Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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Supplementary Appendix

Liraglutide and Renal Outcomes in Type 2 Diabetes

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Supplementary Methods

Imputation of urinary albumin values outside range of quantification

At baseline and throughout the trial, a substantial proportion of the subjects in both trial groups had urinary albumin values below lower level of quantification (<LLOQ). In addition, one subject had a urinary creatinine value <LLOQ and a few subjects had urinary albumin or creatinine values above the upper limit of quantification (>ULOQ). Throughout months 12, 24 and 36, the proportions of subjects with albumin values <LLOQ were slightly higher in the liraglutide group (approximately 18%) than in the placebo group (approximately 17%), whereas at most 15 subjects in any trial group, at any visit, had creatinine values <LLOQ or albumin or creatinine values >ULOQ. Urinary albumin or creatinine values <LLOQ or >ULOQ were not imputed by the central laboratory and, therefore, the corresponding urinary albumin-to-creatinine ratio values were not provided. Subsequently, albumin and creatinine values <LLOQ were imputed using ½LLOQ and albumin and creatinine values >ULOQ were imputed using ULOQ.

Non-prespecified outcomes

Additional endpoints were defined post hoc and analysed using Cox proportional hazards model: the composite endpoint of doubling of serum creatinine (and estimated glomerular filtration rate [eGFR]<45 ml/min/1.73 m^2) and need for continuous renal replacement therapy (end-stage renal disease), doubling of serum creatinine without confirmatory measurement, and new onset of microalbuminuria.

Statistical analyses

Differences in distribution of baseline characteristics between the liraglutide- and placebo-treated group and between the renal risk subgroups were tested using Chi-square test for categorical variables and Student's t-test for continuous variables.

A sensitivity analysis for the primary renal composite endpoint and its individual components taking into account competing risk of death was performed. This was analysed applying a Fine-Grey subdistribution hazards model with treatment as covariate.

For urinary albumin-to-creatinine ratio and eGFR per modification of diet in renal disease (MDRD), changes from baseline were analysed using a mixed-effect model for repeated

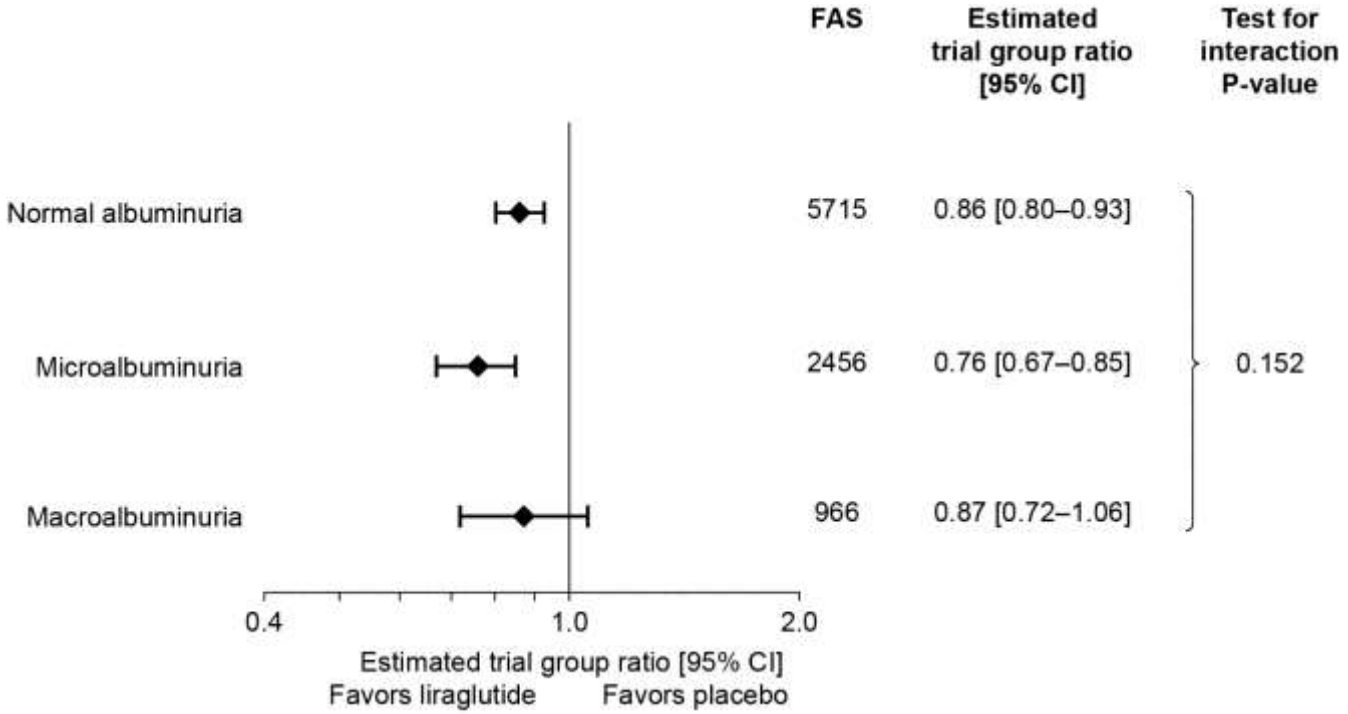
measurements with treatment, anti-diabetic therapy at baseline, region, and sex as factors, and corresponding baseline value and age at baseline as covariates, with all effects nested within visit. From these analyses, the effects of liraglutide vs placebo at 3 years were estimated. Urinary albumin-to-creatinine ratio and eGFR were log transformed before analysis, and consequently the estimated trial group ratio is presented instead of the estimated trial group difference. For absolute changes from baseline, observed mean eGFR and observed median urine albumin-to-creatinine ratio (UACR) is presented in text.

