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	**ClinialTrials.gov Identifier:**	NCT00403624
		Study Code:	L_8128
Generic drug name:	Oxaliplatin	**Date:**	31/Mar/2008

Title of the study:	L_8128: Evaluation of the Neoadjuvant Treatment With Oxaliplatin -UFT- Radiotherapy in Rectal Cancer		
Investigator(s):	Dr. Carlos Fernández-Martos Medical Oncology Unit Instituto Valenciano de Oncología (IVO) Valencia, Spain		
Study center(s):	Instituto Valenciano de Oncología, H. Virgen de los Lirios H. Universitario "La Fe" H. Dr. Peset H. General Universitario de Valencia H. Arnau de Vilanova H. Lluis Alcaynis H. Corporació Sanitária Parc Tauli		
Publications (reference):	NA		
Study period: Date first patient enrolled: 22-Jul-2001 Date last patient completed: 08-Nov-2005		**Phase of development:** IIB	
Objectives:	**Main objectives**: Clinical and pathological response rate and resectable patient rate (sphincter preservation). **Secondary objectives**: safety		
Methodology:	A prospective, multicenter, phase I/II clinical trial		
Number of patients/subjects:	Planned: 25 patients	Randomized:	Treated 25
Evaluated:	Efficacy: 25 patients	Safety: 25	
Diagnosis and criteria for inclusion:	• Histologically proven rectal adenocarcinoma judged to be either inoperable, initially unresectable (i.e., fixed T4), with pelvic recurrence, or with metastatic disease requiring local treatment of the primary tumor		

Investigational product: Dose: Administration:	Oxaliplatin/RT/UFT Oxaliplatin 85 mg/m² -RT-UFT 400 mg/ m²
Duration of treatment: 22-Jul-2001/08-Nov-2005	**Duration of observation:** median observation 26 months
Reference therapy: Dose: Administration:	NA NA NA
Criteria for evaluation:	
Efficacy: Or Pharmacodynamics:	Clinical and pathological response rate, and resectable patient rate (sphincter preservation)
Safety:	Adverse events
Statistical methods:	The Gehan method for phase II trials is used to calculate the sample size. The variable used as calculated target will be the likelihood of obtaining pathological RC.

Summary:

Efficacy results:

or

Pharmacodynamic results:

TREATMENT RESPONSE	N	%
COMPLET	4	16.00
PARTIAL	14	56.00
STABLE	4	12.00
PROGRESSION	1	4.00
NO EVALUATED	2	8.00
TOTAL	25	100.00

sphincter preservation	%	N
YES	10	45.45
NO	12	54.55

Safety results:	Four patients died, 2 related with progression disease and 2 due to other causes.With regard to the safety 3 patients experienced diarrhea G3 and 3 experienced leucopenia G3, so we can conclude that the schedule has a good safety profile.
Date of report:	25-march-2008