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BRIEF REPORT

Efficacy and safety of adding sotagliflozin, a dual sodium-glucose co-transporter (SGLT)1 and SGLT2 inhibitor, to optimized insulin therapy in adults with type 1 diabetes and baseline body mass index ≥ 27 kg/m^2

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Abstract

Sotagliflozin, a dual sodium-glucose co-transporter (SGLT)1/SGLT2 inhibitor, is currently approved in Europe as an adjunct to optimal insulin therapy in adults with type 1 diabetes (T1D) and a body mass index (BMI) ≥ 27 kg/m^2. In this post hoc analysis, efficacy at 24 weeks and safety at 52 weeks from pooled phase 3 clinical trials were evaluated in patients with baseline BMI ≥ 27 kg/m^2. Sotagliflozin 200 mg and 400 mg added to insulin reduced glycated haemoglobin level and increased time in range assessed by continuous glucose monitoring versus placebo and also reduced body weight and systolic blood pressure. Differences in efficacy endpoints between sotagliflozin and placebo tended to be greater among patients with BMI ≥ 27 kg/m^2 compared to those with baseline BMI < 27 kg/m^2. Consistent with published results for the entire population, fewer severe hypoglycaemia and documented hypoglycaemia ≤3.1 mmol/L events and a higher incidence of diabetic ketoacidosis occurred with sotagliflozin versus placebo in patients with BMI ≥ 27 kg/m^2. Sotagliflozin as an adjunct to optimized insulin therapy in overweight/obese patients with T1D addressed some unmet needs and may help achieve optimal glycaemic control, mitigating weight gain without increasing hypoglycaemia risk in this high-risk population.

KEYWORDS

insulin therapy, SGLT2 inhibitor, type 1 diabetes, weight control, glycaemic control

1 | INTRODUCTION

Up to 50% of adults living with type 1 diabetes (T1D) are overweight or obese.[1,2] Excess weight is associated with a high frequency of other cardiovascular risk factors.[1,3] Sotagliflozin, an oral dual inhibitor of sodium-glucose co-transporter (SGLT)1 and 2, improves glycaemic control and reduces body weight and systolic blood pressure when used as an adjunct to optimized insulin in adults

with T1D.[4–6] Thus, sotagliflozin addresses some important unmet needs in T1D.

European regulatory authorities approved sotagliflozin and dapagliflozin as adjuncts to insulin therapy for the treatment of T1D in adults with a body mass index (BMI) ≥ 27 kg/m^2. This subgroup was identified to have an improved benefit–risk profile with SGLT inhibitor use relative to the entire target population.[7–10] The present analysis evaluated the efficacy and safety of adding sotagliflozin to optimized insulin in adults with T1D and baseline BMI ≥ 27 kg/m^2 using pooled clinical results from two phase 3 studies (inTandem1 and inTandem2).

2 | METHODS

This post hoc analysis was conducted using pooled data from two 52-week, phase 3 trials, inTandem1 (NCT02384941) and inTandem2 (NCT02421510), which assessed the safety and efficacy of sotagliflozin 200 mg or 400 mg after a 6-week insulin optimization run-in period.[4,5] Each study comprised a 24-week core treatment period, followed by a 28-week extension period. The primary efficacy endpoint was the change from baseline to week 24 in glycated haemoglobin (HbA1c). The inTandem1 trial was conducted in the United States and Canada and the inTandem2 trial was conducted in Europe and Israel. The trials were conducted in accordance with international standards of good clinical practice, and written informed consent was obtained from each participant. The protocols were reviewed and approved by the respective institutional review boards or independent ethics committees. Trial designs, participant inclusion and exclusion criteria, and primary, secondary and safety results have been published elsewhere.[4,5]

2.1 | Study population and interventions

This analysis included all randomized participants from both trials. In both trials, eligible patients were aged ≥ 18 years with T1D for at least 1 year before trial entry and had a screening HbA1c level of between 7.0% and 11.0% (53 and 97 mmol/mol). BMI entry criteria were 20–45 kg/m^2 inclusive. Participants were eligible whether they were receiving continuous subcutaneous insulin infusion (CSII) or multiple daily injection (MDI) therapy.