Adverse events

Investigator-reported renal adverse events were identified among all systematically recorded AEs by the SMQ 'acute renal failure'. A selective and targeted approach to safety data collection was applied (Food and Drug Administration, CDER, CBER. Guidance for Industry: Determining the Extent of Safety Data Collected Needed in Late-Stage Premarket and Postapproval Clinical Investigations. 2016). All serious adverse events (SAEs) and predefined medical events of special interest (MESIs), were to be reported by the investigators. Renal adverse events (AE) were identified in the trial safety database among all SAEs and non-serious MESIs using the standardized MedDRA (Medical Dictionary for Regulatory Activities) Query 'Acute renal failure'. 'Acute kidney injury' was defined as per the standardized MedDRA "preferred term".

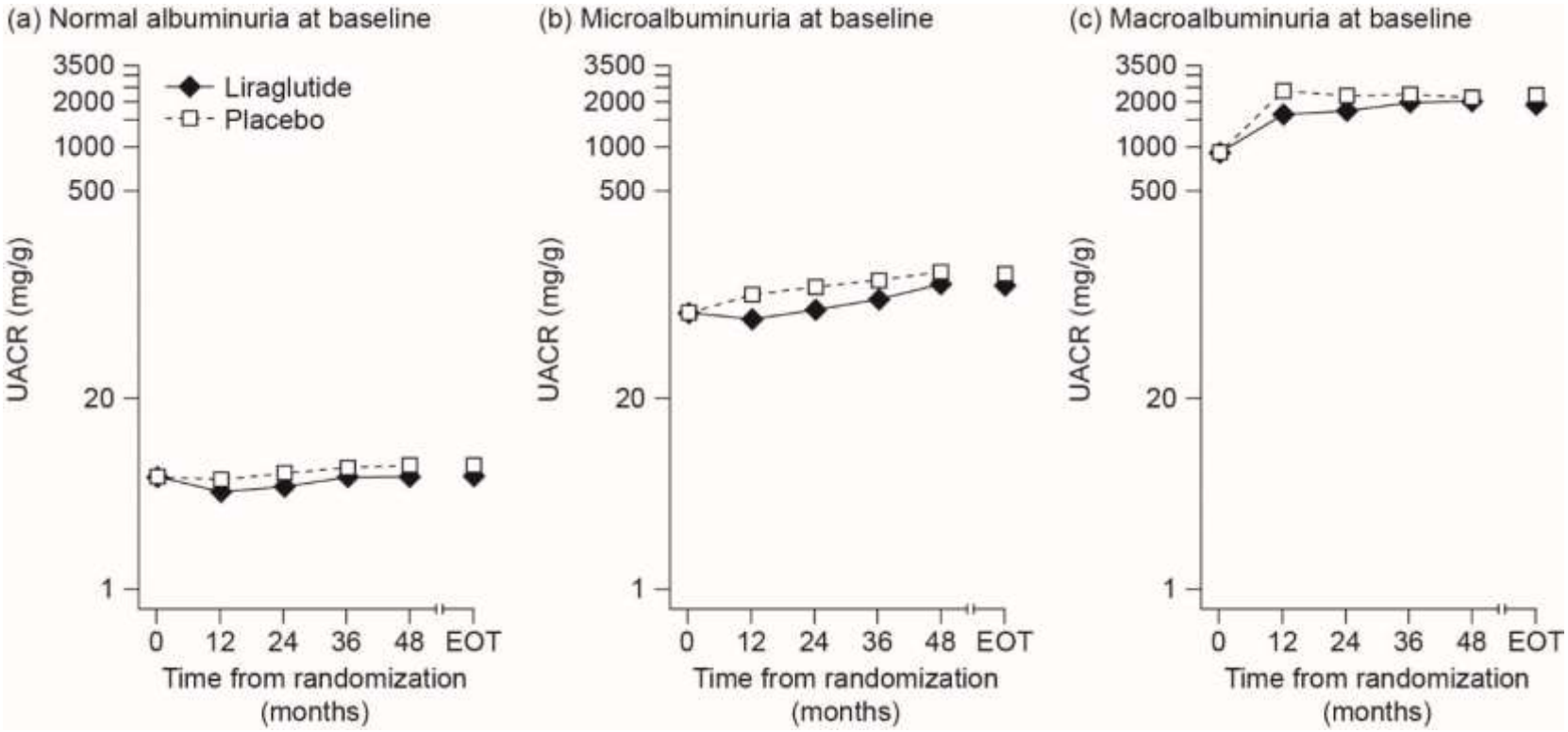
Supplementary Figures and Tables

Figure S1a. Urinary albumin-to-creatinine: ratio to baseline at 3-year visit in subgroups according to albuminuria at baseline



