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:**	NCT00576862
		Study Code:	HOE901_4046
Generic drug name:	insulin glargine	**Date:**	21 December 2007

Title

Multicenter, open, uncontrolled, clinical extension trial in subjects with type 1 diabetes, previously participating in study HMR1964A/3011 in Belgium.

Study duration and dates	17 December 2002 – 22 April 2004	**Phase**	IV

Objectives

Primary objective: to provide further treatment with HOE901 to subjects who have successfully completed study HMR1964A/3011.

Secondary objectives: to evaluate the long-term efficacy and safety of HOE901.

Study design

Local Belgian multicenter, open, uncontrolled clinical extension trial.

Number of subjects planned

The maximum number of subjects was equal to the number of subjects that successfully completed study HMR1964A/3011. The maximum total number of subjects was 32.

Inclusion criteria

Subjects meeting all of the following criteria were considered for admission to the study:

- Subjects having successfully completed study HMR1964A/3011 in Belgium, wishing to continue treatment with HOE901.
- Informed consent had to be obtained in writing for all subjects before admission to the study.

Treatments

HOE901, individually titrated, by subcutaneous injection once daily at bedtime.

Safety data

The safety was evaluated on the basis of the occurrence of serious adverse events, the occurrence of adverse events, the dose of HOE901, the weight of the subject, physical examinations and examination of vital signs.

Statistical procedures

Descriptive analysis was performed.

Interim analysis

No interim analysis was performed.

Results – Study subjects and conduct

A total of 32 patients were included in this extension study: 13 females and 19 males. All patients previously participated to HMR1964A/3001 and HMR1964A/3011 studies.
Frequency of patients visits: every 4 months.
HbA_{1c} values varied at baseline from 6.20% to 9.50% (Mean: 7.92%). Information is missing for 2 patients.
Doses of HOE901 varied at baseline from 8 IU to 40 IU (Mean: 22.2 IU).

Results – Efficacy

The information here-below relates to the 26 patients that have completed the whole follow-up period:

Evolution of efficacy parameters between first study visit (V1) and last study visit (V5) (Mean time interval: 10 months):

- HbA_{1c}: increased in 14 cases, decreased in 7 cases, stable in 2 cases (information missing in 3 cases) – mean variation: +0.30% (variations between –1.30% and +2.30%)
- Weight: increased in 14 cases, decreased in 9 cases, stable in 1 case (information missing in 2 cases) – mean variation: -0.07 kg (variations between –14.70 kg and +7 kg)
- HOE901 dose: increased in 9 cases, decreased in 4 cases, stable in 12 cases (information missing in 1 case) – mean variation: 0.72 IU (variations between –9 IU and +12 IU)

Not all the patients were followed up until the end of the study: 6 patients were lost to follow-up before the end of the trial. In these 6 cases, the evolution of the efficacy parameters between first study visit and last effective study visit was analysed:

Evolution of efficacy parameters between first study visit (V1) and last effective study visit (Mean time interval: 6 months):

- HbA_{1c}: increased in 1 case, decreased in 3 cases, stable in 2 cases – mean variation: +0.13% (variations between –0.70% and +0.30%)
- Weight: increased in 1 case, decreased in 3 cases, stable in 1 case (information missing in 1 case) – mean variation: -0.8 kg (variations between –2.1 kg and +0.1 kg)
- HOE901 dose: increased in 3 cases, decreased in 2 cases, stable in 1 case – mean variation: -1 IU (variations between -6 IU and +2 IU)

Results - Safety

Two adverse events, both 'hypoglycemia', were reported during the course of this extension study: These 2 events were reported for the same patient and were both assessed as not serious but related to study medication. Patient recovered without sequelae in both cases.
No serious adverse events have been reported in this study.
No significant overdoses have been reported in this study.

Report Date

01 December 2004