Real-World Effectiveness and Safety of Insulin Glargine 300 U/mL in Insulin-Naïve People with Type 2 Diabetes: the ATOS Study

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Introduction

Gla-300 is a **second-generation basal insulin analogue**, which has a more **stable and prolonged PK/PD profile** compared with the first-generation basal insulin analogue Gla-100[1]

Efficacy and **safety of Gla-300** has been demonstrated in **randomised clinical trials** and **real-world studies** that were conducted mostly in **US** and **Western Europe**[2-7]

Objective: **ATOS study** evaluated the **real-world effectiveness** and **safety** of **Gla-300** in **wider geographic regions** (Asia, the Middle East, North Africa, Latin America, and Eastern Europe)

Study design

A Toujeo® Observational Study (ATOS): a 12-month prospective, observational study in people with T2DM who initiated Gla-300 therapy after OAD failure

05 regions | **18** countries | **4422** participants

Included population: ≥18 years of age; Uncontrolled T2DM; HbA_{1c} >7.0% to ≤11.0%; One or more OADs; Insulin naïve

The **primary endpoint** was achievement of a predefined **individualised HbA_{1c} target*** at **Month 6**

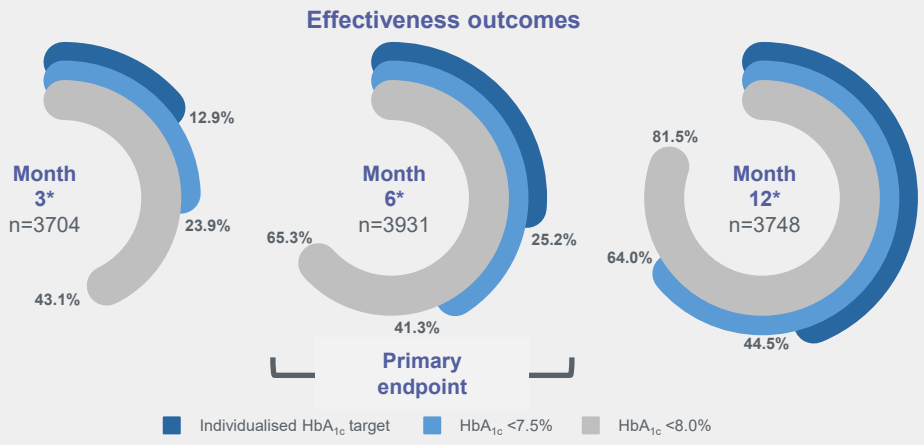
*Individualised HbA_{1c} goal was set by the treating physician at study entry and titration was performed by the treating physician at their discretion using locally applicable titration algorithms

Results: Efficacy

Patient characteristics (N=4422)

- Mean age: **57.2 years**
- Women: **51.8%**
- Mean HbA_{1c}: **9.28%**
- Mean duration of diabetes: **10.2 years**
- Mean physician-set individualised HbA_{1c} target: **7.0%**

Effectiveness outcomes



- **~25%** of participants achieved their predefined individualised HbA_{1c} target **6 months** after receiving **Gla-300** (primary endpoint); this proportion increased to **~45%** by **12 months**
- Proportion of patients achieving HbA_{1c} targets of **<7.5%** and **<8.0%** also **increased** from baseline to Month **6** and Month **12**

*The 3-month period was defined as from the first treatment administration to visit 2 (Month 3); the 6-month period was defined as from the first treatment administration to visit 3 (Month 6) or treatment discontinuation, whichever occurred first, and the 12-month treatment period was defined as from the first treatment administration to visit 4 (Month 12) or treatment discontinuation, whichever occurred first.

Results: Safety

Incidence of hypoglycaemia was low and very few participants reported severe hypoglycaemia

Body weight change was minimal

The incidence of AEs was low, with fewer than 1% of participants reporting AEs related to the study treatment, including one SAE

Incidence of symptomatic hypoglycaemia (N=4422)

- Incidence of BG ≤3.9 mmol/L was **0.86%** at Month 6 and **1.27%** at Month 12
- Incidence of BG <3.0 mmol/L was **0.11%** at Month 6 and **0.20%** at Month 12
- Very few participants reported severe hypoglycaemia at 6 (n=5; [**0.11%**]) and 12 months (n=4; [**0.14%**])

Safety outcomes (N=4422)

- Overall, **treatment emergent AEs** were reported in **6.4%** participants
- Any **treatment related AEs** were reported in **0.3%** participants
- **SAEs** were observed in **1.3%** participants

Conclusions

Initiation of **Gla-300** in **insulin-naïve** people with T2DM uncontrolled on OADs showed an **increase** in the proportion of participants reaching **individualised glycaemic targets**

Gla-300 also showed pronounced **HbA_{1c} reduction** from baseline to Month 6 and Month 12 and **low rates** of **hypoglycaemia** and minimal **weight change**

Results from the **ATOS** study support the effectiveness of **Gla-300** in a **real-world setting*** and are consistent with the data from **RCTs** and other **RWE studies** of **Gla-300**

*Insulin-naïve people with T2DM from Asia, the Middle East, North Africa, Latin America and Eastern Europe. This infographic represents the opinions of the authors. For a full list of declarations, including funding and author disclosure statements

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Abbreviations

AE, adverse event; BG, blood glucose; Gla-100, insulin glargine 100 U/ml; Gla-300, insulin glargine 300 U/mL; HbA_{1c}, glycated haemoglobin; OAD, oral antihyperglycaemic drugs; PD, pharmacodynamic; PK, pharmacokinetic; RCT, randomised controlled trial; RWE, real-world evidence; T2DM, type 2 diabetes mellitus; SAE, serious adverse event.

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