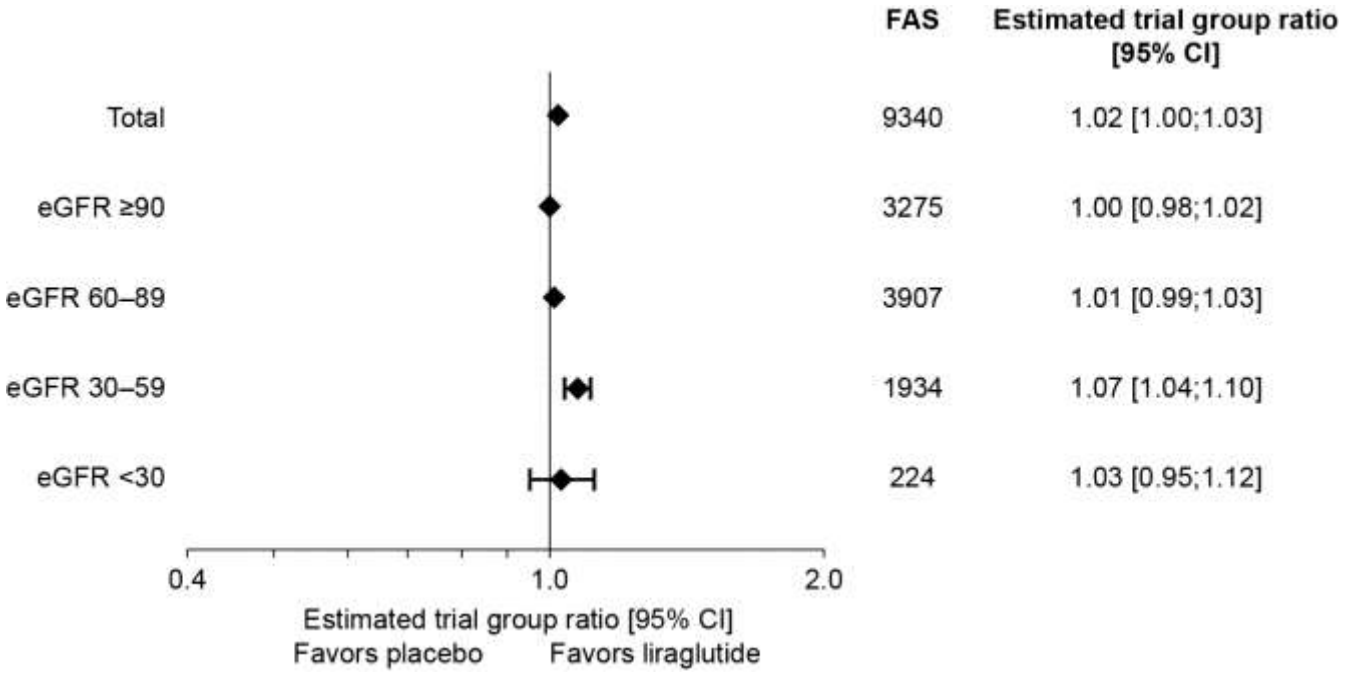
Trial group ratios are estimated using MMRM on the log transformed responses. eGFR per MDRD.
Urinary albumin/creatinine values outside range of quantification are imputed.
CI: confidence interval; eGFR: estimated glomerular filtration rate; FAS: full analysis set (number of patients are shown); MMRM: mixed-effect model for repeated measures.

Figure S1b. Urinary albumin-to-creatinine ratio during trial in subgroups stratified according to albuminuria at baseline



Data are the FAS.
EOT: end-of-trial; FAS: full analysis set; UACR: urinary albumin/creatinine ratio.

Figure S2. Estimated GFR: ratio to baseline at 3-year visit in subgroups stratified according to eGFR at baseline



Trial group ratios are estimated using MMRM on the log transformed responses. eGFR per MDRD.
CI: confidence interval; eGFR: estimated glomerular filtration rate; FAS: full analysis set (number of patients are shown); MMRM: mixed-effect model for repeated measures.

Table S1. Microvascular, renal and eye events

	Liraglutide (N=4668)		**Placebo (N=4672)**		**HR [95% CI]**	**p-value**
Outcomes	**N (%)**	**Rate***	**N (%)**	**Rate***		
Microvascular events	355 (7.6)	19.9	416 (8.9)	23.4	0.84 [0.73;0.97]	0.016
Renal events	268 (5.7)	15.0	337 (7.2)	19.0	0.78 [0.67;0.92]	0.003
Eye events	106 (2.3)	5.9	92 (2.0)	5.2	1.15 [0.87;1.52]	0.33

*Events per 1000 patient–years of observation. The microvascular composite endpoint comprised of the composite renal and eye endpoint. Hazard ratios and P values were estimated with the use of a Cox proportional-hazards model with treatment as a covariate.
CI: confidence interval; HR: hazard ratio.

