

New ADA/EASD Treatment Recommendations

Timely Use of Basal Insulin reinforced as a “Core Therapy” for Type 2 Diabetes

- Experts recommend considering a basal insulin or sulfonylurea when treatment goals not achieved with metformin alone -

Paris, France - October 30, 2008 – Sanofi-aventis commends the *American Diabetes Association* (ADA) and the *European Association for the Study of Diabetes* (EASD) for developing updated treatment recommendations for type 2 diabetes.

Designed by a team of diabetes experts, the updated recommendations provide healthcare professionals with a consensus algorithm that further establishes basal insulins, such as LANTUS® or a sulfonylurea such as AMARYL®, as two preferred second-line treatment options for people with diabetes who are unable to achieve glycemic control targets with lifestyle intervention and metformin alone.

For the first time, the ADA/EASD diabetes treatment recommendations are divided into two tiers.

Tier 1: “Well Validated Core Therapies”

These interventions represent the most established, the most effective and the most cost-effective therapeutic strategy for achieving target glycemic goals. The tier one algorithm which includes basal insulins, is the preferred route of therapy for most people with type 2 diabetes.

Tier 2: “Less Well Validated Therapies”

These interventions represent appropriate treatment options for certain people, but were grouped in tier two due to limited clinical experience or safety caution. Pioglitazone and GLP-1 agonists, one of the newest classes of diabetes medications, were placed in this group.

The updated recommendations describe insulin as the “most effective” treatment for lowering glycaemia and emphasize the need for “early addition of insulin therapy in patients who do not meet target goals.” This is especially important for people with A1C > 8.5%. However, in actual clinical practice, the use of insulin is often delayed until A1C approaches 9%, and many people with type 2 diabetes have already developed diabetes-related complications by the time they begin treatment with insulin. Early addition of basal insulin to oral therapy may improve glycemic control, which can reduce the risk of complications. Premix regimens are not mentioned in the guidelines algorithm and are not recommended for initiation of insulin therapy.

“Basal insulin is an important, yet underutilized, treatment option for many people living with type 2 diabetes. The updated algorithm provides physicians with additional guidance about when it may be appropriate to initiate it”, said Alexandre Moreau, Vice President, Diabetes-Metabolism Franchise. *“In the future, we hope more patients will benefit from the effectiveness and ease-of-use of LANTUS®, the only true once-daily basal therapy from initiation to insulin intensification.”*

Sanofi-aventis offers a complete range of medications (such as Lantus[®], Apidra[®] and Amaryl[®]) and delivery devices (such as SoloSTAR[®]) to combat diabetes at each stage of the disease.

About LANTUS[®] (insulin glargine [rDNA origin])

LANTUS[®] 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[®] demonstrates a peakless and sustained concentration/time profile over 24 hours thus reducing the risk of hypoglycemia and allowing a constant and high efficacy over 24h with one single daily injection. LANTUS[®] is the number one prescribed insulin worldwide.

About APIDRA[®] (insulin glulisine [rDNA origin])

APIDRA[®] 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[®] offers patients mealtime dosing flexibility—it can be taken shortly (0-15 min) before or soon after the meal. APIDRA[®] is also flexible for use in a wide range of patients from lean to obese. APIDRA[®] is the logical partner to LANTUS[®] once prandial insulin is required.

About LANTUS[®] SoloSTAR[®] and APIDRA[®] SoloSTAR[®]

SoloSTAR[®] is a new, easy-to-use disposable pen for administration of LANTUS[®] and APIDRA[®]. SoloSTAR[®] allows administering doses from 1 up to 80 units, in one unit increments, in one injection. SoloSTAR offers a 33% greater maximum capacity than other disposable insulin pens.

SoloSTAR[®] uses a simple, intuitive design with an easy-to-read display, and requires only a few steps to use it properly. SoloSTAR[®] is small, discreet and eliminates the need for the patient to change insulin cartridges. Easy-to-use and easy-to-inject, SoloSTAR[®] reduces the injection force by 30% or more in comparison to other most broadly available pens in its class.

A recent survey of LANTUS[®] SoloSTAR[®] use in everyday clinical practice, involving more than 2000 people with diabetes (16% with manual dexterity problems and 15% with poor eyesight not corrected by glasses) showed that more than 95% of participants declared to be “satisfied” or “very satisfied” with using SoloSTAR[®] to inject insulin, irrespective of diabetes type or previous device experience.

