

Table 1: Baseline demographic and clinical characteristics

	1.2 mg liraglutide (n=225)	1.8 mg liraglutide (n=221)	100 mg sitagliptin (n=219)
Men	116 (52%)	116 (52%)	120 (55%)
Age (years)	55.9 (9.6)	55.0 (9.1)	55.0 (9.0)
Race			
White	184 (82%)	193 (87%)	199 (91%)
Hispanic or Latino	39 (17%)	34 (15%)	35 (16%)
Black	22 (10%)	16 (7%)	10 (5%)
Asian or Pacific Islander	7(3%)	4(2%)	2 (1%)
Other	12 (5%)	8(4%)	8(4%)
Weight (kg)	931 (1804)	94.6 (18.1)	93.1 (18.9)
Body-mass index (kg/m ²)	32.6 (5.2)	33.1 (5.1)	32.6 (5.04)
Duration of diabetes (years)	6.0(4-5)	6.0(5.4)	6.3 (5.04)
Fasting C-peptide (nmol/L)	1.1 (0.6)	1.1 (0.5)	1.1 (0.5)
HbA1c	8.04% (0.8)	8.04% (0.1)	8.5% (0.7)
Fasting plasma glucose (mmol/L)	101(204)	9.9(2.4)	10.0 (2.0)
Systolic blood pressure (mm Hg)	1312 (144)	133-4 (14.5)	1321 (14.8)
Diastolic blood pressure (mm Hg)	80.3 (9.0)	81.5 (8.5)	81.9 (9.1)

Data are number (% of total participants in treatment group) or mean (SD). HbA1c=glycosylated haemoglobin.

Table 2: Change in additional secondary measures of efficacy from baseline to week 26

	Mean change from baseline			1.2 mg liraglutide vs sitagliptin		1.8 mg liraglutide vs sitagliptin	
	1.2 mg liraglutide (n=221)	1.8 mg liraglutide (n=218)	100 mg sitagliptin (n=219)	Estimated treatment difference	p value	Estimated treatment difference	P value
β-cell function							
Fasting insulin (pmol/L)	5.12 (-4.34 to 14.59)	1.29 (-8.04 to 10.62)	-6.77 (-16.18 to 2.64)	11.89 (-084 to 24.63)	0.0672	8.06 (-4.51 to 20.63)	0.2083
Fasting C-peptide (nmol/L)	0.09 (0.03 to 0.15)	0.09 (0.03 to 0.15)	-0.04 (-0.10 to 0.02)	0.13 (0.05 to 0.21)	0.0011	0.14 (0.06 to 0.21)	0.0008
Fasting proinsulin-to-insulin ratio	-0.08 (-0.11 to -0.05)	-0.10 (-0.12 to -0.07)	-0.03 (-0.06 to -0.00)	-0.05 (-0.09 to -0.01)	0.0121	-0.07 (-0.10 to -0.03)	0.0004
HOMA-B	27.23% (19.73 to 34.73)	28.70% (21.34 to 36.06)	4.18% (-3.27 to 11.62)	23.05% (12.95 to 33.15)	<0.0001	24.52% (14.57 to 34.48)	<0.0001
HOMA-IR	-1.06% (-1.70 to -0.42)	-1.50% (-2.13 to -0.87)	-0.94% (-1.58 to -0.30)	-0.12% (-0.99 to 0.75)	0.7834	-0.56% (-1.41 to 0.29)	0.1972
Vital signs							
Systolic blood pressure (mm Hg)	-0.55 (-2.30 to 1.19)	-0.72 (-2.47 to 1.03)	-0.94 (-2.69 to 0.81)	0.39 (-1.96 to 2.73)	0.7464	0.22 (-2.12 to 2.57)	0.8528
Diastolic blood pressure (mm Hg)	-0.71 (-1.88 to 0.46)	0.07 (-1.10 to 1.23)	-1.78 (-2.95 to -0.61)	1.07 (-0.50 to 2.64)	0.1826	1.85 (0.28 to 3.41)	0.0210
Heart rate (beats per min)	2.32 (1.17 to 3.48)	3.94 (2.79 to 5.08)	-0.64 (-1.79 to 0.52)	2.96 (1.41 to 4.51)	0.0002	4.57 (3.02 to 6.12)	<0.0001
Fasting lipid profile							
Total cholesterol (mmol/L)	-0.03 (-0.14 to 0.08)	-0.17 (-0.28 to -0.07)	-0.02 (-0.13 to 0.09)	-0.01 (-0.16 to 0.13)	0.8458	-0.16 (-0.30 to -0.01)	0.0332
LDL cholesterol (mmol/L)	0.08 (-0.01 to 0.17)	0.05 (-0.04 to 0.14)	0.13 (0.04 to 0.22)	-0.05 (-0.17 to 0.07)	0.4414	-0.08 (-0.20 to 0.04)	0.2055
VLDL cholesterol	-0.11 (-0.17 to	-0.20 (-0.27 to -0.14)	-0.15 (-0.21 to -0.09)	0.04 (-0.05 to 0.12)	0.3678	-0.05 (-0.14 to 0.03)	0.2010

