



## FDA Approves SoloSTAR<sup>®</sup> - A New Prefilled Disposable Insulin Pen For Use With LANTUS<sup>®</sup> In People With Type 1 And Type 2 Diabetes

**- New Delivery Method Available for LANTUS<sup>®</sup> (insulin glargine [rDNA origin] injection) -**

**Paris, France - April 30, 2007** – Sanofi-aventis announced today that the U.S. Food and Drug Administration (FDA) approved SoloSTAR<sup>®</sup>, a new prefilled disposable insulin pen for once-daily 24-hour insulin LANTUS<sup>®</sup> (insulin glargine) for the treatment of hyperglycemia in people with type 1 or type 2 diabetes.

The introduction of LANTUS<sup>®</sup>SoloSTAR<sup>®</sup> offers a convenient option for administering once-daily 24-hour LANTUS<sup>®</sup>, the number one prescribed insulin in the world. LANTUS<sup>®</sup> in the SoloSTAR<sup>®</sup> pen provides diabetes patients with an alternative to the traditional needle and syringe for insulin therapy. LANTUS<sup>®</sup>SoloSTAR<sup>®</sup> is the only disposable insulin pen that allows patients to administer doses from 1 up to 80 units, in one injection.

*“Sanofi-aventis is committed to working with the diabetes community to develop new technologies intended to help make the difficult task of managing diabetes simpler and more convenient,”* explained Gilles Lhernould, Senior Vice President Industrial Affairs, sanofi-aventis. *“SoloSTAR<sup>®</sup> is the result of more than 4 years of intensive development and testing with diabetes patients, doctors and nurses,”* he added.

LANTUS<sup>®</sup>SoloSTAR<sup>®</sup> is expected to be available in pharmacies in 2007.

*“Insulin therapy for people with type 2 diabetes is generally initiated very late in the course of the disease, leaving many patients with high blood glucose levels,”* explained Satish Garg, MD, Chief, Young Adult Clinics, Professor of Pediatrics & Medicine, Barbara Davis Center for Diabetes, University of Colorado School of Medicine, Denver, USA. *“Easier delivery devices like disposable pens can make using insulin more convenient.”*

### **New LANTUS<sup>®</sup>SoloSTAR<sup>®</sup> Test Results Published**

In a separate but related event, sanofi-aventis also announced today the publication of LANTUS<sup>®</sup>SoloSTAR<sup>®</sup> dose accuracy and injection force test results. These results appear in the March issue of the journal *Expert Opinion on Drug Delivery*. All testing was performed in a laboratory setting and did not include testing on patients.

Dose accuracy testing was conducted according to International Organization for Standardization (ISO) test standards to evaluate whether the LANTUS<sup>®</sup>SoloSTAR<sup>®</sup> pen would repeatedly deliver the dialed dose under a range of conditions. The results demonstrated that LANTUS<sup>®</sup>SoloSTAR<sup>®</sup> accurately and consistently delivered the dialed dose of insulin well within the ISO standard. Injection force testing was performed to measure the force required to dispense a known volume of insulin within a fixed time period compared to other currently marketed insulin pens. The results showed that the LANTUS<sup>®</sup>SoloSTAR<sup>®</sup> pen had a mean total injection force that was more than 30% less than other frequently used disposable pens.<sup>1</sup>



Press Release

The full study, "Dose accuracy and injection force dynamics of a novel disposable insulin pen," is available at the *Expert Opinion on Drug Discovery* Web site: <http://www.expertopin.com/doi/abs/10.1517/17425247.4.2.165>.

### **About SoloSTAR®**

SoloSTAR® is a prefilled, disposable insulin pen that allows patients to dial their dose from 1 to 80 units of insulin. SoloSTAR® should be kept in cool storage (36° F - 46° F [2° C - 8° C]) until first use. Once in use, it can be kept at room temperature, as long as it remains below 77°F, and can be used for up to 28 days.

### **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.<sup>2</sup> It is estimated more than 20 million Americans have diabetes, including an estimated 6.2 million who remain undiagnosed.<sup>3</sup> At the same time, approximately half of those diagnosed are not achieving the general blood sugar control standard of A1C <7% recommended by the American Diabetes Association (ADA).<sup>4</sup> The A1C test measures average blood glucose levels over a two- to three-month period.

### **About LANTUS®**

LANTUS®, the number one prescribed insulin, is the only 24-hour insulin approved exclusively for use once a day. Most insulins have what is called a "peak of action." The peak refers to the time at which insulin reaches its maximum effect in the body. With LANTUS®, the insulin is released into the bloodstream at a relatively constant rate throughout the day and night; therefore it has no pronounced peak.

### **About sanofi-aventis**

Sanofi-aventis is one of the world leaders in the pharmaceutical industry, ranking number one in Europe. Backed by a world-class R&D organisation, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

### **Forward Looking Statements**

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include financial projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans" and similar expressions. Although sanofi-aventis' management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended*



December 31, 2006. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

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<sup>1</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>2</sup> World Health Organization. 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>3</sup> Centers for Disease Control. National Diabetes Fact Sheet 2005. Available at: [http://www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2005.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2005.pdf). Accessed on November 28, 2006.

<sup>4</sup> 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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