An Open Label Phase II Study of Tipifarnib in Advanced Non-Hematological Malignancies with HRAS Mutations.

Published: 18-05-2017
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Primary objective: To determine the antitumor activity regarding objective response rate (ORR) of tipifarnib in subjects with locally advanced non-resectable or metastatic, relapsed and/or refractory, non-haematological malignancies with HRAS...

Ethical review	Approved WMO
Status	Completed
Health condition type	Endocrine neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON48820

Source
ToetsingOnline

Brief title
Tipifarnib Phase II Study-KO-TIP-001

Condition

- Endocrine neoplasms malignant and unspecified

Synonym
advanced cancer, cancer with a specific genetic mutation

Research involving
Human

Sponsors and support

Primary sponsor: Kura Oncology, Inc

Source(s) of monetary or material Support: De sponsor van het onderzoek

Intervention

Keyword: Non-Hematological Malignancies, Open Label, Phase II, Tipifarnib

Outcome measures

Primary outcome

Response assessments according to RECIST 1.1

Secondary outcome

Treatment-emergent adverse events (TEAE) and SAEs evaluated according to NCI

CTCAE v.4.03

Study description

Background summary

This phase II study will investigate the antitumor activity regarding the ORR of tipifarnib in subjects with locally advanced tumors who are carriers of HRAS mutations and for whom no curative treatment is available. Enrolling subjects may continue based on prior obtained information in the clinical study sites on the HRAS status of the tumor. However, all subjects, except those with anaplastic thyroid gland tumors, must consent to give at least 10 tumor slides (or equivalent tumor tissue block) of a prior diagnostic biopsy for a retrospective test of the RAS gene status, including T81C-polymorphism, in a central institution.

Study objective

Primary objective: To determine the antitumor activity regarding objective response rate (ORR) of tipifarnib in subjects with locally advanced non-resectable or metastatic, relapsed and/or refractory, non-haematological malignancies with HRAS mutations.

Study design

A multi-centre, open-label phase II study.

Subjects will be enrolled in two non-randomised cohorts.

* Cohort 1: Malignant thyroid gland tumors with HRAS mutations.
* Cohort 2: Non-haematological malignancies with HRAS mutations in stage 1. Squamous cell carcinomas in the head-neck area (SCCHN) with HRAS mutations in stage 2.
* Cohort 3: Squamous cell carcinomas with HRAS mutations

Intervention

Tipifarnib will be administered at a dose of 600 mg, orally, twice daily, on days 1-7 and 15-21 of 28 day treatment cycles. If no unmanageable toxicities occur, subjects may continue to receive the treatment with tipifarnib up to 12 months if there is no disease progression and unmanageable toxicity. The treatment may continue for more than 12 months after approval of the investigator and the sponsor.

Study burden and risks

There are certain risks and discomforts associated with study procedures. There can be pain, swelling, and/or bruising at the site where blood is drawn for lab assessments, as well as possible inflammation of the vein or an infection at this site.
Mild skin rash (irritation, reddening or itching) can occur during an ECG at places where electrodes are placed.
An imaging procedure may be uncomfotable and/or giving a claustrophobic sensation and an injection with intravenous contrast may give itching, a rash, hives, or a feeling of warmth throughout the body.

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

- Subject is at least 18 years of age.
- Subject has a histologically or cytologically confirmed diagnosis of non-hematological malignancy for which there is no curative therapy available
- Subject has a tumor that carries a missense HRAS mutation according to a methodology approved by the Sponsor.
- Subject has measurable disease according to RECIST v1.1 and has relapsed (progressive disease) or is refractory to prior therapy

Exclusion criteria

- Ongoing treatment with an anticancer agent not contemplated in this protocol.
- Prior treatment (at least 1 full treatment cycle) with an FTase inhibitor.
- Concomitant disease or condition that could interfere with the conduct of the study, or that would, in the opinion of the Investigator, pose an unacceptable risk to the subject in this study

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-08-2018
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NA
Generic name:	Tipifarnib

Ethics review

Approved WMO Date:	18-05-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-10-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-01-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-02-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-03-2018

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-05-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-06-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-09-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-11-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-06-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-10-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-12-2019
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
EudraCT	EUCTR201500453512-NL
CCMO	NL61057.042.17