After a 6-week insulin optimization period, patients were randomized 1:1:1 to once-daily placebo, sotagliflozin 200 mg, or sotagliflozin 400 mg. Double-blind treatment with insulin optimization continued throughout the full 52-week trial, as previously described.[4,5]

2.2 | Study endpoints, objectives and analysis plan

This pooled data analysis was conducted using a combined dataset from both studies. Endpoints included change from baseline in HbA1c, body weight, systolic blood pressure, total daily insulin dose, and patient-reported outcomes (Diabetes Treatment Satisfaction Questionnaire [DTSQ] and two-item Diabetes Distress Score [DDS2]) at Week 24. A blinded continuous glucose monitoring (CGM) substudy was performed in a subset of patients, with analysis of time in glucose range (3.9–10 mmol/L [70–180 mg/dL]).[11] Adverse events of special interest included genital mycotic infection, diarrhoea, diabetic ketoacidosis (DKA), and severe hypoglycaemia, which was defined as any event that required assistance from another person or during which the patient lost consciousness or had a seizure. Documented hypoglycaemia events defined as a blood glucose level ≤3.1 mmol/L (≤55 mg/dL) were also assessed. Documented and severe hypoglycemia definitions were the same as those used in the inTandem trials.[4,5]

The primary objective was to evaluate the efficacy and safety of sotagliflozin in the cohort of patients with T1D and a baseline BMI ≥ 27 kg/m^2. Continuous endpoints were analysed using mixed-effects model for repeated measures (MMRM) statistics. The analysis model included fixed categorical effects of treatment, insulin delivery (MDI, CSII), baseline HbA1c (≤8.5%, >8.5% [≤69 mmol/mol, >69 mmol/mol]), time (study week), study, baseline variable-by-time interaction (specific to the dependent variable being tested), and a treatment-by-time interaction. For completeness, similar analyses were performed in the cohort of patients with a baseline BMI < 27 kg/m^2.

The secondary objective assessed efficacy and safety endpoints in the BMI subgroups. Statistical analyses were conducted on the consistency of the treatment group effects between the baseline BMI subgroup categories (ie, a test of the statistical interaction of treatment-by-baseline BMI). This analysis was accomplished by including in the original MMRMs an additional fixed term for baseline BMI (<27 kg/m^2, ≥27 kg/m^2) and a first-order interaction term of treatment-by-baseline BMI. Since interaction tests of this type tend to be statistically underpowered, an observed two-sided P value ≤ 0.15 was considered evidence of a noteworthy interaction. The safety analyses were descriptive.

3 | RESULTS

3.1 | Study population

Of the 1575 adults with T1D in this pooled analysis, 916 (58%) had a baseline BMI ≥ 27 kg/m^2. Within subgroups, baseline characteristics were similar across treatment groups (Table S1). Approximately half the participants were women. At baseline in the BMI ≥ 27 kg/m^2 subgroup, the mean HbA1c was ~7.7% (~61 mmol/mol), the mean total daily insulin was ~75 IU, and the mean BMI and weight were ~ 32 kg/m^2 and ~ 94 kg, respectively.

By design, there were differences between BMI subgroups in mean baseline BMI and body weight. Mean baseline age (42 vs. 45 years), total daily insulin dose (0.67 IU/kg vs. 0.80 IU/kg), and systolic blood pressure (118 vs. 124 mmHg) were lower in those with a BMI < 27 kg/m^2 versus those with a BMI ≥ 27 kg/m^2 (Table S1). CSII use was also lower in those with BMI < 27 kg/m^2.

TABLE 1 Changes from baseline to week 24 in select efficacy variables in patients with type 1 diabetes and body mass index <27 and ≥ 27 kg/m^2

