CLAIMS

1. Use of a sodium-glucose co-transporter 2 (SGLT2) inhibitor in the manufacture of a medicament for~~A method of~~ treating chronic kidney disease (CKD) and/or at least one disease, disorder, or condition associated therewith in a patient, wherein ~~the method comprising administering to the patient in need thereof,~~ an effective amount of the~~a~~ sodium-glucose co-transporter 2 (SGLT2) inhibitor is to be administered to the patient in need thereof.

2. The ~~method~~ use according to claim 1, wherein the patient has an eGFR ≥25 and ≤75 mL/min/1.73m^2.

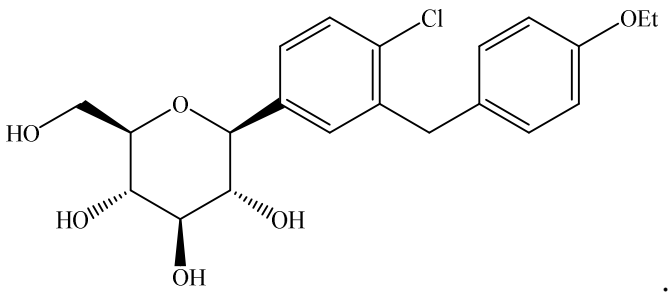
3. The use~~method~~ according to claim 1 or 2, wherein the patient has Type 2 diabetes.

4. The use~~method~~ according to claim 1 or 2, wherein the patient does not have Type 2 diabetes.

5. The use~~method~~ according to any one of claims 1 to 4, wherein the ~~method treats~~medicament is for treating CKD.

6. The ~~method~~ use according to any one of claims 1 to 5, wherein the SGLT2 inhibitor is chosen from dapagliflozin, canagliflozin, empagliflozin, sotagliflozin, ipragliflozin, ertugliflozin, tofogliflozin, and luseogliflozin or a pharmaceutically acceptable salt, solvate, mixed solvate, complex, or prodrug of any of the foregoing.

7. The ~~method~~ use according to any one of claims 1 to 6, wherein the SGLT2 inhibitor is dapagliflozin, having the structure



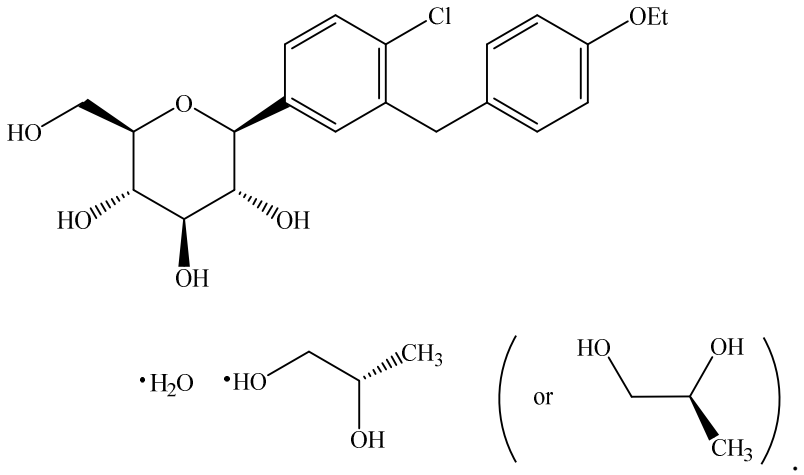
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8. The use~~method~~ according to claim 7, wherein the dapagliflozin is in the form of a pharmaceutically acceptable solvate, mixed solvate, or complex.

9. The use ~~method~~ according to claim 7 or 8, wherein the dapagliflozin is in the form of a non-crystalline solid.

10. The use~~method~~ according to claim 7 or 8, wherein the dapagliflozin is in the form of a crystalline solid.

11. The use ~~method~~ according to any one of claims 7 to 10, wherein the dapagliflozin is in the form of a (S)-propylene glycol ((S)-PG) solvate which has the structure



12. The use~~method~~ according to any one of claims 7 to 11, wherein the dapagliflozin is in a form suitable for oral administration.

13. The use~~method~~ according to claim 12, wherein the dapagliflozin is in the form of a tablet.

14. The use~~method~~ according to any one of claims 7 to 13, wherein the dapagliflozin is to be administered in a dosage of about 2.5 mg/day, 5 mg/day, or 10 mg/day.

15. The use~~method~~ according to any one of claims 7 to 14, wherein the dapagliflozin is to be administered in a dosage of about 10 mg/day.

16. The use~~method~~ according to any one of claims 7 to 15, wherein the dapagliflozin is to be administered once daily.

17. The use~~method~~ according to any one of claims 7 to 16, wherein the dapagliflozin is to be administered in combination with at least one other therapeutic agent.