(mmol/L)	-0.05)						
HDL cholesterol (mmol/L)	0.00 (-0.02 to 0.02)	0.00 (-0.02 to 0.03)	0.00 (-0.02 to 0.02)	0.00 (-0.03 to 0.03)	0.9507	0.00 (-0.03 to 0.03)	0.9225
Triglycerides (mmol/L)	-0.19 (-0.38 to -0.00)	-0.43 (-0.61 to -0.25)	-0.40 (-0.58 to -0.22)	0.21 (-0.04 to 0.46)	0.0962	-0.03 (-0.28 to 0.21)	0.8021
Free fatty acids (mmol/L)	-0.03 (-0.07 to 0.01)	-0.07 (-0.11 to -0.03)	-0.05 (-0.08 to -0.01)	0.02 (-0.03 to 0.07)	0.4502	-0.02 (-0.07 to 0.03)	0.4012
Apolipoprotein B (g/L)	-0.06 (-0.09 to -0.03)	-0.07 (-0.10 to -0.04)	-0.05 (-0.08 to -0.03)	0.00 (-0.04 to 0.03)	0.8028	-0.02 (-0.05 to 0.02)	0.3394
Physical measures							
Waist circumference (cm)	-2.69 (-3.38 to -1.99)	-2.63 (-3.33 to -1.92)	-1.12 (-1.82 to -0.42)	-1.57 (-2.50 to -0.63)	0.0010	-1.50 (-2.44 to -0.57)	0.0017
Waist-to-hip ratio	-0.01 (-0.01 to 0.00)	-0.01 (-0.02 to -0.00)	-0.00 (-0.01 to 0.00)	-0.00 (-0.01 to 0.01)	0.8727	-0.00 (-0.01 to 0.00)	0.3000

Data are least squares mean change from baseline (95% CI) or estimated treatment difference (95% CI). Primary and main secondary efficacy endpoints are detailed in the text and figures 2 and 3.

HOMA-B=homoeostasis model assessment of β -cell function. HOMA-IR= homoeostasis model assessment of insulin resistance.

Table 3: Treatment-emergent adverse events

	1.2 mg liraglutide (n=221)	1.8 mg liraglutide (n=218)	100 mg sitagliptin (n=219)
Serious adverse events*			
Overall	6(3%)	6(3%)	4(2%)
Deaths	0	1<<1%)	1<<1%)
Severe adverse events			
Overall†	7(3%)	7(3%)	8(4%)
Gastrointestinal disorders	3(1%)	3(1%)	4(2%)
Musculoskeletal and connective tissue disorders	2 (1%)	1<<1%)	1<<1%)
Infections and infestations	1<<1%)	1<<1%)	1<<1%)
Neoplasms (benign, malignant, and unspecified)	1<<1%)	0	1<<1%)
Cardiac disorders	0	1<<1%)	1(<1%)
Investigations	0	1(<1%)	0
Nervous system disorders	0	0	1<<1%)
Renal and urinary disorders	0	0	1<<1%)
Adverse events (of any severity) in >5% of participants in any treatment group			
Overall‡	146 (66%)	159 (73%)	127(58%)
Gastrointestinal disorders	73 (33%)	88 (40%)	46 (21%)
Nausea	46 (21%)	59 (27%)	10(5%)
Vomiting	17(8%)	21 (10%)	9(4%)
Diarrhoea	16(7%)	25 (11%)	10(5%)
Constipation	10(5%)	11(5%)	6(3%)
Dyspepsia	7(3%)	14(6%)	5(2%)
Infections and infestations	62 (28%)	59 (27%)	63 (29%)
Nasopharyngitis	21 (10%)	28 (13%)	26 (12%)
Influenza	13(6%)	2(1%)	5(2%)
Nervous system disorders	35 (16%)	39 (18%)	38 (17%)
Headache	20(9%)	25 (11%)	22 (10%)
Musculoskeletal and connective tissue disorders	26 (12%)	33 (15%)	35 (16%)
General and administration-site disorders	26 (12%)	26 (12%)	8(4%)
Metabolism and nutrition disorders‡	22 (10%)	25 (11%)	16(7%)
Decreased appetite	7(3%)	12(6%)	2 (1%)
Investigations	19(9%)	24(11%)	14(6%)
Skin and subcutaneous tissue disorders	16 (7%)	12 (6%)	12 (5%)

Respiratory, thoracic, and mediastinal disorders‡	11(5%)	15 (7%)	18 (8%)
Injury, poisoning, and procedural complications	11(5%)	13 (6%)	17(8%)
Vascular disorders;	8(4%)	12(6%)	7(3%)

Data are number (% of total participants in treatment group). *1.2 mg liraglutide group had one case of each of epiglottic carcinoma, thyroid disorder, hypoaesthesia, coxarthrosis deformans, worsening of coxarthrosis, and infected sebaceous cyst; 1.8 mg liraglutide group had one case of each of pancreatic carcinoma (fatal), heart failure, chest discomfort, subdural haematoma, diabetic retinopathy and papillo-oedema, and mycotic mycetoma of left sphenoidal sinus and epistaxis; 100 mg sitagliptin group had one of each of cardiac arrest (fatal), renal carcinoma, colonic polyp, and postmenopausal vaginal haemorrhage and leiomyoma. †Some patients had more than one type of adverse event. ‡For system organ class categories see webappendix p 4.