An open-label multi-center single agent panobinostat rollover protocol for patients who have completed a previous Novartis-sponsored panobinostat study and are judged by the investigator to benefit from continued single agent panobinostat treatment (CLBH589B2402B)

Published: 13-05-2014
Last updated: 21-04-2024

Primary: To allow continued use of panobinostat to patients receiving single agent therapy with panobinostat in a Novartis-sponsored study.Secondary: To collect long term data on SAEs.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON40870

Source
ToetsingOnline

Brief title
CLBH589B2402B

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
solid tumors; cancer

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma BV

Intervention

Keyword: cancer, monotherapy, panobinostat

Outcome measures

Primary outcome

NA.

Secondary outcome

SAEs.

Study description

Background summary

This is an extension study for subjects who have completed the study CLBH589X2105 (A phase I, open label, multi-center study to evaluate the pharmacokinetics and safety of oral panobinostat in patients with advanced solid tumors and varying degrees of renal function).
By joining the study subjects can continue treatment with panobinostat. In this study the long term effects of the drug will be investigated. All subjects will be treated with active study drug.

Study objective

Primary: To allow continued use of panobinostat to patients receiving single agent therapy with panobinostat in a Novartis-sponsored study.
Secondary: To collect long term data on SAEs.

Study design

Multicenter phase II non-comparative extension study. Continuation of the panobinostat dose during previous study. Dose adjustment possible.
Treatment period until unacceptable side effects, withdrawal of consent or lack of benefit from treatment, max. 5 years.
Approx. 8-15 patients (1 in NL).

Intervention

Treatment with panobinostat.

Study burden and risks

Risk: Adverse effects of study medication.
Burden: Study duration max 5 years. Visits every 3 months. Final visit 30 days post last dose of study treatment. No study related tests and procedures required (investigator judgement).

Contacts

Public
Novartis

Raapopseweg 1
Arnhem 6824 DP
NL
Scientific
Novartis

Raapopseweg 1
Arnhem 6824 DP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patient is currently enrolled in a Novartis-sponsored, Oncology Clinical Development & Medical Affairs study receiving single agent panobinostat and has fulfilled all their requirements in the parent study.
* Patient is currently benefiting from the treatment with single agent panobinostat, as determined by the investigator.

Exclusion criteria

* Patient has been permanently discontinued from panobinostat study treatment in the parent study due to unacceptable toxicity, non-compliance to study procedures, withdrawal of consent or any other reason.
* Patient has participated in a Novartis sponsored combination trial where panobinostat was dispensed in combination with another study medication and is still receiving combination therapy.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-06-2014
Enrollment:	1
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	panobinostat
Generic name:	panobinostat

Ethics review

Approved WMO Date:	13-05-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-06-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-09-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-10-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
Other	clinical trials.gov; NCT01802879
EudraCT	EUCTR2012-005252-41-NL
CCMO	NL48997.058.14