

Trial record **1 of 1** for: AMLSG 23-14

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## Study of Palbociclib in MLL-rearranged Acute Leukemias

**This study is currently recruiting participants.** (see [Contacts and Locations](#))

*Verified July 2016 by University of Ulm*

**Sponsor:**

University of Ulm

**Collaborators:**

Pfizer  
Nationales Centrum für Tumorerkrankungen Heidelberg

**Information provided by (Responsible Party):**

Prof. Dr. Richard Schlenk, University of Ulm

**ClinicalTrials.gov Identifier:**

NCT02310243

First received: December 1, 2014

Last updated: July 22, 2016

Last verified: July 2016

[History of Changes](#)

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[No Study Results Posted](#)

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### Purpose

Diagnosis: Acute myeloid leukemia; Acute lymphoblastic leukemia Age  $\geq$  18 years, no upper age limit Study drug: Palbociclib Phase Ib/IIa, open-label

- Phase Ib: Based on previous experience with 125 mg palbociclib once daily for 21 days followed by 7 days of rest in patients with breast cancer, liposarcoma, non-small cell lung cancer, hepatocellular carcinoma, ovarian cancer, mantle-cell lymphoma, and glioblastoma, this regimen will be chosen for the first dose to be evaluated in the phase Ib. Based on a 3 + 3 modified Fibonacci design, the tolerable dose of palbociclib for the phase IIa is defined.
- Phase IIa: single-agent palbociclib using the tolerable dose defined in the phase Ib part of the study is administered once daily for 21 days followed by 7 days of rest. Based on the optimal two-stage design of Simon, 21 patients are treated in the first stage. If results are positive, 29 additional patients will be recruited into the second stage of the study. An efficacy of the investigational therapy will be rejected in the first stage of 21 treated patients if two or less patients achieve complete remission (CR), CR with incomplete blood count recovery (CRi), partial remission (PR), or anti-leukemic effect (ALE). If three or more patients achieve CR, CRi, PR, or ALE during this first stage, the trial is intended to be continued in the second stage with a total sample size of 50 patients.

Start of recruitment: February 2015 End of recruitment: February 2017 End of study (last patient out): February 2018 The treatment duration of an individual patient is estimated to be 2-6 months, but may be unlimited in patients with sustained response ("case-by-case decision").

Observation time per patient after entry into the study (incl. treatment) is at least 12 months.

<a href="#">Condition</a>	<a href="#">Intervention</a>	<a href="#">Phase</a>
Acute Myeloid Leukemia Acute Lymphoblastic Leukemia	Drug: Palbociclib	Phase 1 Phase 2

Study Type: [Interventional](#)

Study Design: [Endpoint Classification: Safety Study](#)  
[Intervention Model: Single Group Assignment](#)  
[Masking: Open Label](#)  
[Primary Purpose: Treatment](#)

Official Title: Phase Ib/IIa Study of Palbociclib in MLL-rearranged Acute Leukemias **AMLSG 23-14**/Palbo-AL-1

### Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [core binding factor acute myeloid leukemia](#) [cytogenetically normal acute myeloid leukemia](#) [familial acute myeloid leukemia with mutated CEBPA](#)

[MedlinePlus](#) related topics: [Acute Myeloid Leukemia](#) [Chronic Lymphocytic Leukemia](#) [Leukemia](#)

[Drug Information](#) available for: [Palbociclib](#)

[Genetic and Rare Diseases Information Center](#) resources: [Myeloid Leukemia](#) [Acute Myeloid Leukemia](#) [Acute Non Lymphoblastic Leukemia](#) [Acute Lymphoblastic Leukemia](#) [Lymphosarcoma](#)

[U.S. FDA Resources](#)

**Further study details as provided by University of Ulm:**

Primary Outcome Measures:

- Number of Participants with Adverse Events [ Time Frame: 12 months ] [ Designated as safety issue: Yes ]  
Safety assessments
- Maximum tolerated dose of palbociclib [ Time Frame: 12 months ] [ Designated as safety issue: Yes ]
- overall response rate [ Time Frame: 12 months ] [ Designated as safety issue: No ]

Secondary Outcome Measures:

- Relapse-free survival [ Time Frame: three years ] [ Designated as safety issue: No ]
- Overall survival [ Time Frame: three years ] [ Designated as safety issue: No ]
- Evaluation of target (CDK6) inhibition by palbociclib [ Time Frame: three years ] [ Designated as safety issue: No ]
- Assessment of Quality of life [ Time Frame: 6 months ] [ Designated as safety issue: No ]

Estimated Enrollment: 50  
Study Start Date: July 2015  
Estimated Study Completion Date: July 2018  
Estimated Primary Completion Date: July 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Palbociclib Phase 1b: 125 mg palbociclib once daily for 21 days followed by 7 days of rest; this regimen will be chosen for the first dose to be evaluated. phase 1la: single-agent palbociclib using the tolerable dose defined in the phase 1b part of the study is administered once daily for 21 days followed by 7 days of rest.	Drug: Palbociclib oral, once daily (125mg, 100mg or 75mg) for 21 days Other Name: PD-0332991-00

**Eligibility**

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

**Criteria**

Inclusion Criteria:

- Patients with confirmed diagnosis of acute leukemia with MLL rearrangement according to the 2008 WHO Classification
- Patients with MLL-rearranged leukemia who are refractory to standard induction therapy and not immediate candidates for allogeneic HSCT (bridge to transplant is allowed)
- Patients with MLL-rearranged leukemia who relapsed after standard first-line treatment and are not immediate candidates for allogeneic HSCT (bridge to transplant is allowed)
- Patients with newly diagnosed MLL-rearranged leukemia who are not eligible for intensive first-line therapy
- Genetic assessment in the AMLSG central laboratory
- Age ≥ 18 years, no upper age limit
- WHO performance status of ≤ 2
- No prior chemotherapy two weeks before study entry except hydroxyurea to control hyperleukocytosis
- Non-pregnant and non-nursing. Women of child-bearing potential must have a negative serum or urine pregnancy test with a sensitivity of at least 25 mIU/mL within 72 hours prior to registration (WOCBP is defined as a sexually active mature woman who has not undergone a hysterectomy or who has had menses at any time in the preceding 24 months).
- Female patients in the reproductive age and male patients must agree to avoid getting pregnant or to father a child while on therapy and for three months after the last dose of therapy.
- Women of child-bearing potential must either commit to continued abstinence from heterosexual intercourse or begin one acceptable method of birth control (IUD, tubal ligation, or partner's vasectomy). Hormonal contraception is an inadequate method of birth control.
- Men must agree not to father a child and must use a latex condom during any sexual contact with WOCBP while receiving therapy and for three months after therapy is stopped, even if they have undergone successful vasectomy.
- Signed written informed consent

Exclusion Criteria:

- Prior treatment with palbociclib
- Performance status > 2 according to WHO criteria
- Organ insufficiency: creatinine > 1.5 x upper normal serum level; bilirubin, AST, or AP > 2.5 x upper normal serum level; heart failure NYHA III/IV; uncontrolled hypertension; unstable angina; serious cardiac arrhythmia; severe obstructive or restrictive ventilation disorder
- Uncontrolled infection

- Patients with a "currently active" second malignancy other than non-melanoma skin cancer. Patients are not considered to have a "currently active" malignancy if they have completed therapy and are considered by their physician to be at less than 30% risk of relapse within one year.
- Severe neurologic or psychiatric disorder interfering with ability of giving informed consent
- Known or suspected active alcohol or drug abuse
- Known positivity for HIV, active HAV, HBV, or HCV infection
- Bleeding disorder unrelated to leukemia
- Uncontrolled CNS involvement (treatment for CNS-involvement prior to inclusion is allowed)
- QTc > 470 msec (based on the mean value of triplicate ECGs), family or personal history of long or short QT syndrome, Brugada syndrome, or known history of QTc prolongation or Torsade de Pointes
- Uncontrolled electrolyte disorders that can aggravate the effects of a QTc-prolonging drug (e.g., hypocalcemia, hypokalemia, hypomagnesemia)
- No consent for registration, storage, and processing of individual disease characteristics, information on the course of the disease, and information obtained from the family physician and/or other physicians involved in the treatment of the patient about study participation
- No consent for biobanking

