

ZEUS

Safety Profile of Idelalisib in Patients With Refractory Follicular Lymphoma

NCT-Nummer:

[NCT03568929](#)

Studienbeginn:

Mai 2018

Letztes Update:

30.04.2021

Wirkstoff:

Idelalisib

Indikation (Clinical Trials):

Lymphoma, Lymphoma, Follicular

Geschlecht:

Alle

Altersgruppe:

Erwachsene (18+)

Phase:

-

Sponsor:

Gilead Sciences

Collaborator:

-

Studien-Informationen

Brief Summary:

The primary objective of this study is to assess the overall safety profile of idelalisib

monotherapy in patients with refractory follicular lymphoma (FL).

Ein-/Ausschlusskriterien

Inclusion Criteria:

- Individuals who were or are being treated for refractory Follicular Lymphoma (FL) according to the product information for idelalisib and treatment guidelines in routine clinical practice.

Exclusion Criteria:

- Individuals included in clinical trials on idelalisib within the timeframe of this study.

Studien-Rationale

Primary outcome:

1. Overall Safety Profile of Idelalisib as Measured by the Incidence of Adverse Events (AE), Serious AEs, Special Situation Reports, Adverse Drug Reactions (ADR), and Serious ADRs (Time Frame - 250 patient-years (8 months of treatment period, 3 years of retrospective time frame, and 2.5 years of prospective observation period))

Secondary outcome:

1. Overall Response Rate (ORR) (Time Frame - 250 patient-years (8 months of treatment period, 3 years of retrospective time frame, and 2.5 years of prospective observation period)):

ORR is defined as the proportion of participants who achieve a clinical response with or without radiological confirmation as documented within their electronic health record after the initiation of treatment with idelalisib and during the treatment period with idelalisib.

2. Duration of Response (DOR) (Time Frame - 250 patient-years (8 months of treatment period, 3 years of retrospective time frame, and 2.5 years of prospective observation period)):

DOR is defined as the interval from the first documentation of a clinical response with or without radiological confirmation to the earlier of the first documentation of disease progression or death from any cause.

3. Progression-free Survival (PFS) (Time Frame - 250 patient-years (8 months of treatment period, 3 years of retrospective time frame, and 2.5 years of prospective observation period)):

PFS is defined as the interval from the date of initiation of idelalisib to the earlier date of the first documentation of disease progression or death from any cause.

4. Time to Next Treatment (TTNT) (Time Frame - 250 patient-years (8 months of treatment period, 3 years of retrospective time frame, and 2.5 years of prospective observation period)): *TTNT is defined as the interval from the initiation of treatment with idelalisib to the earlier date of the initiation of next systemic treatment of Follicular Lymphoma (excluding palliative care or palliative radiation) or death from any cause.*

5. Overall Survival (OS) (Time Frame - 250 patient-years (8 months of treatment period, 3 years of retrospective time frame, and 2.5 years of prospective observation period)): *OS is defined as the interval from the date of initiation of idelalisib to death from any cause.*

Geprüfte Regime

- Idelalisib (Zydelig®):
Tablets administered according to the product information and treatment guidelines in routine clinical practice

Studienleiter

Gilead Study Director

Study Director
Gilead Sciences

Kontakt

Gilead Clinical Study Information Center

Kontakt:

Phone: 1-833-445-3230 (GILEAD-0)
E-Mail: GileadClinicalTrials@gilead.com

Studienlocations (3 von 94)