Table S2. Baseline characteristics according to trial group

	Liraglutide (N=4668)	**Placebo (N=4672)**
Male sex, N (%)	3011 (64.5)	2992 (64.0)
Age, years	64.2	64.4
Diabetes duration, years	12.8	12.9
HbA_{1c}, %	8.7	8.7
BMI, kg/m^2	32.5	32.5
Systolic blood pressure, mmHg	135.9	135.9
Diastolic blood pressure, mmHg	77.2	77.0
eGFR (ml/min/1.73 m^2)	80.2	80.6
Renal function (eGFR, ml/min/1.73 m^2)		
Normal (eGFR $\geq$90)	1620 (34.7)	1655 (35.4)
Mild impairment (eGFR 60–89)	1932 (41.4)	1975 (42.3)
Moderate impairment (eGFR 30–59)	999 (21.4)	935 (20.0)
Severe impairment (eGFR <30)	117 (2.5)	107 (2.3)
Microalbuminuria	1223 (26.2)	1233 (26.4)
Macroalbuminuria	461 (9.9)	505 (10.8)
Antihypertensive therapy	4329 (92.7)	4303 (92.1)
Beta blockers	2652 (56.8)	2529 (54.1)
Calcium channel blockers	1538 (32.9)	1479 (31.7)

ACE inhibitors and ARB	3905 (83.7)	3836 (82.1)
Others	510 (10.9)	494 (10.6)
Diuretics	1953 (41.8)	1953 (41.8)
Loop diuretics	824 (17.7)	837 (17.9)
Others	1408 (30.2)	1394 (29.8)
Lipid-lowering drugs	3564 (76.3)	3515 (75.2)
Statins	3405 (72.9)	3336 (71.4)
Others	680 (14.6)	710 (15.2)
Insulin-naïve	2630 (56.3)	2541 (54.4)
Not treated	194 (4.2)	166 (3.6)
OAD only	2436 (52.2)	2375 (50.8)
Insulin treated	2038 (43.7)	2131 (45.6)
Insulin only	361 (7.7)	377 (8.1)
Insulin + OAD	1677 (35.9)	1754 (37.5)

Full analysis set. Data are mean ± standard deviation or number of patients (proportion [%] of either liraglutide-treated or placebo-treated group). eGFR per MDRD. eGFR is shown as observed means.
A greater proportion of patients in the liraglutide-treated group were treated with beta blockers at baseline compared with the placebo-treated group (p=0.009). No other statistically significant differences were observed among the baseline characteristics described.
ACE: angiotensin converting enzyme; ARB: angiotensin receptor blocker; BMI: body mass index; eGFR: estimated glomerular filtration rate; OAD: oral antidiabetic drug.

Table S3. Baseline characteristics according to renal status

	Micro- or macroalbuminuria		**eGFR (ml/min/1.73 m^2)**	
	Yes (n= 3422)	**No (n= 5918)**	**<60 (n= 2158)**	**≥60 (n= 7182)**
Male sex	2328 (68.0)	3675 (62.1)	1322 (61.3)	4681 (65.2)
Age, years	64.7 ± 7.2	64.0 ± 7.2	67.3 ± 7.5	63.4 ± 6.9
Diabetes duration, years	14.2 ± 8.2	12.0 ± 7.8	15.1 ± 8.6	12.1 ± 7.7
Glycated hemoglobin, %	9.0 ± 1.7	8.5 ± 1.4	8.6 ± 1.5	8.7 ± 1.5
BMI, kg/m^2	32.3 ± 6.4	32.6 ± 6.3	32.7 ± 6.5	32.4 ± 6.2
Body weight, kg	91.2 ± 21.9	92.1 ± 20.4	91.4 ± 21.4	91.8 ± 20.8
Systolic blood pressure, mm Hg	140.2 ± 19.0	133.4 ± 16.4	136.4 ± 19.5	135.8 ± 17.2
Diastolic blood pressure, mm Hg	78.1 ± 10.6	76.5 ± 9.9	75.1 ± 10.6	77.7 ± 10.0
Renal function (eGFR, ml/min/1.73 m^2)				
Normal (eGFR ≥90)	984 (28.8)	2291 (38.7)	0.0	3275 (45.6)
Mild impairment (eGFR 60–89)	1308 (38.2)	2599 (43.9)	0.0	3907 (54.4)
Moderate impairment (eGFR 30–59)	962 (28.1)	972 (16.4)	1934 (89.6)	0.0
Severe impairment (eGFR <30)	168 (4.9)	56 (0.9)	224 (10.4)	0.0
Microalbuminuria	2456 (71.8)	0	625 (29.0)	1831 (25.5)
Macroalbuminuria	966 (28.2)	0	505 (23.4)	461 (6.4)
Antihypertensive therapy	3204 (93.6)	5428 (91.7)	2068 (95.8)	6564 (91.4)
Beta blockers	1853 (54.1)	3328 (56.2)	1230 (57.0)	3951 (55.0)

Calcium channel blockers	1377 (40.2)	1640 (27.7)	846 (39.2)	2171 (30.2)
ACE inhibitors and ARB	2920 (85.3)	4821 (81.5)	1862 (86.3)	5879 (81.9)
Others	462 (13.5)	542 (9.2)	346 (16.0)	658 (9.2)
Diuretics	1512 (44.2)	2394 (40.5)	1248 (57.8)	2658 (37.0)
Loop diuretics	740 (21.6)	921 (15.6)	746 (34.6)	915 (12.7)
Others	969 (28.3)	1833 (31.0)	736 (34.1)	2066 (28.8)
Lipid-lowering drugs	2570 (75.1)	4509 (76.2)	1730 (80.2)	5349 (74.5)
Statins	2439 (71.3)	4302 (72.7)	1631 (75.6)	5110 (71.2)
Others	490 (14.3)	900 (15.2)	414 (19.2)	976 (13.6)
Insulin-naïve	1671 (48.8)	3500 (59.1)	1005 (46.6)	4166 (58.0)
Not treated	141 (4.1)	219 (3.7)	97 (4.5)	263 (3.7)
OAD only	1530 (44.7)	3281 (55.4)	908 (42.1)	3903 (54.3)
Insulin treated	1751 (51.2)	2418 (40.9)	1153 (53.4)	3016 (42.0)
Insulin only	399 (11.7)	339 (5.7)	373 (17.3)	365 (5.1)
Insulin + OAD	1352 (39.5)	2079 (35.1)	780 (36.1)	2651 (36.9)

