

## **FDA Approves Apidra® SoloSTAR® a Pre-filled Disposable Insulin Pen**

***- Apidra® SoloSTAR® is a convenient insulin delivery device  
to help patients with diabetes to improve glycemic control -***

**Paris, France - February 26, 2009** - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that the U.S. Food and Drug Administration (FDA) approved Apidra® SoloSTAR® (insulin glulisine [rDNA origin] injection), a pre-filled disposable pen containing rapid-acting insulin analog Apidra®, which is indicated to improve glycemic control in adults and children (4 years and older) with type 1 diabetes or adults with type 2 diabetes.

The approval of Apidra® SoloSTAR® follows the approval and launch of Lantus® SoloSTAR® (insulin glargine [rDNA origin] injection) in 2007. People living with diabetes who use both Lantus® and Apidra® to help manage their blood sugar will now have two pen delivery devices to make administration of their insulins convenient. Basal-prandial insulin regimens that combine once-daily Lantus® as a basal insulin analog with rapid-acting Apidra® at mealtime can closely mimic normal physiologic insulin secretion.

*“Patients with diabetes have to contend with the challenges of carbohydrate counting, regular blood sugar monitoring and careful administration of their insulin,”* said Angela Moskow, Vice President, Metabolism Marketing, sanofi-aventis, U.S. *“Apidra® SoloSTAR® represents another innovation introduced by sanofi-aventis that offers patients a convenient option for administering their Apidra®.”*

The Apidra® SoloSTAR® and Lantus® SoloSTAR® pens are the result of over four years of intensive development, and were designed in dialogue with patients, nurses and doctors to meet their needs and meet the highest standards of the industry.

Apidra® SoloSTAR® and Lantus® SoloSTAR® are designed with completely different colors to help patients differentiate between the two pens, which are intended for use with two very different types of insulins (rapid-acting vs. long-acting). The differentiation of the Apidra® SoloSTAR® and Lantus® SoloSTAR® was demonstrated in a specific comparative study. Nevertheless, before using Apidra® SoloSTAR® or Lantus® SoloSTAR®, patients should carefully examine the labeling on the pen, to ensure they are using the correct one. Apidra® SoloSTAR® operates with a low injection force and two studies found that this delivery device required less injection force than the Novo Nordisk FlexPen and the Eli Lilly Humulin/Humalog pen.<sup>i,ii</sup>

Apidra® SoloSTAR® is expected to be available in the U.S. pharmacies this year.

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## About Diabetes

Diabetes is a chronic, widespread condition in which the body does not produce or properly use insulin, the hormone needed to transport glucose (sugar) from the blood into the cells of the body for energy. More than 230 million people worldwide are living with the disease and this number is expected to rise to a staggering 350 million within 20 years.<sup>iii</sup> It is estimated that nearly 24 million Americans have diabetes, including an estimated 5.7 million who remain undiagnosed.<sup>iv</sup> At the same time, approximately 40 percent of those diagnosed are not achieving the blood sugar control target of A1C <7 percent recommended by the ADA.<sup>v</sup> The A1C test measures average blood glucose levels over the past two- to three-month period.

## About Apidra<sup>®</sup> and Apidra<sup>®</sup> SoloSTAR<sup>®</sup>

Apidra<sup>®</sup> is a rapid-acting insulin analog with a unique zinc-free molecular structure that maintains a rapid onset and a short duration of action, indicated for adults, adolescents and children with diabetes. Apidra<sup>®</sup> offers patients mealtime dosing flexibility - it can be taken shortly (0-15 min) before or soon after the meal. Apidra<sup>®</sup> is also flexible for use in a wide range of patients from lean to obese. Apidra<sup>®</sup> is the logical partner to Lantus<sup>®</sup> once prandial insulin is required.

Apidra<sup>®</sup> SoloSTAR<sup>®</sup> is a prefilled, disposable insulin pen that is easy-to-use. Apidra<sup>®</sup> SoloSTAR<sup>®</sup> eliminates the need for the patient to change cartridges.

For more information on Apidra<sup>®</sup> or Apidra<sup>®</sup> SoloSTAR<sup>®</sup> please visit [www.Apidra.com](http://www.Apidra.com).

## About Lantus<sup>®</sup> and Lantus<sup>®</sup> SoloSTAR<sup>®</sup>

LANTUS<sup>®</sup> is indicated for once-daily subcutaneous administration in the treatment of adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia and for adult and pediatric patients (6 years and older) with type 1 diabetes mellitus. LANTUS<sup>®</sup> demonstrates a peakless and sustained concentration/time profile over 24h thus reducing the risk of hypoglycemia and allowing a constant and high efficacy over 24h with one single daily injection. LANTUS<sup>®</sup> is the number one prescribed insulin worldwide.

Lantus<sup>®</sup> SoloSTAR<sup>®</sup> is easy-to-use and requires a few straightforward steps to use it properly. Lantus<sup>®</sup> SoloSTAR<sup>®</sup> eliminates the need for the patient to change cartridges.

For more information on Lantus<sup>®</sup> or Lantus<sup>®</sup> SoloSTAR<sup>®</sup> please visit [www.Lantus.com](http://www.Lantus.com).

## About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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<sup>i</sup> Clarke A, Spollett G. Dose accuracy and injection force dynamics of a novel disposable insulin pen. Expert Opin Drug Deliv. 2007; Mar;4(2):165-74.

<sup>ii</sup> Kouyoumjian, Garen. Dispsense Force of SoloSTAR, Flexpen and Lillypen.DCA Test Report. August 17, 2007.

<sup>iii</sup> The International Diabetes Federation (IDF), Unite for Diabetes Campaign key messages. Available at: [http://www.unitefordiabetes.org/youth/files/UNR\\_key\\_messages\\_20060828.pdf](http://www.unitefordiabetes.org/youth/files/UNR_key_messages_20060828.pdf). Accessed March 28, 2007

<sup>iv</sup> Centers for Disease Control. National Diabetes Fact Sheet 2007. Available at: [http://www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2007.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf). Accessed on June 26, 2008

<sup>v</sup> Ford ES, Chaoyang L, Little RR, Mokdad AH. Trends in A1C Concentrations Among U.S. Adults With Diagnosed Diabetes From 1999 to 2004. Diabetes Care. 2008 Jan; 31: 102-104