

**ALSYMPCA trial - Alpharadin (Radium 223)**  
**A Phase III Study of Alpharadin (Radium-223) in Patients With Symptomatic Hormone Refractory Prostate Cancer With Skeletal Metastases (ALSYMPCA)**

**This study is currently recruiting participants.**

<b>Sponsored by:</b>	<b>Algeta ASA</b>
<b>Information provided by:</b>	Algeta ASA

**► Purpose**

ALSYMPCA is an international Phase III clinical study to evaluate the efficacy and safety of **Alpharadin**, in patients with hormone refractory prostate cancer and skeletal metastases.

<b>Condition</b>	<b>Intervention</b>	<b>Phase</b>
Hormone Refractory Prostate Cancer Bone Metastases	Drug: <b>Alpharadin (Radium-223)</b> Drug: Placebo	Phase III

Study Type:      Interventional

Study Design:    Treatment, Randomized, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Placebo Control, Parallel Assignment, Safety/Efficacy Study

Official Title:    A Double-Blind, Randomised, Multiple Dose, Phase III, Multicentre Study of **Alpharadin** in the Treatment of Patients With Symptomatic Hormone Refractory Prostate Cancer With Skeletal Metastases

**Further study details as provided by Algeta ASA:**

Primary Outcome Measures:

- Overall survival [ Time Frame: Time from date of randomisation to the date of event ] [ Designated as safety issue: Yes ]

## Secondary Outcome Measures:

- Time to occurrence of specific disease events  
[ Time Frame: Time to first on-study specific disease events ]  
[ Designated as safety issue: Yes ]
- Changes and time to progression in PSA [ Time Frame: Study duration ] [ Designated as safety issue: No ]
- Changes and time to progression in total-ALP  
[ Time Frame: Study duration ]  
[ Designated as safety issue: No ]
- Safety endpoints; Adverse events, laboratory values, potential manifestations of late toxicity [ Time Frame: Study duration ]  
[ Designated as safety issue: Yes ]
- Clinical benefit endpoints: Performance status, Health related Quality of Life [ Time Frame: Study duration ]  
[ Designated as safety issue: No ]

Estimated Enrollment: 750  
Study Start Date: June 2008  
Estimated Study Close Date: December 2010

<b>Arms</b>	<b>Assigned Interventions</b>
1: Experimental Alpharadin plus best standard of care	Drug: <b>Alpharadin (Radium-223)</b> <b>Alpharadin (Radium-223)</b> 50 kBq/kg b.w., 6 IV administrations separated by 4 weeks intervals
2: Placebo Comparator Saline solution plus best standard of care	Drug: Placebo Isotonic saline 6 IV administrations separated by 4 weeks intervals

## Detailed Description:

The aim of the study is to compare, in patients with symptomatic HRPC and skeletal metastases, the efficacy of best standard of care plus Alpharadin versus best standard of care plus placebo, with the primary efficacy endpoint being overall survival (OS).

Patients will be randomised in a 2:1 allocation ratio (Alpharadin:Placebo). The study treatment consists of 6 intravenous administrations of Alpharadin or placebo (saline) each separated by an interval of 4 weeks. The patient will be followed until 3 years after first study drug administration.

## ► Eligibility

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Male

Accepts Healthy Volunteers: No

## Criteria

Main inclusion criteria:

- Histologically or cytologically confirmed adenocarcinoma of the prostate
- Known hormone refractory disease
- Multiple skeletal metastases ( $\geq 2$  hot spots) on bone scintigraphy
- No intention to use cytotoxic chemotherapy within the next 6 months
- Either regular (not occasional) analgesic medication use for cancer related bone pain or treatment with EBRT for bone pain

Main exclusion criteria:

- Treatment with an investigational drug within previous 4 weeks, or planned during the treatment period
- Eligible for first course of docetaxel, i.e. patients who are fit enough, willing and where docetaxel is available.
- Treatment with cytotoxic chemotherapy within previous 4 weeks, or planned during the treatment period, or failure to recover from adverse events due to cytotoxic chemotherapy administered more than 4 weeks ago
- Systemic radiotherapy with strontium-89, samarium-153, rhenium-186 or rhenium-188 for the treatment of bony metastases within previous 24 weeks
- Other malignancy treated within the last 5 years (except non-melanoma skin cancer or low-grade superficial bladder cancer)
- History of visceral metastasis, or visceral metastases as assessed by abdominal/pelvic CT or chest x-ray within previous 8 weeks

## ► Contacts and Locations

### Contacts

Contact: Bjørg Bolstad +47 23 00 79 90 [bjorg.bolstad@algeta.com](mailto:bjorg.bolstad@algeta.com)

Contact: Ingvild Haugen +47 23 00 79 90 [ingvild.haugen@algeta.com](mailto:ingvild.haugen@algeta.com)

## **Sponsors and Collaborators**

**Algeta ASA**

## **Investigators**

Study Chair: Christopher Parker, M.D. The Royal Marsden Hospital, UK

## **More Information**

Responsible Party: Algeta ASA, Oslo, Norway

Study ID Numbers: BC1-06