

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 31/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 22/03/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00664326

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

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

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 measure

Response rate of patients with advanced RCC to BAY 73-4506.

Secondary outcome measures

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

Overall study start date

30/04/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

49

Key exclusion criteria

1. Previous/concurrent cancer
2. Previous systemic treatment of RCC
3. Cardiac arrhythmias requiring anti-arrhythmics
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-arrhythmics
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**

England

Finland

France

Germany

Poland

United Kingdom

United States of America

Study participating centre

Mount Vernon Hospital

Northwood

United Kingdom

HA6 2RN

Sponsor information

Organisation

Bayer Healthcare Pharmaceuticals Inc. (USA)

Sponsor details

400 Morgan Lane

West Haven

United States of America

CT 06516

+1 800 468 0894

clinical-trials-contact@bayerhealthcare.com

Sponsor type

Industry

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

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	01/10/2012		Yes	No