

# **Phase II Trial of Patupilone (EPO906) plus Prednisone versus Docetaxel (Taxotere) plus Prednisone in Patients with Metastatic Hormone Refractory Prostate Cancer**

**Protocol #:** CEPO906A2229

## **Study Purpose:**

Novartis Oncology is conducting a clinical research study to evaluate the difference in effectiveness and safety between the investigational drug patupilone and the drug docetaxel, in people who have hormone refractory prostate cancer. The reason for this study is to find out which of these two medicines gives better relief of prostate cancer. Participants who agree to join in this study, may get either 10 mg/m<sup>2</sup> patupilone once every three weeks or 75 mg/m<sup>2</sup> of docetaxel once every three weeks, intravenously (directly into a vein). Prednisone will be given to all patients as supportive therapy. Patupilone is a medicine which has not been approved by the FDA (US Food and Drug Administration) for the treatment of people with prostate cancer. Docetaxel is a medication approved by the FDA to treat breast cancer, non-small cell lung cancer and prostate cancer. Patients who qualify for this study will be randomly assigned to receive either the study drug patupilone or docetaxel, and have a 50 % chance of being treated with either drug. Participants will not have a choice of which medication they will receive. This study is open-label, which means that after participants are randomly assigned to a treatment, they will know which medication they are receiving.

## **Key Eligibility Criteria**

### **Inclusion Criteria:**

- Patients with adenocarcinoma of the prostate.
- Patients must have metastatic disease
- Patients must have documented evidence of disease progression.
- Chemotherapy-naïve patients (unlimited prior regimens of hormonal therapy).
- Age ≥ 18 years
- Written informed consent must be obtained

### **Exclusion Criteria**

- Received radiation therapy to tumors located centrally less than 4 weeks prior to enrollment date.
- Prior strontium chloride (SR 89) or Samarium 153 lexidronam pentasodium treatment
- Known brain metastases

***Additional protocol inclusion/exclusion criteria may apply.  
Eligibility to participate will be determined by a participating physician.***

### **Contact Information**

For more information regarding this trial as well as sites participating, please contact:

[www.novartisclinicaltrials.com](http://www.novartisclinicaltrials.com) – select Prostate Cancer or  
call 1-800-340-6843 – The Novartis Oncology Clinical Trials Hotline

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) – In the search box enter patupilone (will be posted in the near future)