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 **Generic drug name:** Insulin glargine	**Clinicaltrials.gov Identifier:** NCT00349986 **Study Code:** HOE901_4059 **Date:** 5 January 2009

Title of the study:	The investigation of the suggested initial dose and the ideal time of administration of Insulin glargine (Lantus) in T2DM patients being in an inappropriate metabolic status already treated with combined oral antidiabetic therapy		
Investigator(s):	Prof. Dr. Tamás Gyula Semmelweis Univ. I. Dept. Internal Medicine, National Center for Diabetes Care 1083 Budapest 2/A, Korányi Sándor Street. Hungary		
Study center(s):	Semmelweis Univ. I. Dept. Internal Medicine, National Center for Diabetes Care 1083 Budapest 2/A, Korányi Sándor Street		
Publications (reference):	NA		
Study period: **Date first patient/subject enrolled:** 12/Sept/2006 **Date last patient/subject completed:** 20/June/2007	Phase of development: Phase IV		
Objectives:	• Identification of the initial dose, the speed of titration-up and final glargine dose • Determination of the "ideal" time of administration of glargine in 2TDM patients treated orally with combination of metformin+sulfanylurea but being in an inappropriate metabolic state		
Methodology:	Open, prospective, randomized crossover, self-controlled Phase IV		
Number of patients/subjects:	Planned: 50	Randomized: 4	Treated 2
Evaluated:	Efficacy/Pharmacodynamics: 2	Safety: 2	Pharmacokinetics: n.a.
Diagnosis and criteria for inclusion:	• Age:: 40 - 65 years, both sexes, • T2DM treated with combined oral antidiabetic treatment • Onset of diabetes: between 1-10 years • BMI >25 kg/m² , <30 kg/m² • HbA1c within 1 month : > 7.0%-<9.0% • No pregnancy and effective prevention • Signed informed consent		

Investigational product:	Insulin glargine (Lantus)
Dose:	Individually titrated
Administration:	sc

Duration of treatment: 6 months The dose is individually variable, titrated based on the fasting blood sugar and HbA1c Group „A": Lantus injection, sc. administered at 18.00 o'clock and after the crossover at 21.30 o'clock. The crossover will be at the +12th week of the study for each pts. Group „B": Lantus injection, sc. administered at 21.30 o'clock after the crossover at 18.00 o'clock Dosage: according to the SMPC Starting dose: 16 IU Lantus. Targeted blood glucose values: FBG < 5,6 mmol/l. Targeted HgbA1C < 7% by the week 12th and 24th Adjustment of the dose of insulin glargine based on the FBG results: FBG ≤ 4.4 mmol/l or hypoglycemia due to insulin glargine – 2 IU 4.4 mmol/l < FBG ≤ 6.1 mmol/l No change 6,1 mmol/l < FBG ≤ 6.7 mmol/l + 1 IU 6,7 mmol/l < FBG ≤ 7,8 mmol/l + 2 IU 7.8 mmol/l < FBG ≤ 10 mmol/l + 4 IU FBG > 10 mmol/l + 6 IU	**Duration of observation:** 6 months

Criteria for evaluation:	
Efficacy:	Primary: The HgbA1c levels at the end of both periods Secondary: The number of modifications being necessary to the determination of the final dose of glargine, the duration of time necessary to the determination of the appropriate dose The necessary number of dose-changes after the modification of the time of administration
Safety:	Adverse events reported by the patient/subject or noted by the investigator at each visit
Pharmacokinetics:	No pharmacokinetic data were collected
Pharmacokinetic sampling times and bioanalytical methods:	n.a.
Statistical methods:	The statistical plan, the evaluation of the per protocol and ITT CRFs are the duty of ADware Statistics Ltd. CRO.
Summary:	The investigator enrolled 4 pts, 2 of them dropped-out (1 for not fulfilling the inclusion criteria, 1 disappeared after the 1 visit). The chief-investigator became seriously ill and was operated on, he did not recruit more than 4 pts in this study. The study was regularly monitored for the remaining 2 pts. We discontinued the cooperation with the investigator in 2007.
Efficacy results: or Pharmacodynamic results:	No evaluable results are. The data of the 2 per protocol patients are available.
Safety results:	No serious AEs were reported.
Pharmacokinetic results:	n.a.
Date of report:	15/April/2008