A Phase 1 Study to Assess the Safety, Tolerability, Pharmacokinetics, and Biological Activity of SAR405838 in Patients with Advanced Cancer.

Published: 04-05-2012
Last updated: 01-05-2024

Primary objective* To determine safety and the maximum tolerated dose (MTD) of SAR405838 through the characterization of dose-limiting toxicities (DLTs).* To assess biological activities of SAR405838 in patients with dedifferentiated liposarcoma...

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

Summary

ID

NL-OMON44662

Source
ToetsingOnline

Brief title
TED12318

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
advanced cancer

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis

Source(s) of monetary or material Support: sanofi

Intervention

Keyword: advanced cancer, Phase I, Safety, SAR405838

Outcome measures

Primary outcome

* SAR405838 Maximum Tolerated Dose (MTD)

* In MTD cohort, clinical benefit

Secondary outcome

* Adverse events (eg, number of patients experience adverse events)

* PK parameters (Cmax, Tmax, AUC)

* Biomarkers

* Clinical Response

* Drug administration compliance

Study description

Background summary

SAR405838 is a new anti-cancer study drug that may stop the growth of cancer by causing cancer cell death or blocking cancer cell division.
SAR405838 has only shown its ability to slow or stop tumor growth when tested in animal models. Its effects in humans are currently unknown. This research study is the first use of SAR405838 in the treatment of patients.

Study objective

Primary objective
* To determine safety and the maximum tolerated dose (MTD) of SAR405838 through the characterization of dose-limiting toxicities (DLTs).* To assess biological activities of SAR405838 in patients with dedifferentiated liposarcoma during MTD cohort expansion.

secondory objective
* pharmacokinetic (PK) profile of SAR405838
* Biomarkers in association with SAR405838
* Anti- tumor activity in response to SAR405838
* Food effect on SAR405838 PK
* compliance with SAR405838 treatment
* Cytochrome P450 3A4/5 (CYP3A4/5) activity

Study design

This is a multicenter study being conducted in Europe.

Approximately 66 patients will take part in the study in dose finding phase and 16 expansion phase.
The study consists of 3 parts:
*screening,
* study treatment,
* follow-up visit.
The total duration of participation in the study will be approximately 16 to 30 weeks.

Intervention

SAR405838 will be taken at various doses by mouth once daily.

Study burden and risks

Risks are related to blood sampling and possible side effects of study drug.The burden for the patient will be the number of visits to the center as part of the trial.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Histologically or cytologically confirmed diagnosis of a solid tumor for which no further effective standard treatment is available.
* Patients with lymphomas may be enrolled.
* For dose escalation, tumor type that has high biomarker prevalence without molecular confirmation of biomarker status, or any tumor type with molecular confirmation of biomarker status. At a specified dose level, enrollment will be limited to dedifferenitated liposarcoma, and for the MTD cohort, only dedifferentiated liposarcoma will be included.
* Presence of locally advanced or metastatic disease with at least one measurable lesion.

Exclusion criteria

* Age > 18 years.
*Eastern Cooperative Oncology Group (ECOG)performance status of >1.
*Life expectancy <12 weeks.
*Unstable brain or leptomeningeal disease based on history and physical examination.
* Inadequate organ functions, positive pregancy test
* Pregnancy or breast-feeding.
*Any anti-cancer drug therapy within 2 weeks (8 weeks for mitomycin C or nitrosoureas) prior to study treatment or 5 halflives of the drug prior to study treatment, whichever is shorter, prior to study treatment.;Unwillingness, if not postmenopausal or surgically sterile, to abstain from sexual intercourse or employ an effective barrier or medical method of contraception;during the study drug administration and follow-up periods.;Recent (3 months) history of acute pancreatitis

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-07-2012
Enrollment:	57
Type:	Actual

Ethics review

Approved WMO Date:	04-05-2012
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	15-06-2012
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	10-07-2012
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	17-07-2012
Application type:	Amendment

Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	16-01-2013
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	22-01-2013
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	28-02-2013
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	26-03-2013
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	16-05-2013
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	29-07-2013
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	12-12-2013
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	

Date:	18-12-2013
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	14-03-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	20-06-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	26-06-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	31-07-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	28-08-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	14-07-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van

	Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	13-07-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	04-09-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	14-09-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	23-10-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	27-10-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	EUCTR2012-000733-39-NL
ClinicalTrials.gov	NCT01636479
CCMO	NL40400.031.12