An Open Label, Roll Over Study to Provide Idelalisib to Subjects Previously Treated with the Investigational PI3K* Inhibitor, GS-9820

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To provide idelalisib, a marketed PI3K* inhibitor, in lieu of GS-9820, an investigational second generation PI3K* inhibitor, to subjects receiving GS-9820 in Study GS-US-315-0102 at the time of study closure.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43418

Source
ToetsingOnline

Brief title
Idela

Condition

- Other condition
- Leukaemias

Synonym
Chronic Lymphatic Leukemia

Health condition

CLL

Research involving
Human

Sponsors and support

Primary sponsor: Gilead Sciences
Source(s) of monetary or material Support: Industry

Intervention

Keyword: CLL, GS-9820, Idelalisib, PI3K Inhibitor

Outcome measures

Primary outcome

There are no primary endpoints of this study.

Secondary outcome

There are no secondary endpoints of this study

Study description

Background summary

B-cell lymphoid malignancies comprise the most common hematological malignancies. These cancers arise from the accumulation of monoclonal B lymphocytes in lymph nodes and often in organs such as blood, bone marrow, lymph nodes, spleen, and liver. Among the variants of these cancers are non-Hodgkin lymphomas (NHL) * including diffuse large B-cell lymphoma (DLBCL), indolent non-Hodgkin lymphoma (iNHL), and mantle cell lymphoma (MCL) * chronic lymphocytic leukemia (CLL), and Hodgkin lymphoma (HL). The goal of therapy for these diseases is to induce tumor regression and delay tumor progression in order to control disease-related complications and potentially extend life. Patients who require treatment are commonly given chemotherapeutic and/or immunotherapeutic agents. For any of these cancers, further sequential therapies are given in an attempt to control disease manifestations. Despite use of agents with differing mechanisms of action, progressive resistance to treatment develops. Patients with progressive disease have a poor prognosis; median survival for these groups of patients is generally *2 years. Novel mechanisms of action are needed to offer additional treatment options for patients with lymphoid malignancies who are experiencing progressive lymphadenopathy or symptoms due to disease progression. Knowledge of the

critical importance of PI3K* in B-cell biology and neoplasia has encouraged a search for inhibitors of this enzyme that could provide new options in the therapy of lymphoid malignancies, including CLL. Gilead Sciences, Inc has developed novel drugs that can suppress tumor growth through targeting of PI3K activity. High-throughput screening was the basis for the discovery of novel agents that selectively inhibit PI3K isoform function. These efforts initially led to identification of GS-1101 (also known as CAL-101), a 415-Dalton, orally bio-available, investigational drug that represented a first-in-class selective inhibitor of PI3K*.
This rollover study provides access to idelalisib for eligible subjects receiving GS-9820 in Study
GS-US-315-0102 at the time of study closure.

Study objective

To provide idelalisib, a marketed PI3K* inhibitor, in lieu of GS-9820, an investigational second generation PI3K* inhibitor, to subjects receiving GS-9820 in Study GS-US-315-0102 at the time of study closure.

Study design

This study is an open-label, rollover study to provide idelalisib to subjects receiving GS-9820 in Study GS-US-315-0102 at the time of study closure.

Intervention

Idelalisib will be administered on a BID schedule starting on Day 1. Treatment will persist until the earliest of subject withdrawal from study, disease progression, intolerable Idelalisib-related toxicity, pregnancy, substantial noncompliance with study procedures, or study discontinuation

Study burden and risks

The patient is subjected to investigations that would take place in their regular care. However they will be tested for possible infections and will be required to start profylaxis treatment for PJP. Patients will be required to visit the outpatient clinic biweekly for 24 weeks, then monthly. Prior to each visit to the outpatient clinic, a blood sample will be taken to check the blood values. With regular care the patient would come monthly for follow up and will get their blood levels checked. The following side effects have been reported and might have been caused by Idela: infections and death, Severe diarrhea or colitis, Liver injury, Rash, Decrease in a certain type of white blood cell, Fever, Inflammation of the lungs, Severe blistering rash, Toxic epidermal necrolysis. For these patients there are no curative options. There are no standard treatments for these people available. The expectation is that the

drug under study is effective with acceptable toxicity.

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

1) Receiving GS-9820 in Study GS-US-315-0102 with objective evidence of clinical benefit defined as at least stable disease on imaging assessed by the IRC at the time of Study GS-US-315-0102 closure;2) For female subjects of childbearing potential, willingness to use a protocol recommended method of contraception during heterosexual intercourse from the signing of informed consent throughout the study treatment period and up to 30 days from the last dose of idelalisib;3) For male subjects of reproductive potential having intercourse with females of childbearing potential, willing to use a protocol recommended method of contraception during heterosexual intercourse and to refrain from sperm donation throughout the study treatment period and for 90 days following discontinuation of idelalisib;4)

Willingness to comply with scheduled visits, drug administration plan, imaging studies, laboratory tests, other study procedures, and study restrictions, including mandatory prophylaxis for Pneumocystis jirovecci pneumonia (PJP). Note: Psychological, social, familial, or geographical factors that might preclude adequate study participation should be considered.;5) Evidence of a personally signed informed consent indicating that the subject is aware of the neoplastic nature of their disease and has been informed of the procedures to be followed, the experimental nature of the therapy, alternatives, potential benefits, possible side effects, potential risks and discomforts, and other pertinent aspects of study participation.

Exclusion criteria

1) Known hypersensitivity or intolerance to any of the active substances or excipients in the formulation of idelalisib.;2) Toxicities that would preclude initiating therapy with idelalisib prior to enrolment (eg history of drug-induced pneumonitis, ongoing inflammatory bowel disease);3) Concurrent participation in another therapeutic clinical trial.;4) Pregnant or breastfeeding.;5) Ongoing infection, treatment, or profylaxis for CMV within the past 28 days.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2016
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Idelalisib
Generic name:	Zydelig
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	29-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-12-2016

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2015-005766-39-NL
CCMO	NL56615.018.16