Full analysis set. Data are mean ± standard deviation or number of patients (proportion [%] of patients either with and without micro- or macroalbuminuria or subjects with eGFR <60 ml/min/1.73 m^2 or ≥60 ml/min/1.73 m^2). eGFR per MDRD formula.
Significant differences ($p<0.05$) were observed among all baseline categories between the proportions and distributions of subjects with and without micro- or macroalbuminuria, except in those subjects not on insulin/OAD or using other lipid-lowering drugs. Significant differences ($p<0.05$) were observed between subjects with an eGFR <60 ml/min/1.73 m^2 or ≥60 ml/min/1.73 m^2 for all baseline categories described except weight, BMI, SBP, not on insulin/OAD, insulin and OAD or other lipid-lowering drugs. Within the 4 subgroups, there were no significant differences between those randomized

to liraglutide or placebo except for a slightly higher proportion of Black or African-American patients, and a lower proportion of Asian patients in the placebo group of the eGFR <60 subgroup; and slightly more North American patients in the placebo group of the microalbuminuria subgroup. ACE, angiotensin converting enzyme; ARB, angiotensin receptor blocker; BMI, body mass index; eGFR, estimated glomerular filtration rate; OAD, oral antidiabetic drug. Reproduced from New England Journal of Medicine, Marso et al., Liraglutide and Cardiovascular Outcomes in Type 2 Diabetes, 375, 311–22.

Table S4. Sensitivity analyses for the composite renal outcome and components (all cause death as a competing risk)

Endpoint	**Liraglutide**		**Placebo**		**Total**		
FAS	4668		4672		9340		**Hazard ratio [95% CI]**
PYO	17822		17741		35563		
Outcomes	**N**	**Rate***	**N**	**Rate***	**N**	**Rate***	
Composite renal outcome	268	15.0	337	19.0	605	17.0	0.79 [0.67;0.92]
Components of composite							
New onset of persistent macroalbuminuria	161	9.0	215	12.1	376	10.6	0.74 [0.61;0.91]
Persistent doubling of serum creatinine†	87	4.9	97	5.5	184	5.2	0.90 [0.67;1.20]
Continuous renal replacement therapy	56	3.1	64	3.6	120	3.4	0.87 [0.61;1.25]
Death due to renal disease	8	0.4	5	0.3	13	0.4	1.60 [0.52;4.90]

*Per 1000 PYO. † and eGFR<45 ml/min/1.73m^2 per MDRD.
Hazard ratios and P values were estimated with the use of a Fine-Grey subdistribution hazards model.
CI: confidence interval; FAS: full analysis set; HR: hazard ratio; PYO: patient–years of observation.

Table S5. Sensitivity analyses for the composite renal outcome adjusted for RAAS inhibitors (ATC: C09) at baseline

	Liraglutide		**Placebo**		**Total**		**Hazard ratio [95% CI]**	**P-value**
FAS	4668		4672		9340			
PYO	17822		17741		35563			
Outcomes	**N**	**Rate***	**N**	**Rate***	**N**	**Rate**		
Composite renal outcome	268	15.0	337	19.0	605	17.0	0.78 [0.67–0.92]	0.002

*Per 1000 PYO.

ATC: Anatomical Therapeutic Chemical; ATC: C09: agents acting on the renin-angiotensin system; CI: confidence interval; FAS: full analysis set; HR: hazard ratio; PYO: patient–years of observation; RAAS: renin-angiotensin-aldosterone system.

Table S6. First composite renal outcome occurring after month 6 by tertiles of change from baseline HbA_{1c} at month 6 and tertiles of baseline HbA_{1c} – summary – full analysis set

The potential relationship between renal outcomes and HbA_{1c} was assessed and we took into account both baseline HbA_{1c} values and early response to treatment (i.e. change from baseline to month six). We divided baseline HbA_{1c} values into tertiles and we used change of HbA_{1c} at six months, again divided into tertiles, to ensure that we used values obtained early in the trial and before the majority of events had occurred preserving the causality between change in HbA_{1c} and the composite renal outcome. Overall, the results for HbA_{1c} suggest that the beneficial effect of liraglutide on the composite renal outcome is partly independent of improvements in HbA_{1c}. Thus, across all baseline HbA_{1c} tertiles, no consistent trend was observed between first renal event and change in HbA_{1c} as reflected by the similar proportion of subjects in the liraglutide groups across the tertiles within each figure. Furthermore, irrespective of baseline HbA_{1c}, the proportion of subjects with a first composite renal event was generally lower in the liraglutide group than in the placebo group (i.e., mimicking the overall difference) across the HbA_{1c} response tertiles. In other words, there were less composite renal outcomes with liraglutide than with placebo whether there was a small or a large change in HbA_{1c}.

