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A phase II uncontrolled study of BAY 73-4506 in previously untreated patients with metastatic or unresectable renal cell cancer (RCC)

Submission date
12/06/2008

Recruitment status
No longer recruiting

Registration date
31/07/2008

Overall study status
Completed

Last Edited
22/03/2016

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00664326

Protocol serial number
11726

Study information

Scientific Title
A phase II uncontrolled study of BAY 73-4506 in previously untreated patients with metastatic or unresectable renal cell cancer (RCC)

Acronym
DAST

Study objectives
Primary hypothesis:
Response rate of patients with advanced renal cell cancer (RCC) to BAY 73-4506.

Secondary hypothesis:
The evaluation of pharmacokinetic and biomarker data.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brighton East Research Ethics Committee, 06/06/2008, ref: 08/H1107/58

Study design
Interventional single-treatment open-label phase II trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Unresectable and/or metastatic renal cell cancer

Interventions
Patients will be treated with BAY 73-4506 160 mg orally (PO) once daily (OD) for three weeks of every four week cycle (i.e. three weeks on, one week off). Patients will continue treatment with BAY 73-4506 until disease progression, intolerable toxicity or patient refusal to continue with the study or at the investigator's decision to remove the patient from the study.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
BAY 73-4506

Primary outcome(s)
Response rate of patients with advanced RCC to BAY 73-4506.

Key secondary outcome(s)
1. Survival
2. Progression-free survival
3. Time to progression
4. Safety (adverse events [AEs], vitals, labs, electrocardiogram [ECG])
5. Duration of stable disease
6. Pharmacokinetic
7. Pharmacodynamic
8. Duration of response

Completion date
30/11/2011

Eligibility

Key inclusion criteria
1. Greater than or equal to 18 years, either sex
2. Unresectable and/or metastatic clear cell renal cell cancer
3. Previously untreated disease
4. Measurable lesion(s) by computed tomography (CT) scan/magnetic resonance imaging (MRI)
5. Intermediate or low Motzer score
6. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
7. Adequate bone marrow, renal and hepatic function as assessed by specific laboratory tests
8. Life expectancy of at least 12 weeks
9. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previous/concurrent cancer
2. Previous systemic treatment of RCC
3. Cardiac arrhythmias requiring anti-arrythmics
4. History of cardiac disease or congestive heart failure greater than New York Heart Association (NYHA) class 2
5. Uncontrolled hypertension despite optimal medical management
6. Cardiac ventricular arrhythmias requiring anti-arrhythimics
7. Active clinically serious infections

8. History of human immunodeficiency virus (HIV) infection or chronic hepatitis B or C
9. Know history of symptomatic metastatic brain or meningeal tumours
10. Seizure disorders requiring medication
11. History of organ allograft
12. History or evidence of bleeding diathesis
13. Serious non-healing wound, ulcer or bone fracture
14. Patients undergoing renal dialysis
15. Substance abuse, medical, psychological or social conditions that may interfere with the patient's participation in the study or evaluation of the study results
16. Known or suspected allergy to the investigational drug or any agent given in association with the trial
17. Any condition which is unstable or which could jeopardise the safety of the patient and his /her compliance in the study
18. Pregnant or breast-feeding patients
19. Investigational drug therapy outside of the trial within 4 weeks of study entry
20. Prior exposure to the drug
21. Radiotherapy during study or within 3 weeks of start of study drug
22. Major surgery, open biopsy or significant traumatic injury within 4 weeks of start of study
23. Autologous bone marrow transplant or stem cell rescue within 4 months of study
24. Patients unable to swallow oral medications
25. Any malabsorption condition

Date of first enrolment
30/04/2008

Date of final enrolment
30/11/2011

Locations

Countries of recruitment
United Kingdom

England

Finland

France

Germany

Poland

United States of America

Study participating centre

Mount Vernon Hospital
Northwood
United Kingdom
HA6 2RN

Sponsor information

Organisation
Bayer Healthcare Pharmaceuticals Inc. (USA)

ROR
https://ror.org/04hmn8g73

Funder(s)

Funder type
Industry

Funder Name
Bayer Corporation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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?

Results article	results	01/10/2012	Yes	No
Basic results			No	No