KURZPROTOKOLL
CC-5013-PC-002

Öffentlicher Titel	Phase III Studie zu Docetaxel und Prednison mit und ohne Lenalidomid bei Prostatakrebs
Wissenschaftl. Titel	A Phase 3 Study to Evaluate the Efficacy and Safety of Docetaxel and Prednisone With or Without Lenalidomide in Subjects With Castrate-Resistant Prostate Cancer
Kurztitel	CC-5013-PC-002
Studienart	multizentrisch, prospektiv, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: Prostatakrebs - Erstlinie
Ziele	- Overall survival - PFS, Objective Response Rate - Safety of lenalidomide in combination with docetaxel and prednisone
Einschlusskriterien	- Must sign an Informed Consent Form (ICF) - Males >= 18 years of age - Able to adhere to the study visit schedule and requirements of the protocol - ECOG performance status of <= 2 - Life expectancy of >= 12 weeks - Willingness to participate in Patient-Reported Outcomes assessments Serum testosterone levels < 50 ng/dL - Confirmed metastatic adenocarcinoma of the prostate that is unresponsive or refractory to hormonal therapy - Have documented disease progression while receiving or following hormonal therapy as determined by increasing Serum PSA level, Radiological Progression, or 2 new bone lesions - Subjects must agree to receive counseling related to pregnancy, precautions, teratogenic and other risks of lenalidomide - Refrain from donating blood or semen as defined by protocol
Ausschlusskriterien	- A history of clinically significant disease that places subject at an unacceptable risk for study entry - Prior Therapy with thalidomide, lenalidomide or pomalidomide - Prior chemotherapy for prostate cancer - Use of any other experimental drug or therapy within 28 days prior to randomization - Prior radiation to >= 30% of bone marrow or any radiation therapy within 28 days prior to randomization - Prior use of Strontium-89 at any time or Samarium-153 within 56 days prior to randomization - Surgery within 28 days prior to randomization - Concurrent anti-androgen therapy - Abnormal serum chemistry or hematology laboratory values - Significant active cardiac disease within the previous 6 months - Thrombotic or thromboembolic events within the past 6 months - History of peripheral neuropathy of >= grade 2 - History of severe hypersensitivity reaction to drugs formulated with polysorbate 80 - Paraplegia - History of Central nervous system (CNS) or brain metastases

	- History of malignancies other than prostate cancer within the past 5 years, with the exception of treated basal cell/squamous cell carcinoma of the skin - Concurrent use of alternative cancer therapies
Alter	18 Jahre und älter
Sponsor	Celgene GmbH
Förderer	Celgene GmbH
Registrierung in anderen Studienregistern	EudraCT 2008-007969-23