Change from baseline to month 6 in HbA_{1c}	**Liraglutide**		**Placebo**		**Total**	
	N	**(%)**	**N**	**(%)**	**N**	**(%)**
FAS at month 6	4641		4648		9289	
Baseline HbA_{1c}, 0–33.3% tertile	1507		1569		3076	
Change in HbA_{1c}, 0–33.3% tertile	271		32		303	
Change in HbA_{1c}, 33.3–66.7% tertile	855		503		1358	
Change in HbA_{1c}, 66.7–100% tertile	381		1034		1415	
Baseline HbA_{1c}, 33.3–66.7% tertile	1422		1466		2888	
Change in HbA_{1c}, 0–33.3% tertile	738		232		970	
Change in HbA_{1c}, 33.3–66.7% tertile	475		554		1029	
Change in HbA_{1c}, 66.7–100% tertile	209		680		889	
Baseline HbA_{1c}, 66.7–100% tertile	1424		1319		2743	
Change in HbA_{1c}, 0–33.3% tertile	1125		664		1789	
Change in HbA_{1c}, 33.3–66.7% tertile	180		321		501	
Change in HbA_{1c}, 66.7–100% tertile	119		334		453	
Renal outcomes	254	(5.69)	332	(7.14)	596	(6.42)
Baseline HbA_{1c}, 0–33.3% tertile	58	(3.85)	92	(5.86)	150	(4.88)

Change in HbA_{1c}, 0–33.3% tertile	5	(1.85)	4	(12.50)	9	(2.97)
Change in HbA_{1c}, 33.3–66.7% tertile	34	(3.98)	27	(5.37)	61	(4.49)
Change in HbA_{1c}, 66.7–100% tertile	19	(4.99)	61	(5.90)	80	(5.65)
Baseline HbA_{1c}, 33.3–66.7% tertile	76	(5.34)	92	(6.28)	168	(5.82)
Change in HbA_{1c}, 0–33.3% tertile	39	(5.28)	14	(6.03)	53	(5.46)
Change in HbA_{1c}, 33.3–66.7% tertile	25	(5.26)	37	(6.68)	62	(6.03)
Change in HbA_{1c}, 66.7–100% tertile	12	(5.74)	41	(6.03)	53	(5.96)
Baseline HbA_{1c}, 66.7–100% tertile	118	(8.29)	138	(10.46)	256	(9.33)
Change in HbA_{1c}, 0–33.3% tertile	87	(7.73)	68	(10.24)	155	(8.66)
Change in HbA_{1c}, 33.3–66.7% tertile	14	(7.78)	34	(10.59)	48	(9.58)
Change in HbA_{1c}, 66.7–100% tertile	17	(14.29)	36	(10.78)	53	(11.70)

Only first events occurring after month 6 (visit 6) are included in the analysis. 27 subjects on liraglutide and 24 subjects on placebo had died or withdrawn from the trial at month 6 (visit 6) and are excluded from the FAS count. 288 subjects on liraglutide and 294 subjects on placebo were still in the trial but did not have a measurement of HbA_{1c} at month 6 (visit 6). Tertiles are based on the entire population. The cuts for baseline HbA_{1c} tertiles are 33.3%: <7.8%, 66.7%: 7.8–9.0% and <9.0%. The cuts for month 6 (visit 6) HbA_{1c} tertiles are 33.3%: reduction greater than -1.4%, 66.7%: 1.4–0.4%, and reduction less than 0.4%.

%: proportion of subjects; FAS: full analysis set; N: number of subjects.

Table S7. First composite renal outcome occurring after month 6 by tertiles of change from baseline body weight at month 6 and tertiles of baseline body weight – summary – full analysis set

Change from baseline to month 6 (visit 6) in body weight (kg)	Liraglutide		Placebo		Total	
	N	(%)	N	(%)	N	(%)
FAS at month 6	4641		4648		9289	
Baseline Body weight, 0–33.3% tertile	1484		1468		2952	
Change in body weight, 0–33.3% tertile	561		205		766	
Change in body weight, 33.3–66.7% tertile	567		606		1173	
Change in body weight, 66.7–100% tertile	356		657		1013	
Baseline body weight, 33.3–66.7% tertile	1441		1518		2959	
Change in body weight, 0–33.3% tertile	676		288		964	
Change in body weight, 33.3–66.7% tertile	456		562		1018	
Change in body weight, 66.7–100% tertile	309		668		977	
Baseline body weight, 66.7–100% tertile	1504		1436		2940	
Change in body weight, 0–33.3% tertile	811		407		1218	
Change in body weight, 33.3–66.7% tertile	390		421		811	
Change in body weight, 66.7–100% tertile	303		608		911	
Renal outcomes	264	(5.69)	332	(7.14)	596	(6.42)
Baseline body weight, 0–33.3% tertile	104	(7.01)	121	(8.24)	225	(7.62)
Change in body weight, 0–33.3% tertile	39	(6.95)	22	(10.73)	61	(7.96)
Change in body weight, 33.3–66.7% tertile	43	(7.58)	48	(7.92)	91	(7.76)
Change in body weight, 66.7–100% tertile	22	(6.18)	51	(7.76)	73	(7.21)
Baseline body weight, 33.3–66.7% tertile	70	(4.86)	105	(6.92)	175	(5.91)
Change in body weight, 0–33.3% tertile	33	(4.88)	18	(6.25)	51	(5.29)
Change in body weight, 33.3–66.7% tertile	19	(4.17)	28	(4.98)	47	(4.62)
Change in body weight, 66.7–100% tertile	18	(5.83)	59	(8.83)	77	(7.88)
Baseline body weight, 66.7–100% tertile	82	(5.45)	97	(6.75)	179	(6.09)
Change in body weight, 0–33.3% tertile	41	(5.06)	31	(7.62)	72	(5.91)
Change in body weight, 33.3–66.7% tertile	21	(5.38)	26	(6.18)	47	(5.80)
Change in body weight, 66.7–100% tertile	20	(6.60)	40	(6.58)	60	(6.59)

