# *KURZPROTOKOLL*
# *CC-5013-PC-002*

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| **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<br>- PFS, Objective Response Rate<br>- Safety of lenalidomide in combination with docetaxel and prednisone |
| **Einschlusskriterien** | - Must sign an Informed Consent Form (ICF)<br>- Males >= 18 years of age<br>- Able to adhere to the study visit schedule and requirements of the protocol<br>- ECOG performance status of <= 2<br>- Life expectancy of >= 12 weeks<br>- Willingness to participate in Patient-Reported Outcomes assessments Serum testosterone levels < 50 ng/dL<br>- Confirmed metastatic adenocarcinoma of the prostate that is unresponsive or refractory to hormonal therapy<br>- Have documented disease progression while receiving or following hormonal therapy as determined by increasing Serum PSA level, Radiological Progression, or 2 new bone lesions<br>- Subjects must agree to receive counseling related to pregnancy, precautions, teratogenic and other risks of lenalidomide<br>- 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<br>- Prior Therapy with thalidomide, lenalidomide or pomalidomide<br>- Prior chemotherapy for prostate cancer<br>- Use of any other experimental drug or therapy within 28 days prior to randomization<br>- Prior radiation to >= 30% of bone marrow or any radiation therapy within 28 days prior to randomization<br>- Prior use of Strontium-89 at any time or Samarium-153 within 56 days prior to randomization<br>- Surgery within 28 days prior to randomization<br>- Concurrent anti-androgen therapy<br>- Abnormal serum chemistry or hematology laboratory values<br>- Significant active cardiac disease within the previous 6 months<br>- Thrombotic or thromboembolic events within the past 6 months<br>- History of peripheral neuropathy of >= grade 2<br>- History of severe hypersensitivity reaction to drugs formulated with polysorbate 80<br>- Paraplegia<br>- 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<br>- 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 |