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The MRS study

Submission date 06/12/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/01/2008	**Overall study status** Completed	
Last Edited 07/01/2008	**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

Protocol serial number
12602

Study information

Scientific Title
Sorafenib (NEXAVAR®) monotherapy in patients with inoperable/recurrent germ cell carcinoma refractory to chemotherapy

Acronym
MRS

Study objectives
Sorafenib prolongs Progression-Free Survival (PFS) in patients with inoperable/recurrent germ cell carcinoma refrectory to chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitted, not reviewed yet as of 06/12/2007.

Study design
Single arm, non-randomised, single institution, phase II trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Testicular cancer

Interventions
There is only one treatment arm, therefore all participants will receive sorafenib 400 mg (2 tablets of 200 mg twice daily orally) continuously in 4-week cycles till progression or unacceptable toxicity. All patients will be followed/contacted after discontinuation of protocol every 3 months.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Sorafenib (NEXAVAR®)

Primary outcome(s)
Progression Free Survival (PFS)

Key secondary outcome(s))
1. Overall Relapse Rate (ORR)
2. Overall Survival (OS)
3. Toxicity
4. Evaluation of panel of biomarkers, will be assessed every 4 weeks
5. Quality of Life (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire [EORTC QLQ-C30] version 3.0 pol and testicular cancer module), will be assessed every 12 weeks

Completion date

01/09/2010

Eligibility

Key inclusion criteria
1. Male patients greater than 18 years of age
2. Patients with histologically proven germ cell neoplasm (gonadal or extragonadal primary)
3. Patients must have the disease not amendable to cure with either surgery or chemotherapy
4. Patients must have failed at least two cisplatin-based combination chemotherapy regimens
5. Failure on prior regimens will be defined as either:
5.1. A greater than or equal to 25% increase in sum of target lesions, new lesions, or
5.2. An increasing Alpha Fetoprotein (AFP) or Human Chorionic Gonadotropin (HCG) above the nadir level
6. Patients with at least one measurable lesion by Computed Tomography (CT) scan or Magnetic Resonance Imaging (MRI) according to Response Evaluation Criteria in Solid Tumours (RECIST) criteria
7. Adequate bone marrow, liver and renal function, assessed no longer than 14 days before treatment start, defined by the following laboratory test limits:
7.1. White Blood Cells (WBC) greater than 2.0 x 10^9/l and platelets greater than 60 x 10^9/l
7.2. Total bilirubin less than 2 x Upper Limit of Normal (ULN)
7.3. Aspartate Aminotransferase (AST) and Alanine Aminotransferase (ALT) less than 5 x ULN
7.4. Serum creatinine less than 2 x ULN
8. World Health Organization (WHO) performance status 0, 1, 2
9. No concurrent chemotherapy or radiotherapy
10. Life expectancy of at least 12 weeks
11. Absence of any physiological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule
12. A signed informed consent must be obtained prior to any study specific procedures
13. All patients must agree to use adequate contraception during the whole study period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. Patients not fulfilling of inclusion criteria
2. Primary radiotherapy in the field of target lesion
3. Major surgery (Retroperitoneal Lymph Node Dissection [RPLND]) within 4 weeks before the start of study drug or concurrent serious non-healing wounds, ulcers or bone fractures.
4. Known serious and active bacterial, viral or fungal infection (greater than grade II Common

Terminology Criteria for Adverse Events [CTC-AE]) including Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) carrier state
5. Previous or concurrent malignancy except for basal cell carcinoma of the skin
6. Uncontrolled hypertension
7. Thrombotic or embolic event in last 6 months prior to inclusion
8. Impairment of Gastrointestinal (GI) tract, or GI disease that may influence the bioavailability of oral sorafenib
9. Substance and alcohol abuse (nicotine use is allowed)
10. Known or suspected hypersensitivity to sorafenib
11. Participance in any other clinical trial using investigational drug within 4 weeks prior to study entry
12. Prior use of investigational or licensed angiogenesis and Raf kinase or Mitogen-activated Extracellular-signal-Regulated Kinase (ERK) (MEK) inhibitors
13. Patient unwilling or unable to give informed consent
14. Any condition that may in the investigators opinion jeopardize the safety of the patient or his compliance in the study

Date of first enrolment
01/03/2008

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
Poland

Study participating centre
Roentgena 5
Warsaw
Poland
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Sponsor information

Organisation
Prof. Grzegorz Madej Memorial Foundation "Win the health" (Fundacja "Wygrajmy Zdrowie" im Prof. Grzegorza Madeja) (Poland)

Funder(s)

Funder type
Industry

Funder Name
Bayer Pharmaceuticals Poland Sp. z.o.o. (Poland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration