History of this study ↑ Current version of this study

View of NCT00417079 on 2006_12_28

1ère publi protocole sous CTG

ClinicalTrials Identifier: NCT00417079
Updated: 2006_12_28

Descriptive Information

Brief title
XRP6258 Plus Prednisone Compared to Mitoxantrone Plus Prednisone in Hormone Refractory Metastatic Prostate Cancer (TROPIC)

Official title
Randomized, Open Label Multi-Center Study of XRP6258 in Combination With Prednisone Compared to Mitoxantrone in Combination With Prednisone For The Treatment of Hormone Refractory Metastatic Prostate Cancer Previously Treated With A Taxotere®-Containing Regimen

Brief summary

This is a randomized, open-label, multi-center study comparing the safety and efficacy of XRP6258 plus prednisone to mitoxantrone plus prednisone in the treatment of hormone refractory metastatic prostate cancer previously treated with a Taxotere-containing regimen. The primary objective is overall survival. Secondary objectives include progression free survival, overall response rate, prostate-specific antigen (PSA) response/progression, pain response/progression, overall safety, and pharmacokinetics. Patients will be treated until disease progression, death, unacceptable toxicity, or for a maximum of 10 cycles. Patients will have long-term follow-up for a maximum of up to 2 years.

Detailed description

Phase	Phase 3
Study type	Interventional
Study design	Treatment
Study design	Randomized
Study design	Open Label
Study design	Active Control
Study design	Parallel Assignment
Study design	Efficacy Study
Primary outcome	
Secondary outcome	
Secondary outcome	
Secondary outcome	
Secondary outcome	
Condition	Neoplasms
Condition	Prostatic Neoplasms
Intervention	Drug: XRP6258
URL	http://www.sanofi-aventis.com

See also

Recruitment Information

Status	Recruiting
Start date	2006-12

Criteria

Inclusion Criteria

1. Histologically or cytologically confirmed adenocarcinoma of the prostate.
2. Documented progression of disease (demonstrating at least one visceral or soft tissue metastatic lesion, including a new lesion). Patients with non-measurable disease must have documented rising PSA levels or appearance of new lesion.
3. Surgical or hormone-induced castration
4. Life expectancy > 2 months
5. Eastern Cooperative Oncology Group (ECOG) performance status 0 – 2

Exclusion criteria

1. Previous treatment with mitoxantrone
2. Prior radiotherapy to ≥ 40% of bone marrow
3. Surgery, radiation, chemotherapy, or other anti-cancer therapy within 4 weeks prior to enrollment in the study
4. Other prior malignancy, except for adequately treated superficial basal cell skin cancer, or any other cancer from which the patient has been disease-free for less than 5 years
5. Known brain or leptomeningeal involvement
6. Other concurrent serious illness or medical conditions
7. Inadequate organ function evidenced by unacceptable laboratory results

The investigator will evaluate whether there are other reasons why a patient may not participate.

Gender	Male
Minimum age	18 Years
Healthy volunteers	No
Expected enrollment	720

Administrative Data

Organization name	Sanofi-Aventis
Organization study ID	EFC6193
Secondary ID	XRP6258
Sponsor	Sanofi-Aventis
Health Authority	United States: Food and Drug Administration
Health Authority	United Kingdom: Medicines and Healthcare Products Regulatory Agency
Health Authority	Canada: Health Canada