## ▶ 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: NCT02310243

### Locations

#### Germany

Klinikum Augsburg Augsburg, Germany, 86156 Contact: Christoph Schmid, MD <a href="mailto:christoph.schmid@klinikum-augsburg.de">christoph.schmid@klinikum-augsburg.de</a>	<b>Recruiting</b>
Helios Klinikum Bad Saarow Bad Saarow, Germany, 15526 Contact: Daniel Schöndube, MD <a href="mailto:daniel.schoendube@helios-kliniken.de">daniel.schoendube@helios-kliniken.de</a>	<b>Recruiting</b>
Charité Campus Benjamin Franklin Berlin, Germany, 12200 Contact: Claudia Bladus, MD <a href="mailto:claudia.baldus@charite.de">claudia.baldus@charite.de</a>	<b>Recruiting</b>
Vivantes Klinikum Neukölln Berlin, Germany, 12351 Contact: Maike de Wit, MD <a href="mailto:maike.dewit@vivantes.de">maike.dewit@vivantes.de</a>	<b>Recruiting</b>
Charité Campus Virchow-Klinikum Berlin, Germany, 13353 Contact: Jörg Westermann, MD <a href="mailto:joerg.westermann@charite.de">joerg.westermann@charite.de</a>	<b>Recruiting</b>
Universitätsklinikum Bonn Bonn, Germany, 53105 Contact: Karin Tina Mayer, MD <a href="mailto:karin.mayer@ukb.uni-bonn.de">karin.mayer@ukb.uni-bonn.de</a>	<b>Recruiting</b>
Städtisches Klinikum Braunschweig gGmbH Braunschweig, Germany, 38114 Contact: Jürgen Krauter, MD <a href="mailto:krauter.juergen@mh-hannover.de">krauter.juergen@mh-hannover.de</a>	<b>Recruiting</b>
Kliniken Essen Süd, Ev. Krankenhaus Essen-Werden gGmbH Essen Werden, Germany, 45239 Contact: Mohammed Wattad, MD <a href="mailto:m.wattad@kliniken-essen-sued.de">m.wattad@kliniken-essen-sued.de</a>	<b>Recruiting</b>
Malteser Krankenhaus St. Franziskus-Hospital Flensburg, Germany, 24939 Contact: Nadezda Basara, MD <a href="mailto:nadezda.basara@malteser.org">nadezda.basara@malteser.org</a>	<b>Recruiting</b>
Universitätsklinikum Freiburg Freiburg, Germany, 791016 Contact: Ralph Wäsch, MD <a href="mailto:ralph.waesch@uniklinik-freiburg.de">ralph.waesch@uniklinik-freiburg.de</a>	<b>Recruiting</b>
MVZ Osthessen Fulda, Germany, 36043 Contact: Andrea Distelrath, MD <a href="mailto:distelrath@mvz-osthessen.de">distelrath@mvz-osthessen.de</a>	<b>Recruiting</b>
Universitätsklinikum Giessen Giessen, Germany, 35392 Contact: Alexander Burchardt, MD <a href="mailto:alexander.burchardt@innere.med.uni-giessen.de">alexander.burchardt@innere.med.uni-giessen.de</a>	<b>Recruiting</b>
Universitätsklinikum Hamburg-Eppendorf Hamburg, Germany, 20246 Contact: Walter Fiedler, MD <a href="mailto:fiedler@uke.de">fiedler@uke.de</a>	<b>Recruiting</b>
Medizinische Hochschule Hannover	<b>Recruiting</b>