Only first events occurring after month 6 (visit 6) are included in the analysis. 27 subjects on liraglutide and 24 subjects on placebo had died or withdrawn from the trial at month 6 (visit 6) and are excluded from the FAS count. 212 subjects on liraglutide and 226 subjects on placebo were still in the trial but did not have a measurement of body weight at month 6 (visit 6). Tertiles are based on the entire population. The cuts for baseline body weight tertiles are 33.3%: <81.50 kg, 66.7%: 81.50–98.70 kg and <98.70 kg. The cuts for month 6 (visit 6) body weight tertiles are 33.3%: reduction greater than -2.22 kg, 66.7%: 2.22–0.20 kg, and reduction less than 0.20 kg.
%: proportion of subjects; FAS: full analysis set; N: number of subjects.

Table S8. First composite renal outcome occurring after month 6 by tertiles of change from baseline systolic blood pressure at month 6 and tertiles of baseline systolic blood pressure – summary – full analysis set

Change from baseline to month 6 (visit 6) in systolic BP (mmHg)	Liraglutide		Placebo		Total	
	N	(%)	N	(%)	N	(%)
FAS at month 6	4641		4648		9289	
Baseline systolic BP, 0–33.3% tertile	1496		1490		2986	
Change in systolic BP, 0–33.3% tertile	256		189		445	
Change in systolic BP, 33.3–66.7% tertile	465		485		950	
Change in systolic BP, 66.7–100% tertile	775		816		1591	
Baseline systolic BP, 33.3–66.7% tertile	1476		1503		2979	
Change in systolic BP, 0–33.3% tertile	509		437		946	
Change in systolic BP, 33.3–66.7% tertile	563		610		1173	
Change in systolic BP, 66.7–100% tertile	404		456		860	
Baseline systolic BP, 66.7–100% tertile	1468		1441		2909	
Change in systolic BP, 0–33.3% tertile	870		733		1603	
Change in systolic BP, 33.3–66.7% tertile	374		437		811	
Change in systolic BP, 66.7–100% tertile	224		271		495	
Renal outcomes	264	(5.69)	332	(7.14)	596	(6.42)
Baseline systolic BP, 0–33.3% tertile	62	(4.14)	72	(4.83)	134	(4.49)
Change in systolic BP, 0–33.3% tertile	12	(4.69)	7	(3.70)	19	(4.27)
Change in systolic BP, 33.3–66.7% tertile	23	(4.95)	19	(3.92)	42	(4.42)
Change in systolic BP, 66.7–100% tertile	27	(3.48)	46	(5.64)	73	(4.59)
Baseline systolic BP, 33.3–66.7% tertile	74	(5.01)	106	(7.05)	180	(6.04)
Change in systolic BP, 0–33.3% tertile	24	(4.72)	32	(7.32)	56	(5.92)
Change in systolic BP, 33.3–66.7% tertile	20	(3.55)	37	(6.07)	57	(4.86)
Change in systolic BP, 66.7–100% tertile	30	(7.43)	37	(8.11)	67	(7.79)
Baseline systolic BP, 66.7–100% tertile	122	(8.31)	146	(10.13)	268	(9.21)
Change in systolic BP, 0–33.3% tertile	72	(8.28)	59	(8.05)	131	(8.17)
Change in systolic BP, 33.3–66.7% tertile	21	(5.61)	41	(9.38)	62	(7.64)
Change in systolic BP, 66.7–100% tertile	29	(12.95)	46	(16.97)	75	(15.15)

Only first events occurring after month 6 (visit 6) are included in the analysis. 27 subjects on liraglutide and 24 subjects on placebo had died or withdrawn from the trial at month 6 (visit 6) and are excluded from the FAS count. 201 subjects on liraglutide and 214 subjects on placebo were still in the trial but did not have a measurement of systolic BP at month 6 (visit 6). Tertiles are based on the entire population. The cuts for baseline systolic BP tertiles are 33.3%: <128.0 mmHg, 66.7%: 128.0–141.5 mmHg and <141.5 mmHg. The cuts for month 6 (visit 6) systolic BP tertiles are 33.3%: reduction greater than -8.5 mmHg, 66.7%: 8.5–4.0 mmHg, and reduction less than 4.0 mmHg.
%: proportion of subjects; BP: blood pressure; FAS: full analysis set; N: number of subjects.

