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Prescribing decisions should be made based on the approved package insert in the country of prescription

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| **Sponsor/company:** | sanofi-aventis | **ClinialTrials.gov Identifier:** | NCT00280098 |
| **Generic drug name:** | DOCETAXEL | **Study Code:** | XRP6976J/4001 |
| | | **Date:** | 05 August 2008 |

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| **Title of the study:** | Docetaxel (Taxotere) + Prednison for the treatment of hormone independent prostate cancer<br><br>Design: Observational, non comparative Phase IV study, duration 12 months (Treatment 6 months, Follow up 6 months)<br><br>XRP6976J/4001 | |
| **Investigator(s):** | As. MUDr. Michaela Matoušková, Urocentrum 120 00 Prague, Karlovo nám. 3, Czech republic | |
| **Study center(s):** | 1. Urocentrum Prague<br>2. Urological Clinic Motol, Prague<br>3. Complex Oncological cenre Zlín | |
| **Publications (reference):** | NA | |
| **Study period:**<br>Date first **patient/subject** enrolled: 02.01.2006<br>Date last **patient/subject** completed: 15.11.2007 | | **Phase of development:**<br>Non comparative Phase IV study |
| **Objectives:** | Primary: Tolerance of the treatment<br>Secondary: Pain response, PSA response | |

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| **Methodology:** | Non comparative, observational, active treatment + follow-up phase | | |
| **Number of patients:** | Planned: 30 | Randomized: NA | Treated. 30 |
| **Evaluated:** | Efficacy: 30 | Safety: 30 | |
| **Diagnosis and criteria for inclusion:** | Advanced and metastatic, relapsed on hormonal therapy, chemo–naïve, PS 0-1, no serious co–morbidity. Only patients, who are able to tolerate docetaxel treatment according to decision of oncologist | | |
| **Investigational product:**<br>**Dose:**<br><br>**Administration:** | Docetaxel + prednisone<br>Docetaxel 75mg/m2, every 3 weeks to maximum 10 cycles<br>Prednisone 10 mg/day, divided in 2 doses, continually<br><br>Infusion every 3 weeks | | |
| **Duration of treatment:** 30 weeks ( i.e. 10 cycles) | | **Duration of observation:** 6 months | |
| **Reference therapy:**<br>Dose:<br>Administration: | NA<br>NA<br>NA | | |
| **Criteria for evaluation:** | The current report is an abbreviated report, and as such, only the safety results are being presented in full. The following safety criteria were evaluated, and analyzed using descriptive statistics:<br>Tolerance of the treatment, pain improvement, PSA response | | |
| **Statistical methods:** | For summary of clinical parameters frequency tables and standard descriptive statistics (mean, median, minimum, maximum) were used. Statistical significance testing was performed using non-parametric Mann-Whitney test. All computations and graphics were done using Statistica for Windows 8.0, SPSS 12.0.1 and MS Powerpoint. Standard level of statistical significance ?=0.05 was used. | | |

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| **Summary:** | Tolerance of therapy: Adverse events were evaluated for all patients using WHO common toxicity criteria scale and the level of toxicity for individual blood parameters. In four blood parameters (Granulocytes, Bilirubin, AST and ALP) some patients reached Grade 3 of toxicity during therapy with Docetaxel. Platelets, Urea and Bilirubin are parameters with highest percentage of records without toxicity.<br><br>Serious adverse event (SAE), not related to the study medication was noted in one patient. It was Low urinary tract obstruction, decompensation of diabetes mellitus and metabolic derangement. which was cause of death.<br><br>Pain response: Out of 30 patients, in 11 patients was pain associated with disease. Out of them, more than 30% decrease of pain was achieved in 4 patients, in 2 patients there was 90 – 100% pain elimination.<br><br>PSA response: The lowest PSA level achieved significantly corresponds with drug response confirmed by clinical, radiological or ultrasonographical examination (p=0.002). The same relationship can be observed between decrease in the PSA level and drug response (p=0.001). Median of PSA level at the beginning of treatment was 101,7ng/ml (range 2, 7 – 1356, 0). After completion of the therapy declined at median 34,5ng/ml (Range 1, 0 – 1221, 0ng/ml) PSA decline during cytotoxic chemotherapy was seen after the fifth cycle of chemotherapy and correlate with objective treatment results achieved.<br><br>Efficacy: Seventeen of thirty patients completed the treatment in compliance with protocol. Seven patients left the study in complete remission and two patients in partial remission. ORR was 30% (CR 23, 3% and PR 6, 7%). Stabilisation in 30% and progression in 30% of patients. After six months follow up period according to the protocol, all nine patients, where objective remission was achieved are alive. In a group of disease stabilisation five patients are still alive and four patients died. In a group of nine patients with disease progression four patients are alive and five patients died. Information about patient who refused other treatment is not available.<br><br>Patient satisfaction with treatment results: Out of 30 treated patients, 9 patients evaluated treatment efficacy as very good and good, 10 patients as >50% improvement of symptoms. Patient satisfaction with the treatment results clearly correlate with objective response achieved. Patients in complete remission rated satisfaction with the results of therapy as very good in 43%, patients in partial remission as good in 100%. Subjective improvement was obtained also in patients,where only stabilisation and progression was evaluated by physician. |
| **Date of report:** | 17-June-2008 |