A Phase 1 Study to Determine the Safety, Pharmacokinetics and Pharmacodynamics of the Selective Met Inhibitor, JNJ 38877605 in Subjects With Advanced or Refractory Solid Tumors.

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To invetiate the:toxicity and the maximum tolerated dose.To determine the pharmacokinetic (PK) profile of JNJ-38877605 and its N-desmethyl metabolite,JNJ-40434654 and investigate the potential impact of food on the PK profile.To explore...

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

Summary

ID

NL-OMON31546

Source
ToetsingOnline

Brief title
N/A

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Advanced or Refractory Solid Tumors, available therapies, no longer likely to benefit from approved

Research involving

Human

Sponsors and support

Primary sponsor: Johnson & Johnson Pharmaceutical
Source(s) of monetary or material Support: Zie B7

Intervention

Keyword: JNJ 38877605, phase1, selective kinase inhibitor, solid tumors

Outcome measures

Primary outcome

To determine the safety and tolerability of JNJ-38877605 (adverse event

profile, dose-limiting

toxicity and the maximum tolerated dose).

Secondary outcome

To determine the pharmacokinetic (PK) profile of JNJ-38877605 and its

N-desmethyl metabolite,

JNJ-40434654 and investigate the potential impact of food on the PK profile.

To explore pharmacodynamic effects of JNJ-38877605.

To measure antitumor activity in response to administration of JNJ-38877605.

Study description

Background summary

JNJ-38877605 has been identified in preclinical studies as an orally active, selective Met kinase
inhibitor with potent in-vitro and in-vivo antitumor activity and a favorable toxicology profile and is
therefore being investigated as a treatment for cancer.

Study objective

To invetiate the:
toxicity and the maximum tolerated dose.
To determine the pharmacokinetic (PK) profile of JNJ-38877605 and its N-desmethyl metabolite,
JNJ-40434654 and investigate the potential impact of food on the PK profile.
To explore pharmacodynamic effects of JNJ-38877605.
To measure antitumor activity in response to administration of JNJ-38877605.

Study design

This study is a first-in-human, open-label, 2-part, Phase 1 dose escalation study of JNJ-38877605,
administered orally to subjects with advanced or refractory solid tumors with no available, approved
therapeutic alternative. Up to 66 subjects will be enrolled in the study; up to 42 subjects in Part 1 and
up to 24 subjects in Part 2. The total number of subjects to be enrolled will depend on the dose level at
which dose-limiting toxicity (DLT) is observed and the maximum tolerated dose (MTD) can be
defined.

Intervention

NVT

Study burden and risks

NVT

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

histologically or cytologically confirmed advanced or refractory solid tumor and no longer eligible for approved, available standard therapies

Exclusion criteria

known brain metastases

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):	14-05-2008
Enrollment:	33

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	JNJ 38877605
Generic name:	JNJ 38877605

Ethics review

Approved WMO Date:	11-12-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-02-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-09-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-10-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-10-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-01-2009
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-02-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-03-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-05-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-06-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-10-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-11-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-04-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	21-10-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2007-005494-65-NL
CCMO	NL20531.078.07