CLAIMS

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

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

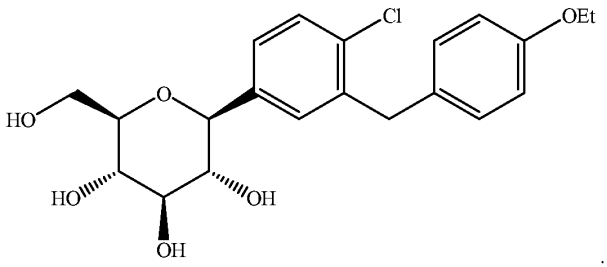
3. The method according to claim 1 or 2, wherein the patient has Type 2 diabetes.

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

5. The method according to any one of claims 1 to 4, wherein the method treats CKD.

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

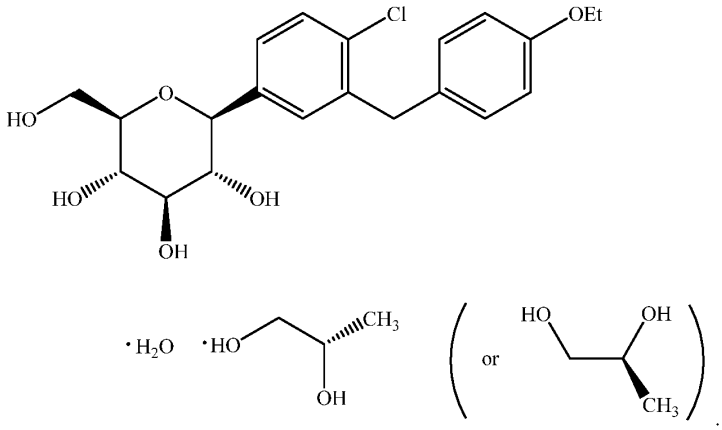


8. The method according to claim 7, wherein the dapagliflozin is in the form of a pharmaceutically acceptable solvate, mixed solvate, or complex.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

28. The method according to any one of claims 1 to 27, wherein method 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 method according to claim 28, wherein the method 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 method according to any one of claims 1 to 29, wherein the method decreases intra-glomerular pressure, hypertension, proteinuria, and/or fluid/sodium overload in the patient.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

59. The 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.