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Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00461344
		Study Code:	XRP6976D_2504
Generic drug name:	Docetaxel	**Date:**	01/Apr/2008

Title of the study:	A Multicenter, open label, phase II trial evaluating docetaxel (Taxotere®) + anthracycline (epirubicin or doxorubicin) x 4 cycles followed by docetaxel (T) single agent x 4 cycles as first-line therapy in patients with Her2 negative locally advanced or metastatic breast cancer who have relapsed = 12 months from completion of neoadjuvant/adjuvant Taxotere®- based chemotherapy **STUDY CODE: XRP6976D/2504**
Investigator(s):	Prof. Dr. Lukács Géza (DEOEC-Debrecen) Dr. Baki Márta (Szent Margit Hospital-Budapest) Dr. Szucs Miklós (Bács Kiskun county Hospital-Kecskemét) Prof. Dr. Thurzó László (SZAOTE- Szeged) Dr. Pikó Béla (Pándy Kálmán Hospital- Gyula) Dr. Cseh József (Szent György Hospital-Székesfehérvár) Dr. Ésik Olga (PTE-Pécs)
Study center(s):	5 active sites- HUNGARY DEOEC-Debrecen Szent Margit Hospital-Budapest Bács Kiskun Megyei Hospital-Kecskemét SZAOTE- Szeged Szent György Hospital-Székesfehérvár
Publications (reference):	NA

Study period: Date first **patient** enrolled: 20-JUL-2004 Date last **patient** completed: 24-JUN-2005	**Phase of development:** II.

Objectives:	Primary: 1. to determine the pathological remission following the chemotherapy combination docetaxel and doxorubicin in large breast cancer Secondary: 1. Clinical response rate 2. to investigate the safety of docetaxel doxorubicin combination in the treatment for neoadjuvant chemotherapy of breast cancer 3. Type of surgery (radical/conservative)
Methodology:	Multicenter, open label, exploratory, non-controlled trial

Number of patients:	Planned: Approximately 100	Randomized: 19	Treated: 19
Evaluated:	18	Safety: 18	Pharmacokinetics: NA
	20 patients participated in this study, but one patient withdrew the consent before the baseline visit. Therefore only 19 patients were eligible in the population for Baseline statistical evaluation For efficacy analysis only 18 patients were considered, because one patient died before the End of the study		
Diagnosis and criteria for inclusion:	**Inclusion criteria** 1. histologically verified breast cancer 2 Large (≥ 3 cm) breast cancer 3. IIb-IIIa stage (AJCC) 4 Age 18-70 years 5 ECOG status: 0-1-2 6 Adequate bone marrow reserve: (Hb = 12g/l, ANC = 2.0x 10^9, Plt =100 000) 7 Laboratory results: - bilirubin = normal upper limit, - SGPT = 2.5 ULN, SGOT = 2.5 ULN, 8 Alk.phosp = 5.0 ULN 9 creatinin = normal upper limit, if borderline calculated at = 60ml/min 10 Normal cardiac function (the result of LVEF must be above the lower limit of normal for the institution) 11 Negative pregnancy test 12 Hormonal receptor status assessed 13 Signed informed consent **Exclusion criteria:** 1. Pregnancy or lactation 2. SGOT and/or SGPT > 1.5 upper limit normal, associated with Alk.phosph > 2.5 ULN 3. Serious medical condition including but not limited to: - Uncontrolled hypertension - Active ulcus pepticum; Non-stable diabetes mellitus - Other contraindication of steroid treatment - Myocardial infarction within the last 6 months prior study entry - Significant neurologic/psychiatric disorders that would prohibit the giving of informed consent - Active infection - Peripheral neuropathy grade ≥ 2 - Instabil angina - Severe arrhythmia 4. Participation in other clinical trial 5. Prior surgery, chemotherapy, hormone-therapy for breast cancer 6. Past or current history of neoplasm other than breast cc., except for: curatively treated non-melanoma skin cancer, in situ carcinoma of the cervix, other cancer curatively treated and with no evidence of disease for at least 7 years 7. History of hypersensitivity to the investigational products or to drugs with similar chemical structures 8. Likelihood of requiring treatment during the study period with drugs not permitted by the clinical study protocol (see Section 6.2) 9. Treatment with any investigational product in the last 1 month before study entry.		

Investigational product: Dose: Administration:	Docetaxel 75mg/m2 Cycle 1-4, 100 mg/m2 Cycle 5-8. IV
Duration of treatment: Chemotherapy cycles will be given every 3 weeks in 1 hour IV infusion; unless criteria for resuming study treatment are not met.	**Duration of observation:** Patients should receive eight study treatment cycles (4 cycles of taxotere in combination anthracycline, followed by 4 cycles of single agent Taxotere). The treatment may continue beyond 8 cycles with single agent Taxotere.
Reference therapy: Dose: Administration:	Doxorubicin 50 mg/m2 over 5-10 minutes IV
Criteria for evaluation:	
Efficacy: Or Pharmacodynamics:	Exploratory trial
Safety:	Adverse events reported by the patient or noted by the investigator. Standard hematology and blood chemistry
Pharmacokinetics:	NA
Pharmacokinetic sampling times and bioanalytical methods:	NA
Statistical methods:	The primary efficacy//safety data will be a descriptive analysis. This descriptive study aims to assess the rate of pathological remission, clinical remission and that of the safety parameters
Summary:	Data of 18 patients were evaluated in efficacy analysis. No longer requires study treatment was the primary reason in 14 cases (77,8 %) from the 18. In other cases the reason was protocol violation (one case, 5,6 %), progression of disease (one case, 5,6 %), adverse event (two cases, 11,1 %). **Primary objective:** *Pathological response* was assessed after surgery based on histological examination. The mean tumor sizes were 27 (std. 17,9) and 26 (std. 20,9) mm at x and y dimensions, respectively (based on data of 13 and 12 patients). Therefore mean tumor sizes decreased with 30 and 22 percentages during the study (based on data of 12 and 9 patients). **Secondary objective** : *Clinical response rates* at the end of cycles were also analyzed by descriptive way. The overall response at the end of study (for 11 patients) had the following distribution: CR (complete response) 45,5 %, PR (partial response) 18,2 %, SD (stable disease) 9,1 %, PD (progression of disease) 9,1 and NE (not evaluable) 18,2 % of patients.
Efficacy results: or Pharmacodynamic results:	The study was terminated, because of the extremely low speed of enrollment and the looses of interests of the investigators.
Safety results:	**Safety analysis**: laboratory data and adverse events were analyzed by descriptive way. *Adverse events* were diverse: 17 several type of them were recorded for 19 patients. The most frequents were: neutropenia (55 %), leukopenia (45 %), alopecia (20 %) and fever (20 %).
Pharmacokinetic results:	NA
Date of report:	08-02-2008