NEW REAL-WORLD EVIDENCE: RISK OF HYPOGLYCAEMIA REDUCED WITH TRESIBA® AFTER SWITCHING FROM OTHER BASAL INSULINS[1,2]

ReFLeCT
REAL-WORLD EVIDENCE

- ✔ ReFLeCT data can enhance your sales calls with real-world evidence that reinforces messages gathered from randomised controlled trials[1–5]
- ✔ Tresiba® significantly reduced rates of overall hypoglycaemia and improved glycaemic control when compared with previous basal insulins such as glargine[1,2]
- ✔ Importantly, Tresiba® improved patient treatment satisfaction[1,2]

ReFLeCT STUDY[1,2]

Multinational
Seven participating European countries

Prospective
Patients recorded daily their insulin dose and hypoglycaemic episodes from four weeks prior to their routine clinical appointment

Other Insulin	Tresiba® used according to standard of care

Patient visits*

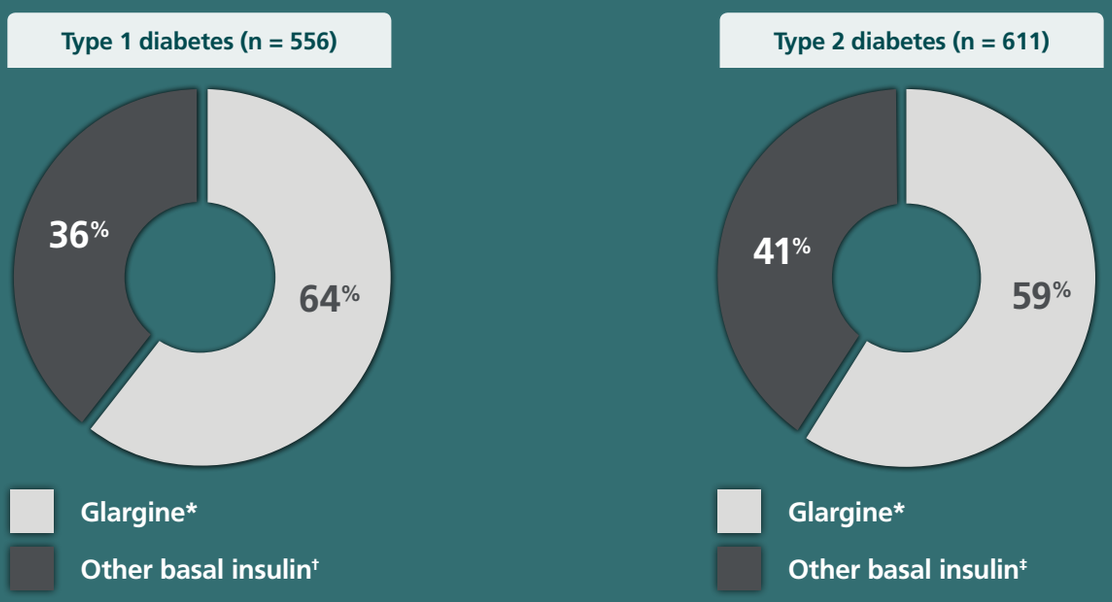
Observational

The number of hypoglycaemic episodes experienced with previous basal insulins was compared to Tresiba®

* Patients were only expected to attend visits that were part of routine clinical practice.

POPULATION

Physician recommended a switch from glargine (for 64% of patients with type 1 and 59% of patients with type 2 diabetes) or other basal insulin to Tresiba® prior to study inclusion.[1,2]



* Data to differentiate glargine U100 or U300 was not collected.
† Other basal insulin: 23% detemir; 13% other / missing.
‡ Other basal insulin: 21% detemir; 20% other / missing.

ASSESSMENTS

Primary endpoint[1,2]

Change in the **number of overall hypoglycaemic episodes** before and after switching to Tresiba®

Secondary endpoints[1,2]

Changes in

- Severe, non-severe, or nocturnal hypoglycaemic episodes
- HbA_{1c}
- Patient satisfaction

- Fasting plasma glucose (FPG)
- Daily insulin dose (basal and bolus)
- Body weight
- Health-related quality of life (HR-QoL) questionnaire scores
- Dose timing flexibility

HYPOGLYCAEMIA

Tresiba® reduced the risk of overall hypoglycaemia after switching from glargine (in 64% of patients with type 1 and 59% of patients with type 2 diabetes) or other basal insulins (*p*<0.001).[1,2]

Type 1 diabetes[1]

20% in overall hypoglycaemia

17% in non-severe hypoglycaemia*

39% in nocturnal hypoglycaemia*

72% in severe hypoglycaemia*†

Type 2 diabetes[2‡]

54% in overall hypoglycaemia

47% in non-severe hypoglycaemia*

65% in nocturnal hypoglycaemia*

* After switching from other basal insulins, *p*<0.001.

† Severe hypoglycaemia was defined by American Diabetes Association, as an episode requiring assistance of another person to actively administer carbohydrate, glucagon, or take other resuscitative actions.

‡ Due to low number of patients, statistical analysis for severe episodes of hypoglycaemia could not be carried out.

