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Internet Archive
300 Funston Avenue
San Francisco, CA 94118

AFFIDAVIT OF CHRISTOPHER BUTLER

1. I am the Office Manager at the Internet Archive, located in San Francisco, California. I make this declaration of my own personal knowledge.

2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.

3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to surf more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a list of available dates. The visitor may select one of those dates, and then begin surfing on an archived version of the Web. The links on the archived files, when served by the Wayback Machine, point to other archived files (whether HTML pages or images). If a visitor clicks on a link on an archived page, the Wayback Machine will serve the archived file with the closest available date to the page upon which the link appeared and was clicked.

4. The archived data made viewable and browseable by the Wayback Machine is compiled using software programs known as crawlers, which surf the Web and automatically store copies of web files, preserving these files as they exist at the point of time of capture.

5. The Internet Archive assigns a URL on its site to the archived files in the format http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL]. Thus, the Internet Archive URL http://web.archive.org/web/19970126045828/http://www.archive.org/ would be the URL for the record of the Internet Archive home page HTML file (http://www.archive.org/) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). A web browser may be set such that a printout from it will display the URL of a web page in the printout's footer. The date assigned by the Internet Archive applies to the HTML file but not to image files linked therein. Thus images that appear on a page may not have been archived on the same date as the HTML file. Likewise, if a website is designed with "frames," the date assigned by the Internet Archive applies to the frameset as a whole, and not the individual pages within each frame.

6. Attached hereto as Exhibit A are true and accurate copies of printouts of the Internet Archive's records of the HTML files for the URLs and the dates specified in the footer of the printout.

7. I declare under penalty of perjury that the foregoing is true and correct.

DATE: 1/26/16

Christopher Butler

CALIFORNIA JURAT

See Attached Document.

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is atached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of San Francisco

Subscribed and sworn to (or affirmed) before me on this

26th day of January, 2016, by

Christopher Butler,

proved to me on the basis of satisfactory evidence to be the person who appeared before me.

LINDA WONG
Commission # 2086421
Notary Public - California
San Francisco County
My Comm. Expires Oct 17, 2018

Signature: _____

Exhibit A

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

This study is currently recruiting participants.
Verified by Sanofi-Aventis, August 2008

Sponsored by:	**Sanofi-Aventis**
Information provided by:	Sanofi-Aventis
ClinicalTrials.gov Identifier:	NCT00417079

Purpose

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.

Condition	Intervention	Phase
Neoplasms Prostatic Neoplasms	Drug: XRP6258 (RPR116258) Drug: mitoxantrone Drug: prednisone	Phase III

MedlinePlus related topics: Cancer Prostate Cancer

Drug Information available for: Docetaxel Mitoxantrone hydrochloride Mitoxantrone Prednisone

U.S. FDA Resources

Study Type: Interventional
Study Design: Treatment, Randomized, Open Label, Active Control, Parallel Assignment, Efficacy Study

Official Title: A Randomized, Open Label Multi-Center Study of XRP6258 in Combination With Prednisone Every 3 Weeks Compared to Mitoxantrone in Combination With Prednisone For The Treatment of Hormone Refractory Metastatic Prostate Cancer Previously Treated With A Taxotere®-Containing Regimen

Further study details as provided by Sanofi-Aventis:

Primary Outcome Measures:

- overall survival defined as the time interval from the date of randomization to the date of death due to any cause. [Time Frame: study period] [Designated as safety issue: No]

Secondary Outcome Measures:

- PSA levels [Time Frame: at screening, day 1 of every treatment cycle, end of study treatment, and in follow-up until documented progression] [Designated as safety issue: No]
- Anti-tumor activity via Computerized Tomography / Magnetic Resonance Imaging (and bone scans, as indicated) [Time Frame: study period] [Designated as safety issue: No]
- Pain via an analgesic consumption score and the Present Pain Index over a one-week period [Time Frame: study period] [Designated as safety issue: No]
- Adverse events; laboratory abnormalities; vital signs [Time Frame: Study period]

[Designated as safety issue: Yes]

Estimated Enrollment: 720
Study Start Date: December 2006
Estimated Study Completion Date: May 2010
Estimated Primary Completion Date: May 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Arm A: Active Comparator	Drug: mitoxantrone administered by IV route Drug: prednisone administered by oral route
Arm B: Experimental	Drug: XRP6258 (RPR116258) administered by IV route Drug: prednisone administered by oral route

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Male
Accepts Healthy Volunteers: No

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.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00417079

Contacts

Contact: Public Registry ICD GV-Contact-us@sanofi-aventis.com

Show 27 Study Locations

Sponsors and Collaborators

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