Table S9. Composite renal outcome according to renal risk at baseline (events confirmed by adjudication)

Subgroup	Trial group	Number of patients	Number of patients with event	Rate per 1000 patient–years of observation	Hazard ratio	95% CI	P-value
Patients with micro- or macroalbuminuria at baseline	Liraglutide	1684	230	36.4	0.81	[0.68;0.96]	0.02
	Placebo	1738	283	43.9			
Patients with eGFR <60 ml/min/1.73 m^2 at baseline	Liraglutide	1116	146	35.2	0.84	[0.67;1.05]	0.13
	Placebo	1042	156	40.9			
Patients with eGFR <60 ml/min/1.73 m^2 and micro- or macroalbuminuria at baseline	Liraglutide	583	131	62.0	0.81	[0.64;1.03]	0.09
	Placebo	547	141	72.6			

*Hazard ratios and P values were estimated with the use of a Cox proportional-hazards model with treatment as a covariate.
The composite renal outcome consisted of the new onset of persistent macroalbuminuria, doubling of serum creatinine and eGFR <45 ml/min/1.73 m^2, need for continuous renal replacement therapy (end-stage renal disease) or death due to renal disease.
There was a similar risk reduction (no interaction between trial-group and renal risk subgroup) for the composite renal outcome in those without micro- or macroalbuminuria at baseline or without eGFR ≥60 ml/min/1.73 m2 and micro- or macroalbuminuria at baseline (also see Figure 2).
CI: confidence interval; eGFR: estimated glomerular filtration rate.

Table S10a. Urinary albumin-to-creatinine: ratio to baseline at 3-year visit by renal function at baseline; values outside the detection limits imputed

Renal function subgroup (eGFR, ml/min/1.73 m^2)	**Subjects**	**Estimated trial group ratio, liraglutide/placebo [95% CI]**	**P-value**
Total	9340	0.83 [0.79;0.88]	<0.001
eGFR ≥90	3275	0.80 [0.73;0.88]	<0.001
eGFR 60–89	3907	0.82 [0.75;0.90]	<0.001
eGFR 30–59	1934	0.90 [0.79;1.03]	0.12
eGFR <30	224	0.76 [0.49;1.17]	0.21

eGFR per modification of diet in renal disease.
CI: confidence interval, eGFR: estimated glomerular filtration rate.

Table S10b. Urinary albumin-to-creatinine: ratio to baseline at 3-year visit by renal function at baseline; values outside the detection limits *not* imputed

Renal function subgroup (eGFR, ml/min/1.73 m^2)	**Subjects**	**Estimated trial group ratio, liraglutide/placebo [95% CI]**	**P-value**
Total	9340	0.81 [0.76;0.86]	<.001
eGFR ≥90	3275	0.78 [0.70;0.87]	<.001
eGFR 60–89	3907	0.80 [0.73;0.89]	<.001
eGFR 30–59	1934	0.82 [0.72;0.95]	0.007
eGFR <30	224	0.83 [0.55;1.30]	0.39

eGFR per modification of diet in renal disease.
Estimated trial group ratio was calculated using a mixed-effect model for repeated measures.
CI: confidence interval, eGFR: estimated glomerular filtration rate.

Table S11. Risk for the composite outcome[*]: persistent doubling of serum creatinine[†] or need for continuous renal replacement therapy (end stage renal disease), according to renal status at baseline

Baseline renal status	Events with liraglutide	Events with placebo	Hazard ratio	95% CI	P value
Full analysis set	109	128	0.85	0.66;1.10	0.20
eGFR <60 ml/min/1.73 m^2	76	89	0.78	0.58;1.06	0.12
Microalbuminuria or macroalbuminuria	92	109	0.85	0.65;1.13	0.26
eGFR <60 ml/min/1.73 m^2 and microalbuminuria/macroalbuminuria	70	83	0.75	0.55;1.03	0.08

[*]Non-pre-specified; [†] and eGFR<45 ml/min/1.73m^2 per MDRD; eGFR per MDRD.
Hazard ratios and P values were estimated with the use of a Cox proportional-hazards model with treatment as a covariate.
CI: confidence interval, eGFR: estimated glomerular filtration rate; MDRD: modification of diet in renal disease.

Table S12a. Investigator-reported adverse renal events (ascertained by the standardized MedDRA query 'Acute renal failure' [preferred terms])

	Liraglutide		**Placebo**	
	Number with event (%)	**Rate***	**Number with event (%)**	**Rate***
Acute kidney injury	111 (2.4)	0.7	99 (2.1)	0.6
Renal failure	25 (0.5)	0.1	38 (0.8)	0.2
Azotemia	3 (<0.1)	<0.1	2 (<0.1)	<0.1
Blood creatinine increased	16 (0.3)	<0.1	13 (0.3)	<0.1
Proteinuria	64 (1.4)	0.4	95 (2.0)	0.6

*Per 100 patient–years of observation.
Total number of patients with events: 234 (5.0%) (liraglutide) and 262 (5.6%) (placebo).
%: proportion of patients; SMQ: standardized MedDRA (Medical Dictionary for Regulatory Activities) query.

Table S12b. Investigator-reported adverse renal events according to eGFR at baseline (ascertained by the standardized MedDRA query 'Acute renal failure' [preferred terms])

	Liraglutide		**Placebo**	
Renal group (eGFR, ml/min/1.73 m^2)	**Number with event (%)**	**Rate***	**Number with event (%)**	**Rate***
eGFR >90 (n= 3275)	34 (2.1)	0.6	45 (2.7)	0.8
eGFR 60 –90 (n= 3907)	78 (4.0)	1.2	86 (4.4)	1.2
eGFR 30– 59 (n= 1934)	100 (10.0)	3.1	108 (11.6)	3.7
eGFR <30 (n= 224)	22 (18.8)	6.9	23 (21.5)	6.8

eGFR per modification of diet in renal disease.
*Per 100 patient–years of observation.
eGFR: estimated glomerular filtration rate.

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