HbA_{1c}

Tresiba® improved glycaemic control by significantly lowering HbA_{1c} levels at 12 months after switching from other basal insulins.[1,2]*

Type 1 diabetes[1]

Baseline HbA_{1c}
8.1%

ETD:
-0.15%
($p<0.001$)

HbA_{1c} at 12 months
7.8%

Type 2 diabetes[2]

Baseline HbA_{1c}
8.2%

ETD:
-0.32%
($p<0.001$)

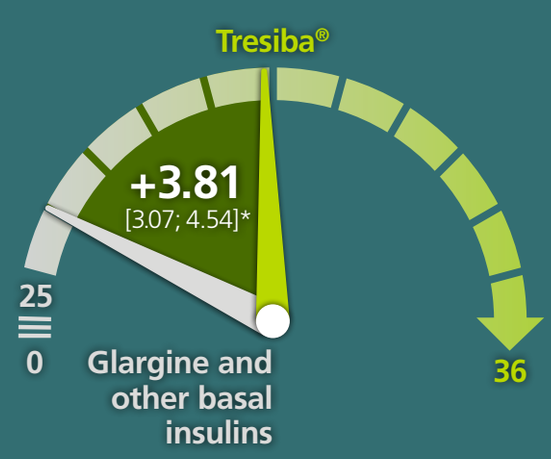
HbA_{1c} at 12 months
7.8%

* Changes in HbA_{1c} were estimated using an analysis of covariance with a mixed model for repeated measures and adjusted for relevant covariates.
ETD, estimated treatment difference.

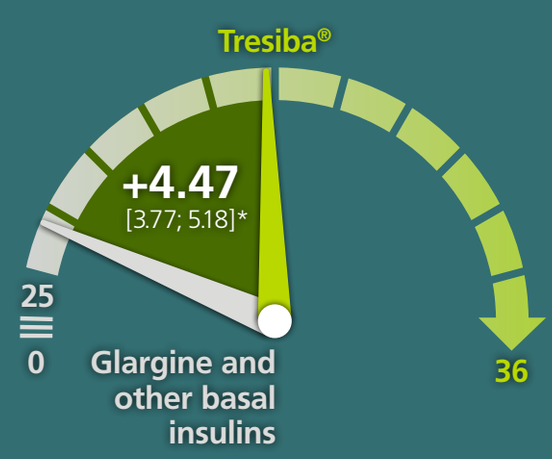
TREATMENT SATISFACTION

Tresiba® helped patients with type 1 or type 2 diabetes experience better treatment satisfaction after switching to Tresiba® from other basal insulins as assessed using satisfaction questionnaires.[1,2]

Type 1 diabetes[1]



Type 2 diabetes[2]



* After switching from other basal insulins, significant difference. DTSQ-s scores for each question range from 6=very satisfied to 0=very dissatisfied and are added up to produce a total score (range 0–36). Higher total scores indicate higher treatment satisfaction.
DTSQ-s, status Diabetes Satisfaction Treatment Questionnaire.

OBJECTION HANDLER

Objection: ReFLeCT is a non-randomised observational study.

> **"I only trust evidence that comes from controlled clinical trials because I'm convinced that the results obtained are treatment effects."***

P **Pause**

Pause and allow your customer to fully express their thoughts

A **Acknowledge**

"I understand that the gold standard for evaluation of treatment efficacy is through controlled and randomised clinical trials"

C **Clarify**

"Would you say that patients you see in your clinic have fairly different stories and patient journeys"

T **Take action**

Alleviate the HCP's concerns and deliver ReFLect benefits

On Tresiba®

Results from ReFLeCT reinforce the safety profile and effectiveness of Tresiba® that has already been established through its extensive clinical trial programme and are therefore highly valuable to patients.[1–5]

On real-world evidence (RWE) studies

RWE studies are critical to understanding how benefits seen in clinical trials translate to credible and real value for patients in everyday clinical practice. They observe behaviours of routine patients like yours.[6]

On ReFLeCT as a prospective study

Contrary to other RWE studies, ReFLeCT is a prospective study, meaning that it is based on a more accurate data collection than a retrospective study because the changes in hypoglycaemic episodes were recorded during the study and were not affected by patient recall and reporting biases.[1,2]

* Please note that this fictional narrative has been created for reference purposes only.

IN SUMMARY

ReFLeCT: real-world evidence that complements results from randomised controlled trials[1–5]*

	Type 1 diabetes	Type 2 diabetes
Hypoglycaemia	↓	↓
HbA_{1c} / FPG	↓	↓
Treatment satisfaction	↑	↑
Basal insulin	↓	↔
Weight	↑	↔
New safety concern	None	None

* After switching from other basal insulins.

References

1. Fadini GP, Feher M, Hansen TK, *et al.* Reduced rates of overall hypoglycaemia in patients with Type 1 diabetes after switching to insulin degludec: a European, multinational, multicenter, prospective, observational study (ReFLeCT). Poster presentation at Diabetes UK Professional Conference. March 6–8 2019, Liverpool, UK.
2. Fadini GP, Feher M, Hansen TK, *et al.* Reduced rates of overall hypoglycaemia in patients with Type 2 diabetes after switching to insulin degludec: a European, multinational, multicenter, prospective, observational study (ReFLeCT). Poster presentation at Diabetes UK Professional Conference. March 6–8 2019, Liverpool, UK.
3. Wysham C, Bhargava A, Chaykin L, *et al.* Effect of insulin degludec vs insulin glargine U100 on hypoglycemia in patients with type 2 diabetes: the SWITCH 2 randomized clinical trial. *Journal of American Medical Association* 2017; 318(1):45–56.
4. Marso SP, McGuire DK, Zinman B, *et al.* for the DEVOTE Study Group. Efficacy and safety of degludec versus glargine in type 2 diabetes. *New England Journal of Medicine* 2017; 377:723–732.
5. Lane W, Bailey TS, Gerety G, *et al.* Effect of insulin degludec vs insulin glargine U100 on hypoglycemia in patients with type 1 diabetes: the SWITCH 1 randomized clinical trial. *Journal of American Medical Association* 2017; 318(1):33–44.
6. ISPOR. *Real-World Evidence*. Available from: https://www.ispor.org/strategic-initiatives/real-world-evidence [Accessed 28 March 2019].

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TRESIBA®
insulin degludec [rDNA origin] injection