	BMI <27 kg/m^2			BMI ≥27 kg/m^2			*P* value for interaction between subgroups
	Placebo (n = 228)	Sotagliflozin 200 mg (n = 219)	Sotagliflozin 400 mg (n = 212)	Placebo (n = 298)	Sotagliflozin 200 mg (n = 305)	Sotagliflozin 400 mg (n = 313)	
HbA1c, % (mmol/mol)							
Mean baseline ± SD	7.7 ± 0.9 (61 ± 9.8)	7.6 ± 0.8 (60 ± 8.7)	7.7 ± 0.8 (61 ± 8.7)	7.6 ± 0.8 (60 ± 8.7)	7.7 ± 0.7 (61 ± 7.7)	7.6 ± 0.7 (60 ± 7.7)	
LS mean change from baseline ± SE, %	−0.06 ± 0.05 (−0.7 ± 0.5)	−0.38 ± 0.05 (−4.2 ± 0.5)	−0.34 ± 0.05 (−3.7 ± 0.5)	−0.04 ± 0.03 (−0.4 ± 0.3)	−0.43 ± 0.03 (−4.7 ± 0.3)	−0.50 ± 0.03 (−5.5 ± 0.3)	
LS mean difference from placebo (95% CI); *P* value		−0.32 (−0.44 to −0.20) (−3.5 [−4.8 to −2.2]); <0.001	−0.27 (−0.40 to −0.15) (−3.0 [−4.4 to −1.6]); <0.001		−0.39 (−0.48 to −0.30) (−4.3 [−5.2 to −3.3]); <0.001	−0.45 (−0.54 to −0.36) (−4.9 [−5.9 to −3.9]); <0.001	0.043
Time in range, %[a]							
Mean baseline ± SD	55.3 ± 12.0	52.3 ± 17.5	51.4 ± 12.2	50.7 ± 14.6	52.2 ± 14.3	50.3 ± 15.9	
LS mean change from baseline ± SE	−2.2 ± 3.0	−0.5 ± 3.0	4.2 ± 3.0	−1.9 ± 2.3	6.3 ± 2.2	13.1 ± 2.0	
LS mean difference from placebo (95% CI); *P* value		1.6 (−6.1 to 9.3); 0.67	6.3 (−1.4 to 14.1); 0.11		8.2 (2.3 to 14.0); 0.007	15.1 (9.4 to 20.7); <0.001	0.46
Body weight, kg							
Mean baseline ± SD	71.2 ± 10.3	70.2 ± 10.4	70.3 ± 10.1	94.2 ± 15.3	94.7 ± 15.4	93.7 ± 16.2	
LS mean change from baseline ± SE	0.6 ± 0.2	−1.4 ± 0.2	−1.9 ± 0.2	0.3 ± 0.2	−1.9 ± 0.2	−3.0 ± 0.2	
LS mean difference from placebo (95% CI); *P* value		−2.1 (−2.5 to −1.6); <0.001	−2.6 (−3.0 to −2.1); <0.001		−2.3 (−2.8 to −1.7); <0.001	−3.3 (−3.9 to −2.8); <0.001	0.014
Systolic BP, mmHg							
Mean baseline ± SD	119.0 ± 14.4	117.2 ± 13.8	117.9 ± 13.5	124.3 ± 14.2	124.6 ± 15.2	123.6 ± 14.4	
LS mean change from baseline ± SE	0.1 ± 0.7	−3.0 ± 0.7	−3.4 ± 0.8	−1.6 ± 0.7	−2.9 ± 0.6	−4.0 ± 0.6	
LS mean difference from placebo (95% CI); *P* value		−3.1 (−5.0 to −1.2); 0.002	−3.5 (−5.4 to −1.6); <0.001		−1.3 (−3.0 to 0.4); 0.13	−2.5 (−4.2 to −0.8); 0.005	0.56
Total daily insulin, IU							
Mean baseline ± SD	46.7 ± 16.9	44.1 ± 15.0	48.9 ± 20.2	77.9 ± 41.5	76.1 ± 41.3	72.2 ± 37.2	
LS mean change from baseline ± SE	2.1 ± 1.3	−7.7 ± 1.4	−8.6 ± 1.4	0.5 ± 1.1	−4.8 ± 1.1	−8.2 ± 1.1	
LS mean difference from placebo (95% CI); *P* value		−9.8 (−13.3 to −6.2); <0.001	−10.7 (−14.3 to −7.2); <0.001		−5.3 (−8.2 to −2.4); <0.001	−8.7 (−11.5 to −5.8) <0.001	0.19

(Continues)

TABLE 1 (Continued)

