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MEDIA INFORMATION
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In Senior Adults Treated with Basal Insulin, Switching to Sanofi's Toujeo® Halved Hypoglycemia Risk

- New DELIVER 3 Real-World Toujeo® Observational Study Confirms Reduction of Hypoglycemia in Real-Life Setting -

San Diego, CA, U.S. – June 10, 2017 – New evidence from a real-world observational study demonstrating significantly less risk of documented hypoglycemia with similar blood sugar control after switching to Sanofi's Toujeo® (insulin glargine 300 Units/mL) compared to switching to another basal insulin including Lantus® (insulin glargine 100 Units/mL), Levemir® (insulin detemir) and Tresiba® (insulin degludec), in an at-risk population of senior adults (aged ≥65 years) with type 2 diabetes. The results of the DELIVER 3 retrospective observational study comparing two cohorts were presented at the American Diabetes Association (ADA) 77th Scientific Sessions Annual Meeting in San Diego, CA, U.S.

In the DELIVER 3 study,[1] patients switching to Toujeo were 57 percent less likely to experience hypoglycemia at 6-month follow-up (Odds Ratio: 0.432, 95% CI: 0.307 to 0.607, p<0.0001) than those who switched to another basal insulin, with similar glycemic control (least squares mean difference -0.09%, p=0.24).

"Older patients with type 2 diabetes are disproportionately impacted by hypoglycemia and its consequences," said Jeremy Pettus, Assistant Professor, Division of Endocrinology, University of California, San Diego, U.S. *"Observational real-world data such as DELIVER 3 can contribute to clinical decision-making, helping physicians to better advise their patients in this important at-risk population."*

These findings are broadly consistent with Toujeo evidence from DELIVER 2, a retrospective observational study that included two matched cohorts of 1,827 (n=3,654) adults with type 2 diabetes using basal insulin who switched to either Toujeo or another basal insulin. DELIVER 2 showed 33 percent fewer hypoglycemic events after 6 months in a broader population of adults with type 2 diabetes, which contributed to an estimate of all-cause healthcare cost savings of up to approximately $2,000 per patient per year.[2]

"The findings from DELIVER 2 and 3 demonstrate the real-life clinical benefit of Toujeo vs. other basal insulins, and how this translates into overall cost savings. Complementing these observational studies in a real-life setting, Sanofi is also conducting a unique program of three randomized, prospective, open-label real-life clinical studies with Toujeo," said Riccardo Perfetti, Head of Global Diabetes Medical Team, Sanofi. *"The methodology of these studies could provide a better understanding of the comparative benefit of Toujeo vs.*

other basal insulins, and the findings might be relevant to future clinical practice and evaluation of overall cost of care."

These randomized, prospective real-life clinical studies, called ACHIEVE CONTROL, REACH CONTROL and REGAIN CONTROL, involve more than 4,500 people with type 2 diabetes across the U.S. and Europe who are starting basal insulin treatment or switching from another basal insulin. In addition to clinical measures, the studies will also collect patient feedback on treatment satisfaction and their experience of hypoglycemia, along with impact on healthcare resource utilization. Initial results are anticipated later in 2017.

Summary of DELIVER program

The DELIVER program comprises several non-interventional retrospective analyses using data from the Predictive Health Intelligence Environment (PHIE) database of U.S. real-world electronic medical records, currently representing 37 integrated health delivery networks. Hypoglycemia was identified in the dataset by diagnosis code (ICD9/10 codes) or plasma glucose (≤70mg/dL by laboratory test).

These findings represent actual prescribing patterns and clinical outcomes outside the confines of a clinical trial, which might include drug use outside U.S. Food and Drug Administration (FDA)-approved prescribing information. As a result, reporting of hypoglycemia at baseline and in both treatment arms were not based on self-monitored blood glucose, which could result in less severe events not being reported by patients. The limitations in the DELIVER studies are similar to those generally observed in such studies.

The DELIVER 3[1] retrospective observational study included 1,610 people with type 2 diabetes aged ≥65 years on basal insulin who switched to either Toujeo or another basal insulin (insulin glargine 100 Units/mL, insulin detemir or insulin degludec). Patients switching to Toujeo were 57 percent less likely to experience hypoglycemia at 6-month follow-up (Odds Ratio: 0.432, 95% CI: 0.307 to 0.607, p<0.0001) than those who switched to another basal insulin. Switching to Toujeo or another basal insulin resulted in comparable changes in HbA_{1c} (least squares mean difference -0.09%, p=0.24).

The DELIVER 2[2] retrospective observational study included two matched cohorts of 1,827 (n=3,654) adults with type 2 diabetes using basal insulin who switched to either Toujeo or another basal insulin (insulin glargine 100 Units/mL, insulin detemir or insulin degludec). After 6 months, patients who switched to Toujeo experienced 25 percent fewer hypoglycemic events than those who switched to other basal insulins (mean hypoglycemia event rate per patient per year: 0.667 vs. 0.902; difference: -0.225 events per patient per year; p<0.01) with comparable blood glucose control. Patients switching to Toujeo experienced significantly fewer all-cause hospital in-patient days (least squares mean difference: −0.714, 95% CI: −1.285 to −0.143, p=0.01), emergency department visits (least squares mean difference: −0.177 events/PPPY, 95% CI: −0.319 to −0.036, p=0.01) and outpatient events (least squares mean difference: −0.985 events/PPPY, 95% CI: −1.610 to −0.359, p<0.01) during 6 months of follow-up compared to patients who switched to another basal insulin, translating to savings of $2,071 per patient per year.

Related multimedia resources available here.

About Toujeo®

Toujeo® is a long-acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus. Toujeo has been approved by the U.S. Food and Drug Administration (FDA), the European Commission, Health Canada, the Therapeutic Goods Administration in Australia, and the MHLW in Japan (where its approved brand name is Lantus® XR), and is under review by other regulatory authorities around the world.

About Sanofi Diabetes & Cardiovascular

Diabetes and cardiovascular disease affect millions of people worldwide, with many managing the complex challenges of both. Building on our portfolio evolution, heritage and expertise, Sanofi has a focused business unit dedicated to delivering innovative, value-based medicines and integrated solutions in these therapeutic areas. We are committed to a collaborative approach that involves strategic alliances with professional and patient associations, research institutions and leaders in healthcare and other industries, with the goal of advancing scientific knowledge, driving the convergence of science and technology, helping to improve outcomes and inspiring an evolution in care.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Consumer Healthcare. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

References

1. Zhou FL et al, Older Adults with Type 2 Diabetes (T2D) Experience Less Hypoglycemia When Switching to Insulin Glargine 300 U/mL (Gla-300) vs. Other Basal Insulins (DELIVER 3 Study), Poster 986-P, American Diabetes Association (ADA) 77th Scientific Sessions, San Diego, CA, U.S., June 10, 2017.
2. Zhou FL et al, Lower Risk of Hypoglycemia and Less Health Care Utilization in Basal Insulin-Treated Patients with Type 2 Diabetes (T2D) After Switching to Insulin Glargine 300 U/mL (Gla-300) vs. Other Basal Insulins in Real-World Clinical Settings, Poster NR 1151, American Association of Clinical Endocrinologists (AACE) 26th Annual Scientific & Clinical Congress, Austin, TX, U.S., May 3-7 2017.

Contacts:

Corporate Communications
Mai Tran
Tel.: +33 (0) 1.53.77.46.46
mai.tran@sanofi.com

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