These results are supplied for informational purposes only.

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

Sponsor/company:	sanofi-aventis	ClinicalTrials.gov Identifier:	NCT00259402
		Study Code:	EFC_7127
Generic drug name:	Oxaliplatin	Date:	02 october 2009

Title of the study:	Phase I-II study with preoperative oxaliplatin, cisplatin and 5-fluorouracil (OPF) and radiation (XRT) in patients with esophageal (ES), gastroesophageal (GE), and gastric (G) cancer.
Investigator(s):	Dr. Joan Maurel Hospital Clinic i Provincial. Barcelona SPAIN
Study center(s):	5 Centers all of them from SPAIN
Publications (reference):	2009 ASCO Annual Meeting Abstract:e15612 Citation:J Clin Oncol 27, 2009 (suppl; abstr e15612) Author(s):M. Pera, R. Gallego, M. Martin-Richard, C. Montagut, M. Iglesias, C. Conill, C. Balaguer, L. Petriz, D. Momblan, J. Maurel; Hospital Universitario del Mar, Barcelona, Spain; Hospital Clinic, Barcelona, Spain; Hospital de Sant Pau, Barcelona, Spain
Study period: Date first patient enrolled: 01-Feb-2000 Date last patient completed: 17-Oct-2008	Phase of development: I-II
Objectives:	Primary Phase I: 1.- To determine the Maximum Tolerated Dose of the cisplatin, oxaliplatin and 5-FU treatment in combination with radiotherapy in patients with esophagus carcinoma in which surgery alone is not considered as the best therapeutical option. Phase II 1.- To determine the efficacy of treatment: to estimate the objective tumoral response rate (complete pathological response)

	Secondary Phase I: 1. To confirm the safety profile of the combination of cisplatin, oxaliplatin and 5-FU with concomitant radiotherapy: adverse events, hematological and biochemichal toxicity at the Recommended Dose level. 2. To estimate the efficacy (Objective Response Rate), free-progression survival and global survival of the study population. Phase II 1. To determine the free-progression interval (intervalo libre de progresión - ILP) and the free-progression survival and the global survival of the study population. 2. To determine the tumor ressectability 3. To confirm the safety profile of the combination of cisplatin, oxaliplatin and 5-FU with concomitant radiotherapy: adverse events, hematological and biochemichal toxicity at the Recommended Dose level. 4. Evaluation of the QoL of the patients.		
Methodology:	Phase I-II, multicentric, single arm, open-label of chemo and radiotherapy study.		
Number of patients:	Planned: 40	Randomized:	Treated: 41
Evaluated:	Efficacy: ITT 41/ PP: 31	Safety: 41	
Diagnosis and criteria for inclusion:	18-75 years old ECOG 0-1; Histological diagnosis: squamous cell cancer and adenocarcinoma of ES, GE or G non operable disease or non resectable; No Previous chemo/radiotherapy		
Investigational product: Dose: Administration:	Oxaliplatin/cisplatin/5-FU + radiotherapy Oxaliplatin 85 mg/m2/d cisplatin 55 mg/m2/d 5-FU 750 mg/m2/d IV. 2 cycles q4w, with concomitant 45 Gy XRT in 25 fractions; surgery was planned 5-8 weeks after XRT.		
Duration of treatment: 2 cycles q4w, with concomitant 45 Gy XRT in 25 fractions; surgery was planned 5-8 weeks after XRT.	Duration of observation: 3 years or until dead		
Reference therapy:	Surgery or surgery + radiotherapy		
Criteria for evaluation:			
Efficacy:	Response rate and pathological complete response		

Safety:	Adverse reactions and haematological toxicity
Statistical methods:	For the categorical variables table will include frequency (n) and percentage (%). For the constant variables table will include the following statisticians: N, N missing, ED, median, IS, P25, P 75,%, Min, Max and IC 95 . Model of Cox's regression, according to the method Backward, with p < 0,3 . For survival analysis we will be use the Kaplan-Meier method.
Efficacy results:	Of the 31 pts who underwent surgery, there were R0=94%/R1=3%/R2= 3%. 7/41 pts (17%) achieved pCR. Using C and MDA classification, 9/14 (61%) and 12/14 (85%) ES achieved grade IV/III and P0/P1 regression, respectively. With EJSO classification 3/17 (18%) GE and G tumors achieved pCR. Median time to progression or death (PFS) was 16.2 (CI:12.2-NR) months (mo). Median overall survival (OS) was 28.9 mo. (CI: 22.5-NR).
Safety results:	Overall adverse events : 61% G3/4 adverse events included asthenia (27%), infection (7%), diarrhea (7%) and stomatitis (5%). There were 2 toxic deaths
Date of report:	28-SEP-09