Hannover, Germany, 30625

Contact: Michael Heuser, MD [heuser.michael@mh-hannover.de](mailto:heuser.michael@mh-hannover.de)

Universitätsklinikum Heidelberg

Heidelberg, Germany, 69120

Contact: Alwin Krämer, MD [Alwin.Kraemer@med.uni-heidelberg.de](mailto:Alwin.Kraemer@med.uni-heidelberg.de)

**Recruiting**

Städtisches Klinikum Karlsruhe gGmbH

Karlsruhe, Germany, 76133

Contact: Mark Ringhoffer, MD [mark.ringhoffer@klinikum-karlsruhe.com](mailto:mark.ringhoffer@klinikum-karlsruhe.com)

**Recruiting**

Universitätsklinikum Schleswig-Holstein Campus Kiel

Kiel, Germany, 24116

Contact: Heinz-August Horst, MD [h.horst@med2.uni-kiel.de](mailto:h.horst@med2.uni-kiel.de)

**Recruiting**

Caritas-Krankenhaus Lebach

Lebach, Germany, 66822

Contact: Stephan Kremers, MD [stephankremers@onkologie-lebach.de](mailto:stephankremers@onkologie-lebach.de)

**Recruiting**

Uni-Klinikum der Otto-von-Guericke-Universität

Magdeburg, Germany, 39120

Contact: Florian Heidel, MD [florian.heidel@med.ovgu.de](mailto:florian.heidel@med.ovgu.de)

**Recruiting**

Universitätsmedizin der Johannes Gutenberg-Universität

Mainz, Germany, 55131

Contact: Thomas Kindler, MD [thomas.kindler@unimedizin-mainz.de](mailto:thomas.kindler@unimedizin-mainz.de)

**Recruiting**

Pius Hospital Oldenburg

Oldenburg, Germany, 26121

Contact: Frank Griesinger, MD [frank.griesinger@pius-hospital.de](mailto:frank.griesinger@pius-hospital.de)

**Recruiting**

Medizinische Universitätsklinik Tübingen

Tübingen, Germany, 72076

Contact: Helmut Salih, MD [Helmut.Salih@med.uni-tuebingen.de](mailto:Helmut.Salih@med.uni-tuebingen.de)

**Recruiting**

University Hospital of Ulm

Ulm, Germany, 89081

Contact: Richard F Schlenk, MD 0049-731-500 ext 45900 [richard.schlenk@uniklinik-ulm.de](mailto:richard.schlenk@uniklinik-ulm.de)

**Recruiting**

#### Sponsors and Collaborators

University of Ulm

Pfizer

Nationales Centrum für Tumorerkrankungen Heidelberg

#### ▶ More Information

Responsible Party: Prof. Dr. Richard Schlenk, Prof. Dr. med., University of Ulm

ClinicalTrials.gov Identifier: [NCT02310243](#) [History of Changes](#)

Other Study ID Numbers: **AMLSG 23-14**

Study First Received: December 1, 2014

Last Updated: July 22, 2016

Health Authority: Germany: Federal Institute for Drugs and Medical Devices

Keywords provided by University of Ulm:

Acute myeloid leukemia

Acute lymphoblastic leukemia

MLL-rearranged leukemia

Palbociclib (PD-0332991-0054)

Additional relevant MeSH terms:

Leukemia

Leukemia, Myeloid

Leukemia, Myeloid, Acute

Precursor Cell Lymphoblastic Leukemia-Lymphoma

Leukemia, Lymphoid

Neoplasms by Histologic Type

Neoplasms

Lymphoproliferative Disorders

Lymphatic Diseases

Immunoproliferative Disorders

Immune System Diseases

Palbociclib

Antineoplastic Agents

Protein Kinase Inhibitors

Enzyme Inhibitors

Molecular Mechanisms of Pharmacological Action

ClinicalTrials.gov processed this record on October 07, 2016