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

Sponsor/company:	**sanofi aventis**	**ClinialTrials.gov Identifier:**	**NA**
		Study Code:	**XRP6976I_2502**
Generic drug name:	**Docetaxel**	**Date:**	**25-JUL-2007**

Title of the study:	An open-label, multi-center, phase II clinical study of combination therapy of Docetaxel with Carboplatin or Cisplatin as a primary treatment in patients with Stage I c-IV ovarian carcinoma(XRP6976I/2502)		
Investigator(s): **Coordinating Investigators**	JaeWook Kim: 134 Shinchon-Dong, Saedaemun-gu, Seoul, Korea (Seoul National University Hospital) HoyPyo Lee: 28 Yeongun-Dong, Chongno-gu, Seoul, Korea (Yonsei University College of Medical Severance Hospital)		
Study center(s):	5 centers (Seoul National University Hospital, Yonsei University College of Medicine,Severance Hospital , Samsung Medical Center, Asan Medical Center, Korea Cancer Center Hospital)		
Publications (reference):	NA		
Study period: Date first **patient/subject** enrolled: 18-Mar-2003 Date last **patient/subject** completed: 27-Jan-2005		**Phase of development:** Phase II b	
Objectives:	Primary : To obtain objective response rate in patients with progressive ovarian cancer after administration of Docetaxel 75mg/m² + Carboplatin AUC 5 or Docetaxel 75mg/m²+ Cisplatin 75mg/m² in every 3 weeks. Objective response rate was evaluated in patients with measurable or evaluable lesion. Secondary : To obtain the duration of progression free survival (PFS), safety, duration of response(DR) and survival in patients with progressive ovarian cancer after administration of Docetaxel 75mg/m² + Carboplatin AUC 5 or Docetaxel 75mg/m² + Cisplatin 75mg/m² in every 3 week.		
Methodology:	*Prospective, Non blinded, parallel group*		
Number of patients/subjects:	Planned: 50	Randomized: NA	Treated: 50

<table>
<tr><td>Evaluated:</td><td colspan="3">Efficacy/Pharmacodynamics
Primary endpoint: Objective response rate, CA 125 response rate
Secondary endpoint: the duration of survival, duration of response(DR), and duration of progression free survival(PFS).</td><td>Safety: Physical & Laboratories examination</td><td>Pharmacokinetics</td></tr>
<tr><td>Diagnosis and criteria for inclusion:</td><td colspan="5">-Patients with histologically confirmed epithelial ovarian carcinoma with FIGO stage Ic-IV.
-CA 125 = 40 U/ml (if measurable lesions are not available)</td></tr>
<tr><td>Investigational product:
Dose:
Administration:</td><td colspan="5">Taxotere®
Docetaxel 75mg/m²
a) Mix Docetaxel 75mg/m² with 250ml 0.9% saline and Intravenous injection for an hour, and immediately,
b) Mix Carboplatin AUC 5 with 500ml 5% glucose and Intravenous injection for an hour. Or
Mix Cisplatin 75 mg /m² with 0.9% NaCl 500 ml and Intravenous injection for 1~3 hours.
After Cisplatin administration, hyperhydration plan was required according to the procedures of the institution
: Day 1, every 3 weeks, 6 cycles
The calculation of Carboplatin dosage was calculated using Calvert formula.
:dosage(mg) = (GFR + 25) x 5</td></tr>
<tr><td colspan="3">Duration of treatment: About 7 months
⇨ 6 cycles (a cycle: every third week)
Maximum 9 cycles</td><td colspan="3">Duration of observation: 6 months</td></tr>
</table>

Reference therapy: Dose: Administration:	*Carboplatin or Cisplatin* Carboplatin AUC 5 or Cisplatin 75mg/m² a) Mix Docetaxel 75mg/m² with 250ml 0.9% saline and Intravenous injection for an hour, and immediately, b) Mix Carboplatin AUC 5 with 500ml 5% glucose and Intravenous injection for an hour. Or Mix Cisplatin 75 mg /m² with 0.9% NaCl 500 ml and Intravenous injection for 1~3 hours. After Cisplatin administration, hyperhydration plan was required according to the procedures of the institution : Day 1, every 3 weeks, 6 cycles The calculation of Carboplatin dosage was calculated using Calvert formula. :dosage(mg) = (GFR + 25) x 5
Criteria for evaluation:	• Primary efficacy endpoint Primary efficacy endpoint was objective response rate. The response was evaluated according to the revised standard of SWOG response evaluation • Secondary efficacy endpoints Secondary efficacy endpoints were the duration of survival, duration of response (DR), and duration of progression free survival(PFS).
Safety:	Physical examination: assessed adverse events and toxicity symptoms (the grade was determined according to NCI-CTC version 2.0). Laboratories examination: assessed bone marrow suppression toxicity, and renal, hepatic and neural toxicity (the grade was determined according to NCI-CTC version 2).
Statistical methods:	Objective response rate and 95% confidential interval were estimated with CA125 response rate. For censored data such as the duration of survival, duration of progression free survival(PFS) and duration of response(DR), the median and 95% confidential interval were calculated using Kaplan-Meier method.

Summary:	Objective response rate was evaluated in patients with measurable or evaluable lesion. Among the total of 50 patients, 27 patients were evaluated for objective response and 22 of the evaluated patients showed an Objective response (81.5%; 95% CI 66.8%, 96.1%). CA125 response rate was calculated in patients who had at least 3 measured serum CA125 level values. For CA125 response, 48 patients had measurable CA125 level, and 45 patients of them (93.8%) showed a decrease in CA 125 value by at least 75% compared to the baseline. For duration of survival, duration of progression free survival (PFS), duration of response (DR), 86% of high survival rate was observed at the time of follow-up completion (677 days), and the annual survival rate calculated from the survival estimation was 89.9%. For the duration of progression free survival (PFS), the annual survival rate calculated from the Kaplan-Meier estimation was 70.8%. For the duration of response, 50% percentile was 395 days.
Safety results:	Among the total of 50 patients, 46 patients (92.0%) experienced adverse events, and 41 patients (82.0%) of them experienced adverse events related to the study drug. Most frequently reported adverse events were adverse events in skin, gastro-intestinal and neural system. The number of patients with grade 3 or higher adverse events was 15 patients (30.0%) and 14 patients of them(28/0%) were related to the study drug. Serious adverse event was reported in 8 patients (16.0%) and 6 of them experienced serious adverse drug reaction (12.0%). Fever in 3 patients (6.0%), diarrhea in 2 patients (4.0%) and infection in 2 patients (4.0%) were reported. For hematological toxicity, neutropenia in grade 3~4 was the most frequently reported in 42 patients (84.0%) and febrile neutropenia, thrombocytopenia, anemia were reported in 5 patients (10.0%), 6 patients (12.0%) and 6 patients (12.0%), respectively.
Date of report:	30-May-2007