



### Media Information:

## Real-world experiences with second generation basal insulin Toujeo® are aligned with results from the BRIGHT randomized controlled trial September 27, 2018

### Background: Importance of minimizing low blood sugar events for patients treated with insulin

As the number of people with diabetes around the world increases, there is a need for treatments that limit periods with high blood sugar, while also minimizing low blood sugar incidents. Experiencing a severe low blood sugar event that requires help from someone else, particularly in the early weeks and months after beginning long-acting insulin treatment, can have an important psychological impact on a person. It might reduce their motivation to stick to their prescribed treatment plan and could even lead them to stop treatment altogether.<sup>1</sup> Either of these decisions may have a substantial impact on long-term health outcomes.

With its long-standing commitment to addressing the needs of people with diabetes, Sanofi has continued its extensive research program comparing the effectiveness of different long-acting insulins. This program includes both randomized controlled trials and more innovative analyses of data collected in different real-world settings, to provide a more accurate picture of what physicians might see in routine care.

**EMBARGOED UNTIL Thursday, September 27, 2018 [09.00 CET]**

## In a real-world setting, starting insulin treatment with second generation basal insulin Toujeo® leads to effective glucose control and low rates of severe hypoglycemia

For patients starting treatment with long-acting insulin, second generation basal insulin Toujeo® (insulin glargine 300 units/mL) provides similar blood sugar reduction compared to insulin degludec 100 units/mL and insulin degludec 200 units/mL. Patients saw comparable rates of low blood sugar (hypoglycemia) and low blood sugar events associated with hospitalization

or ED admission (severe hypoglycemia) with both treatments. These results come from the DELIVER Naïve D retrospective, observational study, which analyzed electronic medical records, from the U.S. Predictive Health Intelligence Environment (PHIE) database (IBM Explorys data).<sup>2</sup>

*“The DELIVER Naïve D study highlights the real-world impact Toujeo brings, as a second-generation basal insulin, in early insulin treatment of people with type 2 diabetes,”* said Rachele Berria, Head of Global Diabetes Medical Affairs at Sanofi. *“The trend toward fewer hypoglycemic events requiring a hospital visit with second generation basal insulin analogs may also suggest differences in the overall cost of care.”*

Incidence of low blood sugar events requiring hospitalization was comparable and low (2.5% of patients or fewer) in both groups. This confirms previous clinical trial findings of low risk of severe hypoglycemia in patients starting basal insulin treatment.<sup>4,5,7</sup>

DELIVER Naïve D follows BRIGHT, the first head-to-head randomized controlled trial comparing the efficacy and safety of Toujeo vs insulin degludec 100 units/mL in adults starting insulin treatment. BRIGHT showed similar reductions in average blood sugar measurement (HbA<sub>1c</sub>) with both treatments, with similar hypoglycemia incidence and event rates throughout the 24-week study period,<sup>4</sup> and significantly lower rates in the first 12 weeks, when most dose adjustment occurs.<sup>5</sup> A pharmacokinetic/ pharmacodynamic study has also demonstrated the flatter profile with fewer within-day fluctuations of Toujeo versus insulin degludec 100 Units/mL.<sup>6</sup>

### **About the DELIVER Naïve D Study<sup>2</sup>**

The DELIVER Naïve D retrospective, observational study analyzed electronic medical records, from the U.S. Predictive Health Intelligence Environment (PHIE) database (IBM Explorys data). The study assessed records for adults with type 2 diabetes who started basal insulin treatment with either Toujeo or insulin degludec (100 units/mL or 200 units/mL), in a real-world setting. It included people who had used oral anti-hyperglycemic medication (OADs) or a GLP-1 receptor agonist, and had not used any kind of insulin, in the year before starting basal insulin.

The study used propensity score matching to provide accurate comparisons between groups and avoid the possible influence of confounding factors. Participants were matched on main baseline demographic and clinical characteristics to produce an overall study population of 1,276 people.

After 90-180 days of treatment, people using Toujeo achieved a 1.67% reduction in average blood sugar from baseline (HbA<sub>1c</sub>, p<0.0001) while those using insulin degludec had an average reduction of 1.58% (p<0.0001; difference: 0.09%, p=0.509, not significant).

Low blood sugar (hypoglycemia) outcomes were similar between groups. Fewer people using Toujeo experienced hypoglycemia and hypoglycemia requiring a hospital visit, although these differences were not statistically significant. In the follow-up period, 10.3% of patients experienced hypoglycemia and 2% experienced severe hypoglycemia with Toujeo, compared with 11.1% and 2.5% respectively with insulin degludec (odds ratios adjusted for baseline hypoglycemia: 0.94 [p=0.75, not significant] and 0.73 [p=0.42, not significant], respectively). Event rates were comparable between groups for all hypoglycemia (difference: -0.004 events per patient-year, p=0.97, not significant) and numerically lower with Toujeo for severe hypoglycemia requiring a hospital visit (difference: 0.045 events per patient-year, p=0.24, not significant).

#### **References**

1. Dalal MR et al, Adv Ther. 2017 Sep;34(9):2083-2092. doi: 10.1007/s12325-017-0592-x.
2. Sanofi. Data on file (DELIVER Naïve D).
3. Zhou FL et al., Poster NR 1151, American Association of Clinical Endocrinologists (AACE) 26th Annual Scientific & Clinical Congress, Austin, TX, U.S., May 3–7, 2017.
4. Rosenstock J, et al. Diabetes Care. 2018, DOI: 10.2337/dc18-0559.
5. Bolli GB, et al. Lower Hypoglycemia Rates with Insulin Glargine 300 U/mL (Gla-300) vs Insulin Degludec 100 U/mL (IDeg-100) in Insulin-Naïve Adults with T2DM on Oral Antihyperglycemic Therapy ± GLP-1 RA: The BRIGHT Randomized Study. Presentation 1032-P, American Diabetes Association (ADA) 78th annual congress in Orlando, Florida, U.S., June 23, 2018.
6. Bailey TS et al., Diabetes & Metabolism, 44(1), 15-21. doi: <https://doi.org/10.1016/j.diabet.2017.10.001>.
7. Bolli GB, et al. Diabetes Obes Metab. 2015;17(4):386–94, DOI: 10.1111/dom.12438.

#### **About Sanofi**

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

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**Global Diabetes Communications**

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