	BMI <27 kg/m^2			BMI ≥27 kg/m^2			*P* value for interaction between subgroups
	Placebo (n = 228)	Sotagliflozin 200 mg (n = 219)	Sotagliflozin 400 mg (n = 212)	Placebo (n = 298)	Sotagliflozin 200 mg (n = 305)	Sotagliflozin 400 mg (n = 313)	
Total daily insulin, IU/kg							
Mean baseline ± SD	0.66 ± 0.23	0.63 ± 0.20	0.69 ± 0.26	0.81 ± 0.37	0.80 ± 0.39	0.76 ± 0.32	
LS mean absolute change from baseline ± SE	−0.00 ± 0.01	−0.05 ± 0.01	−0.04 ± 0.01	−0.01 ± 0.01	−0.03 ± 0.01	−0.05 ± 0.01	
LS mean absolute difference from placebo (95% CI); *P* value		−0.05 (−0.07 to −0.03); *P* < 0.001	−0.04 (−0.06 to −0.02); *P* < 0.001		−0.02 (−0.04 to 0.00); *P* = 0.09	−0.04 (−0.07 to −0.02); *P < 0.001*	
LS mean percent change from baseline ± SE	1.3 ± 1.3	−5.9 ± 1.3	−6.1 ± 1.3	−0.06 ± 1.1	−2.8 ± 1.1	−5.2 ± 1.0	
LS mean percent difference from placebo (95% CI); *P* value		−7.2 (−10.5 to −3.8); <0.001	−7.4 (−10.8 to −4.0); <0.001		−2.8 (−5.6 to 0.03); <0.052	−5.2 (−7.9 to −2.4) <0.001	
DTSQ score							
Mean baseline ± SD	28.2 ± 4.7	28.2 ± 5.3	28.9 ± 4.9	28.7 ± 5.0	28.4 ± 5.2	28.8 ± 4.9	
LS mean change from baseline ± SE	0.0 ± 0.3	1.7 ± 0.3	1.5 ± 0.3	−0.3 ± 0.3	2.3 ± 0.3	2.2 ± 0.3	
LS mean difference from placebo (95% CI); *P* value		1.7 (0.9 to 2.6); <0.001	1.5 (0.7 to 2.3); <0.001		2.6 (1.9 to 3.3); <0.001	2.6 (1.9 to 3.3); <0.001	0.041
DDS2 score							
Mean baseline ± SD	5.2 ± 2.0	5.3 ± 2.0	5.3 ± 2.3	5.1 ± 2.3	5.4 ± 2.0	5.1 ± 2.1	
LS mean change from baseline ± SE	0.1 ± 0.1	−0.2 ± 0.1	−0.4 ± 0.1	0.1 ± 0.1	−0.5 ± 0.1	−0.5 ± 0.1	
LS mean difference from placebo (95% CI); *P* value		−0.4 (−0.7 to −0.0); 0.028	−0.5 (−0.8 to −0.2); 0.002		−0.6 (−0.9 to −0.3); <0.001	−0.7 (−0.9 to −0.4); <0.001	0.23

Abbreviations: BMI, body mass index; BP, blood pressure; CI, confidence interval; DDS2, two-item Diabetes Distress Score; DTSQ, Diabetes Treatment Satisfaction Questionnaire; HbA1c, glycated haemoglobin; LS, least squares; SD, standard deviation; SE, standard error.

[a]Time in range was evaluated in a subgroup of patients who participated in a blinded continuous glucose monitoring substudy (BMI <27 kg/m^2: n = 35 for placebo; n = 30 for sotagliflozin 200 mg; and n = 31 for sotagliflozin 400 mg; BMI ≥27 kg/m^2: n = 58 for placebo; n = 59 for sotagliflozin 200 mg; and n = 65 for sotagliflozin 400 mg).

3.2 | Efficacy endpoints

Table 1 describes efficacy endpoints at Week 24 in both BMI subgroups. In patients with BMI ≥ 27 kg/m^2, HbA1c decreased by 0.39% (4.3 mmol/mol) and 0.45% (4.9 mmol/mol), and time-in-range increased by 8.2% and 15.1% with sotagliflozin 200 mg and 400 mg, respectively, relative to placebo. These improvements in glycaemic control were achieved with total insulin doses that differed from placebo by −2.8% (95% confidence interval [CI] −5.6 to 0.03; $P < 0.052$) and − 5.2% (95% CI −7.9 to −2.4; $P < 0.001$) with sotagliflozin 200 mg and 400 mg, respectively. Body weight decreased by 2.3 kg and 3.3 kg with sotagliflozin 200 mg and 400 mg, respectively, and systolic blood pressure by 2.5 mmHg with sotagliflozin 400 mg. Treatment satisfaction (DTSQ) and diabetes distress (DDS2) also improved with sotagliflozin. In the BMI < 27 kg/m^2 subgroup, significant improvements in HbA1c, body weight, systolic blood pressure, insulin dose, and patient-reported outcome measures were seen with both doses (Table 1).