Landeskrankenhaus Steyr

Steyr
Austria

Status: Zurückgezogen

Ziekenhuis Netwerk Antwerpen Stuivenberg Hospital

2060 Antwerpen
Belgium

Status: Rekrutierend

Centre Hospitalier Universitaire d'Amiens (CHU d'Amiens) - Hopital Nord

80054 Amiens Cedex 1

France

Status: Rekrutierend

Centre Hospitalier Bourg-en-Bresse Fleyriat

Bourg-en-Bresse

France

Status: Rekrutierend

Centre Hospitalier de Cannes

06400 Cannes

France

Status: Rekrutierend

Hôpital Privé Sévigné

Cesson-Sévigné

France

Status: Rekrutierend

Centre Hospitalier Chalon sur Saône William Morey

71100 Chalon-Sur-Saone

France

Status: Rekrutierend

Centre Hospitalier Universitaire Estaing

63003 Clermont-Ferrand

France

Status: Rekrutierend

CHU de Dijon

2100 Dijon

France

Status: Abgeschlossen

Groupe Hospitalier Mutualiste de Grenoble - Institut Daniel Hollard

Grenoble

France

Status: Rekrutierend

Clinique Victor Hugo

72015 Le Mans Cedex 2

France

Status: Rekrutierend

Centre Hospitalier Le Mans

72037 Le Mans

France

Status: Abgeschlossen

Centre Hospitalier de Lens

62300 Lens

France

Status: Rekrutierend

Hôpital de la Conception

13005 Marseille

France

Status: Rekrutierend

Centre Hospitalier Régional d'Orléans

45650 Orléans

France

Status: Rekrutierend

Centre hospitalier de Perigueux

33604 Pessac

France

Status: Abgeschlossen

Centre Hospitalier Lyon Sud

69495 Pierre Bénite Cedex

France

Status: Rekrutierend

Centre Hospitalier Universitaire de Poitiers

86021 Poitiers Cedex

France

Status: Rekrutierend

Hopital Bretonneau, Centre Henri Kaplan

Cedex 37044 Tours

France

Status: Rekrutierend

Klinikum Saint Marien Amberg

92224 Amberg

(Bayern)

Germany

Status: Zurückgezogen

Klinikum Frankfurt Höchst

65929 Frankfurt

(Hessen)

Germany

Status: Rekrutierend

Brustzentrum der Universitätsmedizin Göttingen

Robert-Koch-Straße 40

37075 Göttingen

Deutschland

Status: Rekrutierend

Pankreaskarzinomzentrum am Klinikum Südstadt Rostock

Südring 81
18059 Rostock
Deutschland

Status: Rekrutierend

Caritas Klinikum Saarbrücken

D-66113 Saarbrücken
(Saarland)
Germany

Status: Zurückgezogen

Gemeinschaftspraxis für Hämatologie und Onkologie Westerstede

26655 Westerstede
(Niedersachsen)
Germany

Status: Rekrutierend

University General Hospital of Alexandroupolis

68100 Alexandroupolis
Greece

Status: Rekrutierend

Athens Medical Center-Psychikon branch

11525 Athens
Greece

Status: Rekrutierend

Henry Dunant Hospital

11526 Athens
Greece

Status: Rekrutierend

University General Hospital of Patras

265 04 Patra
Greece

Status: Rekrutierend

Metropolitan Hospital, Department of Hepatology

18547 Piraeus

Greece

Status: Zurückgezogen

AHEPA University General Hospital of Thessaloniki

54636 Thessaloniki

Greece

Status: Rekrutierend

Theagenio Anticancer Hospital of Thessaloniki

Thessaloniki

Greece

Status: Zurückgezogen

Saint James's Hospital

8 Dublin

Ireland

Status: Rekrutierend

Mater Misericordiae University Hospital

Dublin 7 Dublin

Ireland

Status: Rekrutierend

Midland Regional Hospital - Mullingar

Mullingar

Ireland

Status: Rekrutierend

Ospedali Riuniti di Ancona, Clinica Ematologica

60126 Ancona

Italy

Status: Rekrutierend

Ospedale Mazzoni

Ascoli Piceno
Italy

Status: Rekrutierend

Azienda Ospedaliera Policlinico di Bari

70124 Bari
Italy

Status: Rekrutierend

Monsignor Raffaele Dimiccoli Hospital

70051 Barletta
Italy

Status: Rekrutierend

Azienda Socio Sanitaria Territoriale degli Spedali Civili di Brescia

25123 Brescia
Italy

Status: Rekrutierend

Azienda Ospedaliera di Rilievo Nazionale e di Alta Specializzazione Garibaldi

95122 Catania
Italy

Status: Rekrutierend

Azienda Ospedaliero Universitaria Policlinico Vittorio Emanuele

95124 Catania
Italy

Status: Rekrutierend

Ospedale di Civitanova Marche

Civitanova Marche
Italy

Status: Rekrutierend

Azienda Ospedaliero - Universitaria Careggi

50134 Florence

Italy

Status: Rekrutierend

Presidio Ospedaliero di Livorno

Livorno

Italy

Status: Rekrutierend

Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori

47014 Meldola

Italy

Status: Rekrutierend

Fondazione IRCCS Istituto Nazionale dei Tumori

20100 Milano

Italy

Status: Rekrutierend

Fondazione IRCCS Cà Grande Ospedale Maggiore Policlinico

20122 Milano

Italy

Status: Rekrutierend

Istituto Scientifico Universitario San Raffaele

20132 Milano

Italy

Status: Rekrutierend

Azienda Ospedaliera Universitaria Maggiore Della Carita di Novara

28100 Novara

Italy

Status: Rekrutierend

Fondazione IRCCS Policlinico San Matteo

27100 Pavia

Italy

Status: Rekrutierend

Azienda Ospedaliera di Perugia

06129 Perugia

Italy

Status: Rekrutierend

Azienda Ospedaliera Ospedali Riuniti Marche Nord

Pesaro

Italy

Status: Rekrutierend

Azienda Unità Sanitaria Locale di Piacenza-Ospedale Guglielmo da Saliceto

Piacenza

Italy

Status: Rekrutierend

Azienda Unita Sanitaria Locale di Ravenna

48121 Ravenna

Italy

Status: Rekrutierend

Arcispedale Santa Maria Nuova

42123 Reggio Emilia

Italy

Status: Rekrutierend

IRCCS Centro di Riferimento Oncologico di Basilicata di Rionero in Vulture

85028 Rionero in Vulture

Italy

Status: Rekrutierend

Universita degli Studi di Roma La Sapienza

00161 Roma

Italy

Status: Rekrutierend

Istituti di Ricovero e Cura A Carattere Scientifico - Istituti Fisioterapici Ospitalieri

