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Sponsor/company:	sanofi-aventis	ClinialTrials.gov Identifier:	NCT00424853
		Study Code:	XRP6976B_2506
Generic drug name:	Docetaxel	Date:	30/Jun/2009

Title of the study:	Randomized phase II trial of two sequential schedules of docetaxel and cisplatin followed by gemcitabine in patients with advanced non-small-cell lung cancer. XRP6976B/2506		
Cordinating Investigator:	Dr. Enzo Galligioni, Oncologia Medica Ospedale S. Chiara, Largo Medaglie d'Oro, 38100 TRENTO, ITALY		
Study center(s):	15 (ITALY)		
Publications (reference):	NA		
Study period: Date first patient enrolled: 05-May-2005 Date last patient completed: 01-Aug-2008		Phase of development: II	
Objectives:	The primary objective of the study is to assess the antitumor activity of two sequential schedules of docetaxel and cisplatin followed by gemcitabine. The secondary objectives of the study are to determine the time to progression, the time to treatment failure and the overall survival in each treatment arm and to evaluate the quantitative and qualitative aspects of safety in each treatment arm.		
Methodology:	This is a multicenter, open-label, randomized phase II trial.		
Number of patients:	Planned: 84	Randomized: 88	Treated: 85
Evaluated:	85	Safety: 85	
Diagnosis and criteria for inclusion:	Patients with stage IIIB/IV histologically or cytologically confirmed diagnosis of non-small-cell lung cancer, aged 18-70, with at least one measurable lesion according to RECIST criteria and WHO performance status 0-1 are eligible. Patients previously treated with chemotherapy (excluding neoadjuvant or adjuvant chemotherapy if ended at least 12 months before enrollment) or radiotherapy for non-small-cell lung cancer and patients with symptomatic brain metastases or with leptomeningeal disease are excluded.		

Investigational product:	Docetaxel 75 mg/sqm over 30-60 min on day 1 immediately followed by cisplatin 75 mg/sqm over 30-60 minutes on day1 repeated every 21 days for 3 cycles, followed by gemcitabine 1200 mg/sqm day 1, 8 repeated every 21 days for 3 cycles or Docetaxel 25 mg/sqm over 30 min on days 1, 8, 15 immediately followed by cisplatin 25 mg/sqm over 30-60 minutes on days 1, 8, 15 repeated every 28 days for 3 cycles, followed by gemcitabine 1200 mg/sqm day 1, 8 repeated every 21 days for 3 cycles.
Duration of treatment: Patients in both treatments group are treated with the combination of docetaxel and cisplatin according to the schedule to which they are assigned at randomisation. In case of objective response or stable disease after 3 cycles of docetaxel-cisplatin, patients receive 3 cycles of gemcitabine monotherapy for 3 cycles (maximum) or until evidence of progressive disease, unacceptable side effects, treatment refusal.	Duration of observation: At the end of treatment, patients are followed at regularly scheduled intervals (2 months) until death.
Reference therapy:	Not applicable
Criteria for evaluation:	Efficacy: Tumor response evaluated according to RECIST criteria until study treatment stop, duration of progression-free survival, duration of overall survival. Safety: Adverse events reported by the patient or noted by the investigator and standard hematology and blood chemistry.
Statistical methods:	Primary analysis: the proportion of objective responses (CR+PR) for each treatment arm is presented with two-sided 95% exact confidence interval. Secondary analyses: in both arms, progression-free survival and overall survival curves are estimated using the Kaplan-Meier technique. Just for explanatory purpose, the differences in the treatment effects are expressed as a hazard ratio (arm A versus arm B), estimated with a Cox' s proportional hazards model, with a two-sided 95% confidence interval. Frequencies of grade 3-4 adverse events, treatment discontinuations due to adverse event, serious adverse events related to the treatment and toxic deaths is provided for each treatment group. Efficacy analyses are based on the population of all randomized patients that received at least one study drugs administration. Safety analyses include all randomized patients who have been treated, according to the treatment they actually received.
Summary:	Efficacy results: The weekly cisplatin plus docetaxel have demonstrated less activity and efficacy with better haematological toxicity compared with the standard schedule. Safety results: Both regimens were well tolerated. The incidence of grade 3-4 leukopenia and neutropenia was higher on arm A. Arm B resulted in an increased incidence of grade 3 or 4 pain, pulmonary toxicity and stomatitis compared with arm A. On the other hand arm A resulted in an increased incidence of grade 3 or 4 fatigue, diarrhea and alopecia compared with arm B.
Date of report:	25-Mar-2009