3.2.1 | Efficacy comparisons between BMI subgroups

In comparisons between BMI subgroups, HbA1c, body weight, and DTSQ scores had interaction tests with P values ≤ 0.15 (Table 1). Thus, for the primary and other key efficacy endpoints in this pooled analysis, the sotagliflozin versus placebo difference was systematically better in the baseline BMI ≥ 27 kg/m^2 subgroup relative to that observed in the lower baseline BMI subgroup.

3.2.2 | Adverse events

Table 2 shows the incidence of adverse events of special interest over 52 weeks. The incidence of diarrhoea, genital mycotic infection and DKA was greater in sotagliflozin-treated patients than in those receiving placebo. The rates of diarrhoea were similar with sotagliflozin 400 mg between the BMI subgroups and numerically higher with sotagliflozin 200 mg in the BMI < 27 kg/m^2 subgroup. Genital mycotic infections occurred at lower frequency in the lower BMI group for both male and female participants with sotagliflozin 200 mg, but were higher for male and similar for female participants with sotagliflozin 400 mg. The incidence of severe hypoglycaemia was lower among patients treated with sotagliflozin 200 mg or 400 mg than in the placebo group in the BMI ≥ 27 kg/m^2 subgroup. The incidence of DKA with sotagliflozin was lower in the BMI ≥ 27 kg/m^2 subgroup (2.6% and 3.5% with sotagliflozin 200 mg and sotagliflozin 400 mg, respectively) than in the <27 kg/m^2 subgroup (3.2% and 4.3%, respectively). The event rates for documented hypoglycaemia ≤3.1 mmol/L (≤55 mg/dL) were lower with sotagliflozin than with placebo overall, and lower in the BMI ≥ 27 kg/m^2 subgroup (17.9, 13.4 and 14.5 events per participant per year in the placebo, sotagliflozin 200 mg and sotagliflozin 400 mg groups, respectively) compared to the BMI < 27 kg/m^2 subgroup (20.4, 16.9 and 15.7 in the placebo, sotagliflozin 200 mg and sotagliflozin 400 mg groups, respectively).

4 | DISCUSSION

Overweight adults with T1D and inadequate glycaemic control comprise a population with an unmet medical need. Intensified insulin reduces the incidence and progression of long-term diabetes-related complications but is also associated with risks of hypoglycaemia and undesirable weight gain, which in turn are associated with increased cardiovascular risk.[1,3] Therefore, in addition to lowering blood glucose, reducing body weight and systolic blood pressure are of great importance in patients with higher BMI.[1]

Overall, treatment with sotagliflozin significantly improved glycaemic control, including time in range, and reduced body weight

TABLE 2 Adverse events of special interest in body mass index subgroups

	BMI <27 kg/m^2			BMI ≥27 kg/m^2		
Event	Placebo (n = 228)	Sotagliflozin 200 mg (n = 219)	Sotagliflozin 400 mg (n = 212)	Placebo (n = 298)	Sotagliflozin 200 mg (n = 305)	Sotagliflozin 400 mg (n = 313)
Female genital mycotic infection[a], n (%)	3 (2.7)	8 (7.2)	19 (16.8)	9 (6.3)	32 (21.6)	28 (17.6)
Male genital mycotic infection[b], n (%)	2 (1.7)	2 (1.9)	9 (9.1)	1 (0.6)	6 (3.8)	7 (4.5)
Diarrhoea, n (%)	7 (3.1)	18 (8.2)	19 (9.0)	20 (6.7)	16 (5.2)	27 (8.6)
Adjudicated severe hypoglycaemia, n (%)	17 (7.5)	17 (7.8)	11 (5.2)	22 (7.4)	13 (4.3)	12 (3.8)
Adjudicated DKA, n (%)	0 (0.0)	7 (3.2)	9 (4.3)	1 (0.3)	8 (2.6)	11 (3.5)

Abbreviations: BMI, body mass index; DKA, diabetic ketoacidosis.

[a]BMI <27 kg/m^2: placebo (n = 112); sotagliflozin 200 mg (n = 111); sotagliflozin 400 mg (n = 113). BMI ≥27 kg/m^2: placebo (n = 143); sotagliflozin 200 mg (n = 148); sotagliflozin 400 mg (n = 159).

[b]BMI <27 kg/m^2: placebo (n = 116); sotagliflozin 200 mg (n = 108); sotagliflozin 400 mg (n = 99). BMI ≥27 kg/m^2: placebo (n = 155); sotagliflozin 200 mg (n = 157); sotagliflozin 400 mg (n = 154).

and systolic blood pressure in the subgroups of patients with baseline BMI ≥ 27 kg/m^2 or <27 kg/m^2. Furthermore, improved patient-reported outcomes were observed in both subgroups. Interestingly, efficacy responses were better for HbA1c, body weight, and treatment satisfaction assessed using the DTSQ in the BMI ≥ 27 kg/m^2 subgroup compared to the BMI < 27 kg/m^2 subgroup, as noted by a significant treatment by BMI subgroup interaction term. It is possible that the difference may be related to higher insulin resistance in the higher BMI group, and that treatment improved the insulin sensitivity and responsiveness to insulin coupled with the effects of sotagliflozin. The finding that sotagliflozin 200 mg did not significantly reduce systolic blood pressure in the higher BMI subgroup is consistent with results from the inTandem2 trial, where significant blood pressure reductions were seen with sotagliflozin 400 mg but not 200 mg. In addition, the nonsignificant interaction term suggests that the small difference is probably attributable to chance and not an apparent difference between subgroups. Change in time in range from baseline as measured by CGM was significantly different between sotagliflozin and placebo in the BMI ≥ 27 kg/m^2 subgroup but not in the BMI < 27 kg/m^2 subgroup. The lack of a low *P* value for the DDS2 variable was most likely related to the limited range of scores that the variable could attain, and the $P > 0.15$ finding for time in range, despite large numeric differences at the sotagliflozin 400-mg dose, was related to the limited sample size in the CGM substudy. Collectively, these results demonstrate robust clinical efficacy with sotagliflozin in this higher BMI subgroup, although the results, as with all subgroup comparisons, should be interpreted with caution.

In general, patients with diabetes and elevated BMI have increased insulin resistance and thus require higher daily insulin doses. Consistent with this observation, daily insulin dose (expressed as total IU and per kg) was higher in the BMI ≥ 27 kg/m^2 subgroup. Despite these increases in insulin dose, the rates of adjudicated severe hypoglycaemia were lower in sotagliflozin-treated patients. DKA risk is related to insulin levels and tends to be higher in patients using lower insulin doses and in those with lower C-peptide levels, insulin pump users, and patients who consume low-carbohydrate diets.[12,13] It is possible that higher insulin doses in patients with overweight or obesity and T1D who are also using an SGLT inhibitor may be associated with a lower incidence of DKA. In the present analysis, the placebo-adjusted DKA incidence tended to be lower in the BMI ≥ 27 kg/m^2 subgroup relative to those with BMI < 27 kg/m^2, a result supported by a recent pooled analysis of DKA incidence in inTandem 1 and 2, which demonstrated that CSII use, female sex, and baseline total daily insulin dose < 0.7 IU/kg also contributed to increased risk of DKA.[14] A similar trend was noted with dapagliflozin.[15] The DKA rates and total number of events in both the inTandem and DEPICT programmes were low, although between-study comparison is limited by differences in adjudication criteria. Collectively, these results suggest an improved benefit–risk profile in the BMI ≥ 27 kg/m^2 subgroup. However, no BMI threshold will completely prevent DKA, and risk mitigation efforts are required for all patients.[13] The cardiovascular benefits of SGLT inhibitors, as shown in those with type 2 diabetes as well as those without diabetes, may be another factor favouring use of this class as an insulin adjunct for patients with T1D and a higher BMI.[16] Therefore when considering adjunctive therapy for T1D, it is reasonable to start in a patient group that has a better clinical benefit–risk profile.

In conclusion, this analysis showed that adding sotagliflozin to optimized insulin, compared to optimized insulin alone, was associated with a more favourable efficacy and safety profile in adults with T1D with a baseline BMI ≥ 27 kg/m^2 versus those with a baseline BMI < 27 kg/m^2. These findings support European and UK regulatory authorities' approval of adding sotagliflozin to optimal insulin for the treatment of T1D in patients with a BMI ≥ 27 kg/m^2.[7,8]

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CONFLICT OF INTEREST

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AUTHOR CONTRIBUTIONS

Authors working for Lexicon Pharmaceuticals, Inc., contributed to the statistical analysis of data, interpretation of data, and the writing of this manuscript. All authors had full access to all the data in the studies and had final responsibility for the decision to submit for publication. All authors participated in interpreting the data and critically revising the report, and all authors approved the final version to be published.

PEER REVIEW

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DATA AVAILABILITY STATEMENT

Data available upon request from the authors.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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