18. The ~~method~~ use according to claim 17, wherein the at least one other therapeutic agent is chosen from an antidiabetic agent, anti-obesity agent, anti-hyperlipidemic agent, anti-atherosclerotic agent, anti-hypertensive agent, anti-platelet agent, antithrombotic agent, mineralocorticoid antagonist, diuretic, and anticoagulant agent.

19. The use~~method~~ according to claim 17, wherein the at least one other therapeutic agent is an angiotensin-converting enzyme inhibitor (ACE inhibitor).

20. The use~~method~~ according to claim 19, wherein the ACE inhibitor is chosen from captopril, enalapril, and lisinopril.

21. The use~~method~~ according to claim 17, wherein the at least one other therapeutic agent is an angiotensin receptor blocker (ARB).

22. The use~~method~~ according to claim 21, wherein the ARB is chosen from valsartan, losartan, and irbesartan.

23. The use~~method~~ according to any one of claims 17 to 22, wherein the at least one other therapeutic agent, is to be administered before, after, or concurrently with dapagliflozin.

24. The use~~method~~ according to any one of claims 1 to 23, wherein the patient satisfies at least one of the following conditions:

(a) the patient does not have autosomal dominant or autosomal recessive polycystic kidney disease, lupus nephritis, or ANCA-associated vasculitis;

(b) the patient is not receiving cytotoxic therapy, immunosuppressive therapy, or other immunotherapy for primary or secondary renal disease within 6 months prior to treatment;

(c) the patient does not have a history of organ transplantation;

(d) the patient does not have an intolerance to SGLT2 inhibitors;

(e) the patient does not have type 1 diabetes mellitus (T1D);

(f) the patient does not have New York Heart Association (NYHA) class IV Congestive Heart Failure at the time of treatment;

(g) the patient does not have myocardial infarction (MI), unstable angina, stroke, or transient ischemic attack (TIA) within 12 weeks prior to treatment;

(h) the patient does not have coronary revascularization (percutaneous coronary intervention [PCI] or coronary artery bypass grafting [CABG]) or valvular repair/replacement within 12 weeks prior to treatment and is not planned to undergo any of these procedures;

(i) the patient does not have any condition outside the renal and cardiovascular (CV) disease area, with a limited life expectancy of less than 2 years;

(j) the patient does not have an active malignancy requiring treatment at the time of treatment;

(k) the patient does not have hepatic impairment (aspartate transaminase [AST] > 3x the upper limit of normal [ULN], alanine transaminase [ALT] > 3x the upper limit of normal [ULN], or total bilirubin >2x ULN) at time of treatment;

(l) the patient does not have a blood-borne disease chosen from Ebola, Lassa fever virus, Hepatitis A, B, C, D, or E viruses, and HIV type 1 or 2; and/or

(m) the patient is not a women of child-bearing potential who (1) has not been chemically or surgically sterilized or is not willing to use a medically accepted method of contraception, (2) has had a positive pregnancy test, or (3) is breast-feeding.

25. The use~~method~~ according to claim 24, wherein the patient satisfies each of the conditions (a) to (m) of claim 23.

26. The use~~method~~ according to any one of claims 1 to 25, wherein the patient has CKD with albuminuria.

27. The use~~method~~ according to claim 26, wherein the patient has a urine albumin creatinine ratio [UACR] ≥200 and ≤5000 mg/g.

28. The use~~method~~ according to any one of claims 1 to 27, wherein ~~method~~ the medicament reduces the incidence of a composite endpoint of ≥50% sustained decline in eGFR, reaching end-stage renal disease (ESRD), CV death, or renal death in a patient with CKD.

29. The use~~method~~ according to claim 28, wherein the ~~method~~ medicament reduces the incidence of the primary composite endpoint of ≥50% sustained decline in eGFR, reaching ESRD, CV death, or renal death when added to current background therapy in a patient with CKD and albuminuria.

30. The use~~method~~ according to any one of claims 1 to 29, wherein the ~~method~~ medicament decreases intra-glomerular pressure, hypertension, proteinuria, and/or fluid/sodium overload in the patient.

31. The use~~method~~ according to any one of claims 1 to 30, wherein the ~~method~~ medicament reduces systolic blood pressure (BP) of the patient from baseline.

32. The use~~method~~ according to any one of claims 1 to 31, wherein the ~~method~~ medicament reduces systolic BP of the patient further from baseline compared to placebo

33. The use~~method~~ according to either claim 31 or 32, wherein systolic BP of the patient is to be measured at day 30 (±7), 120 (±7), 240 (±7), 360 (±7), 480 (±14), and/or 600 (±14).

34. The use~~method~~ according to any one of claims 1 to 33, wherein the ~~method~~ medicament reduces body weight of the patient from baseline.

