AN OPEN-LABEL SUNITINIB MALATE (SU011248) CONTINUATION PROTOCOL FOR PATIENTS WHO HAVE COMPLETED A PRIOR SUNITINIB STUDY AND ARE JUDGED BY THE INVESTIGATOR TO HAVE THE POTENTIAL TO BENEFIT FROM SUNITINIB TREATMENT

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Ethical review	Approved WMO
Status	Pending
Health condition type	Neoplastic and ectopic endocrinopathies
Study type	Interventional

Summary

ID

NL-OMON31148

Source
ToetsingOnline

Brief title
A6181114

Condition

- Neoplastic and ectopic endocrinopathies
- Nervous system neoplasms malignant and unspecified NEC

Synonym
neuro-endocrine tumors, pancreascancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: continuation protocol, NET, open-label, sunitinib

Outcome measures

Primary outcome

The study, taking the objective into account, has not got any formal hypothesis

testing; therefore, there is no formal primary endpoint.

Secondary outcome

The following will be collected and reported on:

• Duration of clinical benefit

• Type, incidence, severity, timing, seriousness, and relatedness of Adverse

Events

Study description

Background summary

Sunitinib malate (SUTENT®, SU011248) is approved by the US Food and Drug Administration (FDA) for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate and for the treatment of advanced renal cell carcinoma. Marketing Authorization has been granted by the EU Commission for Sunitinib malate for the treatment of

unresectable and/or
metastatic malignant gastrointestinal stromal tumor after failure of imatinib mesylate treatment due to resistance or intolerance and for the treatment of advanced and/or metastatic renal cell carcinoma (MRCC) after failure of interferon alfa or interleukin-2 therapy.

The safety and efficacy of sunitinib malate for the treatment of advanced breast cancer and pancreatic islet cell tumor have not yet been determined and are still investigational.

Study objective

The objective of the study is to provide access to sunitinib treatment for patients who have completed a prior sunitinib study and are judged by the investigator to have the potential to benefit from sunitinib treatment. During this study the duration of clinical benefit, the long-term safety and tolerability of sunitinib, given in a continuous daily dose schedule, will be assessed.

Study design

This is an open-label continuation protocol:

If the subject has previously been on sunitinib, he or she will begin treatment at the dose used at the time of withdrawal from the previous parent trial. If the subject has not previously been on sunitinib in one of the parent protocols, a starting dose of 37.5 mg daily will be used.

Sunitinib-experienced subjects will return to clinic for a study visit at 4 weeks, and every 8 weeks thereafter.
Sunitinib-naïve subjects will return for their first four visits at 2, 4, 6, and 8 weeks and every 8 weeks thereafter.

Subjects may continue to access sunitinib on this protocol as long as there is evidence of disease control and/or clinical benefit in the judgement of the investigator.

There is no predetermined sample size for this study.

Intervention

sunitinib malate (daily taken orally 25, 37,5 en 50 mg, dosis depends on the prior sunitinib study of the subject)

Study burden and risks

Subjects will daily take sunitinib capsules orally. Physical examination and blood draws will be performed.

The most common adverse events from sunitinib are fatigue and nausea, diarrhea, constipation, dermatitis, hypertension, headache etc. (see informed consent document). During the collection of blood samples, there is a risk of bruising, pain, or infection at the site of the blood draw.

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

Subjects must have participated in a previous Pfizer Worldwide medical sponsored parent sunitinib study (A6181111) and, in the opinion of the parent study investigator are thought to have the potential to derive clinical benefit from continued treatment with sunitinib.

Exclusion criteria

Current treatment in another clinical research trial.
Concurrent treatment with another anti-cancer drug except with exemestane as specified in this protocol.
Evidence of neurological signs/symptoms secondary to brain metastases, spinal cord compression, or new evidence of brain or leptomeningeal disease.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2007
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	sutent
Generic name:	sunitinib malate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	06-07-2007

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-08-2007
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	EUCTR2006-006538-16-NL
ClinicalTrials.gov	NCT00428220
CCMO	NL17630.042.07