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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:**	**NCT00280618**
		Study Code:	**L_9202**
Generic drug name:	**oxaliplatin**	**Date:**	**19 February 08**

Title of the study:	Phase II study of Eloxatin+5-FU/LV in patients with unresectable hepatocellular carcinoma (L_9202)		
Investigator(s):	Prof. Shukui Qin, Nanjing Bayi Hospital, No.34-34 Yanggongjing, Nanjing, Jiangsu Province, P.R. China		
Study center(s):	4 sites in China		
Publications (reference):	2006 ASCO abstract 14065---J. Clin. Oncol., 2006, 24(18S Pt. 1), p. 629s 2007 ASCO GI symposium poster		
Study period: **Date first patient enrolled**: 03-Jul-2004 **Date last patient completed**: 27- Nov-2006		**Phase of development:** Phase II	
Objectives:	Primary: To determine the tumor Response Rate(RR) and Time to Tumor Progression (TTP) of patients with hepatocellular carcinoma treated with the combination chemotherapy of Eloxatin+5-FU/LV Secondary: Safety and tolerability of this regimen in these patients.		
Methodology:	Single arm, prospective		
Number of patients:	Planned: 25	Randomized: NA	Treated: 27
Evaluated:	Efficacy/Pharmacodynamics: 22	Safety: 27	Pharmacokinetics: NA
Diagnosis and criteria for inclusion:	1. histologically confirmed hepatocellular carcinoma 2. have at least measurable disease by CT scan 3. unresectable, recurrent or metastatic disease, either chemonaive or may be previously treated 4. WHO performance status: 0 to 2, Absolute neutrophil count ≧1,500/μl; Platelets ≧ 80,000/μl; Total bilirubin < 3.0g/dl; ASAT/ALAT ≦3 UNL		

Investigational product: Dose: Administration:	Oxaliplatin (Eloxatin®) combined with 5FU/LV (FOLFOX4 regimen) OXA 85mg/m^2 d1 LV 200mg/m^2 d1,2 5FU 400mg/m^2 iv bolus d1,2 5FU 600mg/m^2 c.i.v 22h d1,2 Repeated every 2 weeks as a cycle, no more than 6 cycles in total intra-venous	
Duration of treatment: no more than 6 cycles (approximately 3 months). During the treatment, if any progression was observed, the patient would stop the study treatment.		**Duration of observation:** until progression (median: 12 months)
Reference therapy: Dose: Administration:	No reference therapy NA NA	
Criteria for evaluation:		
Efficacy: Or Pharmacodynamics:	Response Rate: evaluated by RECIST	
Safety:	Safety: evaluated by NCI-CTC 2.0	
Pharmacokinetics:	NA	
Pharmacokinetic sampling times and bioanalytical methods:	NA	
Statistical methods:	Descriptive method was applied to analyze the data. The baseline characters of the patients, response rate and adverse events were described as frequency and percentage. The TTP was listed with median value. The difference before and after treatment was compared by paired Chi-square test.	

<table>
<tr><td>Summary:</td><td>From 2004 Jun to 2005 Sep, 25 eligible patients (20 male, 5 female, median age 53[range: 24-76] years old) were recruited and 22 were evaluable for efficacy. 56% had metastatic and another 56% were pre-treated with chemotherapy. Patients received median 4 [range: 1-6] cycles of chemotherapy and 107 cycles in total. No treatment related death was observed. The efficacy and safety data were listed below.</td></tr>
<tr><td>Efficacy results:
or
Pharmacodynamic results:</td><td>Descriptive analysis:
<table>
<tr><td colspan="4">Efficacy (for eligible HCC patients : n=22)</td></tr>
<tr><td>RR</td><td>18.2% (1CR, 3PR, 7SD, 11PD)</td><td>AFP-R</td><td>28%</td></tr>
<tr><td>mTTP</td><td>2.0m [75% range: 1.3-4m]</td><td>mOS</td><td>12.4m</td></tr>
</table>
3 HCC patients were not eligible for efficacy analysis: 1 patient concomitantly used other anti-cancer drug; 1 patient's baseline tumour was not evaluable; 1 patient only received 1 cycle of treatment and did not perform any follow-up tumour assessment.
2 patients were cholangiocarcinoma.. 1 reached PR (No. 14) and the other reached SD (No.9) as their best response. The OS was >12m (No.14) and >9m (No. 9), separately.</td></tr>
<tr><td>Safety results:</td><td>Descriptive analysis:
<table>
<tr><td colspan="4">NCI-CTC AE v2.0 Grade ¾ toxicity (for HCC patients n=25)</td></tr>
<tr><td>Neutropenia</td><td>32%</td><td>Anemia</td><td>4%</td></tr>
<tr><td>Febrile neutropenia</td><td>4%</td><td>Liver transaminase</td><td>16%</td></tr>
<tr><td>Thrombocytopenia</td><td>12%</td><td>Diarrhea</td><td>8%</td></tr>
</table>
There was no treatment related death observed in this study.
For cholangiocarcinoma patients (listing the maximum toxicity):
Patient No. 14 experienced grade 3 thrombocytopenia. No other grade 3/4 toxicity observed.
Only 1 SAE was reported. The nature of SAE was febrile neutropenia plus diarrhea, and fully recovered.</td></tr>
<tr><td>Pharmacokinetic results:</td><td>NA</td></tr>
<tr><td>Date of report:</td><td>24-Oct-2007</td></tr>
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