KURZPROTOKOLL
BAY 88-8223

Öffentlicher Titel	Radium 223 bei ossär metastastasiertem hormonfrefraktärem Prostatakarzinom
Wissenschaftl. Titel	Radium-223 Dichloride (Alpharadin) in Castration-Resistant (Hormon-refractory) Prostate Cancer Patients with Bone Metastasis
Kurztitel	BAY 88-8223
Studienart	prospektiv, offen/unverblindet, einarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: Prostatakrebs - Zweitlinie oder höher
Ziele	- To assess acute and long-term safety and overall survival in patients with castration-resistant (hormone-refractory) prostate cancer - overall survival
Einschlusskriterien	- Has provided written informed consent. Subjects must be able to understand and be willing to sign the written informed consent form (ICF). A signed ICF must be appropriately obtained prior to the conduct of the any trial- specific procedure. - Age >= 18 years - Histologically or cytologically confirmed prostate cancer - Patients diagnosed with progressive bone predominant metastatic CRPC/HRPC with at least two skeletal metastases on imaging 1 with no lung, liver, and/or brain metastasis (lymph node only metastasis is allowed). A standard of practice bone scan for the documentation of at least 2 skeletal metastases can be used as long as it is within 3 months of planned start of treatment. If no bone scan within a 3 month window is available, then a technetium-99m bne scan will be obtained at screening (within 28 days of planned start of study drug). - Progressive disease is defined either by: a) The appearance of new bone lesions. If progression is based on new lesion(s) on bone scan only without an increase in PSA, PSA values from 3 assessments within the last 6 months must be provided; OR b) In the absence of a new bone lesions by 2 consecutive increases in serum PSA over previous reference value, which should not be more than 6 months before screening, each measured at least 1 week apart with the last PSA 5 ng/mL - No intention to use cytotoxic chemotherapy within the next 6 months - Life expectancy >= 6 months - ECOG PS 0-2 - Adequate hematological, liver and renal function: a) Absolute neutrophil count (ANC)>= 1.5 x109/L; b) Platelet count >= 100 x109/L; c) Hemoglobin >=10.0 g/dL (100 g/L; 6.2 mmol/L); d) Total bilirubin level <= 1.5 x institutional upper limit of normal (ULN); e) Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) <= 2.5 x ULN; f) Creatinine <= 1.5 x ULN; g) Albumin > 25 g/L - Willing and able to comply with the protocol, including follow-up visits and examinations
Ausschlusskriterien	- Treatment with an investigational drug within previous 4 weeks, or planned during the treatment period or follow-up - Eligible for first course of docetaxel, i.e., patients who are fit enough, willing, and who are located where treatment with docetaxel is available - Treatment with cytotoxic chemotherapy within previous 4 weeks, prior to screening,1 or failure to recover from AEs due to cytotoxic chemotherapy administered more than 4 weeks previous prior to screening1 (however, ongoing neuropathy is permitted) - Treatment with any prior anticancer therapy (including, therapeutic vaccines), other than the permitted Standard of Care theapies (Please refer to section 6.9), are allowed provided that they are completed 28 days before treatment or 5.5 half-lives of the drugs involved have elapsed before treatment start.

	- Prior hemibody external radiotherapy is excluded. Patients who received other types of prior external radiotherapy are allowed provided that the bone marrow function is assessed and meets the protocol requirements for hemoglobin, absolute neutrophil count and platelets.1 - Received systemic therapy with radionuclides (e.g., strontium-89, samarium-153, rhenium-186, or rhenium-188, or radium-223 chloride) for the treatment of bony metastases - Other malignancy treated within the last 3 years (except non-melanoma skin cancer or low-grade superficial bladder cancer) - Visceral metastases as assessed by abdominal or pelvic computed tomography (CT) (or other imaging modality based on institutional standard of care) - Presence of brain metastases - Lymphadenopathy exceeding 6 cm in short-axis diameter - Any size pelvic lymphadenopathy if it is thought to be a contributor to concurrent hydronephrosis. - Imminent spinal cord compression based on clinical findings and/or magnetic resonance imaging (MRI). Patients with history of spinal cord compression should have completely recovered. - Any other serious illness or medical condition, such as but not limited to: a) Any infection NCI-CTCAE v.4.03 Grade 2; b) Cardiac failure New York Heart Association (NYHA) III or IV; c) Crohn's disease or ulcerative colitis; d) Bone marrow dysplasia - Fecal incontinence
Alter	18 Jahre und älter
Sponsor	Bayer Healthcare
Förderer	Bayer Healthcare
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01618370 EudraCT 2012-000075-16