SUPPLEMENTARY DATA

No evidence of increase in calcitonin concentrations or development of C-cell malignancy in response to liraglutide for up to 5 years in the LEADER trial

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Supplementary Table S1. Baseline demographic and disease characteristics of the trial patients randomized to either placebo or liraglutide

	Placebo (*n* = 4672)	Liraglutide (*n* = 4668)
Age, years		
Mean±SD	64.4±7.2	64.2±7.2
Men, *n* (%)	2992 (64)	3011 (64.5)
HbA_{1c} (%)		
Mean±SD	8.7±1.5	8.7±1.6
HbA_{1c} (mmol/mol)		
Mean±SD	71.1±16.3	71.9±17.0
Diabetes duration		
Mean±SD	12.9±8.1	12.8±8.0
Calcitonin, ng/L, males		
Mean±SD	5.9±7.1	5.9±6.6
Median (IQR)	3.9 (1.0–7.7)	3.9 (1.0–7.5)
Calcitonin, ng/L, females		
Mean±SD	1.4±1.8	1.5±2.2
Median (IQR)	1.0 (1.0–1.0)	1.0 (1.0–1.0)
eGFR, *n* (%)		
Normal (eGFR >90 mL/min/cm^2)	1655 (35.4)	1620 (34.7)
Mild impairment (eGFR 60–89 mL/min/m^2)	1975 (42.3)	1932 (41.4)
Moderate impairment (eGFR 30–59 mL/min/m^2)	935 (20.0)	999 (21.4)
Severe impairment (eGFR <30 mL/min/m^2)	107 (2.3)	117 (2.5)
Patients with established CV disease aged ≥50 years, *n* (%)	3767 (80.6)	3831 (82.1)
Patients with risk factors for CV disease aged ≥60 years, *n* (%)	905 (19.4)	837 (17.9)
Smoking, *n* (%)		
Current	563 (12.1)	567 (12.1)
Previous	2189 (46.9)	2151 (46.1)
Never	1920 (41.1)	1950 (41.8)
Use of proton inhibitors, *n* (%)	1008 (21,6)	1008 (21.6)
Use of H2 blockers, *n* (%)	161 (3.5)	153 (3.3)
History of thyroid disease, *n* (%)	822 (17.6)	804 (17.2)

CT, calcitonin; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HbA1c, glycated hemoglobin; H2, histamine 2; IQR, interquartile range; n, number of patients; SD, standard deviation.

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Supplementary Table S2. Categorical summary of extreme post-baseline calcitonin values

	Liraglutide		Placebo		OR (95% CI)	*P*-value
Males						
Number of patients	3011	(%)	2992	(%)	6003	
Normal	2146	(75.4)	2149	(77.0)	0.97 [0.83; 1.13]	0.6562
High (>ULN)	701	(24.6)	642	(23.0)	1.20 [1.02; 1.42]	0.0321
>20 ng/L	139	(4.9)	133	(4.8)	1.00 [0.73; 1.39]	0.9888
>50 ng/L	16	(0.6)	17	(0.6)	1.07 [0.48; 2.37]	0.8653
>100 ng/L	3	(0.1)	2	(0.1)	4.36 [0.38; 50.7]	0.2395
>ULN and ≤20 ng/L	562	(19.7)	509	(18.2)	1.15 [1.00; 1.33]	0.0558
Females						
Number of patients	1657	(%)	1680	(%)	3337	
Normal	1476	(94.6)	1500	(95.5)	1.09 [0.86; 1.39]	0.4713
High (>ULN)	85	(5.4)	71	(4.5)	1.02 [0.68; 1.51]	0.9405
>20 ng/L	5	(0.3)	5	(0.3)	0.71 [0.16; 3.22]	0.6599
>50 ng/L						
>100 ng/L						
>ULN and ≤20 ng/L	80	(5.1)	66	(4.2)	1.08 [0.74;1.57]	0.7028

N, number of subjects in the summary statistic; %, percentage of subjects; ULN, upper limit of normal. The minimum and maximum values from all scheduled and unscheduled post-baseline visits are used; these values are then categorized according to laboratory range values. The logistic regression is using treatment as the only fixed effect and is adjusted for baseline calcitonin as a continuous covariate.

SUPPLEMENTARY DATA

Supplementary Table S3. Thyroid neoplasm events*

	Liraglutide (*n* = 4668)				Placebo (*n* = 4672)			
	N	%	E	R	N	%	E	R
Number of events	7	0.1	7	0.04	3	0.1	7	0.04
C-cell hyperplasia	0	0.0	0	0.0	0	0.0	0	0.0
Medullary microcarcinoma	0	0.0	0	0.0	1	0.0	2	0.01
Medullary carcinoma†	0	0.0	0	0.0	1	0.0	1	0.01
Other thyroid neoplasms‡	7	0.1	7	0.04	3	0.1	4	0.02

*PYO for patients randomized to liraglutide and placebo is 17,822 and 17,741, respectively. †Stage 2 locally advanced.
‡Other thyroid neoplasms, include follicular variant of papillary carcinoma (three events in three patients receiving liraglutide, and two events in two patients receiving placebo), papillary microcarcinoma (one event in one patient receiving liraglutide), papillary carcinoma (excluding follicular and tall cell variant of papillary carcinoma) (one event in one patient receiving liraglutide, and two events in one patient receiving placebo). The two remaining events in the liraglutide group were benign. Thyroid neoplasm events were EAC-confirmed index events.
E, number of events; EAC, endpoint adjudication committee; N, number of patients; %, proportion of events; PYO, patient years of observation; R, event rate per 100 patient-years of observation.