LANTUS[®] SoloSTAR[®] and APIDRA[®] SoloSTAR[®] were approved by the EMEA in September 2006; LANTUS[®] SoloSTAR[®] was approved by the FDA in April 2007. LANTUS[®] SoloSTAR[®] and APIDRA[®] SoloSTAR[®] are launched in France, UK, Italy, Spain, Germany, Netherlands, Slovakia, Slovenia, Sweden, Norway, Iceland, Poland, Austria, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Latvia, Australia, Lithuania, Lebanon, South Africa, Cyprus, Israel, Jordan, Argentina, Korea, Turkey, Egypt, Tunisia, Romania, Chile, Colombia, Indonesia, Costa Rica, Dominican Rep, Peru, Georgia, Uruguay, Curacao, Nicaragua, Singapore, Guatemala and Switzerland. LANTUS[®] SoloSTAR[®] is launched in the US, Canada, Taiwan, Japan, Venezuela, Syria, China, Iran, Thailand, Malaysia, Hong Kong and India. The preparation for launches in other countries is planned during 2008 and 2009.

The Chicago Athenaeum Museum of Architecture and Design awarded a 2007 GOOD DESIGN™ Award for the new SoloSTAR® disposable insulin injection pen for people with type 1 and type 2 diabetes. The Museum's historic GOOD DESIGN program was founded in Chicago in 1950 by Edgar J.Kaufmann, Jr. with the participation of some of America's most important designers. Every year the jury meets in New York and select products and graphics worthy of the GOOD DESIGN Award for design distinction. GOOD DESIGN remains the oldest and most important Awards program worldwide.



About sanofi-aventis' pen portfolio

Sanofi-aventis having 85 years of innovation in the diabetes is committed to offering people with diabetes an integrated system of insulin products and delivery devices. In addition to the SoloSTAR®, the pen portfolio available for LANTUS® and APIDRA® includes the OptiSet® disposable pen, the OptiClik® and OptiPen® Pro reusable pens, and the Autopen® 24 from Owen Mumford.

About AMARYL®

AMARYL® (Glimepiride) is a second-generation sulphonylurea that effectively controls glycaemia in type 2 diabetes patients and has a more rapid onset and longer duration of action than first-generation agents. It is once a day and well tolerated. AMARYL® is available in more than hundred countries.

A fixed-dose combination of glimepiride plus Metformin in a single presentation (AMARYL M®) has been developed recently. The fixed dose treatment is more efficacious than either agent alone in patients with type 2 diabetes and has equal efficacy compared with the free combination of glimepiride and Metformin. AMARYL M® was launched in 2007.

About Diabetes

Diabetes is a chronic, progressive widespread disease in which the body reduces or does not produce or properly use insulin – the hormone needed to convert glucose (sugar) into energy. In 2008 over 250 million people worldwide are living with diabetes. This number would dramatically increase up to 380 million by 2025. It is estimated more than 24 million Americans have diabetes. At the same time, more than 40% of those diagnosed are not achieving the general blood sugar control. The A1C test reflects average blood glucose levels over a two- to three-month period. Without proper insulin production and action, glucose remains in the blood, leading to chronic hyperglycaemia (raised blood sugar). This can result in short and long-term complications, many of which, if not prevented and left untreated, can be fatal. All have the potential to reduce the quality of life of people with diabetes and their families.

The most common long-term complications are:

- Diabetic nephropathy (kidney disease), which may result in total kidney failure and in the need for dialysis or kidney transplant.
- Diabetic eye disease (retinopathy and macular oedema), damage to the retina of the eye which can lead to vision loss.
- Diabetic neuropathy (nerve disease), which can ultimately lead to ulceration and amputation of the feet and lower limbs.
- Cardiovascular disease, which affects the heart and blood vessels and may cause fatal complications such as coronary heart disease (leading to a heart attack) and stroke.

Diabetes is the fourth leading cause of death by disease globally. Every year, 3.8 million people die from diabetes-related causes.

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, contributes to improving life by providing a broad offering of medicines, vaccines, and integrated healthcare solutions adapted to local needs and means. Sanofi-aventis is listed in Paris (EURONEXT : SAN) and in New York (NYSE : SNY).

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