# *KURZPROTOKOLL*
# *CESAR C-II-010*

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| **Öffentlicher Titel** | Phase II Studie zu Cabazitaxel Dosisindividualisierung beim Prostatakarzinom |
| **Wissenschaftl. Titel** | Randomized phase II Cabazitaxel dose Individualization and Neutropenia prevention Trial |
| **Kurztitel** | CESAR C-II-010 |
| **Studienart** | multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig |
| **Studienphase** | Phase II |
| **Erkrankung** | Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: Prostatakrebs - Zweitlinie oder höher |
| **Ziele** | - Evaluation of a new dose algorithm<br>- PSA Response |
| **Einschlusskriterien** | - (1) Capable of understanding the protocol requirements and risks, and providing written informed consent.<br>- (2) Patients with histologically or cytologically proven, castration-resistant prostate adenocarcinoma, that progressed during or after completion of previous docetaxel treatment.<br>- (3) Patients with a formal indication for monotherapy with IV cabazitaxel at 3-weekly cycles.<br>- (4) Measurable or non-measurable (evaluable) disease according to the RECIST criteria, version 1.1.<br>- (5) ECOG Performance Status (ECOG-PS) status 0-2.<br>- (6) Male patients at least 18 years of age at randomization.<br>- (7) Patients have received prior castration by orchiectomy and/or a Luteinizing Hormone-Releasing Hormone (LHRH) agonist or antagonist with or without antiandrogens, antiandrogen withdrawal, monotherapy with estramustine, or other hormonal agents (antiandrogen treatment is continued during study treatment).<br>- (8) Patients may also having received prior abiraterone acetate, TAK700 or enzalutamide.<br>- (9) Sexually active men must use acceptable contraceptive methods (condom).<br>- (10) Patients suffering from asymptomatic brain metastases can be enrolled in case corticosteroid therapy is not indicated. Prior irradiation must be completed at least 2 week prior to initiating cabazitaxel chemotherapy within the study |
| **Ausschlusskriterien** | - (1) Previous treatment with cabazitaxel.<br>- (2) Prior isotope therapy or radiotherapy to >30% of the bone marrow.<br>- (3) Adverse events grade >1 (excluding alopecia and those listed in the specific exclusion criteria) from any prior anticancer therapy at the time of randomization.<br>- (4) Prior malignancy. Adequately treated basal-cell or squamous-cell skin or superficial (pTis, pTa, and pT1) bladder cancer are allowed, as well as any other cancer for which chemotherapy has been completed >= 5 years ago and from which the patient has been disease-free for >= 5 years.<br>- (5) Participation in another clinical trial and any concurrent treatment with any investigational drug within 30 days prior to randomization. CAINTA / C-II-010 / EUDRACT 2013-005504-34 / Version 1.0 / 06 March 2014 Confidential Page 26 of 73<br>- (6) Concurrent or planned treatment with strong inhibitors or strong inducers of cytochrome P450 3A4/5 (a one week wash-out period is necessary for patients who are already on these treatments) |

- (7) Inadequate organ and bone marrow function as evidenced by: a. Hemoglobin <10.0 g/dL b. Absolute neutrophil count <1.5•109/L c. Platelet count <100•109/L d. AST/SGOT and/or LT/SGPT >1.5•ULN (>5•ULN in case of liver metastases) e. Total bilirubin >1.0•ULN (>2.5•ULN in case of liver metastases) f. Serum creatinine >1.5•ULN. If creatinine 1.5-1.5xULN, creatinine clearance will be calculated according to the CKD-EPI formula and patients with creatinine clearance <60ml/min are excluded
- (8) Other concurrent serious illness or medical conditions
- (9) Any severe acute or chronic medical condition (e.g. active infection, severe heart disease, uncontrolled hypertension or diabetes mellitus) that could impair the ability of the patient to participate to the study, or to comply with the study procedures or interfere with interpretation of study results.
- (10) History of hypersensitivity to taxanes or polysorbate 80 containing drugs
- (11) History of severe hypersensitivity reaction (CTC grade 3) to polysorbate 80 containing drugs
- (12) Contraindications to the use of corticosteroid treatment
- (13) Symptomatic peripheral neuropathy grade >2
- (14) Treatment with cytotoxic or biologic agents or any experimental drug within the 2 weeks prior to beginning treatment on this study

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| **Alter** | 18 Jahre und älter |
| **Fallzahl** | 72 |
| **Prüfzentren** | **Universitätsklinikum Frankfurt** (Rekrutierung beendet)<br>Zentrum für Chirurgie, Klinik für Urologie<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Dr. med. Severine Banek<br>Tel: 069 6301-80072<br>Fax: 069 6301-84029<br>severine.banek@kgu.de |
| **Gütesiegel** | Deutsche Krebshilfe e.V.<br>Deutsche Krebsgesellschaft e.V. |
| **Sponsor** | Central European Society for Anticancer Drug Research |
| **Förderer** | Central European Society for Anticancer Drug Research |
| **Registrierung in anderen Studienregistern** | EudraCT 2013-005504-34 |
| **Therapie** | Cabazitaxel dose every 3 weeks, randomized arm A or B |