SUPPLEMENTARY DATA

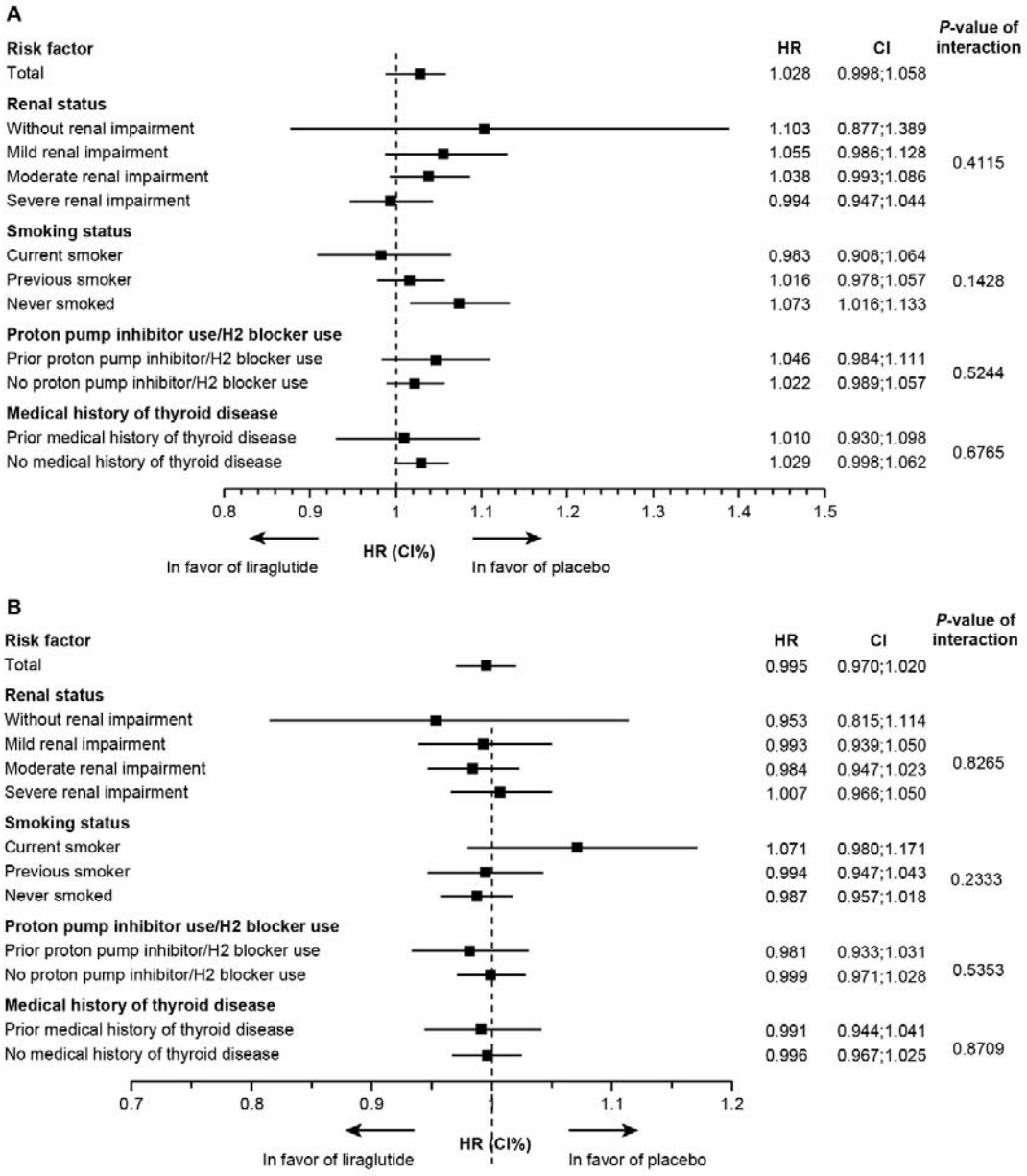
Supplementary Table S4. Thyroid disease – serious adverse events or non-serious MESIs*

	Liraglutide (*n* = 4668)				Placebo (*n* = 4672)			
	N	%	E	R	N	%	E	R
Any event	196	4.2	231	1.30	190	4.1	220	1.24
Serious								
Yes	28	0.6	30	0.17	21	0.4	22	0.12
No	172	3.7	201	1.13	175	3.7	198	1.12
Severity								
Severe	6	0.1	7	0.04	5	0.1	5	0.03
Moderate	49	1.0	53	0.30	37	0.8	40	0.23
Mild	149	3.2	171	0.96	153	3.3	175	0.99

*PYO for patients randomized to liraglutide and placebo is 17,822 and 17,741, respectively.
E, number of events; MESI, medical event of special interest; N, number of patients; %, proportion of events; PYO, patient years of observation; R, event rate per 100 patient-years of observation.

SUPPLEMENTARY DATA

Supplementary Figure S1. Subgroup analysis of the influence on calcitonin levels of renal impairment, smoking status, proton pump inhibitor/H2 blocker use, and medical history of thyroid disease in males (A) and females (B).



The analysis of data was based on the FAS.

CI, confidence interval; ETR, estimated treatment ratio; FAS, full analysis set; H2, histamine 2.

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