A Phase 3b, Multicenter, Open-label, PCI-32765 (Ibrutinib) Long-term Extension Study

Published: 11-08-2016
Last updated: 14-04-2024

The objective of this study is to collect long-term safety and efficacy data for subjects treated with PCI-32765 and to provide ongoing access to PCI-32765 for subjects who are currently enrolled in PCI-32765 studies that have been completed...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Interventional

Summary

ID

NL-OMON43124

Source
ToetsingOnline

Brief title
CAN3001

Condition

- Lymphomas non-Hodgkin's B-cell

Synonym
Non-Hodgekin

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Janssen

Intervention

Keyword: extension trial, Ibrutinib, non-Hodgekin

Outcome measures

Primary outcome

The objective of this study is to collect long-term safety and efficacy data

for subjects treated with PCI-32765 and to provide ongoing access to PCI-32765

for subjects who are currently enrolled in PCI-32765 studies that have been

completed according to the parent protocol (eg, final analysis has been

performed), are actively receiving treatment with PCI-32765, and who continue

to benefit from PCI-32765 treatment.

Secondary outcome

not applicable

Study description

Background summary

A Phase 3b, Multicenter, Open-label, PCI-32765 (Ibrutinib) Long-term Extension Study
PCI-32765 (IMBRUVICA*; ibrutinib; JNJ-54179060) is a first-in-class, potent, orally-administered, covalently-binding small molecule inhibitor of Bruton*s tyrosine kinase. *PCI-32765* and *ibrutinib* refer to the same molecule; hereafter, *PCI-32765* will be used. PCI-32765 is being investigated for the treatment of subjects with chronic lymphocytic leukemia/small lymphocytic lymphoma, mantle cell lymphoma, follicular lymphoma, and diffuse large B-cell lymphoma. PCI-32765 is being co-developed by Janssen Research & Development, LLC and Pharmacyclics, Inc. Ibrutinib was approved by the United States Food and Drug Administration for the treatment of adult patients with mantle cell lymphoma and chronic lymphocytic leukemia who have received at least one prior therapy on 13 November 2013 and 12 February 2014, respectively. Approvals have also been obtained in a number of other countries worldwide. For the most comprehensive nonclinical and clinical information regarding the efficacy and safety of PCI-32765, refer to the latest version of the Investigator's

Brochure.

Study objective

The objective of this study is to collect long-term safety and efficacy data for subjects treated with PCI-32765 and to provide ongoing access to PCI-32765 for subjects who are currently enrolled in PCI-32765 studies that have been completed according to the parent protocol (eg, final analysis has been performed), are actively receiving treatment with PCI-32765, and who continue to benefit from PCI-32765 treatment.

Study design

This Phase 3b, multicenter, open-label study will collect long-term safety and efficacy data and provide PCI-32765 access to subjects in completed PCI-32765 studies. Subjects will continue with the current PCI-32765 dosing regimen established in the parent PCI-32765 study until the investigator determines that the subject is no longer benefitting from treatment (ie, disease progression or unacceptable toxicity has occurred), the study is terminated by the sponsor, the subject withdraws consent, alternative access to PCI-32765 is available and feasible, or for other reasons as defined in this protocol. Subjects can receive treatment with single-agent PCI-32765 until the end of study, which is defined as the time of the last End-of-Treatment safety assessment for the last subject participating in the study or 5 years after the last subject entered, or upon a decision by the sponsor to terminate the study, whichever occurs earlier.

Intervention

Ibrutinib (oral, once daily) based on the treatment scheme in the parent protocol.

Study burden and risks

not applicable

Contacts

Public
Janssen-Cilag

Dr. Paul Janssenweg 150
Tilburg 5026 RH
NL

Scientific
Janssen-Cilag

Dr. Paul Janssenweg 150
Tilburg 5026 RH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Participants must be currently participating in a PCI-32765 clinical study considered completed and have received at least 6 months of treatment with PCI-32765. At study entry, participants must be actively receiving treatment with single-agent PCI-32765;OR;- Subjects must have participated in a PCI-32765 randomized clinical study in which they initially received comparator treatment and now cross-over to ibrutinib. Note: A minimum of 6 months requirement for prior PCI-32765 treatment will not be mandatory in this case and subjects with less than 6 months will be required to have more frequent initial safety assessments (see Time and Events Table 2);- Agrees to protocol-defined use of effective contraception;- Negative blood or urine pregnancy test at screening

Exclusion criteria

- Requires anticoagulation with warfarin or equivalent vitamin K antagonists;- Requires treatment with strong cytochrome P450 (CYP)3A4/5 inhibitors, unless previously approved by sponsor;- Any condition or situation which, in the opinion of the investigator, may put the participant at significant risk, may confound the study results, or may interfere significantly with volunteer*s participation in the study

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2016
Enrollment:	1
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Imbruvica
Generic name:	Ibrutinib
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	11-08-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	20-10-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	25-04-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-01-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2012-004225-24-NL
ClinicalTrials.gov	NCT01804686
CCMO	NL58351.056.16