# A phase II study of Sutent (SU11248) as second line treatment in pleural mesothelioma after first line treatment with a platinum and antimetabolite

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
14/08/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
02/10/2007	Completed	Results
Last Edited	Condition category	[] Individual participant data
15/10/2008	Cancer	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Anna Nowak

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

# Secondary identifying numbers

2005-195

# Study information

#### Scientific Title

# Study objectives

Sunitinib maleate will show anti-tumour activity in terms of objective tumour responses in malignant pleural mesothelioma following failure of first line chemotherapy.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Ethics approval received from the Sir Charles Gairdner Hospital Human Research Ethics Committee in 2005.

# Study design

Non-randomised, phase II, interventional, one-armed, non-controlled trial

# Primary study design

Interventional

# Secondary study design

Non randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

# Participant information sheet

# Health condition(s) or problem(s) studied

Malignant pleural mesothelioma

#### Interventions

Sunitinib 50 mg orally (po) daily x 28 days every 42 days. Treatment continues indefinitely for as long as the patient is receiving benefit (i.e., stable disease or objective response), is not experiencing toxicities requiring withdrawal of study drug, does not withdraw consent to participate, and is considered fit to continue by the investigator. Duration of follow-up is to death.

#### Intervention Type

Drug

#### Phase

# Drug/device/biological/vaccine name(s)

Sunitinib maleate (Sutent [SU11248])

#### Primary outcome measure

Objective response rate, assessed with the Modified RECIST criteria using spiral Computed Tomography (CT) scan at baseline, 6 weeks, 12 weeks, then 12-weekly thereafter while on study.

#### Secondary outcome measures

- 1. Time to Tumour Progression (TTP), assessed from study enrolment to tumour progression as per the Modified RECIST criteria
- 2. Time To Treatment Failure (TTTF), assessed from study enrolment to cessation of study treatment for any reason
- 3. Overall Survival, assessed from study enrolment and including death from all causes
- 4. Change in Forced Expiratory Volume in one second (FEV1) and Forced Vital Capacity (FVC)
- 5. Change in serum mesothelin
- 6. Adverse events and defined by National Cancer Institute (NCI) Common Toxicity Criteria Version 3.0
- 7. Positron Emission Tomography (PET) response is assessed using 2-Fluoro-deoxy-D-Glucose (FDG) PET scan at baseline and at 6 weeks only

# Overall study start date

27/06/2006

# Completion date

01/12/2008

# **Eligibility**

#### Key inclusion criteria

Patients must fulfill all the following criteria to be eligible for this study:

- 1. Histologically or cytologically confirmed diagnosis of malignant mesothelioma of the pleura
- 2. Previous therapy with at least one cycle of a platinum analogue and an antimetabolite with documented progression on, or after completion of, first-line therapy
- 3. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1
- 4. One or more measurable lesions (by Modified Response Evaluation Criteria in Solid Tumours [RECIST] criteria)
- 5. Life expectancy greater than 12 weeks
- 6. Women of child-bearing age must use effective contraception
- 7. Adequate bone marrow function defined as:
- 7.1. Granulocyte count greater than  $1.5 \times 10^9/L$
- 7.2. Platelet count greater than  $100 \times 10^9/L$
- 7.3. Haemoglobin greater than 10 g/dl
- 8. Adequate renal function: calculated creatinine clearance (Cockcroft-Gault formula) greater than 45 ml/min
- 9. Adequate hepatic function defined as a total bilirubin less than Upper Limit of Normal (ULN), Alanine Aminotransferase (ALT) or Aspartate Aminotransferase (AST) less than 2.5 x ULN, or 1.5 x ULN if Alkaline Phosphatase (Alk Phos) less than 2.5 x ULN. Alk Phos less than 5 x ULN unless patient has bone metastases
- 10. Ability to give fully informed written consent according to International Conference on

Harmonisation (ICH)/Good Clinical Practice (GCP) guidelines and to comply with the instructions in the protocol

# Participant type(s)

**Patient** 

# Age group

**Not Specified** 

#### Sex

Both

# Target number of participants

51

# Key exclusion criteria

Any one of the following criteria will render a patient ineligible for this trial:

- 1. Previous second-line systemic chemotherapy for malignant mesothelioma
- 2. ECOG performance status greater than or equal to 2
- 3. Mesothelioma originating outside the pleura (e.g., peritoneum)
- 4. Previous radiotherapy to all measurable lesions
- 5. Symptomatic central nervous system involvement
- 6. Pregnancy or lactation
- 7. Serious concomitant systemic disorders incompatible with the study at the discretion of the investigator, e.g., severe peripheral neuropathy
- 8. Second primary malignancy diagnosed within the last 5 years (except for adequately treated non-melanoma skin cancers and in-situ cervical carcinoma adequately treated by cone excision)

#### Date of first enrolment

27/06/2006

#### Date of final enrolment

01/12/2008

# Locations

#### Countries of recruitment

Australia

6009

Study participating centre
Department of Medical Oncology
Nedlands WA
Australia

# Sponsor information

#### Organisation

Sir Charles Gairdner Hospital (Australia)

# Sponsor details

Hospital Avenue Nedlands WA Australia 6009

### Sponsor type

Hospital/treatment centre

#### Website

http://www.scgh.health.wa.gov.au/

#### **ROR**

https://ror.org/01hhqsm59

# Funder(s)

# Funder type

Industry

#### **Funder Name**

Pfizer (Australia) (ref: IIR 2005-0777)

# Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

#### **Funding Body Type**

Government organisation

# **Funding Body Subtype**

For-profit companies (industry)

#### Location

United States of America

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date
Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration