

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	<ul style="list-style-type: none">- Overall survival- PFS, Objective Response Rate- Safety of lenalidomide in combination with docetaxel and prednisone
Einschlusskriterien	<ul style="list-style-type: none">- Must sign an Informed Consent Form (ICF)- Males \geq 18 years of age- Able to adhere to the study visit schedule and requirements of the protocol- ECOG performance status of \leq 2- Life expectancy of \geq 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	<ul style="list-style-type: none">- 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 \geq 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 \geq grade 2- History of severe hypersensitivity reaction to drugs formulated with polysorbate 80- Paraplegia- History of Central nervous system (CNS) or brain metastases

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- 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
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