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

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

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
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)

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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