issue: No]

  Assessed by 2 items at each cycle/at scheduled patient visit

Estimated Enrollment:	120
Study Start Date:	September 2016
Estimated Study Completion Date:	September 2022
Estimated Primary Completion Date:	September 2021 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Palbociclib + Letrozole Palbociclib will be administered orally once a day for 21 days followed by 7 days off-treatment (schedule 3/1). Letrozole is considered as Non Investigational Medicinal Product (NIMP) and will be prescribed as per local practice. Letrozole, administered orally once daily as continuous daily dosing schedule.	Drug: Palbociclib Capsules, 125mg daily, 21 days, 7 days off, cycles of 28 days. Dose reductions: 100 mg, 75 mg (no change in administration schedule) Number of cycles: until disease progression, intolerable toxicity, death or any other reasons Other Name: Ibrance (US) Drug: Letrozole Letrozole will be administered as basic therapy (commercially available tablets, obtained from local pharmacies) as followed: 2.5mg/daily, oral intake Other Name: Femara

Detailed Description:

This is a prospective, open-label, multi-center, single arm, non-comparative phase II study in postmenopausal women with HR+/HER2- advanced breast cancer receiving palbociclib in addition to letrozole. The study will take place in two countries, Austria (5 study centers) and Germany (40 study centers).

In total, 120 patients will be enrolled in this study. The study seeks to recruit 60 (58-62) patients for first-line treatment (Enrollment Group 1) and 60 (58-62) patients for second- or later-line treatment (Enrollment Group 2) with palbociclib and letrozole. Recruitment will be centrally monitored to allow closure of a respective group as soon as 60 (58-62) patients have been enrolled.

Treatment will be continued until disease progression, intolerable toxicity, death or any other reason. In case letrozole is discontinued, palbociclib has to be discontinued. In case treatment with palbociclib is stopped, letrozole can be continued according to investigator's discretion. Irrespectively of letrozole, the discontinuation of palbociclib is defined as end of treatment (EOT) in this study. After EOT, the patient enters the follow-up period.

Primary end point is clinical benefit response 24 weeks after the first study treatment of the patient.

A study independent, decentral, "virtual" biobank will be established. All patients will be asked to give consent for their tumor samples to be used for future investigational research. Study sites will inform the local pathologists about the patient's consent and ask for the tissue sample to be reserved for future analyses. The site is requested to collect contact details of the pathologist storing the tumor sample, the sample's identification number(s), and to document these in the eCRF.

The decision to perform subsequent investigational research studies on collected samples will be based on outcome data from this study or from new scientific findings related to the drug class or disease, as well as reagent and assay availability.

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Female
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Personally written informed consent prior to beginning protocol specific procedures, including expected cooperation of the patient for the treatment and follow-up, must be obtained and documented according to the local regulatory requirements
2. Women with proven diagnosis of advanced, defined as locally advanced inoperable or metastatic, adenocarcinoma of the breast
3. Hormone-receptor-positive (HR+) disease, defined as estrogen-receptor-positive (ER+) and/or progesterone-receptor-positive (PgR+)
4. Human epidermal growth factor receptor 2-negative (HER2-) disease (HER2 neg/+ or HER2++ with CISH/FISH neg.)
5. Postmenopausal status according to investigator assessment.
6. Age ≥18 years
7. Measurable disease as per Response Evaluation Criterion in Solid Tumors [RECIST] or bone-only disease
8. Patients scheduled for palliative treatment with letrozole for first- or later-line
9. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
10. Adequate organ and marrow function
11. Resolution of all acute toxic effects of prior therapy, including radiotherapy Grade <1 (except toxicities not considered a safety risk for the patient) and recovery from surgical procedures
12. Fluent in spoken and written German

Exclusion Criteria:

1. Prior treatment with any CDK4/6 inhibitor
2. Prior adjuvant therapy with letrozole if last intake <12 months prior to entering the study
3. Prior palliative therapy with letrozole
4. More than one prior palliative chemotherapy
5. Known hypersensitivity to letrozole, or any of its excipients
6. Current use of food or drugs known to be potent inhibitors or inducers of CYP3A4 (refer to Appendix 15.4)
7. Current use of drugs known to prolong the QT interval
8. Participation in other studies involving investigational drug(s) (Phases I-IV) within 2 weeks before the current study treatment begins
9. QTc > 480 msec on the screening ECG (using the QTcF formula and/or the QTcB (Bazett) formula); history of QT syndrome, Brugada syndrome or known history of QTc prolongation, or Torsade de Pointes
10. High cardiovascular risk, including, but not limited to recent myocardial infarction, severe/unstable angina and severe cardiac dysrhythmias in the past 6 months prior to enrollment
11. Diagnosis of any second malignancy within the last 3 years prior to enrollment, except for adequately treated basal cell or squamous cell skin cancer, or carcinoma in situ of the cervix
12. Known, not-irradiated CNS metastases

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02894398

Contacts

Contact: Michaela Wieland 0049- 761- 152420 michaela.wieland@iomedico.com

Contact: iOMEDICO AG 0049- 761- 152420 info@iomedico.com

Locations

Germany

Research Site **Not yet recruiting**
Aachen, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Aschaffenburg, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Baden-Baden, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Berlin, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Bottrop, Germany
Contact: Reaearch Site

Research Site **Not yet recruiting**
Celle, Germany
Contact: Reaearch Site

Research Site **Not yet recruiting**
Donauwörth, Germany
Contact: Reaearch Site

Research Site **Not yet recruiting**
Dortmund, Germany
Contact: Reaearch Site

Research Site **Not yet recruiting**
Dresden, Germany
Contact: Reaearch Site

Research Site **Not yet recruiting**
Erlangen, Germany
Contact: Reaearch Site

Research Site **Not yet recruiting**
Essen, Germany
Contact: Reaearch Site

Research Site **Not yet recruiting**
Esslingen, Germany
Contact: Reaearch Site

Research Site **Not yet recruiting**
Frankfurt, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Freiburg i. Br., Germany
Contact: Research Site

Research Site **Not yet recruiting**
Gerlingen, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Göttingen, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Gütersloh, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Halle, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Hamburg, Germany
Contact: 2 Research Sites

Research Site **Not yet recruiting**
Heilbronn, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Karlsruhe, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Kassel, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Krefeld, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Langen, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Leer, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Mönchengladbach, Germany
Contact: Research Site

Research Site **Not yet recruiting**
München, Germany
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Research Site **Not yet recruiting**
Münster, Germany
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Research Site **Not yet recruiting**
Offenburg, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Recklinghausen, Germany
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Research Site **Not yet recruiting**
Regensburg, Germany
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Research Site **Not yet recruiting**
Rostock, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Singen, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Stolberg, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Ulm, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Wilhelmshaven, Germany
Contact: Research Site

Research Site **Not yet recruiting**
Würzburg, Germany
Contact: Research Site

Sponsors and Collaborators

iOMEDICO AG

Pfizer

Investigators

Study Chair: iOMEDICO AG Freiburg / Germany

More Information

Responsible Party:	iOMEDICO AG
ClinicalTrials.gov Identifier:	NCT02894398 History of Changes
Other Study ID Numbers:	iOM-04318
Study First Received:	August 25, 2016
Last Updated:	September 5, 2016
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices
Individual Participant Data Plan to Share IPD:	No

Keywords provided by iOMEDICO AG:

HR+	Palbociclib
HER2-	Letrozole
Locally Advanced (inoperable or metastatic) Breast Cancer	Postmenopausal women

Additional relevant MeSH terms:

Breast Neoplasms	Steroid Synthesis Inhibitors
Neoplasms by Site	Enzyme Inhibitors
Neoplasms	Molecular Mechanisms of Pharmacological Action
Breast Diseases	Estrogen Antagonists
Skin Diseases	Hormone Antagonists
Letrozole	Hormones, Hormone Substitutes, and Hormone Antagonists
Palbociclib	Physiological Effects of Drugs
Antineoplastic Agents	Protein Kinase Inhibitors
Aromatase Inhibitors	

ClinicalTrials.gov processed this record on September 27, 2016