35. The use~~method~~ according to any one of claims 1 to 34, wherein the ~~method~~ medicament reduces body weight of the patient further from baseline compared to placebo.

36. The use~~method~~ according to claim 34 or 35, wherein body weight of the patient is to be measured at day 30 (±7), 120 (±7), 240 (±7), 360 (±7), 480 (±14), and/or 600 (±14).

37. The use~~method~~ according to any one of claims 1 to 36, wherein the ~~method~~ medicament lowers albuminuria levels in the patient from baseline.

38. The ~~method~~ use according to any one of claims 1 to 37, wherein the ~~method~~ medicament lowers albuminuria levels in the patient further from baseline compared to placebo.

39. The use~~method~~ according to claim 37 or 38, wherein albuminuria levels of the patient is to be measured at day 30 (±7), 120 (±7), 240 (±7), 360 (±7), 480 (±14), and/or 600 (±14).

40. The use~~method~~ according to any one of claims 1 to 39, wherein the ~~method~~ medicament does not reduce eGFR of the patient from baseline.

41. The ~~method~~ use according to any one of claims 1 to 40, wherein the ~~method~~ medicament reduces eGFR of the patient from baseline to a lesser extent compared to placebo.

42. The use~~method~~ according to either claim 40 or 41, wherein eGFR of the patient is to be measured at day 30 (±7), 120 (±7), 240 (±7), 360 (±7), 480 (±14), and/or 600 (±14).

43. The use~~method~~ according to any one of claims 1 to 42, wherein the patient has HbA1c within the range of from about 6.0 to about 6.9%.

44. The use~~method~~ according to claim 43, wherein the patient has HbA1c within the range of from about 5.7 to about 6.5%.

45. The use~~method~~ according to any one of claims 1 to 44, wherein the ~~method~~ medicament reduces the time to first occurrence of CV death in a patient compared to placebo.

46. The use ~~method~~ according to claim 45, wherein the time to first occurrence of CV death is to be measured at day 30 (±7), 120 (±7), 240 (±7), 360 (±7), 480 (±14), and/or 600 (±14).

47. The use~~method~~ according to any one of claims 1 to 44, wherein the ~~method~~ medicament reduces the time to first occurrence of renal death in a patient compared to placebo.

48. The use~~method~~ according to claim 47, wherein the time to first occurrence of renal death is to be measured at day 30 (±7), 120 (±7), 240 (±7), 360 (±7), 480 (±14), and/or 600 (±14).

49. The use~~method~~ according to any one of claims 1 to 48, wherein the ~~method~~ medicament reduces the time to first occurrence of hospitalization for heart failure in a patient compared to placebo.

50. The use~~method~~ according to claim 49, wherein the time to first occurrence of hospitalization for heart failure is to be measured at day 30 (±7), 120 (±7), 240 (±7), 360 (±7), 480 (±14), and/or 600 (±14).

51. The use ~~method~~ according to any one of claims 1 to 50, wherein the ~~method~~ medicament reduces the total number of hospitalizations for heart failure and/or CV death of a patient compared to placebo.

52. The use~~method~~ according to any one of claims 1 to 51, wherein the ~~method~~ medicament maintains or improves the NYHA class of the patient from baseline compared to placebo.

53. The use ~~method~~ according to claim 52, wherein the NYHA class of the patient is to be measured at day 30 (±7), 120 (±7), 240 (±7), 360 (±7), 480 (±14), and/or 600 (±14).

54. The use~~method~~ according to any one of claims 1 to 53, wherein the medicament ~~method~~ improves the health status of the patient assessed by EQ-5D-5L questionnaire compared to placebo.

55. The ~~method~~ use according to claim 54, wherein the health status of the patient assessed by the EQ-5D-5L questionnaire is to be measured at day 30 (±7), 120 (±7), 240 (±7), 360 (±7), 480 (±14), and/or 600 (±14).

56. The ~~method~~ use according to any one of claims 1 to 53, wherein the ~~method~~ medicament improves the health status of the patient assessed by KDQOL 36 questionnaire compared to placebo.

57. The use ~~method~~ according to claim 56, wherein the health status of the patient assessed by the KDQOL 36 questionnaire is to be measured at day 30 (±7), 120 (±7), 240 (±7), 360 (±7), 480 (±14), and/or 600 (±14).

58. The use ~~method~~ according to any one of claims 1 to 57, wherein ~~method comprises administering~~ the SGLT2 inhibitor is to be administered in addition to standard of care therapy.

59. The use~~method~~ according to claim 58, wherein the standard of care therapy comprises treatments to control co-morbidities and/or treatments for reducing the composite of CV death and heart failure events.