



Sanofi Receives rFDA Approval of Once-Daily Basal Insulin Toujeo®

Paris, France - February 26, 2015 - [Sanofi](#) announced today that the U.S. Food and Drug Administration (FDA) approved Toujeo® (insulin glargine [rDNA origin] injection, 300 U/mL), a once-daily long-acting basal insulin, to improve glycemic control in adults living with type 1 and type 2 diabetes. Toujeo® is expected to be available in the U.S. at the beginning of Q2 2015.

“Sanofi is proud of its long heritage in diabetes and insulin therapies, including Lantus® which has supported patients in the management of their diabetes for more than a decade. With the FDA approval of Toujeo, Sanofi builds on its strong legacy and looks forward to bringing a new treatment option to people living with diabetes,” said Pierre Chancel, Senior VP, Global Diabetes, Sanofi.

The approval of Toujeo was based on FDA review of results from the EDITION clinical trial program, which was comprised of a series of international Phase III studies evaluating the efficacy and safety of Toujeo in more than 3,500 adults from broad and diverse diabetes populations (type 1 and type 2). In the clinical trial program leading to approval, once-daily Toujeo was compared to that of once-daily Lantus (insulin glargine [rDNA origin] injection, 100 U/mL) in open-label, randomized, active-control, parallel, treat-to-target studies of up to 26 weeks of duration with 6 months safety extension.

“Nearly 50 percent of people living with diabetes remain uncontrolled,” said John Anderson, MD, internal medicine and diabetes specialist, Frist Clinic of Nashville, TN, and Past President of the American Diabetes Association. *“Despite the proven efficacy of insulin, ensuring effective titration and maintenance can be a challenge for both patients and healthcare professionals due to hypoglycemia concerns. Toujeo provides a new option that may help patients manage their diabetes.”*

All studies of the EDITION program successfully met the primary study endpoints by demonstrating similar blood sugar control with Toujeo as compared to Lantus.^{1,2} The most common adverse events (excluding hypoglycemia) reported for Toujeo® included nasopharyngitis (12.8% in type 1 patients and 7.1% in type 2 patients) and upper respiratory tract infection (9.5% in type 1 patients and 5.7% in type 2 patients).

Toujeo's Pharmacokinetic/Pharmacodynamic (PK/PD) information and its rates of severe and documented symptomatic hypoglycemia can be found in the label.

Toujeo will be available in the Toujeo SoloSTAR®, a disposable prefilled pen which contains 450 units of Toujeo and requires one third of the injection volume to deliver the same number of insulin units as compared to the Lantus SoloSTAR®. The maximum single injection dose of 80 IU meets the needs of the vast majority of patients on basal insulin in the U.S., who require 80 IU or less per day. Toujeo is currently pending marketing authorization with the European Medicines Agency (EMA) and other health authorities around the world.



About Toujeo

Prescription Toujeo® is a long-acting insulin used to treat adults with type 2 and type 1 diabetes for the control of high blood sugar. It should be taken once a day at the same time each day to lower blood glucose.

Do not use Toujeo® to treat diabetic ketoacidosis.

Important Safety Information for Toujeo® (insulin glargine [rDNA origin] injection) 300 Units/mL (U-300)

Do not take Toujeo® during episodes of low blood sugar or if you are allergic to insulin or any of the inactive ingredients in Toujeo®. Toujeo is not approved for use in people under the age of 18.

Do not share needles, insulin pens or syringes with others. Do NOT reuse needles.

You must test your blood sugar levels daily while using any insulin, including Toujeo®. Do not make any changes to your dose or type of insulin without talking to your healthcare provider.

Toujeo contains 300 units per milliliter (300 U/mL). You should always verify that you have the correct insulin before each injection. Your dose for Toujeo may be different from other insulins you have taken. Any change of insulin should be made cautiously and only under medical supervision.

Do NOT dilute or mix Toujeo® with any other insulin or solution. It will not work as intended and you may lose blood sugar control, which could be serious. Toujeo® must only be used if the solution is clear and colorless with no particles visible.

