Durable effects of iGlarLixi up to 52 weeks in type 2 diabetes: The LixiLan-G extension study

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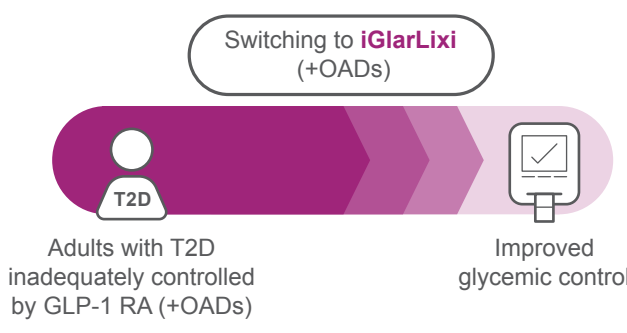
Introduction | Study design | Key results: Population | Key results: Efficacy | Key results: Safety | Conclusion

Introduction

iGlarLixi is a once-daily titratable fixed-ratio combination (FRC) of basal insulin glargine 100 units/mL (iGlar) and the GLP-1 RA lixisenatide (Lixi)



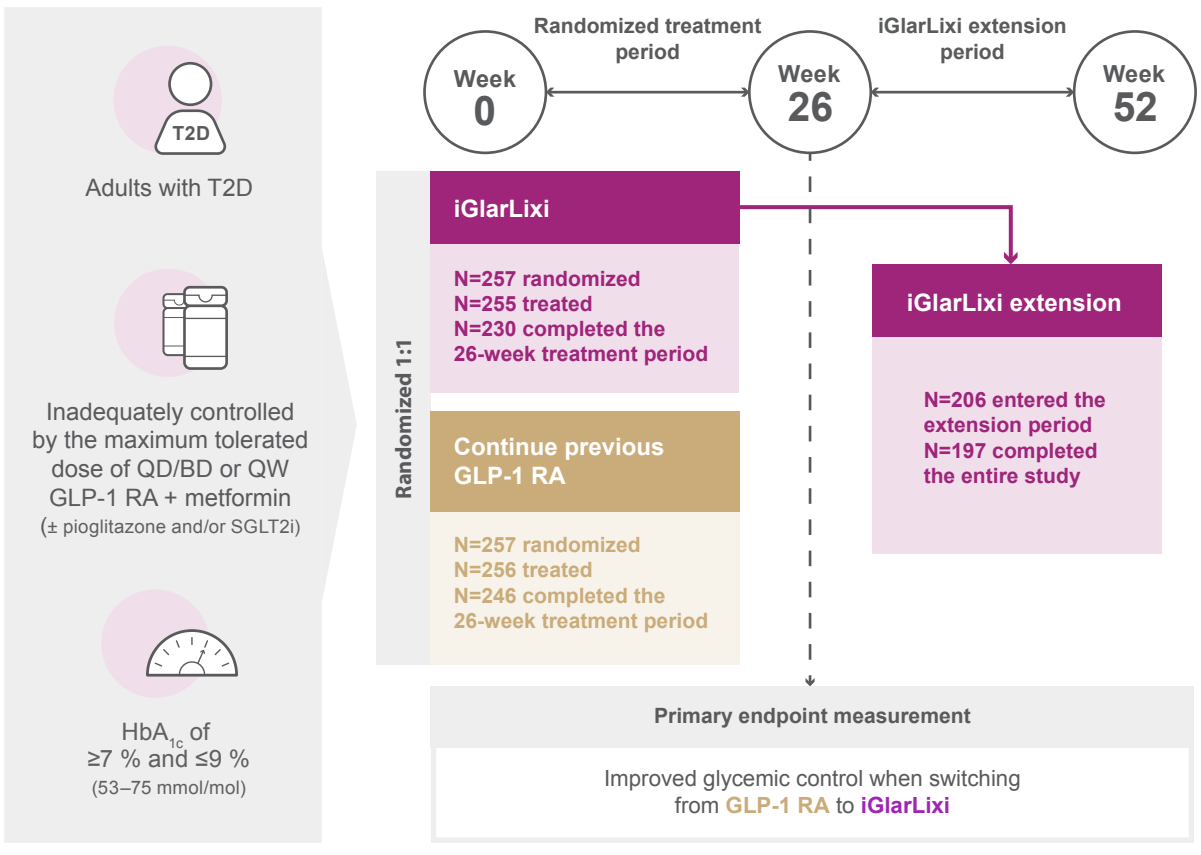
In the LixiLan-G trial, treatment intensification by switching from **GLP-1 RA** therapy to **iGlarLixi** was shown to improve glycemic control in adults with T2D inadequately controlled by a GLP-1 RA plus oral antihyperglycemic drugs (OADs) over 26 weeks

Objective

This is a prespecified, 26-week, single-arm extension of LixiLan-G to determine the durability of **iGlarLixi** efficacy and safety over 52 weeks

Study design

LixiLan-G trial



Key results: Extension Population

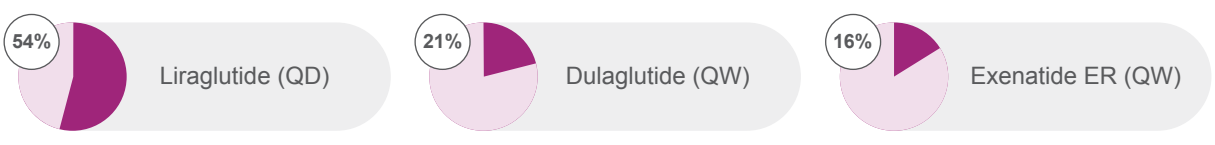
Mean ± SD baseline characteristics

Age: 59.8 ± 9.1 years

BMI: 32.9 ± 4.4 kg/m²

HbA1c: 7.8 ± 0.5 %

GLP-1 RA use at screening



Key results: Efficacy

Glycemic control achieved with iGlarLixi at week 26 was maintained at week 52

	Baseline to week 26		Baseline to week 52
Mean ± SD reduction in	GLP-1 RA	iGlarLixi	iGlarLixi
HbA1c (%)	-0.4 ± 0.8	-1.0 ± 0.9	-1.0 ± 0.9
FPG (mmol/L)	-0.8 ± 2.5	-2.1 ± 2.3	-2.3 ± 2.4
2-hr PPG (mmol/L)	-1.2 ± 3.7	-3.9 ± 3.8	-4.3 ± 3.9
2-hr plasma glucose excursion* (mmol/L)	-0.5 ± 2.8	-1.6 ± 3.2	-1.9 ± 2.9

*2-hr plasma glucose excursion is defined as change in plasma glucose concentration from before a meal to 2 hours after a meal

Results at week 26 were also maintained at week 52 for target achievement endpoints:

	At week 26		At week 52
Percentage at target	GLP-1 RA	iGlarLixi	iGlarLixi
HbA1c <7 %	26%	62%	64%
HbA1c <7 % With no documented symptomatic (<3.0 mmol/L) hypoglycemia	25%	57%	58%

Key results: Safety

Safety results for iGlarLixi over 52 weeks were similar to those seen over 26 weeks

	Week 0–26	Week 0–52
	iGlarLixi	iGlarLixi
Any AE	64%	73%
Any GI disorder	22%	25%
Documented symptomatic (≤3.9 mmol/L) hypoglycemia events PPY	1.54	1.59
Documented symptomatic (<3.0 mmol/L) hypoglycemia events PPY	0.25	0.24

Conclusion

The efficacy and safety of **iGlarLixi** at the end of the 26-week randomized treatment period were maintained at week 52.

In LixiLan G, **iGlarLixi** was an effective treatment for adults with T2D failing to achieve their glycemic target with **GLP-1 RA** and OADs

Abbreviations
AE, adverse event; BD, twice daily; BMI, body mass index; ER, extended release; FPG, fasting plasma glucose; GI, gastrointestinal; GLP-1 RA, glucagon-like peptide-1 receptor agonist; HbA_{1c}, glycated hemoglobin; iGlarLixi, a once-daily titratable fixed-ratio combination of insulin glargine 100 units/mL and the glucagon-like peptide-1 receptor agonist lixisenatide; PPG, post-prandial plasma glucose; PPY, per participant-year; QD, once daily; QW, once weekly; SD, standard deviation; SGLT2i, sodium-glucose cotransporter-2 inhibitor; T2D, type 2 diabetes