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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Phase II

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 x 10^9/L
7.2. Platelet count greater than 100 x 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

Study participating centre
Department of Medical Oncology
Nedlands WA
Australia
6009

Sponsor information

Organisation
Sir Charles Gairdner Hospital (Australia)

Sponsor details
Hospital Avenue
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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