Abstract # 0198-OR

Apidra® Improved A1C In People With Type 2 Diabetes When Added to Basal Insulin And Oral Antidiabetic Treatments (BOT)

First Study to Demonstrate Benefits of Adding a Single Dose Of Rapid-Acting Insulin During Main Meal

Bridgewater, NJ – 24 June 2007 - Results from a new study presented at the American Diabetes Association's (ADA) 67th Annual Scientific Sessions show that adding Apidra® (insulin glulisine [rDNA origin] injection) to a Basal insulin and Oral antidiabetic drug Therapy (BOT+ or Basal *plus*) may provide an effective treatment option for people with type 2 diabetes unable to control their blood sugar (A1C > 6.5%), despite good titration (fasting blood glucose [FBG] < 120 mg/dl), with BOT alone. The findings are from the first prospective study (OPAL study group) assessing the benefits of adding a single dose of rapid-acting Apidra® to BOT for the treatment of people with type 2 diabetes who were inadequately controlled.

When a single dose of Apidra® was added to a basal regimen with Lantus® (insulin glargine [rDNA origin] injection) serving as the basal insulin, A1C was significantly reduced at endpoint (6.99±0.83 vs. 7.32 ± 0.70 percent at baseline, p<0.0001). Overall, 84.2 percent of participants reached the post-prandial target (2h post-prandial blood glucose [ppBG] ≤ 135 mg/dl). Taking Apidra® at the main meal showed a similar response rate in lowering A1C compared with taking Apidra® at breakfast.

The most common adverse event in the study was the rate of on-treatment hypoglycemia, which was similar between the two treatment groups.

"The data suggest that adding one injection of Apidra® at a patient's main meal of the day in addition to a BOT regimen allows patients to achieve significantly improved glycemic control," stated Mark Lankisch, MD, German Diabetes Center, Leibniz Center at Heinrich-Heine-University, Düsseldorf, Germany.

About the OPAL Study
OPAL is a 26-week, randomised, prospective, multi-center study involving 316 patients (per-protocol set) with type 2 diabetes, who had A1C levels between 6.5 percent and 9 percent on previous basal insulin and oral antidiabetic drug therapy.

Participants with FBG level ≤120 mg/dL were stratified by main meal, as determined by the highest postprandial blood glucose level, and randomised to one of the following:

- BOT with Apidra® (recommended dose=5 U/day) given at breakfast (n=162)
- BOT with Apidra® taken at the main meal (n=154)

The OPAL study aimed to show equivalence in baseline to endpoint A1C change between both arms. This was assessed by examining the overall A1C reductions at endpoint. With overall A1C reduced at endpoint (6.99±0.83 vs 7.32±0.70% at baseline and a predefined equivalence margin=0.4%, both regimens were equivalent. The change from baseline was statistically significant (p<0.0001).

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Overall, 84.2 percent of participants reached post-prandial target (2h ppBG ≤135 mg/dL). The rate of on-treatment hypoglycemia (BG < 60 mg/dL) observed in the study was 3.21 per patient year (n=393 safety set) and similar in both groups.

About Diabetes

Diabetes is a chronic, widespread condition in which the body does not produce or properly use insulin – the hormone needed to convert glucose (sugar) into energy. More than 230 million people worldwide are living with the disease. This number is expected to rise to a staggering 350 million within 20 years.[1] It is estimated more than 20 million Americans have diabetes, including an estimated 6.2 million who remain undiagnosed.[2] At the same time, approximately half of those diagnosed are not achieving the general blood sugar control standard of A1C <7 percent recommended by the American Diabetes Association (ADA).[3] The A1C test measures average blood glucose levels over a two- to three-month period.

About sanofi-aventis

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[1] World Health Organization. Unite for Diabetes Campaign key messages. Available at: http://www.unitefordiabetes.org/youth/files/UNR_key_messages_20060828.pdf. Accessed March 28, 2007
[2] Centers for Disease Control. National Diabetes Fact Sheet 2005. Available at: http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2005.pdf. Accessed on November 28, 2006.
[3] Resnick HE. Achievement of American Diabetes Association Clinical Practice Recommendations Among U.S. Adults With Diabetes, 1999–2002. Diabetes Care. 2006 Mar 29:531–537

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