MEK114375: A Rollover Study to Provide Continued Treatment with GSK1120212 to Subjects with Solid Tumors or Leukemia

Published: 13-03-2013
Last updated: 24-04-2024

To provide continued treatment with trametinib.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract neoplasms
Study type	Interventional

Summary

ID

NL-OMON38447

Source
ToetsingOnline

Brief title
MEK114375

Condition

- Respiratory tract neoplasms

Synonym
non-small cell lung cancer; lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: GlaxoSmithKline

Intervention

Keyword: leukemia, solid, trametinib, tumor

Outcome measures

Primary outcome

None.

Secondary outcome

None.

Study description

Background summary

Study MEK114653 is a multicenter randomized open-label phase II parallel group study comparing treatment with GSK1120212 (trametinib, a MEK-inhibitor) with standard treatment with docetaxel in patients with non-small cell lung cancer (NSCLC) stage IIIB or IV with KRAS, NRAS, BRAF of MEK1 mutation.
During a regular interim-analysis it was concluded that the totality of data did not favour trametinib. Therefore the sponsor decided to discontinue trametinib-arm of the study. Patients benefitting from trametinib can proceed with this treatment in a roll-over study.
In the Netherlands only one patient from the study is still on treatment with trametinib. This will be the only Dutch patient that will be enrolled in the roll-over study. The sole objective of Dutch participation in this study is to enable this patient to continue with trametinib.

Study objective

To provide continued treatment with trametinib.

Study design

Open non-comparative phase II study. Treatment with trametinib as monotherapy or in combination.
Treatment duration as long as the patient has clinical benefit from.

Intervention

Treatment with trametinib.

Study burden and risks

Risk: Adverse effects of study medication.
Belasting: Visits every 3 weeks.
Blood draws every visit (during the first 2 years of treatment with trametinib), approx. 10 mL/occasion.
ECG every 9 weeks (during the first 2 years of treatment with trametinib).
MUGA scan every 9 week.
No participation in sub-studies in the Netherlands.

Contacts

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GlaxoSmithKline

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Currently participating in trametinib study and is receiving treatment with trametinib.
• Currently receiving clinical benefit as determined by the investigator from previous treatment with trametinib either as monotherapy or as part of a combination treatment regimen.

Exclusion criteria

• Local access to commercially available GSK1120212.
• Current use of a prohibitive medication(s) as listed in the protocol (section 6.2).
• Bazett-corrected interval >=501 msec at the time of transition to this study.
• LVEF < institutional lower limit of normal.

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):	27-11-2013
Enrollment:	1
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	trametinib
Generic name:	trametinib

Ethics review

Approved WMO Date:	13-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-06-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-11-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	clinicaltrials.gov; registratienummer n.n.b.
EudraCT	EUCTR2010-023015-33-NL
CCMO	NL43632.042.13