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:**	NCT00627471
		Study Code:	LANTU_L_02936
Generic drug name:	Insulin Glargine	**Date:**	01/Jun/2010

Title of the study:	Phase IV Study, national, multi-centre, randomized, open-labeled to compare a Lantus titration algorithm vs. physician's standard practice in insulin naïve patients with type 2 Diabetes. LANTU_L_02936
Investigator(s):	Gustavo Fretchel MD. La Calandria 2143 CABA. (C1416) Argentina.
Study center(s):	Active Centers: 11- Argentina
Publications (reference):	NA

Study period:
Date first patient enrolled: 08-Jan-2008
Date last patient completed: 18-Mar-2009

Objectives:	**Primary** To compare in terms of HbA1c insulin naïve patients with Type 2 Diabetes starting with insulin glargine on an algorithm versus insulin naïve patients starting with insulin glargine on the physician's standard practice. **Secondary** To compare in terms of FBG insulin naïve patients starting with insulin glargine on an algorithm with insulin naïve patients starting with insulin glargine on the physician's standard practice. To compare the percentage of patients achieving HbA1c< 7% in each treatment group. To compare hypoglycaemic events (minor, severe and nocturnal) between groups. To compare average insulin dose between groups. To compare mean changes in body weight between treatment groups.

Design:	A 24 weeks, randomized 1:1, controlled, multi-centre, national, open label, parallel study.	
Number of patients/subjects:	Planned: 200	Included: 8
Evaluated:	Efficacy: not applicable	Safety: not applicable
	Efficacy and safety couldn't be evaluated because of the number patients included.	
Diagnosis and criteria for inclusion:	**Inclusion criteria:** Men or women > 21 and <75 years old. Patients with type 2 diabetes. Patients in treatment with Oral Anti-Diabetics (OADs) (one or more) for at least 1 year who failed metabolic control (HbA1c > 7.1% and < 11%). Fasting Blood Glucose (FBG) $\geq$ 130 mg/dl and $\leq$ 240 mg/dl. Body Mass Index (BMI) < 40 kg/m^2 and >25 kg/m^2. Ability and willingness to follow a tight anti-diabetic therapy and to perform Self-Monitoring Blood Glucose (SMBG) controls.	
Criteria for evaluation:		
Efficacy:	**Primary endpoint:** Mean difference in Glycosylated hemoglobin (HbA1c) between inclusion visit and 24 week **Secondary endpoints:** Mean difference in FBG from baseline to end of treatment Percentage of patients achieving HbA1c$\leq$ 7% Average insulin dose, according to final dose at the end of the trial registered in the Case Report Form (CRF) by the physician. Changes in body weight Minor, severe and nocturnal hypoglycemic events	
Safety:	Adverse events reported by the patient/subject or noted by the investigator	
Statistical methods:	All statistical tests are two-tailed and performed with a significance level of α=5%. Descriptive summary statistics will be presented (mean and standard deviation or median and interquartile range as appropriate) for continuous variables. The frequency distributions of categorical data will be presented.	
Summary:	Number of patients: Planned: 200, Screened: 35, Randomized: 8 Treatment arms: Lantus titration algorithm: 2 patients; Physician's standard practice: 6 patients Gender: Female: 5 patients; Male: 3 patients Age: Range 47-68 years old HbA1c at inclusion visit/at week 24 (n=8): Range (mg/dl): 8.10-10.6 / 6.4-9.6	
Date of report:	17-Feb-2010	