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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:**	NCT00263016
		Study Code:	XRP6976B_2503
Generic drug name:	Docetaxel	**Date:**	18/Mar/2008

Title of the study:	A PHASE II STUDY OF COMBINATION OF IRINOTECAN AND CISPLATIN IN DOCETAXEL/CISPLATIN-RESPONSIVE ADVANCED NON-SMALL CELL LUNG CANCER *Study number:* XRP6976B/2503		
Investigator(s):	Dr James CM Ho Department of Medicine Queen Mary Hospial		
Study center(s):	Single center Department of Medicine, The University of Hong Kong, Queen Mary Hospital, Pokfulam Road, Hong Kong, China		
Publications (reference):	Not applicable		
Study period: Date first **patient** enrolled: 19-May-2005 Date last **patient** completed: 31-Dec-2006		**Phase of development:** II	
Objectives:	Principal objectives: 1. To determine the tumour response rate of combination chemotherapy irinotecan/cisplatin (IC) in advanced NSCLC patients who responded to 3 courses of docetaxel/cisplatin. Secondary objectives: 1. To determine the survival and time to progression after chemotherapy treatment. 2. To determine the toxicity profile. 3. To assess the quality of life.		
Methodology:	Randomised, open-labelled, cross-over		
Number of patients:	**Planned:** 50	**Randomized**: 6	**Treated:** 6
Evaluated:	**Efficacy/Pharmacodynamics**: Tumour response rate	**Safety:** toxicity profile	**Pharmacokinetics:** N/A
Diagnosis and criteria for inclusion:	Histologically or cytologically proven non-small cell lung carcinoma at first diagnosis. Stage IIIB or IV disease. Tumour considered unresectable. Age > 18 years and < 70 years. Performance status Karnofsky index > 60% or WHO performance status Previous therapy: (a) Chemotherapy: Docetaxel and Cisplatin as first line therapy.(b) Previous radiation therapy: prior irradiation for NSCLC is permitted, however, the measurable or evaluable non-measurable disease must be completely outside the radiation portal. Life expectancy > 12 weeks.		

Investigational product:	Docetaxel / Cisplatin If PR/ SD: Irinotecan/cisplatin
Dose:	Docetaxel 75mg/m2, cisplatin 75 mg/m2 Irinotecan 60mg/m2, cisplatin 75 mg/m2
Administration:	IV
Duration of treatment: 3 cycles of Irinotecan/cisplatin regimen	**Duration of observation:** Till disease progression/ death.
Reference therapy:	N/A
Dose:	N/A
Administration:	N/A
Criteria for evaluation:	
Efficacy: Or Pharmacodynamics:	Tumour response rate of combination (primary endpoint) Overall survival Time to progression after chemotherapy treatment.
Safety:	Adverse events reported by the patient or noted by the investigator. Standard hematology and blood chemistry.
Pharmacokinetics:	N/A
Pharmacokinetic sampling times and bioanalytical methods:	N/A
Statistical methods:	This pilot study plans to recruit 60 patients with advanced NSCLC. From previous multicenter phase II Asian trial (TAX-ASI-201) on docetaxel and cisplatin in advanced NSCLC (23), disease progression occurs at around 20% after chemotherapy. Therefore, 48 patients will have response to chemotherapy (CR, PR, or NC), in which they will continue to receive irinotecan and cisplatin. By using the method of comparison of two proportions, defining a response rate of 30% being worthy of further investigation, a total of 48 patients will give a power of 0.8 with α at 0.05. Tumour response rate, time to progression, and survival will be described in median and standard deviation. No comparison between groups will be required.
Summary:	The study is terminated earlier due to low recruitment rate. No data analysis is done due to small patient number.
Efficacy results or Pharmacodynamic results:	The study is terminated earlier due to low recruitment rate. No data analysis is done due to small patient number.
Safety results:	The study is terminated earlier due to low recruitment rate. No data analysis is done due to small patient number.
Pharmacokinetic results:	N/A
Date of report:	20 Feb 2008