Roma

Italy

Status: Rekrutierend

Ospedale Casa Sollievo della Sofferenza

71013 San Giovanni Rotondo

Italy

Status: Rekrutierend

Azienda Ospedaliera Universitaria Senese-L'ospedale Santa Maria alle Scotte

53100 Siena

Italy

Status: Rekrutierend

Ospedale San Bortolo di Vicenza

Vicenza

Italy

Status: Rekrutierend

Instituto Português de Oncologia Francisco Gentil, Centro Regional de Lisboa SA

1090-023 Lisbon

Portugal

Status: Rekrutierend

Fundació Hospital de la Santa Creu i Sant Pau

8025 Barcelona

Spain

Status: Rekrutierend

Hospital General Universitario de Alicante

3011 Alicante

Spain

Status: Rekrutierend

Hospital Universitari Germans Trias i Pujol

08916 Badalona

Spain

Status: Rekrutierend

Hospital Universitari Mútua Terrassa

8221 Barcelona

Spain

Status: Rekrutierend

Hospital Universitario de Burgos

09006 Burgos

Spain

Status: Rekrutierend

Hospital De Cabuenes

33394 Gijon

Spain

Status: Rekrutierend

Hospital Universitario Donostia

20014 Gipuzkoa

Spain

Status: Rekrutierend

Institut Català d'Oncologia

L'Hospitalet de Llobregat

Spain

Status: Rekrutierend

Hospital Universitario Severo Ochoa

28911 Leganés

Spain

Status: Rekrutierend

Hospital General Universitario Gregorio Maranon

28007 Madrid

Spain

Status: Rekrutierend

Hospital San Pedro de Alcantara

28009 Madrid

Spain

Status: Rekrutierend

Hospital Universitario Infanta Leonor

28031 Madrid

Spain

Status: Rekrutierend

Hospital Universitario Ramon Y Cajal, Carretera de Colmenar Viejo Km 9.100

28034 Madrid

Spain

Status: Rekrutierend

Hospital Universitario Ramon Y Cajal, Servicio Hematologia HURyC. Crtra. De Colmenar Viejo, Km 9.100

28034 Madrid

Spain

Status: Rekrutierend

Hospital Universitario Fundacion Jimenez Diaz

28040 Madrid

Spain

Status: Rekrutierend

Hospital General Universitario Morales Meseguer

30008 Murcia

Spain

Status: Rekrutierend

Hospital Universitario Virgen de la Arrixaca

30120 Murcia

Spain

Status: Rekrutierend

Hospital Universitario Rey Juan Carlos

Móstoles

Spain

Status: Abgeschlossen

Hospital Universitario Central de Asturias

33004 Oviedo

Spain

Status: Rekrutierend

Hospital Universitario Son Dureta

Palma de Mallorca

Spain

Status: Rekrutierend

Clínica Universidad de Navarra

31008 Pamplona

Spain

Status: Rekrutierend

Hospital Universitario de Salamanca

37007 Salamanca

Spain

Status: Rekrutierend

Hospital Universitario de Canarias

38320 Santa Cruz de Tenerife
Spain

Status: Rekrutierend

Hospital Universitari Arnau De Vilanova (Huav)

46015 Valencia
Spain

Status: Rekrutierend

Hospital Clinico Universitario Lozano Blesa

50009 Zaragoza
Spain

Status: Rekrutierend

Hospital de Día Quirónsalud Zaragoza

50012 Zaragoza
Spain

Status: Aktiv, nicht rekrutierend

Karolinska Universitetssjukhuset

141 86 Stockholm
Sweden

Status: Rekrutierend

Velindre NHS Trust

Cardiff
United Kingdom

Status: Rekrutierend

St George's Healthcare NHS Trust

SW17 0QT London
United Kingdom

Status: Rekrutierend

South Tees Hospitals Nhs Foundation Trust

TS4 3BW Middlesbrough

United Kingdom

Status: Aktiv, nicht rekrutierend

Abertawe Bro Morgannwg University Health Board

SA2 8QA Swansea

United Kingdom

Status: Rekrutierend

Quelle: ClinicalTrials.gov