Supplementary Materials

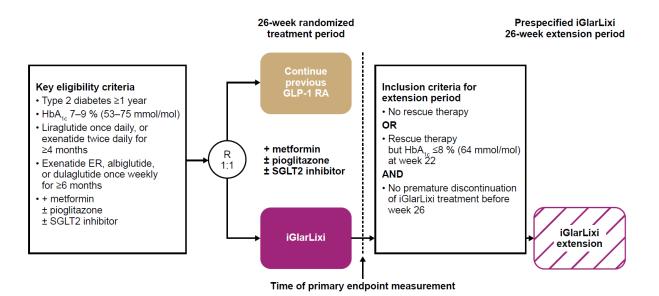
| | Participants randomized to initial 26-week treatment period | | Participants in the 26-week extension period (0–52 weeks) |
|---|--|------------|---|
| | GLP-1 RA | iGlarLixi | iGlarLixi |
| | (n = 256) | (n = 255) | (n = 206) |
| Any AE | 121 (47.3) | 163 (63.9) | 150 (72.8) |
| Participants with any serious AE | 9 (3.5) | 10 (3.9) | 21 (10.2) |
| Participants with any AE leading to death | 0 | 0 | 1 (0.5) |
| Gastrointestinal disorders (overall) | 26 (10.2) | 55 (21.6) | 51 (24.8) |
| Nausea | 6 (2.3) | 22 (8.6) | 19 (9.2) |
| Diarrhea | 6 (2.3) | 14 (5.5) | 15 (7.3) |
| Vomiting | 2 (0.8) | 8 (3.1) | 8 (3.9) |
| Documented symptomatic (≤3.9 mmol/L) hypoglycemia | | | |
| Number of participants with events | 6 (2.3) | 71 (27.8) | 74 (35.9) |
| Events per participant-year | 0.08 | 1.54 | 1.59 |
| Documented symptomatic (<3.0 mmol/L) hypoglycemia | | | |
| Number of participants with events | 1 (0.4) | 24 (9.4) | 37 (18.0) |
| Events per participant-year | <0.01 | 0.25 | 0.24 |

Table S1—AEs* and hypoglycemic events in the safety population.

Data are n (%) unless otherwise stated. *AEs listed are treatment-emergent AEs.

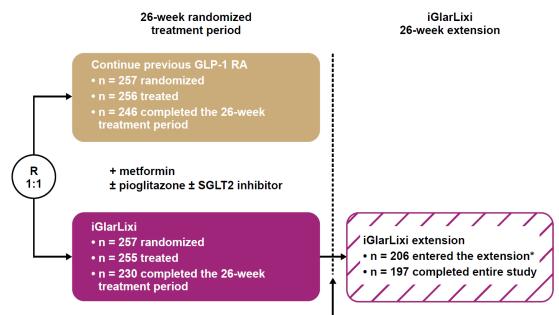
AE, adverse event; GLP-1 RA, glucagon-like peptide-1 receptor agonist; iGlarLixi, titratable fixed-ratio combination of basal insulin glargine 100 units/mL and the GLP-1 RA lixisenatide.

Figure S1—Study design.



ER, extended release; GLP-1 RA, glucagon-like peptide-1 receptor agonist; HbA_{1c}, glycated hemoglobin; iGlarLixi, titratable fixed-ratio combination of basal insulin glargine 100 units/mL and the GLP-1 RA lixisenatide; R, randomization; SGLT2, sodium glucose cotransporter 2.

Figure S2—Patient disposition.



Time of primary endpoint measurement

*Five participants who entered the extension phase had received rescue therapy during the main treatment period but had an HbA_{1c} \leq 8 % (64 mmol/mol) at week 22. The rescue therapies received were insulin glulisine (n=2), insulin lispro (n=1), glimepiride (n=1), and glipizide (n=1).

GLP-1 RA, glucagon-like peptide-1 receptor agonist; iGlarLixi, titratable fixed-ratio combination of basal insulin glargine 100 units/mL and the GLP-1 RA lixisenatide; R, randomization; SGLT2, sodium glucose co-transporter 2.