Tell your doctor about other medicines, especially ones commonly called TZDs (thiazolidinediones), and supplements you are taking because they can change the way insulin works. Before starting Toujeo®, tell your doctor about all your medical conditions, including if you have liver or kidney problems, are pregnant or planning to become pregnant, or are breast-feeding or planning to breast-feed. If you have heart failure, it may get worse while taking TZDs with Toujeo®.

The most common side effect of any insulin, including Toujeo®, is low blood sugar (hypoglycemia), which may be serious and can be life-threatening. Symptoms of serious low blood sugar may include shaking, sweating, fast heartbeat and blurred vision. Severe hypoglycemia may cause harm to your heart or brain. Other possible side effects may include swelling, weight gain and allergic reactions. In rare cases, some allergic reactions may be life-threatening. Injection site reactions are also possible and may include changes in fat tissue at the injection site, skin thickening, redness, swelling and itching.

Toujeo® SoloSTAR® is a disposable prefilled insulin pen. Please talk to your healthcare provider about proper injection technique and follow instructions in the Instruction Leaflet that accompanies the pen.

Please click here for full Prescribing Information for Toujeo:
<http://products.sanofi.us/Toujeo/Toujeo.pdf>.

About Lantus

Prescription Lantus is a long-acting insulin used to treat adults with type 2 diabetes and adults and patients (6 years and older) with type 1 diabetes for the control of high blood sugar. It should be taken once a day at the same time each day to lower blood glucose.



Do not use Lantus to treat diabetic ketoacidosis.

Important Safety Information for Lantus

Do not take Lantus if you are allergic to insulin or any of the inactive ingredients in Lantus.

You must test your blood sugar levels while using insulin, such as Lantus. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made cautiously and only under medical supervision.

Do NOT dilute or mix Lantus with any other insulin or solution. It will not work as intended and you may lose blood sugar control, which could be serious. Lantus must only be used if the solution is clear and colorless with no particles visible. **Do not share needles, insulin pens or syringes with others.**

Tell your doctor about other medicines, especially ones called TZDs, and supplements you are taking because they can change the way insulin works. Before starting Lantus, tell your doctor about all your medical conditions including if you have heart failure or other heart problems, liver or kidney problems, are pregnant or planning to become pregnant, or are breast-feeding or planning to breast-feed. If you have heart failure, it may get worse while you take TZDs with Lantus.

The most common side effect of insulin, including Lantus, is low blood sugar (hypoglycemia), which may be serious. Some people may experience symptoms such as shaking, sweating, fast heartbeat, and blurred vision. Severe hypoglycemia may be serious and life-threatening. It may cause harm to your heart or brain. Other possible side effects may include swelling, weight gain, injection site reactions, including changes in fat tissue at the injection site, and allergic reactions, including itching and rash. In rare cases, some allergic reactions may be life-threatening.

Please click here for the full Prescribing Information: <http://products.sanofi.us/lantus/lantus.html>.

Lantus SoloSTAR is a disposable prefilled insulin pen. Please talk to your healthcare provider about the proper injection technique and follow instructions in the Instruction Leaflet that accompanies the pen.

About Sanofi Diabetes

Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. Driven by valuable insights that come from listening to and engaging with people living with diabetes, the Company is forming partnerships to offer diagnostics, therapies, services, and devices including blood glucose monitoring systems. Sanofi markets injectable, inhaled and oral medications for people with type 1 or type 2 diabetes.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: [SAN](#)) and in New York (NYSE: [SNY](#)).

References

1. Ritzel RA, Roussel R, Bolli GB et al. New insulin glargine 300 U/ml: glycaemic control and hypoglycaemia in a meta-analysis of phase 3a EDITION clinical trials in people with type 2 diabetes mellitus. Poster at European Association for the Study of Diabetes congress, 2014, abstract 963.
2. Home PD, Bergenstal RM, Riddle MC et al. Glycaemic control and hypoglycaemia with new insulin glargine 300 U/mL in people with type 1 diabetes (EDITION 4). Oral presentation at European Association for the Study of Diabetes congress, 2014, abstract 148.



Sanofi 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 projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, 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’s 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, 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 among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group’s ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2013. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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