# A Phase II study to evaluate the efficacy and safety of PTK787 in patients with metastatic cutaneous melanoma

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
15/02/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/04/2006	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
19/03/2020	Cancer			

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Pippa Corrie

#### Contact details

Oncology Centre
Box 193
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 2QQ
+44 (0)1223 216083
pippa.corrie@addenbrookes.nhs.uk

## Additional identifiers

EudraCT/CTIS number

2005-004710-33

IRAS number

## ClinicalTrials.gov number

NCT00563823

## Secondary identifying numbers

CAMEL 02

## Study information

#### Scientific Title

A Phase II study to evaluate the efficacy and safety of PTK787 in patients with metastatic cutaneous melanoma

## **Acronym**

**PTK787** 

## Study objectives

To determine the efficacy of PTK787 in patients with metastatic cutaneous melanoma in terms of objective response rate

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved by the South East Medical Research Ethics Committee on 13/02/2006, reference number 06/MRE01/10

## Study design

Interventional, open-label, uncontrolled, phase II study

## Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Metastatic cutaneous melanoma

#### **Interventions**

Prior to commencing treatment with PTK787/ZK222584, patients will undergo the following interventions:

- 1. Dynamic contrast enhanced magnetic resonance imaging (MRI) scan of liver metastases
- 2. Tumour and adjacent tissue biopsy
- 3. Blood sample to measure soluble markers

## Intervention Type

Drug

#### Phase

Phase II

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

PTK787/ZK222584

#### Primary outcome measure

Objective response rate

#### Secondary outcome measures

- 1. Time to progression
- 2. Survival at six months and one year
- 3. Overall survival
- 4. Safety and toxicity
- 5. Correlation of pharmacological and genetic markers to response
- 6. Correlation of tumour vascularity and permeability to response

#### Overall study start date

03/01/2006

#### Completion date

31/12/2006

## **Eligibility**

## Key inclusion criteria

- 1. Life expectancy >12 weeks
- 2. Performance status 0, 1 or 2 (Eastern Cooperative Oncology Group [ECOG] performance scale)
- 3. Presence of one or more bi-dimensionally measurable lesions, either clinically or radiologically (by chest x-ray, computerised tomography [CT] or conventional magnetic resonance imaging [MRI] scan as appropriate) using response evaluation criteria in solid tumors (RECIST) criteria 4. Age >18 years
- 5. Hb >10 g/dl, platelets >100,000 mm^3, white cell count (WCC) >3.0 x 10^9 /l, absolute neutrophil count (ANC) >1.5 x 10^9 /l
- 6. Bilirubin <1.5 x upper limit of normal (ULN), alkaline phosphatase <3 x ULN, transaminases <3 x ULN, (or alkaline phosphatase and transaminases <5 if liver metastases are present)
- 7. Creatinine < 1.5 x ULN
- 8. Measured creatinine clearance >50 ml/min and total urinary protein <500 mg per 24 hours
- 9. Written informed consent provided by the patient
- 10. Patients of both genders with reproductive potential not employing an effective method of

birth control, barrier contraceptives must be used throughout the trial. Oral, implantable, or injectable contraceptives may be affected by cytochrome P450 interactions, and are therefore not considered effective for this study.

- 11. Prior adjuvant therapy is allowed, as long as it was completed at least six months previously
- 12. One line of prior chemotherapy for advanced disease is allowed, as long as the best response to this treatment was complete response, partial response or stable disease, determined after a minimum of two cycles of planned treatment, using RECIST criteria
- 13. Prior radiotherapy is allowed, however measurable target lesions must not have been irradiated
- 14. Patients must not have a history of other malignant disease other than adequately treated non-melanomatous skin cancer or in situ carcinoma of the cervix

## Participant type(s)

**Patient** 

## Age group

Adult

## Lower age limit

18 Years

#### Sex

Both

## Target number of participants

34

## Key exclusion criteria

- 1. Patients who have received a first line therapy for advanced disease, when the initial response was documented to be disease progression, using RECIST criteria
- 2. Any previous chemotherapy, immunotherapy or investigational agent within the last four weeks
- 3. Any other serious or uncontrolled illness, which in the opinion of the investigator makes it undesirable for the patient to enter the trial
- 4. Any medical or psychiatric condition, which would influence the ability to provide informed consent
- 5. Patients with a history of renal (e.g. glomerulonephritis) or renal vascular disease
- 6. Acute or chronic active liver disease (e.g. hepatitis, cirrhosis)
- 7. Surgery within two weeks of entry into the trial
- 8. Incomplete recovery from previous surgery or non-surgical treatment
- 9. History or presence of central nervous system (CNS) disease i.e. primary brain tumour, malignant seizures, clinically symptomatic CNS metastases or carcinomatous meningitis
- 10. Any of the following concurrent severe and/or uncontrolled medical conditions, which could compromise participation in the trial:
- a. Uncontrolled high blood pressure, history of labile hypertension, or history of poor compliance with an antihypertensive regimen
- b. Unstable angina pectoris
- c. Symptomatic congestive heart failure
- d. Myocardial infarction under six months prior to randomisation
- e. Serious uncontrolled cardiac arrhythmia
- f. Uncontrolled diabetes

g. Active or uncontrolled infection

h. Impairment of gastrointestinal (GI) function or GI disease that may significantly alter the absorption of PTK787/ZK222584 (e.g. ulcerative disease, uncontrolled nausea, vomiting, diarrhoea which might result in malabsorption, any known malabsorption syndrome, bowel obstruction, or inability to swallow the capsules/tablets)

- 11. Patients who are taking warfarin or other similar oral anticoagulants that are metabolised by the cytochrome P450 system, heparin is acceptable
- 12. Pregnant or lactating women
- 13. Women of childbearing potential must have a negative serum pregnancy test with 48 hours of trial entry

## Date of first enrolment

03/01/2006

## Date of final enrolment

31/12/2006

## Locations

## Countries of recruitment

England

**United Kingdom** 

# Study participating centre Oncology Centre

Cambridge United Kingdom CB2 2QQ

## Sponsor information

#### Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

## Sponsor details

Trust Research and Development Department Box 146 Addenbrookes Hospital Hills Road Cambridge England United Kingdom CB2 2QQ

## Sponsor type

Hospital/treatment centre

#### ROR

https://ror.org/04v54gj93

# Funder(s)

## Funder type

Hospital/treatment centre

#### Funder Name

Addenbrookes Charities Research Advisory Committee

## **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

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Results article	results	01/10/2010		Yes	No