

SUPPLEMENTARY TABLE S3. SUMMARY OF KEY GLYCEMIC CONTROL PARAMETERS IN THE CONTINUOUS GLUCOSE MONITORING COHORT VERSUS THE FULL STUDY POPULATION

| | CGM cohort | | | Full study population | | |
|--|-----------------------------|---------------------------|---------------------------|------------------------------|----------------------------|----------------------------|
| | Mealtime lispro (N = 99) | Mealtime URLi (N = 97) | Postmeal URLi (N = 73) | Mealtime lispro (N = 442) | Mealtime URLi (N = 451) | Postmeal URLi (N = 329) |
| Hypoglycemia incidence (≤ 70 mg/dL [3.9 mmol/L]), <i>n</i> (%) from randomization to week 26 | | | | | | |
| Documented symptomatic | 92 (92.93) | 92 (94.85) | 66 (90.41) | 404 (91.40) | 414 (91.80) | 293 (89.06) |
| All documented | 99 (100.00) | 97 (100.00) | 72 (98.63) | 440 (99.55) | 449 (99.56) | 325 (98.78) |
| Non-nocturnal | 93 (93.94) | 94 (96.91) | 70 (95.89) | 421 (95.25) | 433 (96.01) | 311 (94.53) |
| Nocturnal | 79 (79.80) | 78 (80.41) | 57 (78.08) | 328 (74.21) | 344 (76.27) | 251 (76.29) |
| Hypoglycemia rate (events/patient/30 days), (≤ 70 mg/dL [3.9 mmol/L]), LSM (SE) at week 26 | | | | | | |
| Documented symptomatic | 4.93 (0.53) | 5.51 (0.59) | 5.62 (0.61) | 4.94 (0.26) | 4.70 (0.24) | 4.93 (0.27) |
| All documented | 8.33 (0.56) | 8.83 (0.68) | 9.01 (0.71) | 8.14 (0.29) | 7.54 (0.27) | 8.16 (0.31) |
| Non-nocturnal | 5.98 (0.49) | 6.45 (0.62) | 6.77 (0.62) | 5.75 (0.25) | 5.20 (0.23) | 5.92 (0.28)* |
| Nocturnal | 1.17 (0.17) | 1.17 (0.15) | 1.01 (0.15) | 1.16 (0.09) | 1.11 (0.08) | 1.03 (0.08) |
| Insulin dose (U/kg), LSM (SE) at week 26 | | | | | | |
| Basal [‡] | 0.39 (0.01) | 0.38 (0.01) | 0.38 (0.01) | 0.37 (0.00) | 0.38 (0.00) | 0.38 (0.00) |
| Bolus | 0.45 (0.02) | 0.44 (0.02) | 0.44 (0.02) | 0.41 (0.01) | 0.43 (0.01) | 0.42 (0.01) |
| Total | 0.84 (0.02) | 0.84 (0.02) | 0.82 (0.02) | 0.79 (0.01) | 0.81 (0.01) | 0.80 (0.01) |
| HbA1c (%), LSM (SE) | | | | | | |
| Baseline | 7.28 (0.07) | 7.24 (0.07) | 7.24 (0.08) | 7.33 (0.03) | 7.34 (0.03) | 7.36 (0.04) |
| Week 26 | 7.12 (0.06) | 7.15 (0.06) | 7.35 (0.06)* [†] | 7.29 (0.03) | 7.21 (0.03) | 7.42 (0.04)* [†] |
| Change at week 26 | -0.13 (0.06) | -0.11 (0.06) | 0.10 (0.06) | -0.05 (0.03) | -0.13 (0.03) | 0.08 (0.04) |
| HbA1c (mmol/mol), LSM (SE) | | | | | | |
| Baseline | 56.0 (0.72) | 55.6 (0.73) | 55.7 (0.83) | 56.7 (0.34) | 56.7 (0.34) | 56.9 (0.40) |
| Week 26 | 54.4 (0.63) | 54.6 (0.64) | 56.8 (0.70)* [†] | 56.1 (0.34) | 55.3 (0.33) | 57.6 (0.39)* [†] |
| Change at week 26 | -1.4 (0.63) | -1.2 (0.64) | 1.0 (0.70) | -0.6 (0.34) | -1.4 (0.33) | 0.8 (0.39) |

* $P < 0.05$ postmeal URLi versus mealtime URLi.

[†] $P < 0.05$ postmeal URLi versus mealtime lispro.

[‡]Patients were stratified according to basal insulin use during the study. In the main study cohort, formal treatment-by-subgroup interactions analyses were performed for type of basal insulin. No significant treatment by subgroup interactions were identified in analyses of HbA1c or hypoglycemia rate.

LSM, least squares mean; SE, standard error.